

The EQ-5D Index of Elderly Patients with HER2-Positive Breast Cancer: Results from the N-SAS BC 07 Trial for Adjuvant Trastuzumab with and without Chemotherapy

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INTRODUCTION

- As population is aging especially in developed countries, more **elderly patients** receive anti-cancer treatments.
 - Elderly patients with cancer often have comorbidities and/or declined physical functions.
- Standard adjuvant therapy for **HER2-positive breast cancer** is trastuzumab plus chemotherapy.
- N-SAS BC 07 trial showed that omitting chemotherapy results in only slight loss of disease-free survival in **elderly patients** with that disease [1].
 - Effects of omitting chemotherapy on **health status** would inform decision making for treatment.
 - Health utility** also inform cost-utility analysis.
- Objective**
 - To compare EQ-5D index of adjuvant trastuzumab monotherapy with that of trastuzumab plus chemotherapy in N-SAS BC 07 trial.

METHODS

- N-SAS BC 07 trial was a **randomized controlled trial**.

Patients

- Women aged 70–80 years old
- HER2-positive primary invasive breast cancer
- Stage I to IIIA after curative surgery
- ECOG performance status 0–1



Enrolment: 2009–2014 in Japan
Registration: NCT01104935

Adjuvant trastuzumab monotherapy
(H group)

Adjuvant trastuzumab plus chemotherapy
(H+CT group)

- Treatment** (unblinded)
 - 1-year **trastuzumab** (once at 8 mg/kg and then 6 mg/kg every 3 weeks) in both groups
 - 3–6-month **concurrent or preceding chemotherapy** (selected from PTX, DTX, TC, AC, EC, FEC, CMF, TCbH) in H+CT group
- EQ-5D Assessment** (Japanese **EQ-5D-3L** [2, 3])
 - At enrolment, 2 months, 12 months, and 36 months after treatment initiation
 - Calculating EQ-5D index based on societal preferences in general population of Japan [4]
- Statistical Analysis**
 - Analysis population: patients with baseline EQ-5D index in full analysis set
 - Mean EQ-5D index profiles** were compared using linear mixed effect models for repeated measures, adjusting for baseline EQ-5D index.
 - Proportions of the deteriorated and improved EQ-5D index** based on minimally important difference (MID) of 0.1 and 0.05 [5] were compared.

RESULTS

- Of randomized 275 patients, 233 patients were included in the analysis population.

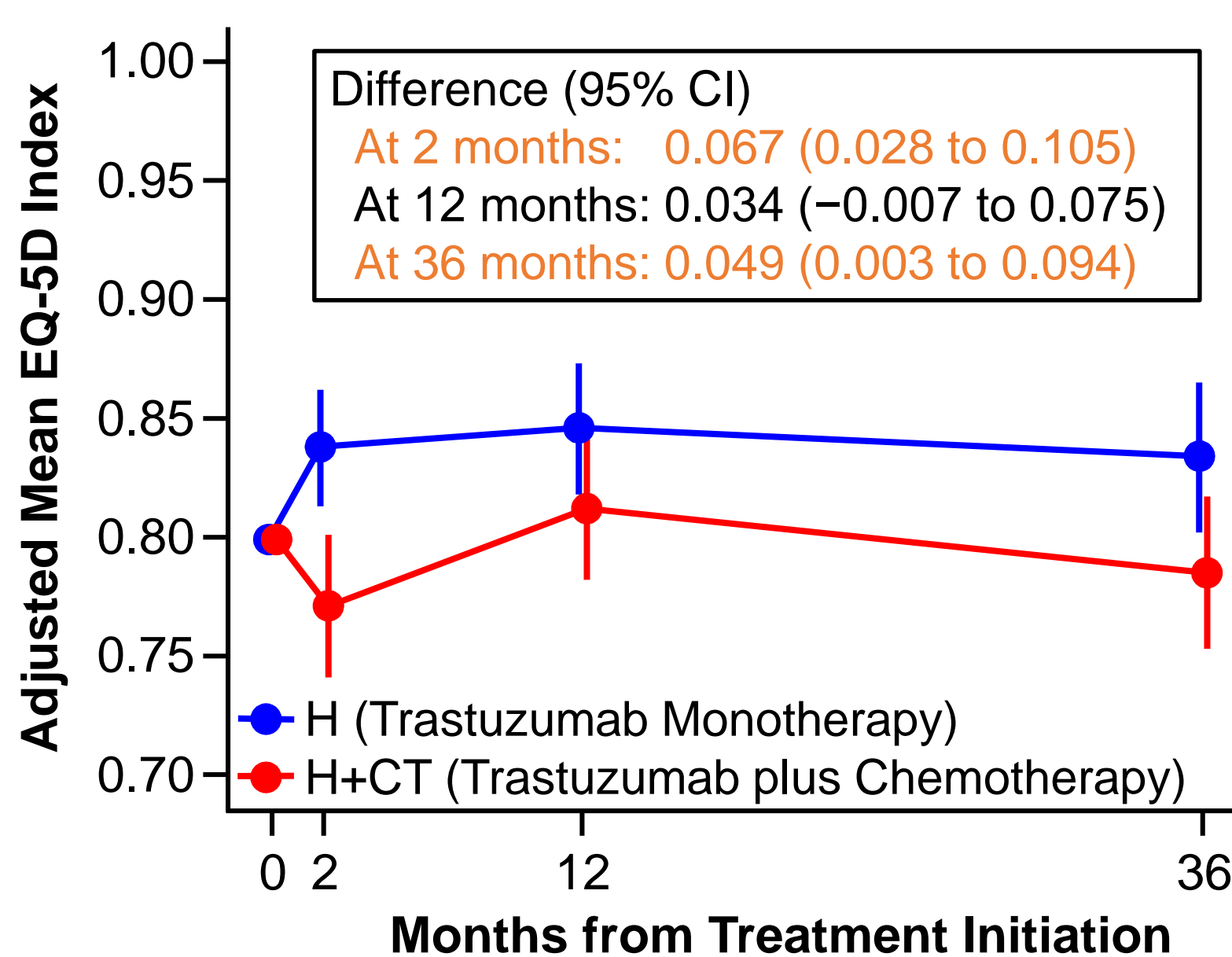
	H group n = 120	H+CT group n = 113
Age (year)	74 (72–76)	73 (71–76)
Stage		
I	52 (43.3)	51 (45.1)
IIA	49 (40.8)	45 (39.8)
IIB	18 (15.0)	15 (13.3)
IIIA	1 (0.8)	2 (1.8)
ECOG PS of 1	9 (7.5)	8 (7.1)
Hypertension	55 (45.8)	52 (46.0)
Diabetes	11 (9.2)	18 (15.9)
Osteoporosis	18 (15.0)	8 (7.1)
Hyperlipidemia	30 (25.0)	31 (27.4)
Baseline EQ-5D index	0.769 (0.672–1)	0.774 (0.707–1)

Data are n (%) or median (interquartile range).

Completion Rates of EQ-5D

	2 months	12 months	36 months
H (n=120)	107/120 (89.2%)	97/119 (81.5%)	95/107 (88.8%)
H+CT (n=113)	91/113 (80.5%)	83/110 (75.5%)	83/103 (80.6%)

Mean EQ-5D Profiles



Responder Analyses

	Proportion (%)		Risk Ratio (95% CI)
	H	H+CT	
Deterioration (0.1 or larger)			
2 months	12.1	29.7	0.41 (0.22–0.75)
12 months	12.4	24.1	0.51 (0.27–0.99)
36 months	11.6	24.1	0.48 (0.24–0.94)
Improvement (0.1 or larger)			
2 months	29.9	14.3	2.09 (1.17–3.74)
12 months	34.0	26.5	1.28 (0.82–2.02)
36 months	31.6	18.1	1.75 (1.01–3.01)

The similar trends were observed in analyses based on MID of 0.05.

DISCUSSIONS

- This study revealed **positive effects** of omitting adjuvant chemotherapy on EQ-5D index in **elderly patients** with resected HER2-positive breast cancer.
 - Negative effects of chemotherapy seemed to be persistent even after end of chemotherapy, despite absence of such persistent effects in many adjuvant trials in younger populations.
 - QALY may be longer with trastuzumab monotherapy than with trastuzumab plus chemotherapy.
- Baseline mean EQ-5D index in this population was similar to that of **the Japanese population norm** of women aged 70 years or older [6].
 - After treatment initiation, however, mean EQ-5D index with trastuzumab monotherapy was better than that of the norm.

CONCLUSION

- Adjuvant trastuzumab monotherapy resulted in improved health status measured by the EQ-5D during adjuvant treatment period and even thereafter.

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