Cancer drug used in combination with other therapies associated with increased risk of death

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An analysis of previous studies indicates that compared with chemotherapy alone, use of the cancer drug bevacizumab in combination with chemotherapy or biological therapy is associated with an increased risk of treatment-related death, according to an article in the February 2 issue of *JAMA*.

A fatal adverse event (FAE) is defined as a death caused in all likelihood by a drug and is a major cause of fatality in the United States. Bevacizumab was approved in combination with chemotherapy for treating many types of advanced cancer, including colorectal cancer, non-small cell lung cancer, breast cancer, and renal cell carcinoma. "Even though a number of FAEs have been reported in patients treated with bevacizumab, its role in the development of these fatal events has not been definitively established. Data across bevacizumab trials reveal conflicting results regarding its associations with FAEs," according to background information in the article.

Vishal Ranpura, M.D., of Stony Brook University Medical Center, Stony Brook, N.Y., and colleagues conducted a review and meta-analysis of published randomized controlled trials (RCTs) to determine whether bevacizumab is associated with increased rates of FAEs in patients with cancer. The researchers identified and included 16 RCTs in the analysis. These RCTs included a total of 10,217 patients with a variety of advanced solid tumors. Eligible studies included RCTs in which

bevacizumab in combination with chemotherapy or biological therapy was compared with chemotherapy or biological therapy alone.

The overall incidence of FAEs with bevacizumab was 2.5 percent. Compared with chemotherapy alone, the addition of bevacizumab was associated with a 1.5 times increased risk of FAEs. This association varied significantly with chemotherapeutic agents but not with tumor types or bevacizumab doses. Bevacizumab was associated with a 3.5 times increased risk of FAEs in patients receiving taxanes or platinum agents (3.3 percent vs. 1.0 percent), but was not associated with increased risk of FAEs when used in conjunction with other agents.

Common specific causes of FAEs included hemorrhage (23.5 percent), neutropenia (a blood disorder; 12.2 percent), gastrointestinal tract perforation (7.1 percent), pulmonary embolism (5.1 percent), and cerebrovascular accident (5.1 percent). Pulmonary (14/23) and gastrointestinal hemorrhage (6/23) accounted for most fatal bleeding events.

The authors write that given the absolute risk of treatment-related mortality appears low, the use of bevacizumab should be considered in the context of overall survival benefits. They add that because bevacizumab is increasingly used in cancer patients, it is particularly important for all health care practitioners and patients to understand and recognize the risk of treatment-related mortality and to monitor closely to identify and treat serious adverse effects.

More information: *JAMA*. 2011;305[5]:487-494.

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