

San Antonio Breast Cancer Symposium

[3064] BCIRG 006: quality of life (QoL) of patients (pts) treated with docetaxel and trastuzumab-based regimens in node positive and high risk node negative HER2 positive early breast cancer.

The following abstract was presented at the San Antonio Breast Cancer Symposium December 13-17, 2007 in San Antonio, TX.

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Background

BCIRG 006, a randomized controlled trial, compared adjuvant AC (doxorubicin, cyclophosphamide x 4 cycles) followed by docetaxel x 4 [AC-T] or two trastuzumab-containing regimens, AC followed by T with trastuzumab x 1 year [AC-TH] or TCarboplatin x 6 with trastuzumab x 1 year [TCH] in pts with node positive or high risk node negative HER2-positive early breast cancer (n=3222). Both AC-TH and TCH 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 is a secondary endpoint of this trial.

Methods

The EORTC QLQC-30 and BR-23 were administered at baseline; mid chemotherapy (mid) and end of chemotherapy (EOC); 6, 12 and 24 months (mos) post chemotherapy. Primary endpoint for QoL compared Physical Function (PF), Global Health Status (Global), Systemic Therapy Side Effects (SE), and Future Perspective (Future) mean changes from baseline to mid, EOC, and 12 month 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. Chi-square was used to assess differences in percent improving or worsening. Due to 3-arm comparisons, $p < .017$ was considered significant.

Results

Questionnaire compliance rates were 88-90% at baseline; 81-84% at mid; 77-81% at EOC, and 65-68% at 12 mos with no differences between arms. PF change scores were -7.2 for TCH, -5.2 for AC-TH and -5.9 for AC-T at mid ($p = .0081$ TCH vs AC-TH); -8.9, -8.9, and -10.1 at EOC (ns); and -0.5, -1.7, and -1.5 at 12 mos (ns). Global change scores were -6.8, -5.4, and -7.2 at mid (ns); -6.7, -8.4, and -8.6 at

EOC (ns); and 3.6, 2.8, and 4.1 (ns) at 12 mos, respectively. SE change scores were 25.4, 25.0, and 26.7 at mid (ns); 20.2, 25.1, and 28.8 at EOC ($p < .0001$ TCH vs AC-TH and TCH vs AC-T; $p = .0007$ AC-TH vs AC-T); and 3.6, 5.1, and 4.2 (ns) at 12 mos. Future change scores were similar between arms, improving at each time point: 3.0 to 4.9, 3.3 to 5.8, and 10.7 to 14.8 at mid, EOC, and 12 mos, respectively. By response analysis, fewer pts on TCH had worse SE (49.7 vs 58.0% for AC-TH, $p < .0005$; and vs 62.1% for AC-T, $p < .0001$). No significant differences were seen for PF, Global, or Future scales by response analysis.

Conclusions

SE change scores were significantly better for TCH pts compared to AC-TH and AC-T at the EOC, and by response analysis, supporting that this regimen is better tolerated. PF was slightly worse at mid chemotherapy for TCH compared to pts just starting their taxane on AC-TH, but otherwise similar between arms. All arms had recovery of the deterioration in PF, Global, and SE QoL scales by one year. Pts future perspective median change scores were always positive and continued to improve throughout treatment and follow-up.