

Common chemotherapy drug triggers fatal allergic reactions

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A chemotherapy drug that is supposed to help save cancer patients' lives, instead resulted in life-threatening and sometimes fatal allergic reactions.

A new study from the Research on Adverse Drug Events and Reports (RADAR) pharmacovigilance program at Northwestern University Feinberg School of Medicine identified 287 unique cases of hypersensitivity reactions submitted to the FDA's Adverse Event Report System between 1997 and 2007 with 109 (38 percent) deaths in patients who received Cremophor-based paclitaxel, a solvent-administered taxane chemotherapy.

Adverse event reports generally only represent from 1 to 10 percent of actual incidence, so the number of hypersensitivity reactions and deaths is likely significantly higher. The severe [allergic reactions](#) are believed to be caused by Cremophor, the chemical solvent - a derivative of castor oil -- that is used to dissolve some insoluble drugs before they can be injected into the blood stream.

Two patients who died from an allergic reaction had early-stage breast cancer, which had been surgically removed, and were being treated with Cremophor-containing paclitaxel to prevent the cancer from coming back. Both of these patients had received medications before the chemotherapy to reduce the risk of hypersensitivity reactions.

The study was led by Charles Bennett, M.D., RADAR program coordinator and a professor of hematology/oncology at Northwestern's

Feinberg School, and Dennis Raisch, a professor of pharmacy at the University of New Mexico.

"The deaths of women with early-stage breast cancer are particularly disturbing because without the adverse reaction, they could have likely had 40 years of life ahead of them," Bennett said.

RADAR investigators also found that 22 percent of all fatalities occurred in patients despite patients having received premedication to prevent hypersensitivity reactions, while another 15 percent of such patients experienced life-threatening respiratory arrest.

The report was presented at the 45th Annual Meeting of the American Society of Clinical Oncology held recently in Orlando, Fla.

Cremophor-containing paclitaxel has been associated with hypersensitivity reactions, with responses ranging from mild skin conditions to more severe effects, including anaphylaxis and cardiac collapse. Current U.S. product labeling for Cremophor containing paclitaxel includes a black-box warning alerting physicians and patients of potential toxicity and recommending the use of corticosteroids and other medications before chemotherapy administration to reduce the risk of hypersensitivity reactions.

"The results of our review suggest that physicians should be vigilant in monitoring the safety of their patients undergoing chemotherapy treatment," said Bennett, who also is the A.C. Buehler Professor in Economics and Aging at the Feinberg School and a member of the Robert H. Lurie Comprehensive Cancer Center of Northwestern University.

"Patients receiving Cremophor-based paclitaxel should be given medications to prevent

hypersensitivity reactions, but what is sobering, as the study has shown and as the black-box warning indicates, women suffer anaphylaxis despite receiving steroid premedication," Bennett said. "Physicians should be diligent in reporting adverse events to regulatory agencies to better monitor the impact of Cremophor on patient safety. Physicians may also want to consider exploring other alternative chemotherapy options that do not include Cremophor."

In addition to the two women with early-stage breast cancer who died after treatment with the Cremophor-based paclitaxel, four other women with early-stage breast cancer experienced life-threatening anaphylaxis reactions. Each of them had received prior medications to prevent the reactions.

"The fatal outcomes observed in patients with early-stage breast cancer were particularly striking as this is a patient population with a good prognosis that is generally treated with curative intent," said Raisch.

For the report, Bennett and Raisch reviewed adverse event reports submitted to regulatory agencies in the U.S., Europe and Japan. The most common cancer diagnosis for these patients with allergic reactions was lung cancer followed by [breast cancer](#) and ovarian cancer.

Source: Northwestern University ([news](#) : [web](#))

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