(Mouridsen H et al. *Cancer Res.* 2009;69[suppl]:66s. Abstract 13) with well characterized adverse events.

5134 POSTER

The cariatide study: evaluation of the impact of educational material on the compliance and persistence rates to adjuvant aromatase inhibitor medication in postmenopausal breast cancer patients

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Rationale: Approximately 430,000 women are diagnosed with breast cancer each year in Europe and recurrence occurs in 20−30% of patients who have undergone surgery with curative intent. Patient adherence to the long-term medication is a multidimensional problem despite the demonstrated efficacy of adjuvant Aromatase Inhibitor (AI) treatment of early breast cancer. Providing educational material may help patients to be more compliant to their treatment; subsequently, understanding the reasons of non-adherence may lead to the design of more adequate interventions aiming to improve patients' compliance to long term hormonal therapy.
Methods: This global, observational study (NCT00681122) will be conducted in 2,732 patients from 350 centres in 18 countries. Impact of educational material (EM) on compliance and adherence of post-menopausal women with hormone sensitive early breast cancer treated or planned to be treated with upfront adjuvant AI will be evaluated. This study investigates whether educational information provided to patient could influence patient's motivation and behaviour, resulting in improved treatment adherence. Adherence on upfront AI medication will be followed for two years of adjuvant hormonal treatment. Patients will be randomised to Group A: Standard Therapy and GroupB: Standard Therapy+EM. Patients in Group B will be supplied with a total of 9 educational packages, including information on the characteristics of early breast cancer, risk of recurrence, hormonal treatment options, benefits and risks of upfront adjuvant endocrine treatment, coping with and adherence to long-term hormonal medication and supporting of active and healthy female lifestyle.
Outcome variables: (1) *Compliance rate* (% number of subjects being 'compliant') for the adjuvant AI medication will be analysed at one year based on the subject's assessment. (2) *Persistence rate* (% number of subjects with a 'persistent' use of adjuvant AI medication) will be evaluated for the first time after one year and a second time after two years. (3) *Time to treatment* and *reasons for discontinuation* of AI will be analysed. Specialized questionnaires will be used to evaluate medication adherence and the patient's feelings and beliefs on the disease and therapy (EORTC-INPATSAT-32, OPTIMA-X, GHQ-12, FACT-ES, compliance questionnaire, and EM feedback questionnaire in Group B patients).
Results: Study accrual has been completed on March 2009; preliminary results after one-year follow-up are expected early 2010 and the study is expected to finish March 2011.

5135 POSTER

Half of breast cancer patients starting on tamoxifen complete five years of endocrinetreatment

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Background: Adjuvant endocrine therapy in women with early stage breast cancer prolongs disease free and overall survival. The aim of the study was to determine first treatment switch and discontinuation in breast cancer patients starting on tamoxifen and to analyze the predictors of discontinuation.
Patients and Methods: Patients with early stage breast cancer were selected from the Eindhoven Cancer Registry from 1998 to 2006 and linked to the PHARMO Network to select drug use during follow-up. Patients starting on tamoxifen were included in the study cohort. Continuous use of endocrine treatment was determined as the time between start and stop of therapy, allowing a 60 days gap between refills. The switch from tamoxifen to an aromatase inhibitor (anastrozole, exemestane or letrozole) was determined. Cox regression was used to identify independent determinants of discontinuation of any endocrine treatment (tamoxifen and/or aromatase inhibitor use) during five years of follow-up.
Results: A total of 1,451 new breast cancer patients started on tamoxifen. Of those, 26% had a treatment switch to: anastrozole (n = 203), exemestane (n = 113) or letrozole (N = 64) with a mean duration until first switch of 2.0 (SD = 1.3) years. Of the patients followed for five years, 51% discontinued any endocrine treatment before the completion of five years (see table). Multivariate analyses showed that discontinuers were less likely to be aged 50−69 years (versus 70 years; HR = 0.74; 95%CI: 0.60−0.91) and were more likely to have 2 or more concomitant diseases (versus no comorbidity; HR = 1.54; 95% CI: 1.06−2.26).

Table. Continuous use of any endocrine treatment of patients who start tamoxifen

Treatment	Start	Continuous use at . . . *									
		1 year		2 years		3 years		4 years		5 years	
	N	N	n (%)	N	n (%)	N	n (%)	N	n (%)	N	n (%)
Hormonal	1,451	1,336	1,168 (87)	1,120	872 (78)	896	621 (69)	676	423 (63)	499	245 (49)

* % calculated as number of continuous users, "n" (still on therapy) at a specific day of follow-up, divided by "N" total number of patients in study population at start of interval.

Conclusions: Only half of the breast cancer patients starting tamoxifen continued five years of endocrine treatment. Identification of patients at risk of discontinuation will assist in the development of interventions to improve adherence.

5136 POSTER

Tamoxifen and exemestane adjuvant multinational (TEAM) trial; findings from the Dutch/belgian subset

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Background: At 2.75 years of follow-up, the multinational TEAM trial (N = 9779) showed that upfront adjuvant therapy with exemestane (E) in postmenopausal, hormone-sensitive breast cancer (BC) patients may be more effective than tamoxifen (T) (DFS (ITT) HR 0.89; 95% CI 0.77−1.03, p = 0.12). Subgroup analyses suggested that some patient categories (i.e. age $\geqslant$70 years, N1) might benefit more from upfront E. To further explore the effectiveness of E as upfront strategy and in specific subgroups, the Dutch/Belgian TEAM data were analysed as there was a high inclusion rate throughout these countries (N = 3167), and this population was very homogeneous and representative for the real-world of patients being given adjuvant hormonal therapy.
Methods: Postmenopausal, hormone-sensitive early BC patients being eligible for adjuvant endocrine therapy were randomized to open-label E or T. After 2.5−3 years, T patients switched to E; endocrine therapy was given for 5 years in both arms. The first co-primary endpoint was DFS of T versus E at median follow-up of 2.75 years. Cox regresion stratified for important prognostic variables was used to compare treatments.
Results: Comparing the Dutch/Belgian with the Global study cohort, the first group consisted of significantly more high-risk patients (70% N+ vs 48% N+) and patients $\geqslant$70 years (30% vs 27%), explaining the different event rate (10.3% and 7.6%, resp.). DFS at 2.75 yrs was 90.7% in E and 88.1% in T patients (HR T/E 0.77; 95%CI 0.62−0.96, p = 0.02). RFS, DFS on study drug, and time to distant metastases significantly favored E; HRs (95%CI; p-value) were 0.74 (0.58−0.94; 0.015), 0.72 (0.57−0.92; 0.008), and 0.68 (0.52−0.90; 0.006), respectively, all stronger than in the main study. In patients $\geqslant$70 years (HR 0.59; p = 0.005, numbers needed to treat (NNT) 15.7) and with 1−3 positive nodes (N1) (HR 0.67; p = 0.008, NNT = 26.5) the HRs were even stronger than the overall Dutch/Belgian results, but not significantly different.
Conclusions: In the Dutch/Belgian cohort of the TEAM study, being at high risk of disease recurrence, E was more effective than T after 2.75 years. Although the Dutch/Belgian data show stronger HRs, the data are in line with the results of the main study. Further, the Dutch/Belgian data suggest more benefit from upfront E for patients $\geqslant$70 years and with N1 disease. However, the identification of specific subgroups potentially benefiting from an aromatase inhibitor upfront remains to be analysed in larger study cohorts.