Health-related quality of life (HRQOL) and psychological distress in Japanese postmenopausal women with breast cancer treated with tamoxifen, exemestane or anastrozole for adjuvant endocrine therapy: a final analysis for HRQOL in National Surgical Study of Breast Cancer (N-SAS BC) 04

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Introduction

TEAM Trial

Tamoxifen (TEAM) and exemestane (EXE)- Adjunct Multicenter (TEAM) trial is a phase III, randomized, and open-label trial that compares efficacy and tolerability of 5 years of EXE with 2.5 to 3 years of TAM followed by EXE for a total of 5 years. Adjuvant EXE as an upfront use of at least 2.5 years had a superior efficacy to TAM in terms of disease-free survival of postmenopausal women with hormone-receptor positive, invasive breast cancer. National Surgical Adjuvant Study of Breast Cancer (N-SAS BC) 04 is a Japan sub-study of the TEAM trial. It consists of two protocols as follows:

TEAM Japanese protocol

To evaluate the relative impact of EXE, TAM, and exemestane (ANA) on lipid metabolism, bone mineral density, bone and joint pain, and overall quality of life (QOL), adverse events, and psychological distress as secondary and tertiary endpoints.

TEAM International protocol

To evaluate the relative impact of EXE and TAM on blood coagulation, HRQOL, and psychological distress as secondary endpoints. We reported interim analyses of N-SAS BC 04 for HRQOL and psychological distress at San Antonio Breast Cancer Symposium 2006, New Orleans, USA. The final analysis is reported here.

Objective

To evaluate the impact of adjuvant EXE, TAM, and ANA on HRQOL and psychological distress in postmenopausal women with hormone receptor positive breast cancer.

Patients

Inclusion criteria

-Postmenopausal women with surgically treated stage I to IIIA estrogen receptor positive and/or progesterone receptor positive, and/or human epidermal growth factor receptor 2 positive, and/or HER2 positive invasive breast cancer, and who had one of the following clinicopathologically ≤0.5 cm in a maximum tumor size, pathologically positive nodes, nuclear grade 3 invasive ductal carcinoma or invasive lobular carcinoma.
-They were required to have adequate hematology, hepatic, and biochemical functions, and to have Eastern Cooperative Oncology Group performance status of ≤1.

Exclusion criteria

-Prior history of other invasive carcinomas within 5 years, deep vein thrombosis, ischemic heart disease, congestive heart failure, myocardial infarction, current treatment for cancer, including radiation, or another disease.
-Hormone replacement therapy within 4 weeks of enrollment.
-Other breast cancer.

Eligible patients who met the following criteria were on the TEAM International protocol, and were randomly assigned 1:1:1 to receive EXE, TAM, or ANA.

Other eligible patients were on the TEAM Japanese protocol, and were randomly assigned 1:1:1:1 to receive EXE, TAM or ANA.

Figure 1. Patient enrollment and distribution

Table 1. The number of patients of the TEAM International groups and TEAM Japanese groups

<table>
<thead>
<tr>
<th>TEAM International protocol</th>
<th>EXE</th>
<th>TAM</th>
<th>ANA</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEAM Japanese protocol</td>
<td>EXE</td>
<td>TAM</td>
<td>ANA</td>
<td>Total</td>
</tr>
<tr>
<td>Total</td>
<td>94</td>
<td>90</td>
<td>95</td>
<td>279</td>
</tr>
</tbody>
</table>

HRQOL and Psychological Distress

-Percentage of patients who completed the required assessment questionnaires at each time point were consistently over 94% in each group throughout the study period.
-There were no significant between-group differences in baseline scores for any of the scales used to assess HRQOL and psychological distress.

Conclusion

HRQOL was better in Japanese patients than in the patients on EXE or ANA over the period of the study (Figure 4).

References