DISTANT RECURRENCES AT MEDIAN OF 5-YEARS AMONG 9,779 POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR-POSITIVE EARLY BREAST CANCER TREATED ON THE TEAM TRIAL OF ADJUVANT ENDOCRINE THERAPY


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Background: The TEAM (Tamoxifen Erexemtane Adjuvant Multinational) trial is a multinational study of the effects of 5 years of adjuvant endocrine therapy, either exemestane (E) or the sequence of tamoxifen followed by E (T—E) in postmenopausal early breast cancer. The 5-year results showed no difference in disease-free survival between both arms (Rea, SABCS 2009). The present analysis explores the sites of first reported distant recurrences (DR).

Methods: Between 2001 and January 2006, 9,779 postmenopausal women with hormone receptor-positive early breast cancer were randomized to E or T—E for 5 years after completion of locoregional therapy with or without adjuvant chemotherapy. Thirteen patients withdrew consent.

Results: Based on an intention-to-treat analysis, among 9,767 patients 420 DR occurred in patients randomized to T—E and 408 DR in E (Table). At 5 years cumulative incidence of DR was 8.9% in T—E and 8.4% in E (hazard ratio for E 0.93; 95% confidence interval 0.81–1.07; p-value 0.31). Table: Sites of 1st reported DR

<table>
<thead>
<tr>
<th>Site</th>
<th>T—E arm (408)</th>
<th>E arm (408)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone only (1)</td>
<td>115 (2.5%)</td>
<td>116 (2.4%)</td>
</tr>
<tr>
<td>Visceral only (2)</td>
<td>122 (2.5%)</td>
<td>99 (2.1%)</td>
</tr>
<tr>
<td>Bone+Visceral (3)</td>
<td>90 (1.9%)</td>
<td>92 (2.0%)</td>
</tr>
<tr>
<td>Other/unknown (3)</td>
<td>93 (2.0%)</td>
<td>93 (1.9%)</td>
</tr>
<tr>
<td>Overall</td>
<td>420 (8.9%)</td>
<td>408 (8.4%)</td>
</tr>
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</table>

Conclusions: This explorative analysis showed that there is no difference in time to DR between upfront E and sequence of T—E. In addition the site of the first reported DR is not significantly different between both arms. As such, both regimens are appropriate treatment options for postmenopausal patients with hormone receptor-positive early breast cancer.

Disclosure: D. Rea is the recipient of a research grant from Pfizer. He has also disclosed that he is on the speaker’s bureau for Pfizer, AstraZeneca and Novartis. C. Markopoulos received research grants and honoraria for lectures from AstraZeneca, Novartis, and Pfizer. S. Jones has disclosed that he is on the speaker’s bureau for Pfizer USA. He has also disclosed that he is a consultant for Pfizer. All other authors have declared no conflicts of interest.

HER2 STATUS AS PREDICTOR OF MAMMOGRAPHIC SCREENING DETECTION: COMPARISON OF INTERVAL- AND SCREEN-DETECTED BREAST CANCERS

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Introduction: To determine whether markers of poor prognosis are associated with risk of breast cancer diagnosis in the interval between screening examinations, we estimated the effect of the mode of detection on distribution of breast cancer molecular subtypes using population cancer registry data.

Materials and methods: Subjects (n = 641) comprised all breast cancers systematically collected by the Cancer Registry of Parma Province and diagnosed in women aged 50-69, from 2004 to 2007. These included 370 screen-detected and 271 symptomatic breast cancers (63 women with screen-detected cancers had not attended screening). We used logistic regression to determine whether interval cancers were associated with selected clinical and biologic characteristics. We also estimated the relative risk of cause-specific fatality and disease-free survival (DFS) by each resulting predictive factor (screen-detected compared to either symptomatic or interval cancers).

Results: Interval-detected cancers occurred more in younger women and were of more advanced tumor stage than screen-detected cancers. In unconditional logistic regression models adjusted for age and tumor stage, tumors with high histologic grade (odds ratio [OR] = 2.2; 95% CI =1.0–5.4), high proliferation rate (OR =2.7; 95% CI =1.5–4.8), or positive HER2 status (OR =2.6; 95% CI =1.3–5.1) were more likely to surface in the interval between screening examinations. After adjusting for various potential biases, women with screen-detected breast cancer had a substantial survival advantage over those with symptomatic breast cancer. In a multivariate model, positive HER2 status independently predicted poor DFS when the mode of...
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cancer detection was included as covariate in addition to age, histologic grade, proliferation rate, and tumor stage.

Conclusions: This is the first population-based cancer registry study demonstrating that HER2-positive tumors account for a substantial proportion of mammographic screening failure to detect breast cancer. Our data indicate that molecular subtype distribution of screen-detected breast cancer differs from that of interval cancers and accounts in part for the better outcome of screen-detected cancer.

Disclosure: All authors have declared no conflicts of interest.

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ABCSCG-24: EFFICACY OF ANTHRACYCLINE- AND TAXANE-BASED NEOADJUVANT THERAPY + CAPECITABINE (C) IN TRIPLE-NEGATIVE EARLY BREAST CANCER (TNBC)

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Background: In the ABCSG-24 randomised, phase III trial we previously showed that the integration of C into a standard epirubicin and docetaxel (ED) neoadjuvant regimen significantly improves pCR rate (24.3% vs 16.0%; p=0.02; [Steger G, et al. Eur J Cancer Suppls 2009;7:3(Abst 4BA)]). Here we assess whether the addition of C produces a pCR benefit in patients with TNBC.

Methods: Patients with biopsy proven operable breast cancer, except T4d, were included. Patients were randomised to receive 6 cycles of either ED or EDC, or ED followed by 6 cycles of EDC. Tumor response was measured after 4 and 8 cycles of neoadjuvant treatment. Estrogen receptor (ER)+/progesterone receptor (PR)+ tumors, HER2-negative tumors were eligible for pCR by digital mammography.

Results: 512 pts are eligible for safety and efficacy assessment (257 ED; 255 EDC). Addition of C to ED was associated with higher but manageable toxicity. Logistic regression analysis confirmed that patients with TNBC had a significantly greater chance of achieving a pCR than non-TNBC (odds ratio [OR] 5.29, 95% CI 3.22-8.68; p=0.0011); this was true irrespective of the regimen used. The highest pCR rates were attained with the addition of C to ED in patients with TNBC (47.5%), representing a 16% increase in pCR rate vs the ED group (31.2%), but this was not significant. There was no interaction between C therapy and TNBC in terms of pCR (p=0.675).

Conclusions: Integration of C into standard ED neoadjuvant therapy achieves a significant pCR benefit in patients with TNBC who represent a difficult-to-treat group with the highest unmet therapeutic needs. Patients with non-TNBC also achieved benefit from EDC therapy.

Disclosure: R. Greil: Corporate sponsored research from Roche, not related to breast cancer. B. Minnitzerich: Participation in advisory boards for AstraZeneca and Amgen. A. Lang: Dr Lang received an unrestricted research grant from Jansen Cilag. C. F. Singer: Amgen research grant received, 10000 Euro / 3 years. M. Gnant, On behalf of The Austrian Breast and Colorectal Cancer Study Group (abcsg): Research support from and serving as a consultant for AstraZeneca, Novartis, Roche and Pfizer, and receiving lecture fees and honoraria for participation on advisory boards AstraZeneca, Novartis, Sanofi Aventis, Roche, Schering, Amgen and Pfizer. All other authors have declared no conflicts of interest.

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ADJUVANT ENDOCRINE THERAPY, ALONE OR IN COMBINATION WITH ZOLEDRONIC ACID (ZOL), IN PREMENOPAUSAL PATIENTS (PTS) WITH ENDOCRINE-RESPONSIVE EARLY BREAST CANCER (EBC): SUBGROUP ANALYSES OF ABCSG-12

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Background: Initial 48-month results of the ABCSG-12 trial, which examined the efficacy of ovarian suppression using goserelin in combination with tamoxifen (TAM) or anastrozole (ANA) ± ZOL in premenopausal pts with EBC, showed that adding ZOL significantly reduced the risk of disease-free survival (DFS) events by 36% (P = 0.01). However, no differences were seen between TAM and ANA. Longer follow-up results are presented here.

Methods: Premenopausal pts with EBC (N = 1803) were randomized to goserelin (3.6mg q24w) and TAM (20mg/d) or ANA (1mg/d) ± ZOL (4mg q6mo). Endpoints included DFS and overall survival (OS); both were analyzed using log-rank test and Cox models.

Results: After a median follow-up of 62 months, 186 DFS events and 66 deaths were reported. Overall, ZOL reduced the risk of DFS events by 32% (HR = 0.68 [95% CI = 0.51,0.91]; P = 0.008) vs no ZOL. The risk reduction by ZOL was nearly identical in the TAM and ANA arms (HR = 0.67 [0.44, 1.03]; P = 0.065 for TAM, HR = 0.68 [0.45, 1.02]; P = 0.059 for ANA). Similarly, ZOL had a nearly identical risk reduction for node-negative (N-) and node-positive (N+) pts (HR = 0.66 [0.43, 1.03]; P = 0.063 for N-, HR = 0.67 [0.45, 0.99]; P = 0.043 for N+). Overall, ZOL produced a 35% trend toward reduced risk of death (HR = 0.65 [0.40, 1.06]; P = 0.087). The OS benefit was more pronounced in the N+ subgroup (HR = 0.61; P = NS). There was no difference in DFS between pts who received TAM alone vs ANA alone (HR = 1.11 [0.84, 1.50]; P = 0.44); however, ANA pts did worse with respect to OS (HR = 1.74 [1.05, 2.87]; P = 0.03) vs TAM, likely because of differences in post-relapse treatment. Treatments were generally well tolerated, with no cases of renal failure or osteonecrosis of the jaw reported.

Conclusions: Addition of ZOL (4mg q6mo) in the ABCSG-12 trial consistently improves disease outcomes in the TAM and ANA strata, and in N– and N+ pts. Although there was no difference in DFS between TAM and ANA, ANA pts had inferior OS vs TAM, likely due to fewer treatment options after relapse. Based on these results and the known anticaner activity of adjacent ZOL, adding ZOL to endocrine therapy could benefit premenopausal pts with EBC.

Disclosure: M. Grant: Research support and consultancy fees from AstraZeneca, Novartis, and Pfizer as well as lecture fees and honoraria for participating in advisory boards from AstraZeneca and Amgen. R. Greil: Consultant and honoraria for participation in advisory boards - GlaxoSmitKline, Pfizer, Sanofi, Cephalon. G. Luschin-Eistrach: Lecture fees - AstraZeneca, Novartis S. Poestlberger: Consultant and honoraria for participation in advisory boards - AstraZeneca, Novartis and Roche. G. G. Steger: Dr. Steger received lecture fees from AstraZeneca and Novartis. R. Jakesz: Consultancy and honoraria for participation in advisory boards - AstraZeneca, Roche, Sanofi-Aventis; Lecture fees - AstraZeneca, Roche, Sanofi-Aventis. N. Herbst: Dr. Eichmann received honoraria for participation in advisory boards and lecture fees from AstraZeneca and Novartis. R. Greil: Consultancy and honoraria for participation in advisory boards - AstraZeneca. All other authors have declared no conflicts of interest.

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THE DEVELOPMENT OF A FORMULATION OF TRASTUZUMAB FOR SUBCUTANEOUS ADMINISTRATION

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Trastuzumab has been shown to improve disease-free and overall survival in patients with HER2-positive early-stage breast cancer (BC). Standard trastuzumab treatment requires 18–22 infusions over 1 year after chemotherapy and can result in discomfort, inconvenience and a significant time commitment for both health care providers and patients. Subcutaneous administration could significantly simplify treatment, shortening administration and improving patient experience. Recombinant human hyaluronidase (rHuPH20) has been developed and approved to improve dispersion and absorption of co-administered drugs. It has been combined with trastuzumab to
allow injection volumes 23 mL to be safely and comfortably administered subcutaneously. The aims of the Phase Ib study were to select the dose of a new subcutaneous trastuzumab formulation with HAU/FL20 giving comparable exposure to intravenous (IV) trastuzumab and to assess its safety and tolerability in male volunteers and HER2-positive BC patients. Three groups of 6 volunteers received subcutaneous doses of 6, 8 and 10 mg/kg, and 40 patients who had previously received trastuzumab received subcutaneous doses of 8 mg/kg or 12 mg/kg. Doses were delivered through a 27-gauge needle at approximately 2 mL/min. Controls were 6 male volunteers and 6 patients who received the approved 6 mg/kg IV maintenance dose. The 8 mg/kg dose of the subcutaneous trastuzumab resulted in a Cmax of 10.0 mg/L and a C1/2 in the range of the approved 6 mg/kg IV dose in both male subjects and HER2-positive patients. The formulation was well tolerated, with no apparent increase in incidence of adverse events (AEs) with increasing dose. The majority of AEs (72%) were mild. The most common AEs were headache, musculoskeletal pain, diarrhea, lethargy and nausea. Injection site reactions included discolouration, erythema and mild discomfort. The total volume administered varied between 3.4–11.9 mL. Subcutaneous trastuzumab can be delivered comfortably and safely while achieving serum exposure comparable to the approved IV formulation in male volunteers and HER2-positive BC patients. The patient experience was favourable. These results support further testing of subcutaneous trastuzumab.

Disclosure: C. McIntyre and B. Bittern: is an employer of F. Hoffmann-La Roche Ltd. All other authors have declared no conflicts of interest.
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**PROSPECTIVE TRANSGEICAM STUDY OF ONCOTYPE DX® IN CLINICAL DECISION MAKING IN ESTROGEN RECEPTOR-POSITIVE NODE-NEGATIVE BREAST CANCER WOMEN**

J. Albanel, R. Colomer, M. Ruiz-Borrego, J.A. Garcia Saenz, E. Alba, M. Martin, J. Palacios, I. Faull, J.M. Corominas, A. Lluch 1,2

1Medical Oncology, Hospital del Mar, Barcelona/Spain. 2Oncology, Centro Oncológico MD Anderson, Madrid/Spain. **Purpose**: The Oncotype DX 21-gene Recurrence Score (RS) assay quantifies the risk of distant recurrence of breast cancer patients with lymph node-negative, estrogen receptor-positive breast cancer and predicts magnitude of chemotherapy benefit. U.S. studies have shown an impact in clinical decision making. Whether RS might affect clinical recommendations in European countries is, as yet, not reported. For this reason, we performed a multicenter study in seven GEICAM (Spanish Group of Breast Cancer Research) sites to prospectively examine whether RS affects medical oncologist adjuvant treatment selection.

**Patients and methods**: Patients with lymph node-negative, estrogen receptor-positive, HER2 negative, early-stage breast cancer, without contraindication to hormonal treatment and chemotherapy, were enrolled. Before and after obtaining the Oncotype DX assay, medical oncologists stated their adjuvant treatment recommendation and confidence in it.

**Results**: To date, 92 patients have been recruited and pre- and post-RS recommendations are available from 71 cases. 40 (56.3%) with low RS (<18), 25 (35.2%) with intermediate RS (18-30) and 6 (8.5%) with high RS (>31). Treatment recommendation changed for 20 patients (28%). In 11 (15.5%) patients the shift was from chemotherapy plus hormonal therapy (CHT) to hormone therapy alone (HT) and in 9 (12.7%) from HT to CHT. All patients with low RS received HT and all with high RS received CHT. In the group with intermediate RS, 11 received HT and 14 CHT. The probability of changing the initial recommendation based on the RS was 10% (95%CI: 0.05 to 0.26). In 25 high-risk, 29.4% (12/41) in intermediate grade, and 43% (6/14) in high grade tumors, suggesting a possible relation between tumor grade and the likelihood of recommendation shift. Tumor grade was not available in 3 tumors. In 47 (66%) cases, the medical oncologist’s confidence in their recommendation increased by assessing RS.

**Conclusion**: The results support the concept of clinical utility for RS assay on medical oncologist adjuvant treatment recommendations in a GEICAM setting.

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Disclosure: J. Albanel, R. Colomer, J. Palacios, I. Faull and J.M. Corominas: Disclosure: RTICC support, ISCiii, Spain

**LETROZOLE OR ANASTROZOLE FOR THE TREATMENT OF HORMONE POSITIVE BREAST CANCER: A CLINICAL COMPARISON USING INDIRECT STATISTICAL TECHNIQUES**

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**Background**: Letrozole (LET) and anastrozole (ANA) are more effective than tamoxifen (TAM) in preventing disease recurrence in postmenopausal women with early stage breast cancer. Recent data from BIG1-98 study also suggests that LET may improve overall survival (Regan SABCS, 2009), a finding that has not been demonstrated with ANA. Ongoing trials (FACE, MA.27) comparing the aromatase inhibitors should help confirm the potential survival benefit with LET.

**Disclosure**: S. Kaura is an employee of Novartis. G. Dranitsaris: Mr. Dranitsaris has received consultancy fees and research funding from Novartis in relation to the research.

**ECONOMIC IMPACT OF ONCOTYPE DX® ASSAY IN AXILLARY NODE NEGATIVE BREAST CANCER, (AEN-BC) WITH POSITIVE HORMONE RECEPTOR (REC+) AND NORMAL HER-2 (HER-2)**: E. Wilson 1, D. McDonnell 2, G. Gulo 3, J. Healy 4, G. Carroll 5, G. Schofield 6, J. Barlow 1, J.P. Crown 1

1Medical Oncology, St. Vincent’s University Hospital, Dublin/IRELAND. 2Chemical Research and Divisive Technologies, Dublin/IRELAND

**Background**: Approximately 70% of patients (pts) with AEN-BC are cured by loco-regional therapy. For pts with rec+ disease, adjuvant endocrine therapy (ERT) reduces the relapse risk (RR) by approximately 1/3. Adjunct chemotherapy (CTRx) reduces RR a further 1/3, and is widely used. Thus 90% of pts may receive unnecessary or futile CTx. The Oncotype DX assay (OTDX) uses the expression of 21 genes in BC as a prognosticator, dividing pts into high (HR), intermediate (IR) and low risk (LR) groups based on “recurrence scores” (RS) of >30, 18-30 and <18 respectively. HR pts benefit from CTx, whereas LR pts do not benefit from CTx. The data for IR are unclear, and are the subject of the TailorRx Trial (E2105). While widely used in the USA, there is limited European experience with OTDX. We studied the potential economic impact of OTDX based on a large single institution European experience.

**Methodology**: The tumors of 140 pts with AEN-BC were scored using the Oncotype® DS assay. Pts with RS <11 received EXR only, RS 11-25 EXR +/- CTx by randomization, and RS 25-40 received CTx. CTx decisions by size, grade and presence or absence of lymphovascular invasion was also made. The cost of OTDX testing the entire cohort and administering CTx (4 x
docteaxed 75 r-cyclophosphamide 600), to those with different RS groups, was compared to giving CTx to pts based on classic pathology. The unit cost of OTDX was Euro 2,911 and the drug costs of T4 + GCSF-C13, 264 Results: Using standard criteria, a total of 108/140 pts would have received CTx, at a cost of €1,432. OTDX cost for 140 pts €487K. OTDX

**RESULTS**: LR 24, IR 89, HR 27. The CTx cost for 27 hi-risk was €388K, and for 116 high +intermediate risk was €51.58. The CTx cost for pts with RS 18 is approximately €596K.

**Conclusions**: On a strict drug-cost versus OTDX cost comparison (which does not include institutional overhead and staff costs and thus understates CTx cost), the OTDX assay will result in savings for European health systems if RS <18 is used as a cut-off for LR, or if CTx is reserved for TailorRx-defined HR. The final economic impact of the OTDX will depend on the results of the TailorRx trial.

**Conclusion**: An indirect statistical comparison between LET and ANA was performed. Such an analysis is feasible in this case because TAM was the common comparator in both trials and patients had similar baseline characteristics.

**Methods**: Data in terms of early distant recurrences, disease free survival (DFS) and overall survival (OS) were extracted from the BIG 1-98 and ATAC trials. After a median follow up of 74 months, the hazard ratio (HR) for OS based on an inverse probability censoring weighted (IPCW) analysis for LET was 0.83 (95% CI 0.73 - 0.97, p < 0.05). From ATAC after a follow up of 98 months, the HR was 0.97 (95%CI 0.85 to 1.12, p = 0.70). An indirect statistical comparison between LET and ANA was then performed on early distant recurrences, DFS and OS using the method of Bucher et al. (1997), which maintains in part the benefits of randomization on the effect size.

**RESULTS**: There was little difference between the two drugs with respect to DFS (HR=0.9; 95%CI 0.83 to 1.15). However, the analysis did identify a substantial risk reduction for early distant recurrences between 2 to 2.5 years with LET (HR=0.75; 95%CI 0.52 to 1.07) over ANA. This translated to a trend for improved OS with LET (HR=0.86; 95%CI 0.70 to 1.05).

**Conclusion**: Keeping in mind the caveats associated with each trial comparisons, this indirect statistical comparison suggests that LET may be more effective than ANA in reducing early distant recurrences and mortality at 5 years. It is possible that the reduction in early distant metastases with LET is responsible for the later improvement in OS. Ongoing trials (FACE, MA.27) comparing the aromatase inhibitors should help us confirm the potential survival benefit with LET.

**Disclosure**: S. Kaura is an employee of Novartis. G. Dranitsaris: Mr. Dranitsaris has received consultancy fees and research funding from Novartis in relation to the research.
Background: We prospectively investigated the prognostic value of serum HER2 ECD + and fluorescent in situ hybridization was performed in patients with an Henri Becquerel (CHB) between April 1, 2005 and December 31, 2006 were considered.

Patients and methods: Levels in patients treated for PBC with adjuvant or neo-adjuvant chemotherapy and a trend towards significance (p = 0.08). Multivariate analysis confirmed that elevated HER2 ECD level (p = 0.002), with negative hormone receptor status showing significantly different between exemestane and tamoxifen (P = 0.05 at both timepoints). Bone turnover markers decreased with tamoxifen. BMD and bone turnover changes appeared to stabilise after initial treatment.

Disclosure: All authors have declared no conflicts of interest.

Objective: The goal of this retrospective study was to describe the prevalence of HER2+ disease among patients with early breast cancer receiving care in a community outpatient setting and to evaluate corresponding rates of trastuzumab use.

Methods: Female breast cancer patients receiving adjuvant care in the US Oncology network over a 36 month period (7/1/06 – 6/30/09) were identified using the iKnowMed (iKM) electronic medical record system. Patients were characterized with respect to HER2 status, trastuzumab utilization, ER/PR status, age, and practice region. HER2 status was determined by FISH or IHC testing. Associations between HER2 status, trastuzumab use and clinical characteristics were evaluated using chi-squared and t-tests.

Results: Overall, HER2 status was available for 86% of patients. Among 26,839 patients with documented HER2 status, 18% (n=4,871) were HER2+; 79% (n=21,128) were HER2- and 3% (n=831) had an inconclusive HER2 status (i.e. HER2 overexpression + by IHC with no subsequent confirmatory HER2 testing documented). Not surprisingly, there was a strong association between HER2 status and trastuzumab utilization (P < 0.001). Among 2,647 patients receiving trastuzumab with documented HER2 status, 2,503 (95%) were HER2+; 79 (3%) were HER2- and 63 (2%) had inconclusive HER2 status. Ninety-two percent of actively treated HER2+ patients received trastuzumab vs. 1% of HER2- patients and 36% of patients with inconclusive HER2 status. Hormonal status was associated with trastuzumab use (25% of ER and/or PR patients received trastuzumab; p < 0.001). No age differences were observed between patients receiving trastuzumab and those not receiving trastuzumab.

Conclusion: Results suggest that rates of HER2+ disease in early breast cancer, found to be high in this study, will differ from those found in the general breast cancer population. Patients who had inconclusive HER2 status received less trastuzumab. Treatment decisions may benefit from additional testing to facilitate informed treatment decisions.

Disclosure: M. Brummer: I am an employee Genentech, Inc a wholly owned subsidiary of the Roche group, sponsor of this project. I additionally maintain financial interest in the execution of this project from Genentech, Inc a wholly owned subsidiary of the Roche group. D. Lalla: I am an employee Genentech, Inc a wholly owned subsidiary of the Roche group, sponsor of this project. D. Forysth: I am an employee Genentech, Inc a wholly owned subsidiary of the Roche group, sponsor of this project. I additionally maintain financial interest in the form of stock options for the Roche group. J. Doan: I am an employee Genentech, Inc a wholly owned subsidiary of the Roche group, sponsor of this project. I additionally maintain financial interest in the form of stock options for the Roche group. M. Forysth: I am an employee of US oncology Inc, which received funding from project sponsor, Genentech, to execute and complete the project.
Methods: A single institution retrospective analysis was performed using the Vall d’Hebron University Hospital database to identify EBC pts. Data regarding surgical procedures and tumor clinical-pathological characteristics, including margin status, were collected. Margins were classified as PM or CM.

Results: Between 2008 to 2009, 85 BC pts, median age 55 years (range 25-94), underwent S2 for PM (42.4%) or CM (17.6%): immediate re-excision (8.8%), late re-excision (30.6%), and mastectomy (61.2%). Median time from S1 to S2 was 3.9 weeks (range 0-32.4). Median time from S1 to the initiation of Tx was 8.9 weeks (range 2-56.7). 31 pts (37.9%) initiated Tx within 8 weeks (G1) and 54 (63.3%) beyond 8 weeks (G2). With a median follow-up of 4.9 years (0.21-9.8), 12 pts (14.1%) recurred: 3 in G1 and 9 in G2. Median DFS was 8.6 years (95% CI 0.8-9.2). Median OS was not reached as only 4 pts died (all G2). In G1, median DFS was 9.1 years (95% CI 8.2-10 compared with 7.9 years in G2 [95% CI 7.1-8.8]), the difference not reaching statistical significance (p=0.355). No relationship was found between clinico-pathologic characteristics (tumor size, lymph node, histological grade, hormonal receptor, HER2, Ki67, vascular invasion status), type of S2 and timing to Tx.

Conclusion: Initiation of systemic treatment is more often delayed in patients with positive/close margins following BCS. Although not statistically significant, most recurrences in our series occurred in the group receiving adjuvant chemotherapy beyond 8 weeks of initial surgery. The impact of a second surgery for PM/CM and the consequent delay of adjuvant treatment should be carefully evaluated in clinical practice.

Disclosure: All authors have declared no conflicts of interest.

A MULTICENTER STUDY OF IMAGE-GUIDED RADIOTHERAPY ABERRATION OF SMALL BREAST CARCINOMAS

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Background: Locally ablative therapy of early breast cancer represents the next frontier in the evolution of minimally-invasive breast conservative therapy. We performed this Phase II trial to determine the efficacy and safety of Radiofrequency (RF) ablation of small localized invasive breast carcinomas as a multicenter study in Japan.

Methods: Forty patients with core-biopsy proven invasive breast cancer, T1a/b (≤2 cm) in diameter on ultrasound and MRI were enrolled in this trial. Under ultrasound guidance, the tumor and at least a 5mm margin of surrounding breast tissue were ablated with saline-cooled RF electrode followed by surgical resection. Pathologic and immunohistochemical stains were performed to assess tumor viability.

Results: Thirty-eight patients completed the treatment. The mean tumor size on ultrasound was 1.38 cm. The mean ablation time was 12 minutes using mean power of 80.0 watts. During ablation, the tumor became progressively echogenic that corresponded with the region of sever electrolyte injury at pathologic examination. Of the 38 treated patients, HandE and NADPH viability staining was available for 21 patients and in 21 (100%), there was no evidence of viable cancer cells. HandE and or sDNA staining were available for another 17 patients. In total, complete thermal injury to the target lesions was recognized in 32 of 38 treated patients (84.2%). No severe adverse effect on the skin and chest wall were noted.

Conclusion: RF ablation is a promising minimally invasive treatment of small breast carcinomas, as it can achieve effective cell killing with a low complication rate. We are planning a multicenter observational study for RF ablation of small breast carcinomas.

Disclosure: All authors have declared no conflicts of interest.

LONG TERM PERSISTENT ALPOECIA AND SUBOPTIMAL HAIR REGROWTH AFTER ADJUVANT CHEMOTHERAPY FOR BREAST CANCER: ALERT FOR AN EMERGING SIDE EFFECT: FRENCH ALOPERS OBSERVATORY

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Background: Since 2003, through the impetus given by Pr Erick Gamelin and the Regional Health Agency in Western France (Bretagne, Pays de Loire), a network called OMTI (“Drugs and Emerging Therapeutics Observatory”) has been created, including the Breast Cancer Forum. Anthracyclins and taxanes are the cornerstones of adjuvant chemotherapy for breast cancer. In France, since the PACS 01 publication, FEC 100 followed by docetaxel 100 mg/m2 has been the standard adjuvant chemotherapy regimen in breast cancer.

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ADJUVANT CHEMOTHERAPY FOR EARLY BREAST CANCER IN ITALY: WHAT HAS CHANGED TODAY versus the EARLY 2000’S. A COMPARISON BETWEEN TWO OBSERVATIONAL NATIONAL STUDIES – NORA AND NEMESI

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Background: A study conducted in Italy (NORA, Annals of Oncology 26; 17: 1386-1392) investigated the factors that affected therapeutic decisions in patients who had undergone surgery for early breast cancer (EBC) between 2000 and 2003. Five years later, a new retrospective observational study (NEMESI) was conducted in order to evaluate how attitudes to the adjuvant treatment of EBC patients have changed in Italy.

Results: A total of 3515 patients were enrolled in NORA and 1984 patients in NEMESI, respectively. 68.3% and 57.8% of patients (p=0.0001) received chemotherapy (+/- endocrine therapy), which is in accordance with an earlier diagnosis. The use of CMF-like regimens decreased from 37% in NORA to 9.1% in NEMESI (p<0.00001). Also anthracycline-containing regimens decreased (from 52.1% to 48.8%; p=0.001). In particular, “three-drug” regimens decreased (38.9% vs 25.5%), whereas there was a highly significant increase in the use of regimens containing anthracyclines and taxanes, combined in sequence (38.4% vs 0.9%, p<0.00001). The use of taxanes alone remained low (3.5% vs 3.7%, ns). The overall use of anthracyclines and taxanes increased from 53.0% to 87.1% and from 43.3% to 42.5%, respectively; both differences are highly significant (p<0.00001).

Conclusions: Attitudes to adjuvant chemotherapy regimens for EBC have changed over recent years. In fact, CMF regimens are now rarely used, whereas the administration of taxanes, used alone or in sequence with anthracyclines, has greatly increased. This positive trend reflects the fact that once chemotherapy is deemed necessary, the best available regimen should be used, which at present is represented by third-generation anthracyclines. Sponsored by Sanofi-Aventis – Italy.

ACCESS OF HIGH-RISK BREAST CANCER PATIENTS TO ADJUVANT CLINICAL RESEARCH PROGRAMS IN FRENCH COMPREHENSIVE CANCER CENTRES: A SURVEY BY THE REMAGUS GROUP

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Objectives: to evaluate what is the “real-life” access of patients with high-risk breast cancer (BC) to ongoing clinical adjuvant research programs in 3 comprehensive cancer centres (CCC).

Patients and methods: We have prospectively evaluated the adjuvantonline(TM)-based risks of recurrence and breast-cancer death in all invasive BC patients seen post-operatively by the dedicated multidisciplinary teams of 3 large French CCC during a 1-month period. We evaluated the risks in the absence of treatment and as all the residual risks following optimal treatments planned according to shared guidelines. We noted whether they were eligible for ongoing adjuvant trials and whether participation was proposed. Major international adjuvant trials were available on site. High-risk was defined as a calculated residual risk of death as high as the residual risks following optimal treatments planned according to shared guidelines. We noted whether they were eligible for ongoing adjuvant trials and whether participation was proposed. Major international adjuvant trials were available on site.

Results: During May 2009, 218 files of invasive BC patients were recorded for this survey. Main characteristics of patients: median age 60 (range 26-88), median PT 15 (range 1-110), median grade II, ER+ 85%, PR+ 69%, Her2 by IHC or Fish 10.3%, (NN+ 33%). Of all patients, 48% were proposed adjuvant chemotherapy. Of 23 Her2+ cases, 21 were proposed adjuvant trastuzumab, while 98% ER+ and/or PgR+ cases were
proposed adjuvant hormone therapy. Calculated median risks of cancer death and relapse without and after planned treatment were 9% and 26% vs 6% and 14% respectively. Only 34 patients (16%) were considered as patients with a high-risk status. Of them, 8 were Her2+; although these did not have a correct evaluation of risk through adjuvantonline!, 7 were eligible for ongoing adjuvant trials; 7 other high-risk cases were triple-negative cases, 6 being eligible for clinical trials; conversely, amongst the 19 high-risk ER+ and/or PgR-Her2- cases left, only 1 patient was eligible in 1 trial.

Conclusion: More than half of high-risk patients bear a luminal B breast cancer profile. While high-risk Her2+ and triple-negative BC patients have a large access to clinical research programs, luminal B patients have currently a very limited access to such adjuvant programs. New strategies are eagerly awaited for this population.

Disclosure: All authors have declared no conflicts of interest.

Background: Breast cancer (BC) is the most common tumor in Mexican women. Invasive BC, stages I to IIB, ductal or lobular, treated with surgery were included. Pts with in situ or inflammatory BC, or neoadjuvant chemotherapy were excluded. Pts were divided into four groups according to Ki67 levels: 1) Ki67 < 5%, 2) 6% to 20%, 3) 21% to 30%, and 4) > 51%.

Objective: To determine a correlation between Ki67 and prognostic factors, recurrence and overall survival in early BC.

Patients and methods: From January 2000 to December 2008, pts > 18 yrs old with invasive BC, stages I to III B, ductal or lobular, treated with surgery were included. Pts with in situ or inflammatory BC, or neoadjuvant chemotherapy were excluded. Pts were divided into four groups according to Ki67 levels: 1) Ki67 < 5%, 2) 6% to 20%, 3) 21% to 30%, and 4) > 51%.

Results: 132 pts were analyzed. Groups 1 to 4 were integrated by 23 pts (17.4%), 49 pts (37.8%), 26 pts (20%) and 16 pts (12.4%) respectively. In each group, adjuvant chemotherapy was indicated in 84.2%, 89.7%, 90.4% and 94% respectively.

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Conclusions: In early BC, high cellular proliferation through Ki67 is related to poor prognosis factors and high frequency of recurrence of the disease and lower time of survival.

Disclosure: All authors have declared no conflicts of interest.

The biological characteristics of early breast cancer (EBC), from NEMESI, an Italian retrospective observational study

M. Venturini, N. Barbagallo, N. Piccardo, A. Santoro, S. Siena, S. Supekar, S. De Placido

Methodology: Adjuvant chemotherapy of EBC in Italy between Jan 1 and June 30, 2008. Participating Centers were selected among those censored by the Italian Association of Medical Oncology, in order to closely represent the Italian scenario. Patients and methods: From January 2000 to December 2008, pts > 18 yrs old with invasive BC, stages I to III B, ductal or lobular, treated with surgery were included. Pts with in situ or inflammatory BC, or neoadjuvant chemotherapy were excluded. Pts were divided into four groups according to Ki67 levels: 1) Ki67 < 5%, 2) 6% to 20%, 3) 21% to 30%, and 4) > 51%.

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Conclusions: In early BC, high cellular proliferation through Ki67 is related to poor prognosis factors and high frequency of recurrence of the disease and lower time of survival.

Disclosure: All authors have declared no conflicts of interest.

Annals of Oncology
Background: NEMESI examined the clinical practice in the Italian Oncology Institutions on adjuvant treatment in EBC.

Methods: This retrospective observational study describes adjuvant treatment in EBC, involving, between January 1 and June 30, 2008, at least 1,500 cases, 30 consecutive visits in each center and representative of the Italian situation, in terms of geographical distribution and type of institution, as evidence from the census reported on the white Book of the Italian Association of Medical Oncology (AIOM). Inclusion criteria: age ≥ 18 years, histological diagnosis of early stage operated breast cancer (stage I-II TNM AJCC version VI), ≥ 1 cycle of adjuvant chemotherapy (CT) and/or hormone therapy.

Results: A total of 1,894 were included. Tumor characteristics: pT1: 67.0% (22.3%: pT1mic + pT1a + pT1b); pN0: 61.0%; pN1: 29.1%; pN2: 6.3%; pN3: 3.6%; ER pos (20%): 81.2%; ER neg (0-9%): 18.6%; median ki67: 17%; HER2 pos: 16%. Adjuvant treatment without CT was administered in 799 patients (42.2%), while the remaining 1,095 (57.8%) received systemic CT. Administration of CT is influenced by pN: 43.5% of pts with pN0 received CT; 76.6% of pN1; 89.1% of pN2; 94.2% of pN3. In the pN0 group administration of CT is influenced by pT: 30.6% of pts with pT1.1-2.0 cm received CT; 64.4% of pT1.1-2.0 cm; 71.6% of pT2.1-3.0 cm. Use of CT is influenced by recurrence risk. The use of Anthracycline and Taxanes increases with risk: pN1 45.0%; pN2-3 >70%.

Conclusions: Italian Oncology Centers frequently use adjuvant CT in EBC. Choice of adjuvant CT is influenced by prognostic factors (pT and pN). There is still widespread use of first-generation CT drugs, independent from disease severity. In particular for pN0-pN1 class there is an underuse of taxane-based CT, which is administrated above all for EBC with high recurrence risk (pN2 and pN3). Study supported by sanofi-aventis Italy.

Disclosure: M. Venturini: Membership of the advisory board of this study. S. Rossi: Employed by sanofi-aventis as Medical Advisor in Oncology, Medical Department. All other authors have declared no conflicts of interest.
Results: According to the initial recommendation (blinded for MP) of these 3 academic teams, 13 of 34 HR patients remained without CT and 9 of 11 MP LR patients would still receive chemotherapy. Subsequently, unblinded for the MammaPrint result, these 3 academic teams changed their recommendation in 6 of 13 MP HR patients. Ultimately, from the 78 patients classified as High risk by MammaPrint, 7 remained without chemotherapy treatment recommendation in this multidisciplinary adjuvant treatment planning (9%).

Conclusions: This study demonstrates high variability in the adjuvant strategies between multidisciplinary teams based on traditional patient and tumour related parameters. In our study population, the MammaPrint gene profile would have modified adjuvant treatment recommendation in at least 10% of patients

Disclosure: All authors have declared no conflicts of interest.

THE OUTCOMES OF THE SPECIALIZED GENETIC PROGRAM PROVIDED FOR THE CARRIERS OF THE GENETIC ALTERATIONS PREDISPOSING TO THE BREAST CANCER

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The f-up program for individuals carrying mutations in breast/ovarian cancer predisposing genes has been provided at the specialized unit of the Dept. of Oncol., General Teaching Hospital, Prague, in close collaboration with the Dept. of Med. Genetics and Biochem. and Exp. Oncol. since 1999. The mutation status of the BRCA1 and BRCA2 genes has been analyzed since its beginning, testing of other genes involved in hereditary breast cancer (HBC) development has been introduced later (Table 1).

Table 1. Basic characteristic of tested population.

<table>
<thead>
<tr>
<th>Analyzed gene</th>
<th>No. tested individuals</th>
<th>No. tested families</th>
<th>No. mut. carriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRCA1</td>
<td>1336</td>
<td>156</td>
<td>190</td>
</tr>
<tr>
<td>BRCA2</td>
<td>1336</td>
<td>48</td>
<td>67</td>
</tr>
<tr>
<td>CHEK2</td>
<td>1336</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>P53</td>
<td>1211</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>ATM</td>
<td>1211</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

Conclusion: Specific preventive program for mutation carriers is an effective option for identification of high-risk BC patients at early and highly curable stages. Acknowledgement: The study was supported by the grant MS.M002162.00808.

Disclosure: All authors have declared no conflicts of interest.

ADJUVANT CHEMOTHERAPY PRESCRIPTION ACCORDING TO MULTIDISCIPLINARY TEAM DECISION OR THE MINDACT PROTOCOL (MICROARRAY IN NODE-NEGATIVE AND 1 TO 3 POSITIVE LYMPH NODE DISEASE MAY AVOID CHEMOTHERAPY) (EORTC10041 BIG 3-04)

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Introduction: The European-based MINDACT trial is a multicentre prospective phase III randomised study. It compares a genomic test (G) (MammaPrint®) developed with microarray technology to traditional clinical-pathological (C) criteria (age, tumor grade, stage, hormone receptor expression) included in a modified version of Adjuvant! Online (AIO) for assessing the risk of recurrence in women with lymph node negative or 1-3 node positive breast cancer. Patients assessed as “High Risk” by both MammaPrint® and AIO are advised to have CT whereas for those assessed “Low risk” by both methods no chemotherapy is recommended. Discordant cases are randomised to treatment decision based on G or C criteria. We compared the prescription of CT defined by the protocol to the one decided in the multidisciplinary tumour board as traditionally done.

Materials and methods: Among the 35 patients enrolled between May 2008 and January 2010, 16 patients were classified as low risk (CL-LG) by both methods, 4 patients were classified as high risk (CH-GH) by both methods and 15 patients were in the discordant group.

Results: The 16 CL-LG patients did not receive CT in accordance with the protocol. Eight of these patients would have been proposed CT by the tumour board. The 4 CH-GH patients were proposed CT in accordance with the protocol and would also have been recommended CT by the tumour board. For the 2 patients with a CL-LG randomised to no CT, the decision was also identical between the protocol and the tumour board. Among the 13 patients with CH-LG, 12 would have received CT according to the tumour board while following the protocol randomisation only seven received CT. Overall, from the 35 patients included, 15 (43%) avoided CT due to the MINDACT protocol.

Conclusions: Since breast cancers with similar clinical characteristics can have strongly different outcomes, even if treated similarly, the current decision-making for adjuvant CT needs to be improved. If the added value of the molecular profile is validated, a personalisation of the treatment strategy could be considered for each patient.

Disclosure: All authors have declared no conflicts of interest.

DYNMICS OF CIRCULATING ENDOTHELIAL CELLS AND ENDOTHELIAL PROGENITOR CELLS IN BREAST CANCER PATIENTS RECEIVING CYTOTOXIC CHEMOTHERAPY

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Background: Anti-angiogenic therapy has become an important field in cancer treatment. Few studies have described circulating endothelial cells (CECs) and circulating endothelial progenitor cells (CEPs) values change after cycles of chemotherapy. However, there is no study to describe the CEC and CEP dynamic change “during” each consecutive cycle of chemotherapy in human, of which may give us a way to evaluate the timing of adding anti-angiogenic agents.

Materials and methods: We collected blood samples from breast cancer patients who received systemic chemotherapy. CECs, viable circulating endothelial cells (V-CECs) and CEPs were measured by six-color flow cytometry (7-AAD for CECs and CEPs) of these patients, examined within 7 days prior to chemotherapy, twice a week during first and second cycle chemotherapy, then once a week at subsequent cycles of chemotherapy. When analyzing, point of measurement were divided into Day 1 of chemotherapy, 1st week of chemotherapy and after 1st week of chemotherapy. The Day 1 of chemotherapy was set as reference point.

Results: There were total 36 courses of chemotherapy for the 15 patients included in our study. The means of CEC, V-CEC and CEP were all significantly decreased in the 1st week of chemotherapy compared to those in the Day 1 of treatment, the differences were -2.0%/5% CI (-3.98, -0.12), -1.57%/5% CI (-3.06, -0.14); and -0.40%/5% CI (-0.60, -0.20) respectively. After 1st week of chemotherapy, the means of CEC, V-CEC, and CEP came back to a similar level compared to Day 1 of treatment. The differences were 0.07%/5% CI (-1.17, 1.85), 1.11%/5% CI (-1.49, 1.70), and 0.39%/5% CI (-0.54, 0.16) respectively. There was a trend towards increase in total number of CEP after cycles of chemotherapy. The other factors including existence of tumor, status of operation, drug used, and use of GCSF, were not statistically significantly affected these results.

Conclusions: Although the CECs and CEPs decrease in one week after chemotherapy, the number recovered soon, and with a trend towards increase in CEP number after several cycles of chemotherapy. The possible impact of this phenomenon on tumor re-grow warrant further studies.

Disclosure: All authors have declared no conflicts of interest.

IMPACT OF DIFFERENT PROGNOSTIC FACTORS ON THE DEVELOPMENT OF BRAIN METASTASIS IN ADJUVANT BREAST CANCER PATIENTS

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Background and aim: The brain is increasingly being recognized as a sanctuary site for metastatic tumor cells in high risk breast cancer patients. Symptomatic brain metastases develop in 10%-20% of patients with metastatic breast cancer, most often following disease progression at other sites, carrying a poor 1- and 2-year survival rates of only 20% and <2%, respectively.

Patients and methods: We retrospectively analyzed breast cancer patients eligible for adjuvant systemic treatment who presented to us in the period from 2000 till 2006. Relationship between BDFS and different factors was done.
Results: Our study included 1752 patients of which 75 developed brain metastasis. The 5-year DFS was 84.5% for ER-ve, 86.4% for PR-ve, 84.5% for PR-ve +ve patients compared to 93.5% for ER +ve (p<0.001), 93.7% for PR +ve (0.006) and 92.5% for Her-2/neu-ve (0.002) patients respectively. Patients with grade III tumors had a lower 5-year DFS of 81.2% compared to 93.1% for those with grade I-II disease (p<0.001). Positive lymph nodes had a marginal significance of a lower DFS as well (96.2% vs. 94.5%; p=0.042). There was no significant difference seen according to age, pathological type or menopausal status. In a multivariate analysis model, histological grade and negative hormonal receptor status were the most significant. Her-2/neu score was missing in a quite a large number of patients which did not allow us to draw solid conclusions regarding its predictive value. By comparing DFS among different subgroups of Breast cancer namely Hormone Receptor positive (HR+), Her2 positive (Her2+) and Triple negative (TN), no statistical significant difference was found with median DFS of 35.7, 26.3, 26.9 months respectively (p=0.487).

Conclusion: Patients with poorly differentiated tumors appear to have a higher probability of developing brain metastases as well as those with negative hormonal status. We could not draw solid conclusions regarding the predictive value of Her-2/neu gene. These patients could be good candidates for trials investigating the role of any prophylactic intervention to decrease their risk to develop brain metastases.

Disclosure: All authors have declared no conflicts of interest.
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Results: Median age of the 170 patients included, was 56 years (45.8-64.3), 37.1% were premenopausal and 62.9% were postmenopausal. Estrogen receptors in our series were positive in 64.2%, progesterone receptors were positive in 44.7%. Grade 1 in 11.2%, II in 55.9% and III 32.9%. HER2 was positive in 21%. Clinical stage was IIIA 36.6%, IIIB 23.3%, IIIB 20.3% and IIIB 19.8%. Surgery of the primary tumor was conservative in 39.4% and mastectomy in 60.6%. Patients received a median of 4 cycles (3-8) of neoadjuvant CT, 70.3% with anthracyclines and 29.7% with anthracyclines associated to taxanes. pCR obtained was 14% in schedules with anthracyclines and 23% in CT containing both anthracyclines and taxanes. In the univariate analysis, patients obtaining pCR presented significantly an increased rate of grade 3 tumors and negative estrogen and progesterone receptors. Patients with pCR completed an increased number of cycles of CT and surgery underwent was more frequently conservative. In the multivariant analysis molecular prognostic factors maintaining significance were grade and estrogen receptors.

Conclusions: Negative estrogen receptors, and grade 3 are both predictive factors useful for decision in the neoadjuvant setting. Tumors with these features are strongly associated with an increased probability of obtaining pCR in this setting.

Disclosure: All authors have declared no conflicts of interest.

THE 70-GENE EXPRESSION PROFILE FOR BREAST CANCER PATIENTS IN ITALIAN HOSPITALS


Background: The 70-gene tumor expression profile “MammaPrint” was established as a powerful predictor of disease outcome in breast cancer. The St Gallen 2009 recommendations include gene-expression signatures as an indicator for adjuvant therapy. Here we determined in an Italian cohort how the 70-gene profile could assist in patient management.

Methods: Fresh tumor samples (n=584) from breast cancer patients (clinical T1-4N0-3M0) aged 26 to 98 years (median age 63 years), were collected in 12 Italian hospitals in 2008 and 2009 by core needle biopsy or from a surgical specimen (study protocol MP 090). We assessed agreement between the treatment advice as recommended by the 2009 St Gallen Highlights and classification according to the 70-gene MammaPrint profile.

Results: According to the St Gallen 2009 treatment recommendations, 4 patients could forego any adjuvant treatment (<1cm, LNO, PVI1). Of these patients, 3 were classified to be poor prognosis signature by MammaPrint. Another 17 patients with tumors <1cm, LNO, PVI1 are ER+ and are recommended endocrine treatment, of whom 9 are MammaPrint high risk. The 126 Her2+ patients were recommended anti-Her2 treatment as well as adjuvant chemotherapy according to the 2009 recommendations. Of these patients, 19 (15%) were classified as good prognosis signature by MammaPrint. All 47 (ER-) patients who were recommended chemotherapy alone are classified as poor prognosis by MammaPrint. For the 389 ER-, HER2- patients, 17 would be recommended no adjuvant chemotherapy (Grade I and LN0 and III, or34LN, or >5cm, or ER <50%). Of these 215 patients, 73 (34%) are classified as low ER >50%) and 198 would be recommended adjuvant chemotherapy being either Grade II in 55.9% and III 32.9%. HER2 was positive in 21%. Clinical stage was IIA 36.6%, IIB 23.3%, IIIB 20.3% and IIIB 19.8%. Surgery of the primary tumor was conservative in 39.4% and mastectomy in 60.6%. Patients received a median of 4 cycles (3-8) of neoadjuvant CT, 70.3% with anthracyclines and 29.7% with anthracyclines associated to taxanes. pCR obtained was 14% in schedules with anthracyclines and 23% in CT containing both anthracyclines and taxanes. In the univariate analysis, patients obtaining pCR presented significantly an increased rate of grade 3 tumors and negative estrogen and progesterone receptors. Patients with pCR completed an increased number of cycles of CT and surgery underwent was more frequently conservative. In the multivariant analysis molecular prognostic factors maintaining significance were grade and estrogen receptors.

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Disclosure: All authors have declared no conflicts of interest.

EVALUATION OF COMPLETENESS AND QUALITY OF THE INFORMATION PROCESS DURING GENETIC COUNSELLING FOR CANCER PREDISPOSITION. PRELIMINARY RESULTS OF THE GENETIC COUNSELLING SERVICE (GCS) OF SOUTHERN SWITZERLAND

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Introduction: Phase 3 studies showed the way information is provided can impact patients’ comprehension of risk, their concerns and anxiety, the last two dimensions being generally overestimated by physicians. Informative and relational dimensions of cancer predisposition assessment can affect individuals’ quality of life and negatively impact their psychological condition.

Subjects and methods: A pilot prospective survey assessed satisfaction and distress associated with genetic counselling in patients and probands of the GCS of Southern Switzerland. Subjects were given:
1) The STAI (C.D. Spielberger) to evaluate State and Trait Anxiety. 2) A specifically designed questionnaire (26 items) to evaluate informative, emotional and interactive dimensions of the counselling interview and genetic testing indication.

Preliminary results: The survey was conducted in 100 consecutive subjects: 59% affected patients and 45% probands. Age was <50 years in 53% of subjects, where 61% were females and 66% had at least a high school degree. The vast majority of the subjects (84%) reported to be satisfied with the consultation, the proportion being slightly higher in patients (49%) as compared to probands (39%). Sixty-nine per cent of the respondents seemed to understand the implications and consequences of genetic testing with no apparent difference between the 2 subgroups. As regards the psychological impact, 76% of the population reported the same level of concern and fear as compared to pre-counselling.

Conclusions and future perspectives: Overall, the preliminary data analysis showed a high degree of satisfaction in terms of well-being during the consultation, clarity and understanding of the information given. The degree of anxiety before and immediately after counselling, as specifically investigated by the STAI instrument, is being currently analysed. Next steps include a detailed qualitative analysis of weaknesses and limits of the questionnaire (i.e. type and formulation of some questions) in order to develop an improved tool to be shared with different cancer genetic services in Northern Italy.

Disclosure: All authors have declared no conflicts of interest.

BREASTFEEDING IN BREAST CANCER SURVIVORS: PATTERN, BEHAVIOUR AND EFFECT ON BREAST CANCER OUTCOME

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Background: We have recently presented a metaanalysis confirming the safety of pregnancy in breast cancer (BC) survivors [Azim HA Jr et al; EBCC 2010]. However, very little is known regarding the safety and feasibility of breastfeeding in these women.

Methods: We searched the database of the European Institute of Oncology from 1988-2006 for women ≤ 40 years at BC diagnosis. We constructed a questionnaire and performed a survey among patients who had a completed pregnancy following BC therapy to examine their lactation behaviours and its effect on BC outcome.

Results: 32 women were identified, 20 were reachable and accepted to take the survey. 15 women were previously subjected to breast conservative surgery (BCS) while the rest were subjected to mastectomy. Only 10 (30%) women initiated breastfeeding. The main reasons for not initiating breastfeeding were “uncertainty regarding maternal safety” and “a prior unreasibility” expressed either by the obstetrician or by the medical oncologist. In those who breastfed their babies, 4 stopped within 1 month and 6 had long-term success with a median period of 11 months (7-17 m). The latter were all previously subjected to BCS and received lactation counselling at delivery. Out of 15 women who underwent BCS and radiotherapy, 14 reported hypoplasia of the irradiated breast during pregnancy. 7/15 attempted to breastfeed from the affected breast but milk production was significantly reduced with difficulty in latching. Only 2 women were able to breastfeed from both breasts but only for 2 weeks. At a median of 48 months following delivery, all 20 women were alive with z6lapses; 1 in each group (i.e. lactating and non-lactating).

Conclusions: Breastfeeding from the affected breast is challenging but exclusive lactation from the contratateral breast is feasible. Previous mastectomy was associated with short lasting (< 1 month) breastfeeding, even if all women who had a previous BCS used 1 breast for lactation. This emphasises the importance of body image in the

by guest on 02 July 2018
Materials and methods: The study group consisted of 34 premenopausal women with breast cancer. The diagnosis was histopathologically proven and hormone receptors were positive.

Objective: In this study, we intended to investigate osteoporosis progression in the early stages after ovarian ablation in premenopausal women with breast cancer whose hormone receptors were positive.

Materials and methods: The study group consisted of 34 premenopausal women with breast cancer. The diagnosis was histopathologically proven and hormone receptors were positive in all patients. Control group consisted of 15 healthy individuals. 18 patients were observed over 2 years, 16 patients were observed over one year. Ovarian ablation was made in 7 of 34 patients by chemical therapy, and in 27 of 34 patients by hormone therapy. The levels of baseline, sixth month, first year, and second year of calcium, phosphate, ionized calcium, ALP, FSH, LH, estradiol, urine deoxypyridoline, osteocalcin, and PTH were obtained. Lumbar spine and femur neck bone mineral density was measured.

Results: The measurements of patients and control groups in baseline showed no significant statistical difference. Patients observed over 2 years (18/34) had no significant statistical difference in calcium, phosphate, ionized calcium, ALP, FSH, LH, estradiol, urine deoxypyridoline levels. However, osteocalcin levels were significantly increased at second year (P<0.004). Levels of estradiol were significantly decreased at six month, first year and second year (P<0.001). When compared with the basic measurement there was a statistically significant decrease in L1-4 bone mineral density of at 6th month, 1st year, 2nd year (P<0.001). There was a statistically significant decrease in T score of femur neck between baseline and sixth month and second year (P=0.038). While none of the patients had osteoporosis at the beginning, at the end of 1 year one patient and at the end of 2 year 3 of 18 patients had osteoporosis. Among patients observed through one year only one patient had developed osteoporosis.

Conclusion: Ovarian insufficiency caused by hormone therapy may result in osteoporosis. A decrease in bone mineral density of 10% of patients undergo ovarian ablation; these patients must be followed closely due to these risks.

Disclosure: All authors have declared no conflicts of interest.
FEATURES OF RECURRENCE OF TRIPLE NEGATIVE (TN) NON-METASTATIC BREAST CANCER (NMBC) PATIENTS: A SINGLE INSTITUTION STUDY

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Background: TN breast cancer (BC) are the most aggressive type of BC, and we do not have a target therapy against this type. Our goal is to determine the rate of recurrence, the affected organs and the DFS in these patients.

Materials and methods: We reviewed 1042 charts of all diagnosed BC patients from January/2000 to December/2005 and choose 215 who were TN-NMBC. The data was analyzed by analytic and descriptive statistics in SPSS v. 17.0

Results: The rate of TN-NMBC were 20.6%(215) of them 18.6%(40) patients had recurrences with an average age of 52.5(±9.3) years. The median DFS were 27 months with a median follow-up of 64 months. The Stage I, II and III were 7.5%(3); 32.5%(13) and 60%(24) respectively for patients with recurrence. The most frequent involved organs with recurrence were visceral (lung and liver) 37.5%(15), bone 25%(10), skin 20%(8), CNS 12.5%(5) and contralateral breast 5%(2). Additionally we found five patients with history of familiar BC, and four of them were stage II with negative node at diagnoses.

Conclusion: TN-NMBC are 20.6% of all BC, the majority of them were stage III (60%), the median DFS for patients with recurrence were 27 months, and the most frequent sites involved were visceral (37.5%) and bone (25%). It is very interesting pay attention even in early stages to patients with history of familiar BC for risk of recurrence, BRCA positive?.

Disclosure: All authors have declared no conflicts of interest.

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CLINICAL RESPONSE OF TRIPLE NEGATIVE BREAST CANCER TO TAXANES

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Background: Most of triple-negative breast cancer (TNBC) has close association with the BRCA1 gene dysfunction. It has been demonstrated that BRCA1 genotype affects sensitivity of breast cancer to chemotherapeutic agents. DNA-damaging agents such as platinum are promising in the treatment of TNBCs harboring BRCA1 dysfunction. Although previous experimental studies have indicated that tumors with BRCA1 mutation are less sensitive to taxanes, it remains to be clinically determined whether TNBCs are sensitive to taxanes.

Objective: The aim of this study is to analyze the clinical response of TNBC patients to the neoadjuvant chemotherapy with taxanes.

Patients and methods: Between 2003 and 2010 at our institutes, patients were retrospectively selected for this study according to the following criteria: (1) Female breast cancer patients who received 4 cycles of doxorubicin (60 mg/m²) or epirubicin (90 mg/m²) and cyclophosphamide (600 mg/m²) every 3 weeks followed by 12 cycles of weekly paclitaxel (80 mg/m²) or 4 cycles of triweekly docetaxel (75 mg/m²) as a neoadjuvant setting. (2) Patients who were evaluated by the imaging studies as CT or MRI following in the three points: 1) before treatment, 2) after anthracyclines and 3) after taxanes.

Results: A total of 71 patients fulfilled the eligibility criteria for this study. We compared the clinical responses of TNBCs to taxanes with that of non-TNBCs.

Conclusion: There were 24 TNBCs (33%). The median age of TNBCs was 52 years (31-68 years). Eight and 16 patients were clinical stage II and III respectively. Twenty-three patients received weekly paclitaxel, and one patient received triweekly docetaxel. Overall clinical responses of AC (EC) followed by taxanes in TNBCs were 91% (CR, 5; PR, 17). Primary tumor progression was seen in 4 patients (16.6%) while receiving taxanes. One of 4 patients experienced progressive disease (PD) by the RECIST criteria. Four patients with tumor progression were associated with young age or having family history or great response to anthracyclines. No tumor progression while receiving taxanes occurred in the patients with non-TNBCs.

Disclosure: These data suggest that TNBCs, especially associated to BRCA1 dysfunction, may be less sensitive to taxanes in clinical settings.

DISCLOSURE: All authors have declared no conflicts of interest.

FACTORS INFLUENCING THE TIME OF SENTINEL NODE VISUALIZATION IN BREAST CANCER PATIENTS USING INTRADERMAL INJECTION OF THE RADIOTRACER

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Background: The objective of our study was to determine the important factors which have influence on the time of sentinel node visualization using intradermal injection of 99mTc-Antimony sulfide colloidal.

Methods: 250 consecutive patients with the diagnosis of early stage breast cancer were evaluated. Anterior and lateral views were acquired in various intervals after intradermal injection of the tracer till 180 minutes or visualization of the sentinel node. The effect of several variables on the time of sentinel node visualization was evaluated by univariate and multivariate analyses.

Results: The time of sentinel node visualization was significantly correlated with age, BMI, and interval between biopsy and sentinel node mapping. Standardized beta values for these variables were 0.1, 0.3, -0.35 respectively.

Conclusions: Older age and higher BMI can result in slow sentinel node visualization. Longer interval between biopsy and sentinel node mapping can be associated with rapid sentinel node detection.

Disclosure: All authors have declared no conflicts of interest.

SENTINEL LUMP NODE MAPPING IN EXCISIONAL BIOPSY

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Background: The aim of this study was to determine rate of recurrence, BRCA positive?.

Methods: We reviewed 1042 charts of all diagnosed BC patients from January/2000 to December/2005 and choose 215 who were TN-NMBC. The data was analyzed by analytic and descriptive statistics in SPSS v. 17.0

Results: The rate of TN-NMBC were 20.6%(215) of them 18.6%(40) patients had recurrences with an average age of 52.5(±9.3) years. The median DFS were 27 months with a median follow-up of 64 months. The Stage I, II and III were 7.5%(3); 32.5%(13) and 60%(24) respectively for patients with recurrence. The most frequent involved organs with recurrence were visceral (lung and liver) 37.5%(15), bone 25%(10), skin 20%(8), CNS 12.5%(5) and contralateral breast 5%(2). Additionally we found five patients with history of familiar BC, and four of them were stage II with negative node at diagnoses.

Conclusion: TN-NMBC are 20.6% of all BC, the majority of them were stage III (60%), the median DFS for patients with recurrence were 27 months, and the most frequent sites involved were visceral (37.5%) and bone (25%). It is very interesting pay attention even in early stages to patients with history of familiar BC for risk of recurrence, BRCA positive?.

Disclosure: All authors have declared no conflicts of interest.

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Despite the successful application of sentinel node mapping in breast cancer patients, its use in patients with the history of previous excisional biopsy of the breast tumors is the matter of controversy. In this present study we evaluated the accuracy of sentinel node biopsy in this group of patient and compared the results with those in whom the diagnosis of breast cancer was established by core needle biopsy. 80 patients with the early stage breast carcinoma were included into our study. 40 patients had the history of previous excisional biopsy and the remainder 40 have undergone core needle biopsy. Intradermal injections of 99mTc-antimony sulfide colloid as well as patent blue were both used for sentinel node mapping. Sentinel nodes were harvested during surgery with the aid of surgical gamma probe. All patients underwent standard axillary lymph node dissection subsequently. Detection rate was 97.5% for both groups of the study. Number of detected sentinel node during surgery was not significantly different between groups. False negative rate was 0% for both groups of the study. In conclusion sentinel node biopsy is reliable in patient with previous history of excisional biopsy of the breast tumors and has low false negative rate.

Disclosure: All authors have declared no conflicts of interest.

261 PHASE II STUDY OF DOCETAXEL AND DOXORUBICIN COMBINATION AS NEOADJUVANT CHEMOTHERAPY IN OPERABLE BREAST CANCER PATIENTS

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Background: The idea of using neoadjuvant chemotherapy in patients with operable breast cancer is validated from experimental and clinical observations as well as theoretical hypotheses on tumor cell growth and dissemination. Several recently reported trials of neoadjuvant therapy incorporating newer agents such as taxane in sequence with breast cancer was established by core needle biopsy. Thirty-eight women were treated with intravenous doxorubicin 50 mg/m2 over 15 min followed by a 1-h infusion of docetaxel 75 mg/m2 every 3 weeks for six cycles. Dexamethasone and anti emetic drugs as premedication was allowed. Granulocyte colony-stimulating factor was not given as primary prophylaxis. The primary end point was the pathological response rate and its correlation with the improved outcomes.

Results: In our interim analysis, the overall pathological response rate was 13%. There were 9 complete and 24 partial clinical responses for an overall response rate of 89% (95% confidence interval (CI) 79% to 95%) in the evaluable population (n = 37). Disease-free and overall survival rates were 83% (95% CI 71% to 94%) and 96% (95% CI 85% to 99%), respectively, after a median follow-up of 36.6 months. Grade 3/4 neutropenia was observed in 46% of patients and 13% reported grade 4 febrile neutropenia.

Conclusions: Docetaxel and doxorubicin is an effective and well-tolerated combination in the neoadjuvant therapy for operable breast cancer.

Disclosure: All authors have declared no conflicts of interest.

262 PREGNANCY AND BREAST CANCER

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Background: Choosing proper tactics for the treatment of pregnancy-associated breast cancer (PABC) remains very complicated. Methods: We have performed an analysis of treatment outcomes of 87 patients with PABC, who underwent treatment in N.N. Petrov Research Institute of Oncology in 1990-2009. In 29 patients tumor was detected during pregnancy, in 58 – during lactation (first months after childbirth). In 37 (42.5%) patients early BC (T1-2N0-1M0) was detected, in 22 patients – locally-advanced BC (T3-4N1-2M0), 25 patients had metastatic BC. The control group consisted of 242 patients with BC not associated with pregnancy, who had received treatment in the same time frame. It included 128 patients with early BC, 56 patients with locally advanced BC and 58 patients with metastatic disease. Patients with locally advanced BC received FAC (70%) or TAC (30%) neoadjuvant chemotherapy. All patients with early BC and about 80% of patients with locally-advanced BC (after neoadjuvant chemotherapy) underwent surgery: 43 of 59 had mastectomy and 10 patients had breast-conserving surgery in PABC group. Patients with metastatic disease in both groups received CMF, FAC or taxane-based chemotherapy.

Results: 7 year mean follow-up showed no significant difference in survival of patients who underwent surgery either for early or for locally advanced BC either associated with pregnancy or not (75.5% and 77%, respectively). Moreover, no difference in overall survival between patients with PABC and non-associated with pregnancy BC was found (68% vs 62% P=0.50). There was no difference in overall survival between groups of patients with metastatic PABC and non-associated with pregnancy BC (14.6 and 15.6 months, respectively).

Conclusion: No significant difference in survival between patients with PABC and non-associated with pregnancy BC was found. Though there is an obvious connection of prognosis and survival with clinical stage of disease and detection of locally advanced form.

Disclosure: All authors have declared no conflicts of interest.

263 MALE BREAST CANCER

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Background: Male breast cancer is rare; it constitutes 0.2–1.3% of all malignant tumours in men and 1% of all breast cancers.

Patients and methods: The goal of this retrospective study is to analyse the epidemiologic, clinic, therapeutic and evolutive profiles of this disease in 122 cases collected at the National Institute of Oncology in Rabat, Morocco, between the years 1997 and 2007

Results: The median age was 60 years (27-90). The average consultation’s delay was 14 months. The main clinical complaint was a mass beneath the areola in 98% of the cases, associated with ulceration in 39% of the cases. For that, the disease was diagnosed at an advanced stage. Infiltrating ductal carcinoma was the most frequent pathologic type (96% of cases). Lymph node involvement was found in 93% of cases. The oestrogen and progesterone receptors were positive in 92%. Management consisted especially of radical mastectomy, followed by adjuvant radiotherapy and hormonal therapy with or without chemotherapy. It was possible to follow 100 of the patients. The median of follow-up was 49 months. The five-year disease free survival and OS rates were 66% and 82% respectively. The evolution has been characterized by local recurrence, after a median delay of 12 months, in 2 cases. Metastasis occurred, after a median delay of 16 months, in 27 cases (53% of all patients). The site of metastasis was the bone in 10 cases, lung in 8 cases, liver in 8 case and skin in one case. There were 2 cases of death. Progression was observed in one case

Conclusion: Male breast cancer is a rare disease (about 1% of breast cancer) with a poor prognosis (32% 10 years disease free survival). An early diagnosis and better knowledge of the disease would certainly lead to improvement of prognosis.

Disclosure: All authors have declared no conflicts of interest.

264 AN EXPLORATORY STUDY TO CONFIRM OR REFUTE THE NOVEL HYPOTHESIS THAT IATROGENIC HYPERCORTISOLISM CAUSES OSTEOPOROSIS IN BREAST CANCER SURVIVORS ON AROMATASE INHIBITORS

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Background: To determine if aromatase inhibitors (AIs) cause accumulation of upstream adrenal biosynthetic intermediates with diversion of hormones down the 17 alpha-hydroxylase/17,20-lyase (CYP17) or the 11beta-hydroxylase (CYP11B) pathway.

Results A Results B
Slope 0.0551 0.1563
Intercept 30.0002 8.7036
R2 0.1340 0.1071
F 0.1912 2.1306
Regression ss 135.12 955.488
Pearson 0.1307 0.4191

Disclosure: All authors have declared no conflicts of interest.

Results: From October 2008 and January 2010, 19 patients were enrolled on the trial. Data analysis was in May 2010. No statistically significant alteration occurred in the levels of androstenedione, DHEAS, 17(OH) progesterone, 11-deoxycorticisol and a 24 hr urinary free cortisol were measured. Also the bone formation marker procollagen 1 propeptide (PINP) and bone resorption marker, type 1 collagen amino telopeptide (NTx) were measured. Urinary NTx was correlated with 24 hr urinary free cortisol by linear regression analysis.

Results: From October 2008 and January 2010, 19 patients were enrolled on the trial.
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population) (Results B). On reanalysis a moderate correlation was found (Pearson 0.42). Diagram 2: Urinary NTX versus 24hr urinary cortisol

Conclusion: There is a moderate correlation between the bone resorption marker Ur. NTX and 24 hr urinary free cortisol (Pearson 0.42) in patients on AIs a possible cause of osteoporosis. Further studies in larger patient cohorts are indicated to confirm this important advance.

Disclosure: C.F. Kelleher: The Hospital received 10,000 euro to fund this study from Novartis. All other authors have declared no conflicts of interest.

OUTCOME IN YOUNG WOMEN WITH BREAST CANCER: MOROCCAN EXPERIENCE

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Background: Breast cancer is uncommon in young women and correlate with poor prognosis. The aim of this study was to determine demographic and molecular characteristics, outcome and prognostic factors in young women with breast cancer.

Methods: Four hundred and nine women aged less than 35 years were diagnosed with breast cancer at the national institute of oncology between 2003 and 2007. Demographic, molecular and treatment characteristics were taken from patient record.

Conclusions: The relation between molecular, clinico-therapeutic characteristics and event-free survival (EFS) and overall survival (OS) was assessed.

Results: Median age was 32 years. Fifty three patients (13%) had metastatic disease at diagnosis. Three hundred and 56 patients (87%) had localized disease. Twenty-eight patients (9.9%) had a family history of breast cancer. BRCA mutation was diagnosed in one only patient and was positive. Fifty eight % of the patients had estrogen receptors (ER) positive. ERBB-2 gene amplification was diagnosed in 57 patients and was positive in 24. Three hundred and 47 patients received surgery for localized disease. Seventy six patients (21.3%) received neoadjuvant chemotherapy from which 2 patients had pathologic complete response. The median follow-up was 32.2 months. Patients with stage I, II, III and IV disease had 100%, 89.3%, 74.7%, and 57.8% survival after 3 years respectively. This difference was statistically significant (p<0.001). In patients with localized disease. In multivariate analysis, we showed that ER negative status was the only prognostic factor significantly influencing the OS (HR = 2.43, 95% CI = 1.25-4.66, p=0.009). Also, ER status and stage III disease were the only factors associated with poorer EFS (HR = 1.73, 95% CI = 1.05-2.86, p=0.03 and HR = 5.35, 95% CI = 1.60-17.84, p=0.01 respectively).

Conclusion: Breast cancer is a rare condition in women aged ≤ 35 years. It had aggressive clinical and biological behaviors. From our retrospective investigation we confirmed that factors influencing survival and event free survival in univariate and multivariate analysis were the stage of disease and the ER status. Research and clinical trials were needed in young women with breast cancer to improve their outcome.

Disclosure: All authors have declared no conflicts of interest.

PHARMACOGENOMIC PREDICTION OF TAMOXIFEN (TMX) EFFICACY IN WOMEN WITH ESTROGEN RECEPTOR (ER) POSITIVE BREAST CANCER BASED ON CYP 2D6 AND MDR-1 POLYMORPHISMS (PMS)

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Introduction: TMX metabolism and conversion to active endoxifen with 100-fold greater affinity to the ER is mainly dependent on CYP2D6. Studies suggest endoxifen production is reduced in patients (pts) with inactivated (null) CYP2D6 or in combination (comd) of potent CYP2D6 inhibitors. The role of P-glycoprotein and pms of its gene MDR-1 (PM) detected in 42% of premp pts and in 50% of postmp pts with DFS 46.8 m and in 14 postmp pts (17.3%) with mDFS 30.7 m. In the group with recurrence with /without TMX therapy were inactivated pms of CYP2D6 (IM+PM) detected in 42% of premp pts and in 50% of postmp pts with disease recurrence.

Conclusion: Our preliminary results do not clearly support the hypothesis that the polymorphisms of CYP2D6, MDR-1 and the comedication with CYP2D6 inhibitors can influence the efficacy of TMX therapy.

Disclosure: All authors have declared no conflicts of interest.

PRE-METASTATIC NICHE IDENTIFICATION IN NODE-NEGATIVE BREAST CANCER TO ASSESS METASTASIS RISK: PATHOLOGICAL AND CLINICAL IMPLICATIONS

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Approximately 20% of patients (pts) with infiltrative node negative breast cancer (BC) at the time of surgery will relapse within 10 years. Bone marrow-derived hematopoietic progenitor cells (HPCs) seem to participate in early spread of cancer cells by forming a peculiar and highly organized micro-environment, called pre-metastatic niche (PMN). Identifying such HPCs in the PMNs is emerging as a key step in assessing risk of metastasis. We immunohistochemically analyzed 626 nodes (603 pN0 and 23 pN1a) obtained from 51 pts undergone surgery for ductal invasive BC, in the period 1998-2007, in order to verify if HCPs may represent the first step of the metastatic spread and correlate immunohistochemical data and clinic-pathological characteristics. Formalin-fixed paraffin-embedded 4 mm-thick serial sections were treated with the following monoclonal antibodies: VEGF-R1, CD 133, CD 117, CD-34. CD34 and CD117 appeared as the most useful HPCs markers, whereas Rh-1 and CD133 exhibited a variable rate of immunostained elements. After a median follow-up of 62.6 months (6-136), 29 pts are still alive: 23 disease-free and 6 with metastases. 18 pts dead: 14 for BC and 4 for other causes. 4 pts are lost to follow-up. The main metastatic sites were bone, lung and liver. A significant relationship (p<0,001) was found between immunohistochemical detection of HPCs and development of metastasis, high K67 values as well mortality for BC. Our data show that immunomorphologic aspect of node microenvironment could provide a powerful tool for identification of patients at high risk of metastases, in order to optimize BC therapeutic strategies and reduce morbidity and mortality.

Disclosure: All authors have declared no conflicts of interest.

BREAST INVASIVE LOBULAR CARCINOMA. IS IT WORTH DOING ANY COMPLEMENTARY STUDY?

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Aims: The purpose of this study was to determine the status of different biologic markers in invasive lobular carcinoma (ILC), to categorize this histologic type with the novel molecular classification and to check the matching cyto receptors.

Methods: 39 patients with invasive lobular carcinoma who underwent surgery at the Rio Carrio General Hospital between 1997 and 2005 had tissue available for analysis (age range, 37-88 years; mean, 65 years). Estrogen and progesterone receptors (ER, PR), E-cadherin, Her2/neu, Ki-67, CKs 8/18 and CKs 5/6 were evaluated by immunohistochemical analysis (IHC). Her2/neu was also evaluated by SISH (Silver In Situ Hybridization), together with the chromosome 17 centromere.

Results: All cases were E-cadherin negative. All the ILCs were ER positive. EP were positive in 12 cases (32%). CKs 8/18 were positive in all cases and CK 5/6 were entirely negative in 24 cases (61.5%) were Her2/neu negative with IHC, 7 cases (17.9%) were 1+ and 8 (20.5%) were 2+. We found no case considered as 3+. With the

Disclosure: All authors have declared no conflicts of interest.
**Background:** The main goal of preoperative chemotherapy is the achievement of pathological complete remission (pCR). We report the data of activity and safety of the anthracycline-containing regimen MCX with the introduction of oral fluoropyrimidine capecitabine as preoperative chemotherapy for large operable and locally advanced breast cancer. **Methods:** Patients with operable breast cancer (T2-T3) or locally advanced breast cancer (T4, N2-N3) were treated with non-pegylated liposomal doxorubicin (Myocet 50 mg/m² day 1), capecitabine 60 mg/m² day 1 and metronomic capecitabine 1500mg daily continuously (MCX) for six courses followed by radical surgery and radiotherapy. In patients whose tumours were endocrine-responsive concurrent endocrine therapies (letrozole if postmenopausal or triptorelin if premenopausal) were given daily continuously (MCX) for six courses followed by radical surgery and radiotherapy. If recurrent breast cancer (T4, N2-N3) were treated with non-pegylated liposomal doxorubicin (Myocet 50 mg/m² day 1), capecitabine 60 mg/m² day 1 and metronomic capecitabine 1500mg daily continuously (MCX) for six courses followed by radical surgery and radiotherapy. Conclusion: Our careful selection of the patients (avoiding those who have increased risk to develop CT) and a low ECD may contribute to the low rate of CHF verified in our study. As epirubicin CT is usually a late event, we suggest cardiac surveillance at the subsequent years after finish CHT. **Disclosure:** All authors have declared no conflicts of interest.

### NEW PREOPERATIVE CHEMOTHERAPY WITH LYPOSOMAL ANTHRACYLINE, CISPLATIN AND METRONOMIC CAPECITABINE FOR OPERABLE AND LOCALLY ADVANCED BREAST CANCER: DATA OF EFFICACY AND SAFETY

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**Background:** The main goal of preoperative chemotherapy is the achievement of pathological complete remission (pCR). We report the data of activity and safety of the anthracycline-containing regimen MCX with the introduction of oral fluoropyrimidine capecitabine as preoperative chemotherapy for large operable and locally advanced breast cancer. **Methods:** Patients with operable breast cancer (T2-T3) or locally advanced breast cancer (T4, N2-N3) were treated with non-pegylated liposomal doxorubicin (Myocet 50 mg/m² day 1), capecitabine 60 mg/m² day 1 and metronomic capecitabine 1500mg daily continuously (MCX) for six courses followed by radical surgery and radiotherapy. In patients whose tumours were endocrine-responsive concurrent endocrine therapies (letrozole if postmenopausal or triptorelin if premenopausal) were given daily continuously (MCX) for six courses followed by radical surgery and radiotherapy. **Results:** Twenty patients were enrolled. Median age was 51 years (range 29-71), premenopausal 44%. At the core biopsy: ER and/or PgR > 1% in 60%, Ki-67 expression ≥ 20% in 67%, Her2/neu negative in all patients. Clinical stage at diagnosis was II B in 20%, II A in 30%, IIB in 30% IIC in 15%. Sixteen patients are evaluable for clinical response, thirteen patients are evaluable also for pathological response. There were 4 pCR (1/3, 30%), 12 partial remissions (PR) (9/16, 75%) and 4 complete remissions (CR) (4/16, 25%). Six patients out of 13 received breast conserving surgery. The worst toxicity was non febrile grade 4 neutropenia in 2 pts (15%), grade 3 anemia in 1 pt (8%), nausea/emesis grade 2 in 10 pts (50%) and alopecia in 6 (37%). No cardiac toxicity was observed. **Conclusions:** This combination is effective as preoperative treatment. The combination of metronomic capecitabine in an anthracycline-containing regimen is promising in terms of clinical activity and safety. **Disclosure:** All authors have declared no conflicts of interest.

### EPIRUBICIN CARDIOTOXICITY ON BREAST CANCER ADJUVANT SETTING

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**Background:** Anthracyclines (ANT) are the most active drugs in breast cancer (BC) treatment (tr). With the improvement on survival of the BC patients, concerns about long term toxicities are raising and cardiac toxicity (CT) of ANT must be taken into account. **Objective:** The aim of this retrospective study was to evaluate epirubicin CT in a portuguese population with BC treated with 5-fluorouracil 500 mg/m², epirubicin 100 mg/m², and cyclophosphamide 500 mg/m², every 21 days (FEC100), at the adjuvant (ADJ) setting. **Methods:** We reviewed all cases of BC patients (pts) treated with FEC100 in the ADJ setting between 2003-2004, at Instituto Português de Oncologia-Porto. Left ventricular ejection fraction (LVEF) determination was performed with multigated radionuclide angiography scans (MUGA). Congestive heart failure (CHF) was classified according to New York Heart Association (NYHA). Statistical analyses were carried out using the SPSS 18.0. **Results:** We identified 302 pts. The median age was 52 (range: 20-88) years. 10.9% had arterial hypertension, 2.8% diabetes mellitus and 0.9% previous cardiac disease. 7.8%, 54.1% and 38.1% were on stage I, II and III, respectively. All pts were submitted to surgery, 72.3% to ADJ hormonotherapy and 88.6% to radiotherapy (41.4% to the left chest wall). 94% of the pts completed the 6 cycles of chemotherapy (CHT) with an adequate dose intensity. Median epirubicin cumulative dose (ECD) was 511 mg/m² (range: 335-600). During CHT, most of these pts had cardiovascular risk factors and 2 of them have undergone radiotherapy to left chest wall. There were no deaths related to CT. **Conclusion:** Data on outcome of patients treated in community settings is scarce and may be different from clinical trials.

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time of last follow-up or death. Study was approved by IRB of the American University of Beirut. Data was entered and analyzed using SPSS. Survival was calculated and estimated according to Kaplan Meier method.

Results: Total number of patients with primary non-metastatic breast cancer was 383. There were 14 cases of DCIS and/or LCIS. Analysis was carried out on remaining 369 patients with invasive breast cancer with complete follow up. 25% of pts had stage I, 45% had stage II and 30% had stage III (Locally Advanced Breast Cancer: LABC) Stages I: Total number was 93 pts. Median age at diagnosis was 49 yrs (Range 23-77 yrs). 12% had missing receptor status. 76% had positive hormonal receptors. Overall Survival (OS) at 5 years was 98%, at OS at 10 years 92%. Stage II: Total number was 167 pts. Median age at diagnosis was 48 yrs (Range 31-85 yrs). 14% had missing receptor status. 67% had positive hormone receptors. OS at 5 yrs was 90% and OS at 10 yrs was 78%. Stage III (LABC): Total number was 109 pts. Median age at diagnosis was 48 yrs (Range: 21-78 yrs). 17% had missing receptor status. 65% had positive hormone receptors. OS at 5 yrs was 68% and OS at 10 yrs was 34%. Partial mastectomy was mostly performed in earlier stages and mastectomy for more advanced cases. Pre-operative therapy, adjuvant chemotherapy, hormonal therapy and radiation therapy were conformal with standard current guidelines. Adjuvant trastuzumab was used starting June 2005. Patients were followed closely every three months and compliance with therapy was excellent.

Conclusions: Application of stringent modern multimodality therapy learned from clinical trials for breast cancer results in excellent 5 and 10-year survival rates in stages I and II in clinical practice. OS for stage III drops to 68% at 5 years and 34% at 10 years indicating continued need for early detection to improve outcome and survival of newly diagnosed patients with breast cancer.

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