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Docetaxel and estramustine compared with mitoxantrone and prednisone for advanced refractory prostate cancer.

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Abstract

BACKGROUND: Mitoxantrone-based chemotherapy palliates pain without extending survival in men with progressive androgen-independent prostate cancer. We compared docetaxel plus estramustine with mitoxantrone plus prednisone in men with metastatic, hormone-independent prostate cancer.

METHODS: We randomly assigned 770 men to one of two treatments, each given in 21-day cycles: 280 mg of estramustine three times daily on days 1 through 5, 60 mg of docetaxel per square meter of body-surface area on day 2, and 60 mg of dexamethasone in three divided doses before docetaxel, or 12 mg of mitoxantrone per square meter on day 1 plus 5 mg of prednisone twice daily. The primary end point was overall survival; secondary end points were progression-free survival, objective response rates, and post-treatment declines of at least 50 percent in serum prostate-specific antigen (PSA) levels.

RESULTS: Of 674 eligible patients, 338 were assigned to receive docetaxel and estramustine and 336 to receive mitoxantrone and prednisone. In an intention-to-treat analysis, the median overall survival was longer in the group given docetaxel and estramustine than in the group given mitoxantrone and prednisone (17.5 months vs. 15.6 months, $P=0.02$ by the log-rank test), and the corresponding hazard ratio for death was 0.80 (95 percent confidence interval, 0.67 to 0.97). The median time to progression was 6.3 months in the group given docetaxel and estramustine and 3.2 months in the group given mitoxantrone and prednisone ($P<0.001$ by the log-rank test). PSA declines of at least 50 percent occurred in 50 percent and 27 percent of patients, respectively ($P<0.001$), and objective tumor responses were observed in 17 percent and 11 percent of patients with bidimensionally measurable disease, respectively ($P=0.30$). Grade 3 or 4 neutropenic fevers ($P=0.01$), nausea and vomiting ($P<0.001$), and cardiovascular events ($P=0.001$) were more common among patients receiving docetaxel and estramustine than among those receiving mitoxantrone and prednisone. Pain relief was similar in both groups.

CONCLUSIONS: The improvement in median survival of nearly two months with docetaxel and estramustine, as compared with mitoxantrone and prednisone, provides support for this approach in men with metastatic, androgen-independent prostate cancer.

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