

Study of adjuvant endocrine treatment for breast cancer reveals cost of noncompliance

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The largest study in the world of treatments for post menopausal, hormone positive breast cancer has shown that patients who continue to take exemestane or tamoxifen do significantly better than patients who start to take one or other drug (or tamoxifen followed exemestane) but then stop.

Professor Cornelis van de Velde, principal investigator at the central data office for TEAM (tamoxifen exemestane adjuvant multinational) trial told Europe's largest cancer congress, ECCO 15 - ESMO 34, in Berlin today (Tuesday 22 September) that differences in compliance between the nine countries involved in the trial shed light on the role that it played in patient outcome.

"In the Dutch/Belgian part of the TEAM trial, more patients were node positive compared to those in other countries (and were therefore at higher risk of recurrences), because the existing Dutch treatment guidelines (which have since been changed) indicated that only 'high risk' patients should receive [chemotherapy](#), endocrine treatment or both. Yet despite this handicap, recurrences of breast cancer in The Netherlands and Belgium were 12% for patients using tamoxifen and 9% of patients using exemestane compared to 8% and 7% internationally. This is probably due to better compliance with treatment in The Netherlands, which was significantly better than in other countries.

"Across the whole study, up to a cut-off point of two years nine months, non-compliance amongst women on tamoxifen was 19.8% and 12.9%

for women on exemestane. However, these percentages were considerably lower in the Dutch/Belgian part of the TEAM trial where non-compliance was 14% for tamoxifen and 9% for exemestane. Patients who stopped study treatment (tamoxifen or exemestane) had significantly higher chance of a recurrence; the chance was between four and five times higher among this group than among those who continued their treatment. This underlines the need for good information for patients concerning the side-effects of drugs and treatment efficacy," said Prof van de Velde, who is Professor of Surgery at the Leiden University Medical Centre (Leiden, The Netherlands) and President of the European Society of Surgical Oncology. Compliance with medication in the TEAM study was lower than in any previous study of adjuvant aromatase inhibitors.

The TEAM study is a randomised phase III clinical trial comparing the efficacy of the aromatase inhibitor exemestane versus the current "gold standard" treatment tamoxifen as adjuvant endocrine therapies for hormone sensitive early breast cancer in postmenopausal women. After two years nine months a total of 9,779 women had been included in the trial from nine countries: France (1230 patients), Germany (1480), Greece (211), Japan (184), The Netherlands (2753), Belgium (414), UK/Ireland (1275), and the USA (2232).

The trial was started in 2001 but in 2004, based on results from another trial (Intergroup Exemestane Study) that showed a significant survival advantage for patients on exemestane, the TEAM study was changed so that patients receiving tamoxifen were switched to exemestane after having been in the trial for between two and a half to three years. The results presented today relate to data on disease-free survival in patients on the trial for no longer than two years nine months and they focus particularly on issues of compliance in the Dutch/Belgian TEAM patients, as well as on side effects, and disease-free and overall survival across the whole of the study.

Prof van de Velde said: "Adverse side effects were the main reasons why patients discontinued their treatment - about half of all patients who discontinued did so because of side effects. Out of all the patients in the study, 6.3% discontinued tamoxifen and 4.4% discontinued exemestane because of side effects.

Adverse side effects included heart, skin, hormonal, digestive, metabolic, neurological, muscle and skeletal problems. Exemestane was associated with significantly higher rates of arthralgia, carpal tunnel syndrome, diarrhoea and high cholesterol levels, but with significantly lower rates of hot flushes, vaginal bleeding and discharge, and thromboembolism than tamoxifen. Fractures and heart problems were similar between the two groups.

"The safety profile has been better for exemestane than for tamoxifen and I think this is a contributory factor to the lower discontinuation rates amongst the patients on exemestane," said Prof van de Velde.

After two and three-quarter years of follow-up, among the women on exemestane there were 11% fewer cases of a local recurrence of the tumour, distant metastases, breast cancer in the other breast (contralateral breast cancer) and deaths occurring without a relapse of the disease, than among the women on tamoxifen (352 in the exemestane patients and 388 in the tamoxifen patients). There were no differences between the two groups for time to contralateral breast cancer or overall survival, and no unexpected safety issues were reported. Patients aged 70 or over and women with breast cancer that had spread to only one to three lymph nodes had a significantly better disease-free survival on exemestane than on tamoxifen.

"The current analysis covers a short period of time with relatively few deaths occurring and this makes it difficult to see significant differences between the two groups. However, the data from TEAM indicate that

early use of exemestane in these high risk patients appears to be safe and a more effective endocrine treatment than tamoxifen for reducing breast cancer recurrence," said Prof van de Velde. "The study is continuing and the next end point has already been reached, so that we now have enough events to conclude whether starting with [tamoxifen](#) and switching to exemestane is better or worse than starting with exemestane. These results will be presented at the San Antonio [breast cancer](#) symposium in December."

Source: ECCO-the European CanCer Organisation

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