



Letter to the Editor

New clinical perspectives from nurses on aprotinin and fibrin sealants

To the Editor:

A group of prominent surgical nurses, along with a hospital materials manager, met in New York, New York, December 12, 2007, to provide clinical perspectives and updates on a range of issues related to aprotinin and fibrin sealants. The panel consisted primarily of practicing nurses from the endovascular, neurosurgical, cardiothoracic, pediatric, and general surgery specialties. Discussion focused on recent findings associated with aprotinin injection, aprotinin as a component of fibrin sealant, and related patient-safety concerns.

Fibrin sealants (fibrin glues and fibrin tissue adhesives) are a class of topical adjunctive hemostat, consisting primarily of purified, virus-inactivated fibrinogen and thrombin, that promote the formation of a fibrin clot. In wide use in Europe since the 1970s,¹ fibrin sealants were approved by FDA in 1998. Since then, fibrin sealants have played an increasingly prominent role as a supplement to primary methods of hemostasis in an increasing range of procedures. In January, 2008, a fibrin sealant received an indication from FDA for general hemostasis in surgery, expanding the uses of this product class to new surgical specialties.

Some fibrin sealants contain aprotinin, an antifibrinolytic agent that can be administered intravenously or topically to increase clot longevity. In recent years, the intravenous version of aprotinin has been associated with increased risk of renal failure, stroke, myocardial infarction, and mortality.² In November, 2007, the FDA requested the marketing suspension of aprotinin injection in response to preliminary data from a randomized, blind trial in Canada, that indicated an increased risk of mortality after use of the drug in some types of cardiac surgery.³ In addition, a recent proliferation of prospective trials, case studies and clinical reviews has suggested a causal link between the use of topical preparations containing aprotinin and rare cases of intra- and post-operative hypersensitivity in patients.^{4,5} Safety warnings and drug labeling restrictions issued by the US FDA have given special emphasis to repeated administrations of aprotinin within a limited interval. Recently a clinical literature review of aprotinin-specific anaphylactic reactions reported between 1963 to 2003 determined a 2.8% chance of anaphylaxis in patients re-exposed to aprotinin in any form within 36 months.⁶

Panel participants agreed that awareness of patient safety issues related to aprotinin is insufficient, given that aprotinin and aprotinin-containing products continue to be used in many health-care facilities throughout the United States. Participants posited peer recruitment (ie, surgeon and nurse champions) and tailored informal communications (eg, concise e-mails) as effective strategies for conveying messages about aprotinin to clinicians. In addition, the panel urged hospital management to include surgeons and surgical staff in hospital value-analysis teams to facilitate enhanced communication between nurses and materials-acquisition personnel.

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