

Study likely spells end for anti-bleeding drug



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An anti-bleeding drug probably will stay off the market, experts say, after a rigorous study found patients getting the medication during heart surgery were much more likely to die than patients given other drugs.

Bayer AG, the maker of the drug Trasylol, said it is still deciding what to do and is awaiting details from the Canadian study. Bayer faces dozens of lawsuits claiming Trasylol led to excess deaths and that the company hid evidence of harm.

But experts in Canada and the United States say the study appears to seal the drug's fate, given that several prior studies linked Trasylol to an elevated risk of death after surgery — and studies that didn't find a higher risk had many weaknesses.

The latest study was the first head-to-head comparison of Trasylol, also known as aprotinin, and two other drugs that surgeons use to prevent massive blood loss during heart surgery. The findings were released Wednesday by the New England Journal of Medicine.

"In all likelihood, this is the end of the aprotinin story," Wayne A. Ray and C. Michael Stein of Vanderbilt University School of Medicine wrote in an editorial accompanying the study.

Trasylol was approved in 1993 but questions about its safety didn't surface until 2006, when one large study linked it to increased risk of death, heart attack, stroke and kidney failure.

The Canadian study, paid for by the government, included more than 2,300 patients who were at high risk of bleeding or had multiple health problems. They were chosen randomly to receive Trasylol or two other anti-bleeding drugs during heart surgery. The study was stopped early last October when preliminary results showed a higher rate of death in the Trasylol group. Bayer temporarily pulled the drug off the market two weeks later.

"There was no way we could ethically enroll (more patients) in the trial because we had our answer," said lead researcher Dean A. Ferguson, a transfusion medicine expert at the Ottawa Health Research Institute. "I think the results are quite definitive, certainly for high-risk cardiac surgery, and it's going to be very tough to justify its use in lower-risk surgery."

An analysis of the data showed Trasylol increased chances of death by 54 percent, compared to two much-cheaper drugs. Six percent of the Trasylol patients died within 30 days of surgery, compared with 4 percent who got either Amicar or Cyklokapron, despite a slightly lower percentage of the Trasylol patients suffering from massive bleeding or needing transfusions.

The researchers found those who died in the Trasylol group had a much higher proportion of heart complications after surgery, including heart attacks.

Bayer noted in its 2007 annual report that 46 lawsuits had been filed over Trasylol and additional cases are expected. The drug still is available under a special program in some countries, including the United States.

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