

[12] Extended Follow-up and Analysis By Age of the US Oncology Adjuvant Trial 9735: Docetaxel/Cyclophosphamide

Is Associated With an Overall Survival Benefit Compared to Doxorubicin/Cyclophosphamide and is Well-tolerated in Women 65 or Older.

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6-year Results (%) by Regimen

| | TC | (# of pts) | AC | (# of pts) | P value | (HR) |
|-------------|-----|------------|-----|------------|---------|--------|
| Overall DFS | 85% | 506 | 79% | 510 | 0.018 | (0.69) |
| OS | 88% | 506 | 84% | 510 | 0.045 | (0.73) |
| DFS <65 | 88% | 428 | 82% | 428 | | (0.64) |
| DFS ≥65 | 82% | 78 | 75% | 82 | | (0.69) |

Background

At SABCS 2005 we reported 5-year results of a randomized trial of 4 cycles of docetaxel/cyclophosphamide (TC) compared to 4 cycles of standard (doxorubicin/cyclophosphamide (AC) in women with node(-) (~50%) and node(+) early breast cancer (BC). A significant improvement in disease-free survival (DFS), but not overall survival (OS), was observed. (Jones, et al. JCO. 2006;24:5381) Older women are not commonly enrolled on adjuvant chemotherapy (CT) trials. Muss, et al reported that only 8% of women on CALBG trials were ≥65. (Muss, et al. JAMA. 2005;293:1073) In the AC/TC trial 16% (160 pts) were ≥65 years (yrs) of age. With 2 more yrs of follow-up, we now report on OS as well as the effect of treatment by age (using 65 as the cutoff) on outcome and toxicity.

Patients and Methods

Pts were eligible if they had Stage I-III operable invasive BC with complete surgical excision of the primary tumor. Between June 1997 and December 1999, 1016 pts were assigned to 4 cycles of either standard-dose AC (60/600mg/m²) [n=510], or TC (75/600mg/m²) [n=506], by intravenous infusion every 3 weeks as adjuvant CT. Radiation therapy (as indicated) and tamoxifen, for pts with hormone receptor positive disease, were given after completion of CT.

Results

Baseline characteristics of all pts and those in the 2 age subgroups were well-matched. The median age in women <65 was 50 (range, 27-64) and for women ≥65 was 72 (range, 65-77). Median follow-up is now 6.9 yrs and the difference in OS between TC and AC is significant. Results are summarized in the table above.

In the TC group, there were 75 DFS events (15%) and 57 deaths (11%); the AC group had 108 DFS events (21%) and 83 deaths (16%). Younger women in both the TC and AC groups had less febrile neutropenia (4.4% and 2.3%, respectively) compared with older women (7.7% and 3.7%, respectively [not significant]). Toxicity, by treatment, was similar in both age groups to the groups as a whole, and will be presented.

Conclusions

With longer follow-up, TC was associated with improved DFS as well as OS compared to standard AC. TC should now be a standard non-anthracycline combination for early BC. In addition, TC was well-tolerated in older women without excessive toxicity compared to their younger counterparts, and may be preferable due to its lack of cardiotoxicity.

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