

BCIRG 006: Quality of life of patients treated with docetaxel and trastuzumab-based regimens in node positive and high risk node negative HER2 positive early breast cancer.

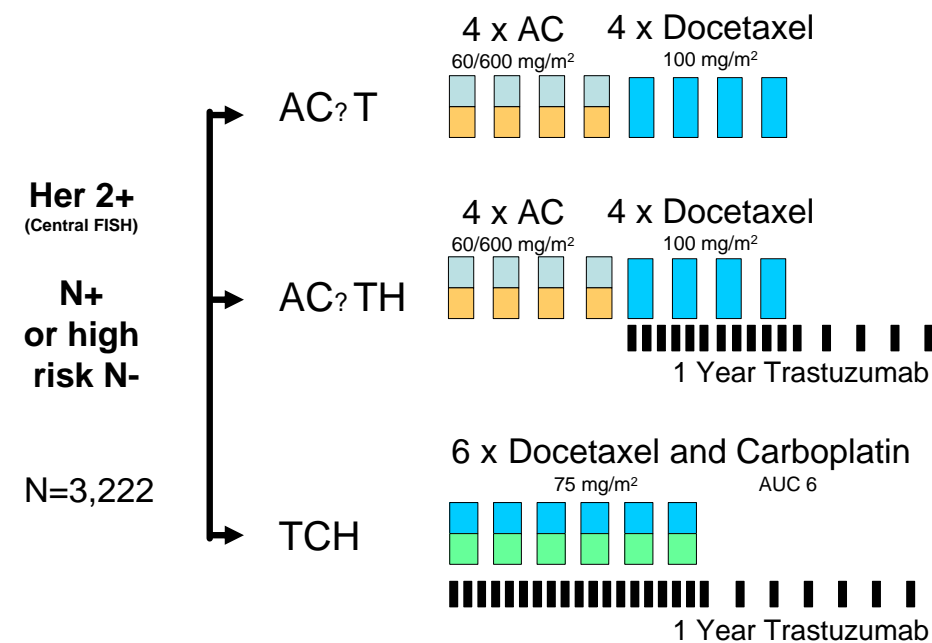


Heather-Jane Au, Nicholas Robert, Wolfgang Eiermann, Tadeusz Pienkowski, John Crown, Miguel Martin, Marek Pawlicki, Arlene Chan, Valerie Bee and Dennis Slamon.



Background

•BCIRG 006, a large international randomized controlled trial, compared three adjuvant regimens in patients (pts) with node positive or high risk node negative HER2-positive early breast cancer:



•Both AC-TH and TCH significantly improved DFS and OS over AC-T¹. Global safety profile was acceptable in all arms and more favorable in TCH than AC-TH.

Objective

A comparison of the health-related quality of life (QoL) of patients between the 3 above mentioned arms was a secondary objective of the 006 study. The QoL results are presented here.

Methods

Study Population

To be included in the QOL analysis, pts must have met the trial entry criteria, completed a baseline and one or more follow-up QOL questionnaires.

Instrument

The **EORTC QLQ-C30** was used which contains:

- five functional domains (physical [PF], role, cognitive, emotional, and social)
- nine symptom scales and items (fatigue, nausea / vomiting, pain, dyspnea, sleep, appetite loss, constipation, diarrhea, and financial impact)

- global quality of life (Global)

The **EORTC QLQ-BR23** was also used which contains:

- four functional domains (body image, sexual functioning, sexual enjoyment, and future perspective [Future])
- four symptom scales (systemic therapy side effects [SE], breast symptoms, arm symptoms, upset by hair loss)

Schedule

- Questionnaires were completed at baseline, on and after chemotherapy at:
- 9 weeks [wk](Cycle 4 [Mid]), 18 wks(Cycle 7/end of chemotherapy [EOC]) & 24 wk from treatment start (+/-31days) as well as at 6 & 12 months [mo] (+/-3 mo), and 24 mo (+/-6mo)

Analysis

- Primary endpoint compared PF, Global, SE, and Future mean changes from baseline to mid, EOC, and 12 months using a two-sample t-test.
- Positive change scores denote improved QoL except for the SE scale, which is reversed.
- Response analysis classified pts as improved, stable or worse QoL depending whether two consecutive change scores were 10 points or greater in a favorable or unfavorable direction^{2,3}. Chi-square was used to assess differences in percent improving or worsening.
- Due to 3-arm comparisons, $p < .017$ was considered significant.

Results

Table 1: Questionnaire Compliance

	AC ? T N=836	AC ? TH N=869	TCH N=872
Assessment	% of Eligible	% of Eligible	% of Eligible
Mid	86.2	87.4	87.3
EOC	80.6	79.2	83.5
Month 12 FU	75.0	75.9	77.5

Mid = mid chemotherapy; EOC = end of chemotherapy

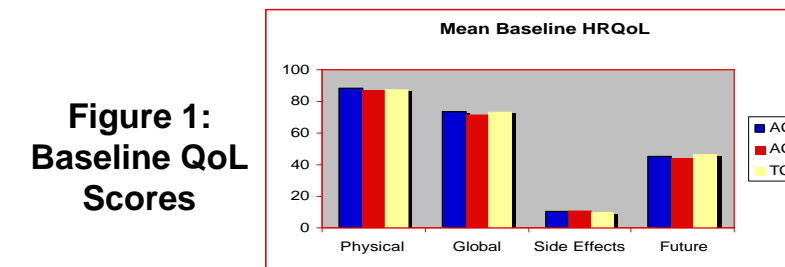
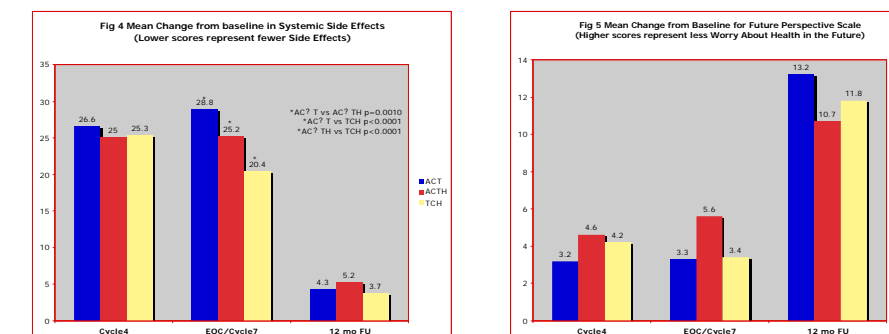
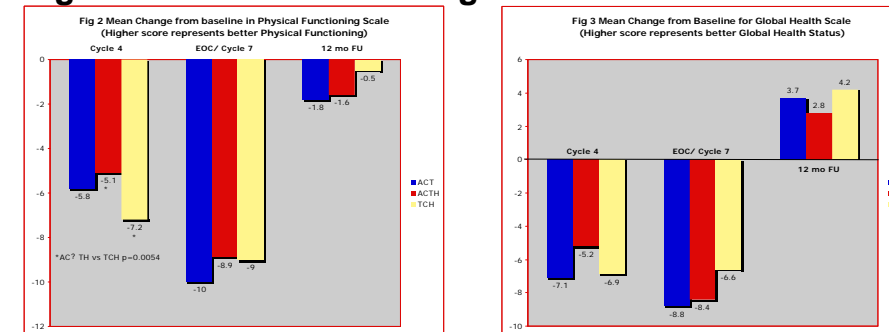


Figure 1: Baseline QoL Scores

Figures 2 to 5: Mean Change in QLQ C30/BR23 Scores

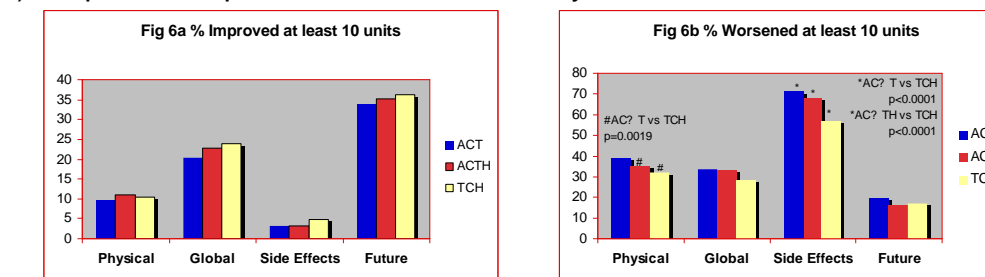


Results

Figures 6: Response Analysis

6a) Proportion of patients who improved by at least 10 units on QoL scale

6b) Proportion of patients who worsened by at least 10 units on QoL scale



Discussion & Conclusions

- QoL compliance and baseline scores were comparable across treatment arms.
- Pts Future perspective mean change scores were always positive and continued to improve throughout treatment and follow-up on all arms.
- Systemic Therapy Side Effects change scores were significantly better for TCH pts at the EOC, and by response analysis, supporting that this regimen is better tolerated.
- Physical Function was slightly worse at Cycle 4 for TCH compared to pts just starting their taxane on AC-TH, but otherwise similar between arms. Fewer patients on TCH had a clinically important worsening PF by response analysis.
- All arms had recovery of deterioration in PF, Global, and SE QoL scales by one year.

References

1. Slamon D, et al. SABCS Oral presentation, 2006.
2. Osoba D, et al Eur J of Ca 41:280-287. 2005.
3. Osoba D, et al J Clin Oncol 16:139-144, 1998.