(S27) THERAPY-RELATED ACUTE LEUKEMIA IN MITOXANTRONE-TREATED VETERANS WITH MULTIPLE SCLEROSIS


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Background: Mitoxantrone is one of two drugs approved for patients with worsening relapsing-remitting and progressive-relapsing multiple sclerosis (MS). However, serious and potentially life-threatening side effects are associated with its use. In addition to the widely publicized cardiotoxic effects, there are several reports from the cancer and MS literature suggesting that mitoxantrone use is associated with an increased risk of acute leukemia that appears to be dose-dependent. Objectives: To assess whether treatment with mitoxantrone increases the risk of developing therapy-related acute leukemia within the VHA MS population. Methods: During the period from October 1998 through September 2008, we identified 20,344 veterans with MS. Of these, 445 had received mitoxantrone; 43 died within 10 months of their first dose, leaving 402 patients for analysis. From the VHA inpatient and outpatient utilization databases we determined the date of death and date of first occurrence of an acute leukemia diagnosis (ICD9: 204–208, 238). We also calculated the total dosage, duration of use, and dates of administration from the VHA pharmacy databases. Results: A total of 278 (1.4%) of MS patients had been diagnosed with an acute leukemia. However, only six patients had also been treated with mitoxantrone at least 1 year prior to the leukemia diagnosis. The odds ratio for acute leukemia given treatment with mitoxantrone was 0.99 (95% confidence interval, 0.44–2.40). All of these cases occurred in male patients. Additional analyses are under way to assess the impact of the cumulative dose and duration of treatment on the risk of developing treatment-related acute leukemia. Conclusions: These preliminary findings suggest that there was not an increased risk of treatment-related acute leukemia among the VHA MS population treated with mitoxantrone. Results from the additional analyses currently under way should help clarify whether MS patients treated with mitoxantrone have an increased risk of developing an acute leukemia.

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