INAHTA Briefs

Issue 2009/075

Title **Endobronchial Valves in the Treatment of Severe Pulmonary Emphysema: a Rapid Health Technology Assessment**

Agency **KCE, Belgian Health Care Knowledge Centre**
Kruidtuinlaan, 55 B-1000 Brussels, Belgium;
Tel: +32 2 287 3388, Fax: +32 2 287 3385; info@kce.fgov.be, www.kce.fgov.be

Reference Report no. 114 (C), 2009

Aim

To systematically review the cost effectiveness of endobronchial valves (EBVs) as an additional modality to optimal noninvasive therapy in patients with severe pulmonary emphysema.

Conclusions and results

No data from randomized controlled trials (RCTs) have been published. The available evidence indicates that the efficacy of EBVs on the outcome measures important to patients is, on average, limited. Subgroups of patients that are to be identified may benefit more substantially from the procedure, but future research needs to resolve such issues.

The findings indicate that the safety of EBV insertion in patients with severe emphysema remains a concern. The procedure may induce pneumothorax, and the presence of a foreign object in the bronchial tree seems to induce chronic obstructive pulmonary disease (COPD) exacerbations and lead to more hospitalizations during follow-up.

Recommendations

Reimbursement of EBVs in patients with end-stage pulmonary emphysema cannot be supported due to poorly demonstrated clinical benefit, potential adverse effects, and high costs for limited efficacy.

Assignment of a CE-label to a medical device does not guarantee its effectiveness or clinical safety, and such labeling may mislead patients and physicians. KCE recommends inclusion of this issue on the agenda of the Belgian presidency of the European Union in 2010.

Methods

A systematic literature search identified no RCT on the efficacy of EBV, but found 9 case series in peer-reviewed journals. A search of ClinicalTrials.gov, revealed 5 registered trials. Contact with manufacturers and principal investigators of these studies and a search of the grey literature identified data on some of the registered trials. Minutes from an FDA meeting presented some results from the yet unpublished VENT trial.

A cost-effectiveness sub-study of the VENT trial was set up to gather utilization and quality of life information on patients enrolled in the clinical VENT study (ClinicalTrials.gov identifier NCT00137956) to analyze the relative cost effectiveness of the EBV procedure. This sub-study was stopped prematurely because "Emphasys Medical decided to discontinue the study due to resources and cost required to execute the study as compared to the amount of additional data being received."

Further research/reviews required

The devices may provide a larger benefit in subgroups of patients, but it is unclear how these subgroups can be identified and whether the clinical improvement would outweigh the potential harms. The possible benefit of EBVs in such subgroups should be proven in a prospective RCT including patient-oriented endpoints.

Written by Van Brabandt H, KCE, Belgium

ISSN 1654-501X