BREAKING NEWS: ANTIFIBRINOLYTICS AND CARDIAC SURGERY

Prof. Gamal Fouad S Zaki, MD
Professor of Anesthesiology, Ain Shams University

Recently, international media reverberated with news involving the safety of the serine protease inhibitor drug Aprotinin (Trasylol®, Bayer AG, Leverkusen, Germany). On September 30, 2006, the New York Times reported on its front page that the US Food and Drug Administration (FDA) had issued a warning that aprotinin, widely used to reduce bleeding during cardiac surgery, could cause renal failure, congestive heart failure, stroke or death.

The story started with a lot of experts expressing skepticism about the safety of aprotinin since its approval by the FDA in 1993. In January 2006, Mangano et al. published an observational study in the New England Journal of Medicine, on behalf of the Multicenter Study of Perioperative Ischemia (McSPI) Research Group, involving 4374 patients who underwent coronary revascularization at 69 centers in 17 countries\(^1\). The widely publicized study suggested that the use of aprotinin as compared with no antifibrinolytic agent, aminocaproic acid, or tranexamic acid, was associated with an increased incidence of renal failure requiring dialysis (more than twice), myocardial infarction (+55%), stroke and encephalopathy (+181%), congestive heart failure and death. Another study published during 2006 by Karkouti et al. suggested that aprotinin administration increased the risk of renal dysfunction or failure with no increased incidence of cardiovascular or cerebrovascular complications\(^2\). What brought the drug to the front page on September 30 was the revelation that Bayer failed to notify the FDA before the meeting of the presence and results of a similar study contracted by Bayer and showing increased mortality and renal damage in patients who received aprotinin.

References: