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Implementation of guidelines for adjuvant endocrine therapy in early breast cancer

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Background: Several large international studies have shown a survival benefit with aromatase inhibitors in patients with hormone-receptor positive early breast cancer (HR+EBC), either alone or sequentially after tamoxifen. Regional and national guidelines have been developed in the UK to inform appropriate use of licensed drugs in HR+EBC. Choice of regimen is influenced by menopausal status and risk of recurrence. Implementation of guidance, particularly ensuring the switch of therapy in appropriate women after 2 or 3 years, is a multidisciplinary challenge.
Materials & Methods: An audit of adherence and implementation of South East London Cancer Network guidelines for adjuvant endocrine therapy was conducted. The multidisciplinary meeting record was used to identify all patients with HR+EBC diagnosed between 1/7/05 – 31/10/05 at Guy's Hospital. Case notes were then used to determine a patient's menopausal status, risk of recurrence and endocrine treatment.
Results: 75 HR+EBC patients were diagnosed in the study period (see Table 1). Post-menopausal high risk and pre-menopausal women were managed according to guidelines, with the exception of 1 pre-menopausal patient who was switched inappropriately. 33% of post-menopausal moderate risk patients who should have switched after 2 to 3 years on tamoxifen had no documented switch. 27% of low risk post-menopausal women were switched unnecessarily to an AI.
Conclusions: The management of adjuvant endocrine therapy in HR+EBC patients was appropriate in the pre-menopausal and high risk post menopausal subgroups. However in low and moderate risk groups some patients did not switch appropriately. This may reflect the nature of an evolving complex evidence base and highlights the need for clear guideline production. In addition responsibility for ensuring switching needs to be clearly allocated within the multidisciplinary team at a local level.

Group	Treatment according to Guidelines	Total number of patients	Number advised appropriate starting treatment	Number suitable for AI switch without switch occurring	Number switched inappropriately to an AI
Pre-menopausal	Tamoxifen 5 years	27	27 (100%)	NA	1 (4%)
Post-menopausal					
Low risk	Tamoxifen 5 years	16	15 (94%)	NA	4 (27%)
Moderate risk	Tamoxifen 2−3 years then switch to Exemestane/Anastrozole	17	11 (65%)	3 (33%)	NA
High risk	Anastrozole/Letrozole 5 years	15	13 (87%)	NA	NA

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Bisphosphonates do not prevent bone fractures in early breast cancer: a meta-analysis

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Background: Recent data suggest that fractures might affect quality of life and survival in early breast cancer patients. Bisphosphonates are effective in treatment and prevention of cancer treatment-induced bone loss, but their value in the prevention of fractures is still investigational. We conducted a systematic review and meta-analysis of randomized clinical trials to evaluate the fracture rate in breast cancer patients receiving adjuvant bisphosphonates compared with those receiving no treatment or placebo.
Methods: Trials were located through PubMed, ISI, Cochrane Library, and major cancer scientific meetings searches. We identified 21 potentially eligible trials. Of these, fourteen studies reported fracture data and were included in the analysis. Overall, 7,461 early breast cancer patients were randomized, 3691 received bisphosphonates and 3770 received either placebo or no treatment.
Results: Adjuvant breast cancer treatment with bisphosphonates did not reduce the fracture rate compared to placebo or no use either in intent to treat analysis (12 trials, OR: 0.99, 95% CI 0.73−1.34, p = 0.932), in comprehensive analysis (all 14 trials included, OR: 0.84, 95% CI 0.65−1.09 p = 0.197), in postmenopausal patients (7 trials, OR: 0.82, 95% CI 0.55−1.20 p = 0.298), and in patients receiving aromatase inhibitors (6 trials, OR: 0.79, 95% CI 0.53−1.17 p = 0.242).
Conclusion: Our meta-analysis provides substantial evidence that bisphosphonates in the adjuvant setting among women with breast cancer do not decrease the number of fractures compared with placebo or no treatment.

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European Cooperative Trial in Operable Breast Cancer II (ECTO II): activity of primary chemotherapy in ER negative early breast cancer

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Background: To improve the pathological complete remission rate documented in the ECTO trial (Clin Cancer Res.2005:8715) we activated a randomized Phase II two-stage protocol with chemotherapy in ER negative early breast cancer >2 cm at diagnosis.
Methods: 127 patients were enrolled from June 2005 to March 2008. Patients were randomly allocated to 3 regimens: A (AT, doxorubicin 60 mg/m^2 + paclitaxel 200 mg/m^2, q 3 w × 4 followed by CMF q 4 w × 4); B (AT as above followed by CM + capecitabine 1850 mg/m^2 for 14 days q 4 w × 4); C (AC, doxo 60 mg/m^2 + cyclophosphamide 600 mg/m^2 q 3 w × 4 followed by paclitaxel 100 mg/m^2 d1+8 + capecitabine as above q 3 w × 4).
Results: All patients were assessed for the first step of the analysis plan. Baseline characteristics (age, menopause, PgR and HER2) were balanced and left ventricular ejection fraction (LVEF) was similar in all 3 groups.
Rates of complete pathological absence of invasive cancer in the breast (pCR) and in the breast and axilla (tnpCR) are reported in the table and would have allowed for expanding to stage 2 only in the case of regimen A.

	Regimen A	Regimen B	Regimen C
# patients	43	41	43
% pCR	53.5 (37.7−68.8)	41.5 (26.3−57.9)	39.5 (25.0−55.6)
% tnpCR	44.2 (29.1−60.1)	36.6 (22.1−53.1)	37.2 (23.0−53.3)

() 95% confidence limits

Treatment was well tolerated. More frequent delays occurred during the last four cycles of each regimen. Grade 3 neutropenia was more frequently observed during AC (8%) than during AT (1%) and one episode of G3 thrombocytopenia was documented during AC. G3 neutropenia was more frequent after paclitaxel and capecitabine (12%) than after CMF (7%) and CMX (7%). CTC 2 LVEF modification during chemotherapy was documented in one patient in each of the study arms. A bank of paraffin embedded biopsies and tumor blocks successfully collected more than 95% of the specimens.
Conclusions: All regimens were feasible and achieved a high rate of pCR in ER-negative tumors. Regimen A was the only one meeting the threshold to move to stage 2 of the study. The combined analysis of pCR rates and feasibility was in line with the findings of the ECTO trial. The study was therefore closed confirming that the sequence of AT and CMF is a feasible and very active therapeutic option for women with early breast cancer.
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Resource-based data availability for erbB2-driven breast cancer in Asian women: experts' opinion

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Background: Breast cancer incidence is increasing throughout Asia. However, the biological characteristics in Asian breast cancer are not always well understood due to the limited availability of tests and local data plus their inadequate inclusion in global literature databases. Recent