

Aprotinin associated with increased risk of death

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Aprotinin is associated with a 50 per cent increase in the relative risk of death, according to a major Canadian clinical trial comparing three drugs routinely used to prevent blood loss during heart surgery. The trial, published in the *New England Journal of Medicine*, shows that approximately six per cent of patients who received aprotinin died within 30 days of surgery compared to four per cent of patients who received tranexamic acid or aminocaproic acid.

BART (Blood Conservation using Antifibrinolytics in a Randomized Trial) is one of the largest heart surgery trials ever conducted, involving more than 2,000 high-risk cardiac surgery patients and more than 100 cardiac surgeons, anesthesiologists, pharmacists and coordinators from 19 Canadian centres. This publicly-funded collaborative trial was led by Senior Scientists at the Ottawa Health Research Institute, the research arm of The Ottawa Hospital and an affiliated institute of the University of Ottawa.

“These three drugs have been routinely used in heart surgery for more than a decade, but this is the first trial to rigorously compare them in a meaningful setting with meaningful clinical outcomes,” said Dr. Dean A. Fergusson, BART Co-Principal Investigator and Senior Scientist. “The results demonstrate the great value of and the need for independent academic clinical trials.”

“Overall, our study supports the use of tranexamic acid or aminocaproic acid over aprotinin during high-risk heart surgery,” said Dr. Paul C.

Hébert, BART Co-Principal Investigator and Critical Care Physician. “I’ve treated many patients with complications from heart surgery so I know how important these results are to patients, to their families and to health care providers.”

BART was prematurely stopped by the trial’s Steering Committee in October 2007 following advice from an independent Data Safety and Monitoring Board, which detected a trend towards increased mortality in one arm of the triple-blinded study. Shortly after these preliminary results were made public, the manufacturer of aprotinin announced that the drug would be suspended from the market pending analysis of the final results of the trial.

The final results show that although aprotinin appeared to decrease some of the consequences of massive bleeding, including the need for repeat surgery, these benefits were outweighed by the risks. The analysis showed that the increased aprotinin-associated mortality was related to cardiac complications.

It has been estimated that between 1 and 1.25 million people undergo heart surgery every year. The use of antifibrinolytics such as aprotinin, tranexamic acid or aminocaproic acid has become standard practice to reduce bleeding during these surgeries. The cost of aprotinin has been estimated at between \$1,200 and \$1,500 per patient compared to approximately \$150 for tranexamic acid or aminocaproic acid.

Source: Ottawa Health Research Institute

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