

Analysis details Avastin's rare fatal side effects

February 1 2011, By CARLA K. JOHNSON , AP Medical Writer

(AP) -- A new analysis raises fresh questions about the risks of the blockbuster cancer drug Avastin, suggesting the chance of dying from side effects linked to it is higher than the risk for patients on chemotherapy alone.

The drug's alarming problems - severe bleeding, holes in the bowel, problems with [wound healing](#) - are already known. The new review, based on an analysis of 16 studies and including more than 10,000 patients, quantifies the risk of death and clarifies how it cuts across different cancers.

Avastin was first approved for treating advanced [colon cancer](#) in 2004. Since then, it gradually gained federal approval for treating other advanced cancers, including breast, kidney and lung. Then in December, federal regulators began the process of withdrawing approval for its use as a breast cancer treatment.

The drug - which can cost up to \$10,000 a month - is given to patients with advanced cancers, some of whom may be willing to take a chance to get a few more good months. But it's still unclear which patients are most likely to benefit from it, so the new findings underscore the complicated risk-benefit analysis that doctors must consider.

"It really points out how little we know," said Dr. Neil Spector of the Duke Cancer Institute in Durham, N.C., who wasn't involved in the study. "We need research to tell us who we can look in the face and say

this drug warrants the potential risk."

Deaths from Avastin's side effects are rare and the small risk should be weighed against the drug's possible benefits, said senior study author Dr. Shenhong Wu of Stony Brook University Cancer Center in New York.

"Patients need to be aware of the risks when they consider their treatment options," said Wu. His research appears in Wednesday's [Journal of the American Medical Association](#).

Charlotte Arnold, a spokeswoman for Avastin's maker, Genentech, said the new analysis is based on known information and includes studies in cancer types for which the drug isn't approved. She said the company supports research to find biomarkers that might reveal which patients may respond to Avastin. The company "takes patient safety very seriously," she said.

There was great hope for Avastin in the beginning. It was the first drug designed to slow tumors by blocking new blood vessels. It worked differently from chemotherapy and didn't cause hair loss or nausea. That may have encouraged some doctors to let their guard down, Spector said.

"We tend to look at it as a safer option, when, in fact, here's a drug that is unfortunately associated with fatal events," he said.

The Food and Drug Administration said Avastin should not be used to treat breast cancer after a research review suggested it failed to help those patients live longer or provide enough benefit to outweigh its risks.

It is still approved for advanced cancers of the colon, kidney, brain and lung. California-based Genentech, a unit of Swiss drugmaker Roche, is studying Avastin in other cancers. The company has appealed the FDA's decision on breast cancer, and some breast cancer patients are upset,

saying they want the drug as an option.

The new analysis found 2.5 percent of patients on Avastin died from bleeding and other side effects thought to be caused by the drug. Fatal side effects were 1.5 times more frequent among patients on Avastin plus chemotherapy than among those getting chemotherapy alone.

The highest risk was seen in patients with prostate and lung cancer, the lowest in patients with kidney and breast cancer. The drug isn't approved for prostate cancer, but has been studied in those patients.

Overall, there were 148 deaths from side effects in 5,589 patients on Avastin and chemotherapy. There were 72 deaths from side effects in 4,628 patients on chemotherapy alone.

Just as the drug blocks new blood vessels that nourish tumors, it may also block new vessels that help the body heal and keep tissues strong. The findings highlight the importance of monitoring patients on Avastin for bleeding and other warning signs.

Experts have called on [Genentech](#) to do research to sort out which patients are most likely to benefit or be harmed by Avastin.

"That's an important part of clinical research," said Dr. Daniel Hayes, clinical director of the [breast cancer](#) program at the University of Michigan. Hayes wrote an accompanying editorial in the journal but wasn't involved in the analysis.

Avastin's enormous costs also must be considered, he said. The drug is dripped into a vein and must be given in a medical office or hospital.

"This drug is as expensive as any therapy we've ever had in cancer," he said. "We can't afford to give a drug to everybody when it helps only a

portion of those to whom it is given."

Roche reported [Avastin](#) sales of nearly \$6 billion in 2009.

More information: JAMA: <http://jama.ama-assn.org>

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