A randomised trial of lung sealant versus medical therapy for advanced emphysema.

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Publication Date: 2015

Abstract:

Uncontrolled pilot studies demonstrated promising results of endoscopic lung volume reduction using emphysematous lung sealant (ELS) in patients with advanced, upper lobe predominant emphysema. We aimed to evaluate the safety and efficacy of ELS in a randomised controlled setting.Patients were randomised to ELS plus medical treatment or medical treatment alone. Despite early termination for business reasons and inability to assess the primary 12-month end-point, 95 out of 300 patients were successfully randomised, providing sufficient data for 3- and 6-month analysis.57 patients (34 treatment and 23 control) had efficacy results at 3 months; 34 (21 treatment and 13 control) at 6 months. In the treatment group, 3-month lung function, dyspnoea, and quality of life improved significantly from baseline when compared to control. Improvements persisted at 6 months with >50% of treated patients experiencing clinically important improvements, including some whose lung function improved by >100%. 44% of treated patients experienced adverse events requiring hospitalisation (2.5-fold more than control, p=0.01), with two deaths in the treated cohort. Treatment responders tended to be those experiencing respiratory adverse events.Despite early termination, results show that minimally invasive ELS may be efficacious, yet significant risks (probably inflammatory) limit its current utility.