ADverse effects of fibrin sealants in thoracic surgery. The safety of a new fibrin sealant: Multicentre, controlled, prospective, parallel group randomised clinical trial.

Authors: Cardillo G., Lococo A., De Massimi A.R., D'Agostino A., Carleo F., Larocca V., Santini P.F., Gonfiotti A.

Publication Date: 2011

Abstract:

Objectives: The safety of fibrin sealants has been questioned in the light of recent reports of adverse effects, mainly thromboembolic events and fatal anaphylaxis. We evaluated the safety of a new fibrin sealant (FS) in a randomised controlled trial (RCT). Methods: Multicentre, prospective, open-label phase II/III RCT to evaluate the safety of FS. The trial was approved by the Ethic Committee. FS includes two components (component 1: fibrinogen; component 2: thrombin), each of them subjected to two viral inactivation procedures. Out of 200 screened patients, 185 eligible patients (49 females, 136 males), aged between 18 and 75 years, undergoing major thoracic surgery were randomised to receive FS (# 91 patients) as an adjuvant for air leak control or no treatment (#94 patients). Safety variables were: percentage of subjects with adverse events associated with the therapy; formation of antibodies against bovine aprotinin; vital signs (blood pressure, body temperature, heart and respiratory rate); laboratory parameters (haematology and blood chemistry). Results: None of the adverse events was considered as treatment-related. 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 inhospital stay or within one month from discharge. 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 serious and non-serious adverse events, and of surgical complications, related to the use of FS. The proportion of treated patients that developed bovine aprotinin antibodies was in compliance with literature data.