Background: Mitoxantrone plus prednisone reduces pain and improves the quality of life in men with advanced, hormone-refractory prostate cancer, but it does not improve survival. We compared such treatment with docetaxel plus prednisone in men with this disease.

Methods: From March 2000 through June 2002, 1006 men with metastatic hormone-refractory prostate cancer received 5 mg of prednisone twice daily and were randomly assigned to receive 12 mg of mitoxantrone per square meter of body-surface area every three weeks, 75 mg of docetaxel per square meter every three weeks, or 30 mg of docetaxel per square meter weekly for five of every six weeks. The primary end point was overall survival. Secondary end points were pain, prostate-specific antigen (PSA) levels, and the quality of life. All statistical comparisons were against mitoxantrone.

Results: As compared with the men in the mitoxantrone group, men in the group given docetaxel every three weeks had a hazard ratio for death of 0.76 (95 percent confidence interval, 0.62 to 0.94; P=0.009 by the stratified log-rank test) and those given weekly docetaxel had a hazard ratio for death of 0.91 (95 percent confidence interval, 0.75 to 1.11; P=0.36). The median survival was 16.5 months in the mitoxantrone group, 18.9 months in the group given docetaxel every 3 weeks, and 17.4 months in the group given weekly docetaxel. Among these three groups, 32 percent, 45 percent, and 48 percent of men, respectively, had at least a 50 percent decrease in the serum PSA level (P<0.001 for both comparisons with mitoxantrone); 22 percent, 35 percent (P=0.01), and 31 percent (P=0.08) had predefined reductions in pain; and 13 percent, 22 percent (P=0.009), and 23 percent (P=0.005) had improvements in the quality of life. Adverse events were also more common in the groups that received docetaxel.

Conclusions: When given with prednisone, treatment with docetaxel every three weeks led to superior survival and improved rates of response in terms of pain, serum PSA level, and quality of life, as compared with mitoxantrone plus prednisone.

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Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced...