



Title	Endobronchial Valves in the Treatment of Diffuse Heterogeneous-Type Pulmonary Emphysema
Agency	AVALIA-T, Axencia de Avaliación de Tecnoloxías Sanitarias de Galicia Edificio Administrativo San Lázaro, 15781 Santiago de Compostela, Spain; Tel: +34 881 541 831, Fax: +34 881 542 854; avalia-t@sergas.es, http://avalia-t.sergas.es
Reference	Report no. CT 2009/04. www.sergas.es/MostrarContidos_N2_T01.aspx?IdPaxina=60058

Aim

To assess the efficacy and safety of reduction in pulmonary volume by bronchoscopic implantation of endobronchial valves in treating diffuse heterogeneous-type emphysema resistant to conventional medical treatment at maximum doses.

Conclusions and results

The following were selected: 3 case series and the randomized Emphasys Bronchial Valve for Emphysema Palliation Trial (VENT Study), undertaken using the Zephyr valve. At 6 months, the Zephyr group in this trial registered a 5.6 times higher risk of death or severe complications than did the control group. This risk declined to 2.23-fold at 12 months. Similarly, the Zephyr group displayed more COPD-related complications and thoracic-pulmonary problems than did the control group ($p < 0.01$). The Zephyr group showed statistically significant improvements in forced expiratory volume (FEV₁) versus the control group, with no differences observed in the other variables. Only 20% of the Zephyr group registered clinically significant improvements in FEV₁ (>15%) versus 7.9% in the control group ($p = 0.016$). During the procedure, 14.8% of valves were discarded, essentially due to problems in placement. This led to placement being modified by fitting a calibrator into the catheter holder. Bearing in mind that, on average, 3.8 valves were inserted into each patient, the estimated cost was about 21 333 euros (EUR) per patient.

The studies in this review were few and suffered from methodological shortcomings. Hence, rigorous conclusions cannot be drawn about the effectiveness and safety of endobronchial valves in treating diffuse heterogeneous-type emphysema. Treatment using endobronchial duckbill valves reflects a significantly higher number of adverse effects and rehospitalizations than what was observed for the control group. Reports of the preliminary results of the VENT study do not reflect overall clinically significant improvements among patients with diffuse heterogeneous-type emphysema. The procedure

appears to display differing efficacy in line with patients' baseline status and the treatment strategy used. The current dearth of studies renders it impossible to draw conclusions about endobronchial umbrella valves.

Recommendations

Available scientific information does not allow for endobronchial duckbill valves to be recommended in treating diffuse heterogeneous-type emphysema. Moreover, the efficacy or appropriateness of these devices should be assessed in the context of other possible indications, eg, overdistension of the native lung following single-lung transplantation owing to emphysema or persistent bronchopleural fistulae irresolvable by surgical treatment.

Methods

The scientific literature was reviewed, stipulating no time limit and covering the following databases: MEDLINE; EMBASE; HTA (Health Technology Assessment); DARE (Database of Abstracts of Reviews of Effectiveness); NHSEED (National Health Service Economic Evaluation Database); Cochrane Library Plus; CSIC-Cindoc (*Consejo Superior de Investigaciones Científicas-Centro de Información y Documentación Científica*); and the Clinical Trials Registry. From the papers yielded by the search, we selected those that met the selection criteria, extracted data, and summarized the evidence.

Further research/reviews required

Quality studies of sufficient statistical robustness need to furnish definitive data on the efficacy and safety of this technique and enable firm conclusions to be drawn.