



# 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 endocrine symptoms of the FACT-ES, and an assessment of joint symptoms.

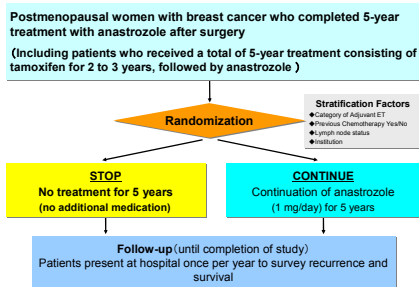
## Results

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. Most SF-36 scale profiles showed good average values, except for slight decreases in physical functioning and role-physical as compared with national standard values. Mean sub-scale scores of FACT-ES were all less than 2. Joint pain was reported by 61% of patients, and 59% had joint stiffness, but both symptoms were grade 1 in 80%. The location of joint pain was the knee in 41% and the hand in 24%. Joint stiffness mainly affected the fingers, occurring in the morning or on awakening in 50%.

## 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.

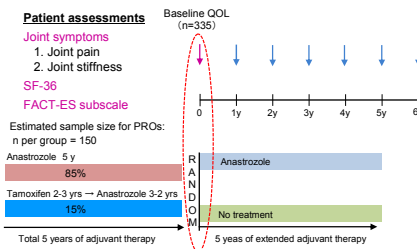
## Study Design: UMIN00000818



## Study Endpoints

- Primary Endpoint**
  - Disease-free survival (DFS)
  - Estimated sample size for DFS as primary endpoint: 2500 pts in total
- Secondary Endpoints**
  - Overall survival (OS)
  - Distant-disease-free survival (DDFS)
  - Adverse events, HR-QOL, Cost & benefits
- Other endpoints**
  - Bone mineral density
  - Joint symptoms

## QOL Assessment Schedule



## Survey Items of Self-administered Questionnaires

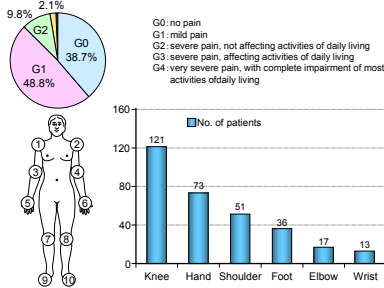
- Joint symptoms**
- Joint pain
  - Joint stiffness

Short Form 36-item Health Survey (SF-36)

FACT-ES sub-scale

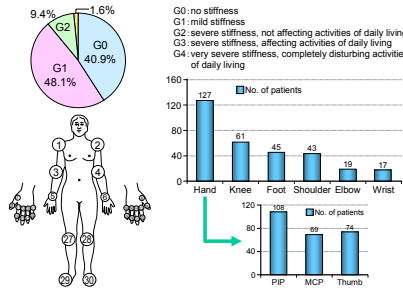
### 1. Joint pain

Patients with pain: 201/328 (61.3%)

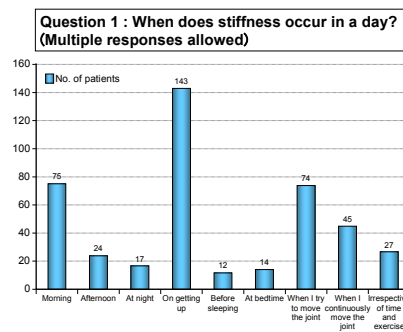


### 2. Joint stiffness

Patients with joint stiffness: 188/318 (59.1%)

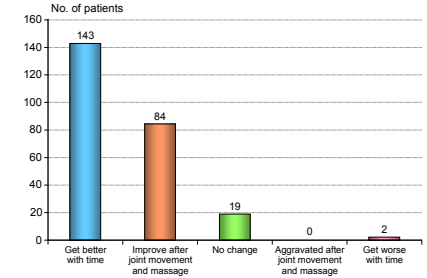


### 2. Joint stiffness

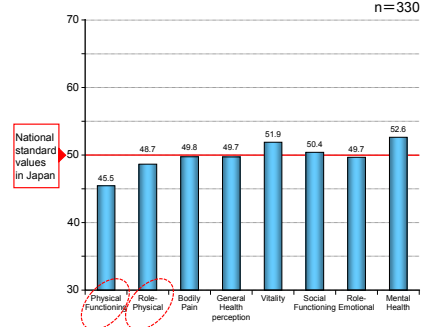


## 2. Joint stiffness

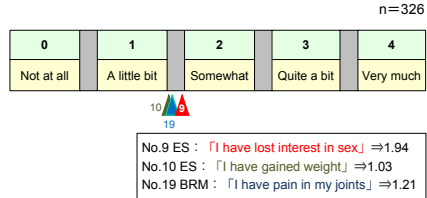
**Question 2: On days when you have joint stiffness, do the symptoms change? (Multiple responses allowed)**



### SF-36



### FACT-ES



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.

## 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  
UMIN00000818