

Widely used cancer drug associated with significantly increased risk of blood clots

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An analysis of randomized controlled trials indicates that use of the cancer drug bevacizumab is associated with an increased risk of venous thromboembolism (blood clots in the deep veins of the legs or in the lungs), according to an article in the November 19 issue of *JAMA*.

Angiogenesis, a process involving the proliferation of new blood vessels, plays a crucial role in the growth and metastasis of cancer. Bevacizumab, a new, widely-used angiogenesis inhibitor, has shown benefits in the treatment of many types of malignancy including colorectal cancer, non-small cell lung cancer (NSCLC), renal cell cancer and breast cancer. Concerns have arisen regarding the use of bevacizumab and the risk of venous thromboembolism, one of the leading causes of illness and death in patients with cancer.

To determine the risk of venous thromboembolism associated with bevacizumab use, Shobha Rani Nalluri, M.D., of Stony Brook University, Stony Brook, N.Y., and colleagues conducted a meta-analysis of 15 randomized controlled trials (RCTs), which included a total of 7,956 patients with a variety of advanced solid tumors.

The researchers found that among patients receiving bevacizumab, the incidence of all-grade venous thromboembolism was 11.9 percent, and for high-grade venous thromboembolism, it was 6.3 percent. The risk of developing venous thromboembolism was 33 percent greater with bevacizumab than with controls. The risk was significantly increased for both all-grade and high-grade venous thromboembolism. Both high (5 mg/kg per week) and low (2.5 mg/kg per week) doses of bevacizumab were associated with a 31 percent increased risk of venous thromboembolism.

The incidence of all-grade venous thromboembolism with bevacizumab varied among different tumors. The highest incidence was

observed among patients with colorectal cancer (19.1 percent); for patients with NSCLC, the incidence was 14.9 percent, while for patients with breast cancer, the incidence of all-grade venous thromboembolism was 7.3 percent. The lowest incidence was seen in patients with renal cancer at 3.0 percent.

"The association of venous thromboembolism with new agents presents a challenge for recognition because many RCTs may not be powered to reveal a significant relationship. Our meta-analysis of 15 RCTs has overcome this limitation of individual trials and demonstrated that bevacizumab may be associated with a significantly increased risk of venous thromboembolism in patients with a variety of metastatic solid tumors. The increased risk is observed not only for all-grade venous thromboembolism, but also for clinically significant high-grade venous thromboembolism. This finding will help physicians and patients to recognize the risk of venous thromboembolism with the administration of bevacizumab," the authors write.

Source: *JAMA* and Archives Journals

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