Baseline assessment of patient-reported outcomes (PROs) for breast cancer patients after 5-years of endocrine treatment in a randomized clinical trial: NSAS-BC 05

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Abstract
To evaluate patient-reported outcomes (PROs) at baseline after completing 5 years of anastrozole-based adjuvant endocrine therapy in the N-SAS BC 05 trial, this randomized clinical trial was performed to assess the efficacy of an additional 5 years of anastrozole in postmenopausal women with breast cancer.

Methods
Patients registered in NSAS-BC 05 were requested to respond to validated health-related quality of life (HRQOL) instruments, including the Short Form 36-item Health Survey (SF-36), sub-scales for joint symptoms of the FACT-ES, and an assessment of joint symptoms.

Results
Baseline data on HRQOL and joint symptoms were collected from 335 patients at 64 institutions between November 2007 and March 2010; 283 patients received anastrozole for 5 years, and 52 received tamoxifen followed by anastrozole for a total of 5 years. Mean age was 64 years, and body mass index was less than 25 in 74% of the patients. Joint pain was reported by 61% of patients, and 59% had joint stiffness, but both symptoms were grade 1 or less. Mean sub-scale scores of FACT-ES were all less than 2.

Conclusion
After 5 years of anastrozole, HR-QOL was generally good in this study population, and joint pain and stiffness were mild, despite the high prevalence.

Study Design: UMIN000000818
Postmenopausal women with breast cancer who completed 5-year treatment with anastrozole after surgery (including patients who received a total of 5-year treatment consisting of tamoxifen for 2 to 3 years, followed by anastrozole)

Study Endpoints
- Primary Endpoint
  - Disease-free survival (DFS)
- Secondary Endpoints
  - Overall survival (OS)
  - Distinct-disease-free survival (ODFS)
  - Adverse events: HR-QOL, Cost & benefits
  - Other endpoints
    - Bone mineral density
    - Joint symptoms

Study Group
National Surgical Adjuvant Study of Breast Cancer

Discussion
In patients who were enrolled in the study after receiving 5 years of treatment with anastrozole (or tamoxifen followed by anastrozole):

- A self-administered questionnaire survey revealed that about 60% of patients had stiffness, which generally did not impair activities of daily living.
- The “knee” was the most common site of joint pain, whereas the “hand” was the most common site of stiffness.
- HR-QOL was generally good, and endocrine-related symptoms were also mild.

We plan to continue to evaluate these changes at 1-year intervals.

Study Group
National Surgical Adjuvant Study of Breast Cancer

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Registered Trial Number
UMIN000000818

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| Question 1 : When does stiffness occur in a day? (Multiple responses allowed) |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
|                             | 0               | 1               | 2               | 3               | 4               |
| Sore at night               | No change       | Aggravated after | Get worse       | Get better      | No change       |
| Sore in the morning         |                 |                 |                 |                 |                 |
| Sore on awakening           |                 |                 |                 |                 |                 |
| Sore in the late afternoon  |                 |                 |                 |                 |                 |

Among 19 questions of FACT-ES additional concerns, the mean score for 3 questions was more than 1, but the scores for the other 16 questions were all less than 1.