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.

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Background

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

Objective

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

Study Population

- Six hundred sixty patients were randomized to 3 arms: 4x AC (60mg/m² weekly x 4), 6x TH (60mg/m² q3w x 6, 600mg/m² q3w x 6); and 6x TCH (60mg/m² q3w x 6, 600mg/m² q3w x 6, 1 year trastuzumab).

Methods

- EORTC QLQ-C30, a 30-item questionnaire, and EORTC QLQ-BR23, a 23-item questionnaire, was used which contains:
  - nine symptom scales and items (fatigue, nausea/vomiting, pain, dyspnea, appetite, financial impact)
  - four functional domains (body image, sexual functioning, sexual enjoyment, and future perspective [Future])
  - four functional domains (physical [PF], role, cognitive, emotional, and social)

- Analysis

- Changes from baseline to mid, EOC, and 12 months using a two-sample t-test.
- Wilcoxon signed-rank test was used which contains:
- Categorical change, comparing baseline and end of chemotherapy (EoC) and before and after taxane.
- Chi-square was used to assess differences in percent improving or worsening.
- One sample t-test was used for the assessment of worsening.

- Primary endpoint compared PF, Global, SE, and Future mean change from baseline to EOC and 12 months using a two-sample t-test.
- Subset analysis compared DF, Global, SB, and future mean change from baseline to end of taxane, and 12 months using a two-sample t-test.
- Proportion of patients who worsened by at least 10 units on QoL scale
- Proportion of patients who worsened by at least 10 units on QoL scale compared to baseline.

Results

- Both AC-TH and TCH significantly improved DFS and OS over AC-T.
- BCIRG 006 study significantly improved DFS and OS over AC-T.
- Global safety profile was acceptable in all arms and more favorable in TCH than AC-TH.
- QoL compliance and baseline scores were comparable across all arms.
- QoL results are presented here.

Discussion & Conclusions

- QoL, compliance and baseline scores were comparable across all arms.
- PF Future perspective mean change scores were always positive and continued to improve throughout 2 cycles to 12 months.

References