

Docetaxel plus Prednisone versus Mitoxantrone plus Prednisone as First-Line Chemotherapy for Metastatic Castration-Refractory Prostate Cancer: Long-Term Effects and Safety in Chinese Patients

Introduction and Objective: Docetaxel plus prednisone as first-line treatment for metastatic castration-refractory prostate cancer (mCRPC) was approved by FDA in 2004. It has been shown to be effective and well tolerated by Western patients. However, it was unknown whether this regimen can also benefit Chinese mCRPC in the long term. Therefore this study was to compare docetaxel plus prednisone with mitoxantrone plus prednisone as first-line chemotherapy for Chinese mCRPC.

Materials and Methods: From January 2007 through August 2010, 62 men with mCRPC who received 5 mg of prednisone twice daily were randomly assigned to receive 12 mg of mitoxantrone per square meter of body-surface area every three weeks (Group A) or 75 mg of docetaxel per square meter every three weeks (Group B). The cycles of each regimen were no more than ten. The primary end point was overall survival. The secondary end points were PSA response rate, the duration of PSA response and the objective tumor response rate (ORR). All statistical comparisons were performed between two groups.

Results: There were 31 patients enrolled in Group A who received a median 4 cycles of regimen (range 1-10), whereas 30 patients enrolled in Group B received a median of 7 cycles of regimen (range 2-10). 45.2% patients in Group A and 70.0% in Group B had PSA response ($P<0.05$). The duration time of PSA response was 120.5 days (range 20-323 days) in Group A and 168 days (range 42-447 days) in Group B, respectively. The ORR was 3/20 in Group A and 3/29 in Group B, respectively. The median survival was 511 days (95%CI: 357-665 days) in Group A and 833 days (95%CI: 634-1032 days) in Group B, respectively ($P<0.05$). The incidence of thrombocytopenia in Group A was higher than Group B ($P<0.05$), while the incidences of nausea and vomiting, diarrhea, fatigue, and alopecia in Group B were higher than Group A ($P<0.05$). There were no other adverse events statistically significant between 2 groups.

Conclusions: Docetaxel plus prednisone was feasible and well tolerated in Chinese mCRPC, with a superior overall survival and PSA response rate to that observed in Western patients.