

Randomized Phase III Study of Docetaxel Compared With Paclitaxel in Metastatic Breast Cancer

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Purpose

This randomized, controlled, multicenter, open-label, phase III study compared docetaxel versus paclitaxel in patients with advanced breast cancer that had progressed after an anthracycline-containing chemotherapy regimen.

Patients and Methods

Patients (n=449) were randomly assigned to receive either docetaxel 100 mg/m² (n=225) or paclitaxel 175 mg/m² (n=224) on day 1, every 21 days until tumor progression, unacceptable toxicity, or withdrawal of consent.

Results

In the intent-to-treat population, both the median overall survival (OS, 15.4 v 12.7 months; hazard ratio [HR], 1.41; 95% CI, 1.15 to 1.73; *P*=.03) and the median time to progression (TTP, 5.7 months v 3.6 months; HR, 1.64; 95% CI, 1.33 to 2.02; *P*<.0001) for docetaxel were significantly longer than for paclitaxel, and the overall response rate (ORR, 32% v 25%; *P*=.10) was higher for docetaxel. These results were confirmed by multivariate analyses. The incidence of treatment-related hematologic and nonhematologic toxicities was greater for docetaxel than for

paclitaxel; however, quality-of-life scores were not statistically different between treatment groups over time.

Conclusion

Docetaxel was superior to paclitaxel in terms of OS and TTP. ORR was higher for docetaxel. Hematologic and nonhematologic toxicities occurred more frequently in the docetaxel group. The global quality-of-life scores were similar for both agents over time. **OA**

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Visit www.oagpo.com to view the full study as published in the 8/20/2005 edition of the Journal of Clinical Oncology. This study is linked under the [News and Events](#) section on OA's homepage.

Randomized Controlled Trial of Azacitidine in Patients With the Myelodysplastic Syndrome

A Study of the Cancer and Leukemia Group B

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Purpose

Patients with high-risk myelodysplastic syndrome (MDS) have high mortality from bone marrow failure or transformation to acute leukemia. Supportive care is standard therapy. We previously reported that azacitidine (Aza C) was active in patients with high-risk MDS.

Patients and Methods

A randomized controlled trial was undertaken in 191 patients with MDS to compare Aza C (75 mg/m²/d subcutaneously for 7 days every 28 days) with supportive care. MDS was defined by French-American-British criteria. New rigorous response criteria were applied. Both arms received transfusions and antibiotics as required. Patients in the supportive care arm whose disease worsened were permitted to cross over to Aza C.

CONCLUSION

Aza C treatment results in significantly higher response rates, improved quality of life, reduced risk of leukemic transformation, and improved survival compared with supportive care. Aza C provides a new treatment option that is superior to supportive care for patients with the MDS subtypes and specific entry criteria treated in this study.

Results

Responses occurred in 60% of patients on the Aza C arm (7% complete response, 16% partial response, 37% improved) compared with 5% (improved) receiving supportive

care (*P*<.001). Median time to leukemic transformation or death was 21 months for Aza C versus 13 months for supportive care (*P*=.007). Transformation to acute myelogenous leukemia occurred as the first event in 15% of patients on the Aza C arm and in 38% receiving supportive care (*P*=.001). Eliminating the confounding effect of early cross-over to Aza C, a landmark analysis after 6 months showed median survival of an additional 18 months for Aza C and 11 months for supportive care (*P*=.03). Quality-of-life assessment found significant major advantages in physical function, symptoms, and psychological state for patients initially randomized to Aza C. **OA**

To view this entire study, visit OA's website at www.oagpo.com. The study is linked under the [News and Events](#) section on the homepage.