

Scientists puzzled by severe allergic reaction to cancer drug in the middle Southern US

A patient's expectations about the side effects of chemotherapy usually focus on nausea, hair loss, fatigue and other side effects. Worries about severe allergic reactions to their therapy is usually not a concern.

A recent study from the Lineberger Comprehensive Cancer Center at the University of North Carolina at Chapel Hill, the Vanderbilt-Ingram Comprehensive Cancer Center and the Sarah Cannon Cancer Center in Nashville have identified an unusually high rate of allergic reaction in cancer patients living in the middle South who received a common drug used for treating their cancer.

This study was presented at the 43rd annual meeting of the American Society of Clinical Oncology in Chicago in June, 2007 and appears online Aug. 17th in the *Journal of Clinical Oncology*.

The drug, cetuximab, marketed by Bristol-Meyers Squibb as Erbitux, is a widely used chemotherapeutic agent for treating colon cancer, head and neck tumors, and is being studied in the treatment of ovarian, lung, breast and gastrointestinal tumors.

When cetuximab was first approved, the first three patients treated at UNC had severe reactions to the drug. Doctors at both Sarah Cannon and Vanderbilt also had more patients than expected react with a drop in blood pressure and shortness of breath or other hypersensitivity reactions within minutes of infusion of cetuximab.

"After speaking with others, we realized that patients who lived on a line across North Carolina, Tennessee, northern Arkansas and southern Missouri had these adverse reactions to the drug," said study leader Dr. Bert O'Neil, assistant professor of medicine, division of hematology and oncology at UNC. "So, we thought it appropriate to see what common bonds were there."

Cancer researchers from UNC and Vanderbilt pooled their patients dating back to when the drug received approval from the Food and Drug Administration, in 2004. More than 140 patients from ongoing clinical trials (at Vanderbilt) and current clinical records (at UNC) were reviewed for the presence of immediate, severe hypersensitivity reactions as well as pertinent demographics to determine this region's rate of allergic reactions and to see if a profile of the potentially allergic patient was evident.

The nationwide rate of severe allergic reactions to cetuximab is only about 2 percent. However, 22 percent of patients in this study showed severe allergic reactions to the drug. Cetuximab normally is infused over a two-hour period, but allergic patients had a reaction within minutes of starting the infusion, a classic anaphylactic reaction. The strongest predictor of a reaction to cetuximab was a history of other hypersensitivities, such as allergic asthma, food allergies, bee stings or allergies to other drugs, such as penicillin.

What is it about this strip across the middle South? "A good question," said O'Neil. "The most likely places to look would be food- or plant-based allergens. If it is of plant origin, finding the source could be a needle-in-a-haystack search. And it's a narrow geographic band; colleagues in Atlanta or the University of Virginia haven't seen this type of reaction."

The research team felt that clinicians in this middle South region must obtain a thorough history of allergic reaction and be prepared to use an alternative drug, such as panitumumab, for patients with a history of hypersensitivity reactions, O'Neil said.

“Bristol-Myers Squibb is studying a screening test for the specific factor that leads to the reaction. In the meantime, doctors in the middle South need to be aware of, and be prepared to treat, sudden, severe allergic reactions when using cetuximab,” O’Neil said.

Based on the results of this study, UNC has a physician, physician assistant or nurse practitioner present for the first 30 minutes of all infusions of cetuximab. The Sarah Cannon Cancer Center halted all studies the drug.

“This is a curious problem, but not a problem we can’t deal with,” said O’Neil. “As long as we know the patient’s allergy history, we know what to do.”

Source: University of North Carolina at Chapel Hill

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