

Controlled clinical studies of fibrin sealant in cardiothoracic surgery--a review.

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Abstract:

OBJECTIVE: More than 2300 clinical papers have been published on the surgical applications of fibrin sealant (FS), with the largest number in the speciality of cardiothoracic surgery. The purpose of this review of the literature was to find and evaluate controlled studies published in the field of cardiothoracic surgery, to clarify the indications and emphasize the benefits of FS available to the practising surgeon. **METHODS:** A database of the surgical publications of FS was created. Up to the end of 1995, at least 24 controlled clinical studies had been published; these may be divided into 20 studies with a positive outcome and 4 studies where the results were not different from the controls. In none of the studies was the clinical result worse after the use of FS. **RESULTS:** In most of the cardiac studies, FS was successfully used at bleeding sites in reoperations and in congenital heart surgery. Postoperative bleeding may also be reduced by the anterior mediastinal spray application of FS or by preparing woven Dacron prostheses with the sealant. In addition, FS has been found to improve results after type A aortic dissections and, by adding an antibiotic to the sealant, the postoperative infection rate for active endocarditis of the aortic root can be reduced. In pulmonary surgery FS can be used to reduce pulmonary air leakage, however the results of some studies diverge due to different clinical test conditions and the inclusion of only a small number of patients in the "negative" studies. In none of the controlled studies of esophageal surgery could FS prevent leakage from esophageal anastomoses. **CONCLUSIONS:** Fibrin sealant is safe when it is applied properly, but there is a learning curve for surgeons who start using it. An autologous sealant or a sealant containing human instead of bovine thrombin is preferred, since repeated use of bovine

thrombin may induce coagulopathies. The number of controlled clinical studies of FS is currently increasing, with the majority of the papers revealing a beneficial effect of FS when it is used as a hemostatic or sealing agent in cardiothoracic surgery.