

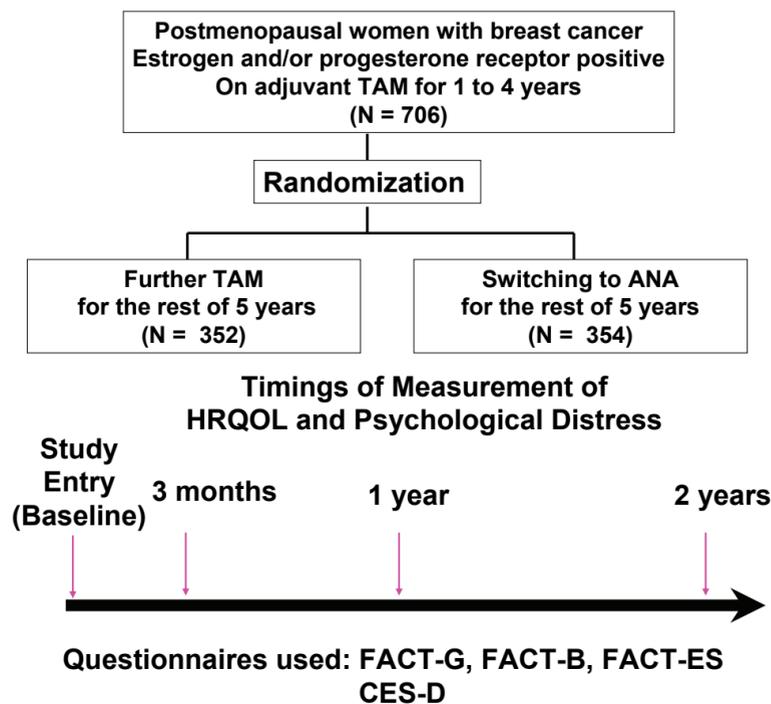
## Background

Three years ago, we reported the interim results regarding health-related quality of life (HRQOL) outcomes of the patients who switched their adjuvant endocrine therapy from several years of tamoxifen (TAM) to anastrozole (ANA) and those who had TAM for a total of 5 years in the randomized trial, National Surgical Adjuvant Study of Breast Cancer (NSAS BC) 03<sup>1)</sup>. We present the final results of HRQOL and psychological distress in the NSAS BC 03.

## Patients and Method

Recurrence-free postmenopausal breast cancer patients who had received definitive surgery for hormone receptor positive breast cancer, and had been taking TAM for 1 to 4 years after the surgery were enrolled in the randomized trial: N-SAS BC 03. They were randomly assigned to continue TAM for the remaining periods of a total of 5 years or to switch from TAM to ANA and take the latter for the remaining periods. Primary endpoints of the N-SAS BC 03 trial were disease-free survival and adverse events. HRQOL and psychological distress were evaluated as secondary endpoints. They were asked to answer patient-administered instruments to assess HRQOL (FACT-B [breast cancer scale] and FACT-ES [endocrine symptom scale]) and psychological distress (CES-D: Center for Epidemiologic Studies Depression scale) at the randomization (baseline), 3 months, 1 and 2 years after the randomization. HRQOL and psychological distress scores during this period were compared using t-test and the general linear model with correlated errors.

## Study Design



## Scores at Baseline

	TAM group	ANA group
<b>FACT-G</b>		
Physical well-being	25.0±3.20	25.0±3.33
Social well-being	18.5±5.95	18.3±6.74
Emotional well-being	18.3±4.10	18.2±4.11
Functional well-being	22.1±5.18	21.7±5.75
<b>FACT-BCS</b>	23.5±5.07	23.6±4.77
<b>FACT-ES</b>	59.9±8.32	60.7±8.37
<b>FACT-G total</b>	84.0±12.2	83.4±13.8
<b>FACT-B total</b>	107.5±15.1	106.8±16.2
<b>FACT-ES total</b>	143.8±17.2	143.9±18.2
<b>CES-D</b>	10.1±6.76	10.2±7.16
	(mean±SD)	(mean±SD)

There was no difference in demographic and medical characteristics between the two treatment groups. The response rates of the questionnaires were 98.6%, 97.2%, 90.9% and 78.5% at baseline, 3 months, 1 and 2 years after the randomization, respectively. At baseline 694 patients (346 in the TAM group and 348 in the ANA group) answered them. The total scores of FACT-G, and FACT-ES and the scores of FACT-G physical well-being (PWB) subscale were statistically significantly better in the TAM group than in the ANA group ( $P = 0.042$ ,  $0.038$ , and  $0.005$ , respectively) after the randomization, while those of FACT-B in the former were marginally better than those in the latter ( $P = 0.066$ ). However, there were no statistically significant differences between the two treatment groups for the scores of CES-D, and subscales other than PWB of FACT-G, FACT-B, and, FACT-ES.

Although there was not a statistically significant difference between the two treatment groups in the scores of the endocrine symptom subscale of FACT-ES, some items in the endocrine symptoms showed statistically significant differences. Hot flash and vaginal discharge were worse in the TAM group than the ANA group ( $P = 0.0002$ , and  $< 0.0001$ , respectively), while dizziness, diarrhea, and headache were worse in the ANA group than the TAM group ( $P = 0.0165$ ,  $< 0.0001$ , and  $0.0023$ , respectively) (Data not shown).

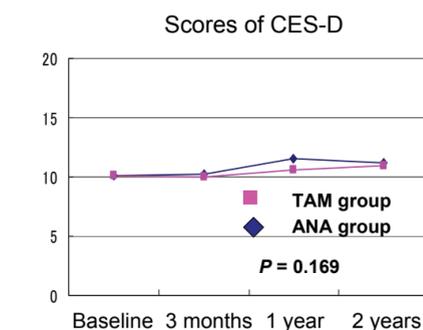
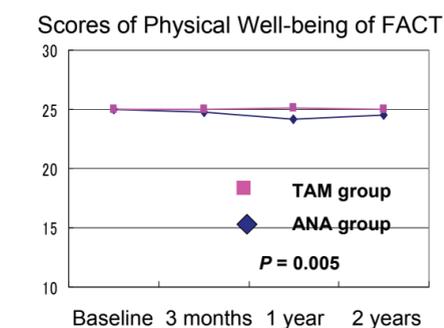
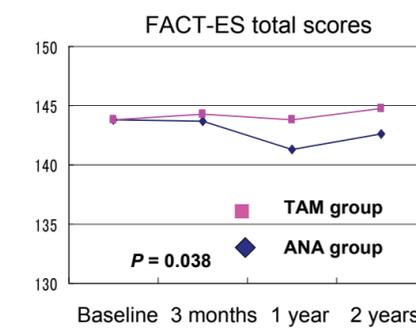
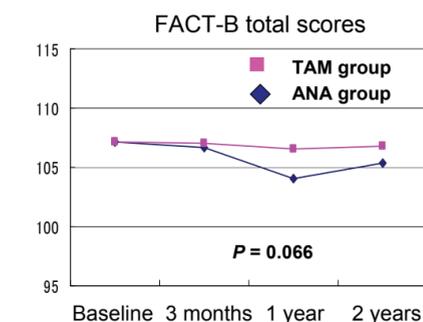
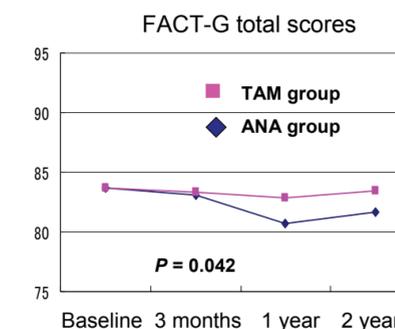
## Conclusion

Further TAM treatment after adjuvant TAM for 1 to 4 years may provide postmenopausal breast cancer patients with slightly better HRQOL comparing with switching to ANA.

## Discussion

The total scores of FACT-G, FACT-ES, and the scores of PWB subscale of FACT were better in the TAM group than in the ANA group. There may have been a bias in favor of HRQOL in the TAM group in this trial because the patients who entered this trial had been taking TAM for several years without severe problems, namely those who had problems by taking TAM possibly discontinued TAM before entering this trial. However, in NSAS BC 04, another randomized trial we have done in the adjuvant setting, we have also shown that HRQOL in the TAM group was better than those of the AI groups<sup>2)</sup>.

## Results



## References

- 1) Ohsumi S, et al. Breast Cancer Res Treat. 2005; 94: S99 (# 2044).
- 2) Takehara M, et al. Breast Cancer Res Treat. 2007; 100: S114 (# 2088).