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# The influence of three years adjuvant anastrozole on conventional and independent biochemical risk factors for coronary heart disease in elderly breast cancer patients

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**Background:** Aromatase inhibitors, such as anastrozole, reduce the effects of estrogen on cancer and other estrogen-dependent cells by potent preventing their biosynthesis from androgens. Since they might reduce estrogen level even to undetectable values, aromatase inhibitors are anticipated to exert adverse effect in estrogen-sensitive targets, including lipid/lipoprotein metabolism. Sub-protocols of large clinical trials provide solely results on the influence of anastrozole on basic lipid parameters [i.e. total- (TCH), high density lipoprotein (HDL-CH)-, low density lipoprotein (LDL-CH)-cholesterols and triglycerides (TG)], whereas data on changes in the concentrations of independent biochemical risk factors for coronary heart disease [apolipoprotein A-I (APO-A) and B (APO-B) as well as C-reactive protein (CRP)] under anastrozole treatment are scarce. Moreover, although the age is the risk factor for cardiovascular disease by itself, elderly patients, though commonly treated with aromatase inhibitors, are under-represented in trials and there are no data concerning the relationship between aromatase inhibition and lipid metabolism in the subpopulation of breast cancer patients over 70 years of age.

**Patients and Methods:** This prospective study enrolled fifty seven consecutive postmenopausal women (median age: 78 years, range: 71–94) with histologically confirmed estrogen- and/or progesterone-receptors positive early breast cancer. All the patients primary underwent surgery with curative intent and then some of them adjuvant chemotherapy and/or loco-regional radiation therapy. Following a twelve-hour fast, blood samples were analyzed for lipid (TCH, HDL-CH, and LDL-CH, TG) and lipoprotein (APO-A, APO-B) profiles as well as CRP serum levels; all the parameters were measured at baseline and then after 1, 3, 6 months of therapy and every 6 months afterwards.

**Results:** Three years of adjuvant therapy with anastrozole in elderly breast cancer women did not have a significant impact on any parameter analyzed in the study, i.e.: 1) basic serum lipid profile: TCH ( $p=0.78$ ), HDL-CH ( $p=0.67$ ), LDL-CH ( $p=0.77$ ) and TG ( $p=0.49$ ); 2) serum lipoproteins (APO-A;  $p=0.88$  and APO-B;  $p=0.71$ ) and CRP ( $p=0.89$ ) thought to be an independent risk factors for coronary heart disease; 3) atherogenic risk ratios: APO-B to APO-A ( $p=0.75$ ), TCH to HDL-CH ( $p=0.69$ ), LDL-CH to HDL-CH ( $p=0.73$ ) as well as BMI values ( $p=0.81$ ).

**Conclusions:** Three years of adjuvant anastrozole therapy appears to have a neutral effect on conventional and independent biochemical risk factors for coronary heart disease in elderly breast cancer women – an ideal target population for endocrine therapy. The study is being continued to assess the influence of 5 years adjuvant anastrozole on lipid/lipoprotein profile and answer the question whether certain biochemical parameters may serve as surrogate endpoint for assessment of cardiovascular risk in breast cancer women treated with aromatase inhibitors.

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# Factors affecting DFS in triple negative early breast cancer patients – a single institution experience

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**Introduction:** Breast cancer patients with negative ER, PR, and HER2 are termed as triple negative (TN) patients and they belong to a group of patients with worse prognosis.

**Patients and Methods:** Disease free survival (DFS) was retrospectively analyzed in breast cancer patients treated at our Institute from December 2004 to December 2006. Out of 1,184 patients treated for early breast cancer, 138 (11.65%) patients were TN. The average follow-up period was 23.4 months (range, 12–33 months). Sixty-one (44.20%) patients were treated with conservative surgery and irradiation combined with adjuvant chemotherapy. FAC regimen was administered in 40 (65.57%) patients while 21 (34.43%) patients received CMF chemotherapy. Seventy-seven (55.80%) patients underwent radical surgery and 28 of them received radiotherapy. There were 64 (43.38%) premenopausal and 74 (53.62%) postmenopausal patients. Grade 3 malignancy was found in 61 (44.20%) patients. Negative finding of axilla was in 32 (23.19%) patients. Out of 106 (76.81%) patients with positive finding of axilla, 71 (66.98%) patients had

more than three positive lymph nodes. All patients were alive through the entire study period.

**Results:** The relapse occurred in 27 (19.57%) patients. Average DFS period to the occurrence of relapse was 17.4 months (range: 7–31 months). The relapse occurred in breast in case of six (22.22%) patients, nodal disease recurrence was found in five (18.51%) patients, and distant metastases in 16 (59.25%) patients. No difference was found between the patients treated with conservative or radical surgery, i.e. radiotherapy. The relapse frequency was slightly higher in premenopausal than in postmenopausal patients but the finding had no statistical significance. In the group of patients with the relapse, 13 (56.52%) patients received CMF regimen and 16 (59.25%) patients received FAC ( $p=0.02$ ). The size of primary tumor had no statistical significance but the status of axillary lymph nodes was statistically significant. In patients with 3 or more positive lymph nodes DFS was shorter and in average it was 12.6 months (range: 3–26 months) ( $p=0.002$ ). The patients with G3 tumor had experience relapse more frequently. Out of 61 patients 17 (27.86%) of them relapsed ( $p<0.001$ ).

**Conclusion:** Although the study group was small and follow-up period was short, it can be said that TN early breast cancer patients present a risk group with short DFS. It was particularly observed in patients with G3 tumor, in patients with three or more positive lymph nodes, and in patients treated with CMF chemotherapy. The risk is primarily associated with the appearance of distant metastases.

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# Feasibility of adjuvant treatment with docetaxel/doxorubicin/cyclophosphamide (the TAC regimen) in routine clinical practice

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**Background:** The TAC regimen improves survival when used for the adjuvant treatment of node-positive breast cancer. Many oncologists, especially in the UK are reluctant to use this regimen though, because of toxicity concerns. We examined the feasibility of using this regimen in routine UK clinical practice.

**Materials and Methods:** We audited the treatment of all women diagnosed with node-positive breast cancer over a 6 month period. Out of 44 eligible women, 25 were treated with the TAC regimen. Differences between these women and those that received other regimens were explored. For women on TAC, retrospective information was retrieved regarding hospitalisations, dose reductions, cycle delays, regimen changes, achieved dose intensities and adjunctive treatments such as antibiotics and haematopoietic growth factor use.

**Results:** Women that received TAC were younger (mean age 52.7 years) than women that received other regimens (mean age 59.4 years) or did not receive chemotherapy (mean age 73.2 years). No differences regarding tumour size, grade, number of involved lymph nodes, hormone receptor or HER2 status were found. 21 of the 25 women received the full 6 planned cycles of the regimen. Out of 136 cycles of TAC administered, 3 (2.2%) resulted in hospitalisation. 9 (6.6%) cycles were delayed and in 28 (20.6%) cycles one or more drugs were administered in less than full dose. For all 25 patients the achieved chemotherapy dose intensity was 93.84%. The mean delivered dose of docetaxel was 404 mg per patient (89.8% of the planned dose). The impact of prophylactic G-CSF and antibiotic support was significant. 36% of the cycles with inadequate support were complicated by hospitalisation, cycle delay, subsequent need for dose reduction or an alternative regimen. These complications were seen in only 7% of cycles with adequate cover.

**Conclusions:** The TAC regimen is feasible for fit women with node-positive breast cancer in routine clinical practice. Complications are minimised with adequate haematopoietic growth factor and prophylactic antibiotic administration.

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# Skeletal events of Anastrozole versus Tamoxifen on bone mineral density and bone biomarker Osteocalcin in post menopausal women with early breast cancer

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**Introduction:** Post Menopausal women with breast cancer are at increased risk of bone loss because of age-related estrogen deficiency face which accelerated with the use of aromatase inhibitors (AI's). we aimed to study the effect on bone mineral density (BMD) and bone formation biomarker Osteocalcin level in post menopausal breast cancer patients, for the first 3 years of adjuvant hormonal treatment of both groups Tamoxifen versus Anastrozole.

**Materials and Methods:** One hundred post menopausal early breast cancer were prospectively randomized to receive either Tamoxifen