# Adverse effects of fibrin sealants in thoracic surgery: The safety of a new fibrin sealant: Multicentre, randomized, controlled, clinical trial.

Authors: Cardillo G., Carleo F., Carbone L., De Massimi A.R., Lococo A., Santini P.F., Janni A., Gonfiotti A.

Publication Date: 2012

## Abstract:

Objectives: The safety of fibrin sealants (FS) has been questioned in the light of recent reports of adverse effects. We evaluated the safety of a new FS in a randomized controlled trial (RCT). Methods: Multicentre, open-label Phase II/III RCT to evaluate the safety of the new FS. The trial was approved by the Ethic Committee of each three participatingCentre. FS includes two components (component 1: fibrinogen; component 2: thrombin), each of them subjected to two viralinactivation procedures. Out of 200 screened patients, 185 eligible patients (49 females, 136 males), aged between 18 and 75 years, undergoing major thoracic surgery were randomized to receive FS (#91 patients) as an adjuvant for air leak control or no treatment (#94 patients, control group). Safety variables were: percentage of subjects with adverse eventsassociated with the therapy; formation of antibodies against bovine aprotinin; vital signs (blood pressure, body temperature, heart and respiratory rate); laboratory parameters. Results: Overall operative mortality was 3.2% (6/185), 1.1% in the FS group and 5.3% in the control group, respectively. Twenty patients (22%) had adverse events in the FS group and 22 (23.4%) in the control group. Atrial fibrillation (five patients in the FS group and four in the control group) and hyperpyrexia (five and seven patients, respectively, in the two groups) were the most common adverse events. No patient reported thromboembolic events (pulmonary embolism or deep vein thrombosis) during the in hospital stay or within 1 month from discharge. None of the adverse events was considered as treatment related. The formation of bovine aprotinin antibodies was reported in a total of 34 patients (37.4%) in the FS group and was

not related to any adverse effect. Conclusions: The present RCT did not show any increased risk of adverse events, and of surgical complications, related to the use of the new FS. 