Safety and effectiveness of a new fibrin pleural air leak sealant: A multicenter, controlled, prospective, parallel-group, randomized clinical trial.

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

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Abstract:

Background: This study evaluated the sealing capacity and safety of a new fibrin sealant (FS) to reduce alveolar air leaks (AALs) after pulmonary resections in a randomized controlled clinical trial conducted in 3 Italian centers. Methods: The study randomized (1:1) 185 patients with an intraoperative AAL graded 1 to 3 according to the Macchiarini scale: 91 received FS and 94 had standard lung closure. The primary outcomes were the length of postoperative AAL duration and the mean time to chest drain removal. Other end points included the percentage of patients without AAL, the development of serum antibodies against bovine aprotinin, and any adverse event related to FS. Chest drains were removed when fluid output was 100 mL/day or less, with no air leak. Results: The study groups were comparable with respect to demographic variables and surgical procedures. The FS group showed a statistically significant reduction in duration of postoperative AALs (9.52 vs 35.8 hours; $p < 0.005$) and in the percentage of patients with AALs at wound closure (81.11% vs 100%; $p < 0.001$); the difference in time to chest drain removal was not significant. Pleural empyema developed in 1 patient with FS treatment vs in 4 with standard treatment, and antibodies against bovine aprotinin were found in 34 of 91 FS-treated patients. Conclusions: The present study showed that the new FS is safe and effective in preventing AALs after lung resections and in shortening the duration of postoperative AALs.