

Clarifying risks reported in a meta-analysis

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The debate over risks associated with erythropoiesis-stimulating agents (ESAs) continues. In June 2007, the RADAR project (Research on Adverse Drug Events And Reports) presented a poster at the annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago. This poster reported on the risks of venous thromboembolism (VTE) and mortality associated with ESAs. A meta-analysis revealed an increased risk of VTE and death in clinical trials conducted since 2003. ESA administration was consistently associated with increased VTE risks, while increased mortality risks were noted in exploratory trials in which ESAs were admin-

istered to anemic cancer patients who were not receiving chemotherapy.¹

It is important to emphasize that the meta-analysis presented at ASCO in June showed no new safety concerns beyond those presented at the US Food and Drug Administration's Oncologic Drugs Advisory Committee (ODAC) meeting on May 10, 2007. When ESAs are used in combination with radiation therapy for head and neck cancer or to achieve target hemoglobin levels greater than the correction of anemia, increased risks of VTE and of mortality are noted. These findings had been presented in detail at the ODAC meeting in May.

However, when ESAs are used to achieve hemoglobin levels within the

recommended range and for patients with chemotherapy-associated anemia (about 90% of patients), the drugs pose no greater mortality risks, although there is an increased risk of VTE.

Given the large number of patients who receive ESAs and the attention these drugs have been given in the lay press, it is crucial that the risks identified in the meta-analysis be clarified.

Reference

1. Gleason K, Tigue C, Yarnold P, McKoy J, et al. Recombinant erythropoietin (Epo)/ darbepoetin (Darb) associated venous thromboembolism (VTE) in the oncology setting: findings from the Research on Adverse Drug Events And Reports (RADAR) project. *J Clin Oncol* 2007;25(18S):2552.

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