Effect of Endobronchial Coils vs Usual Care on Exercise Tolerance in Patients With Severe Emphysema

The RENEW Randomized Clinical Trial

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ABSTRACT

Importance Preliminary clinical trials have demonstrated that endobronchial coils compress emphysematous lung tissue and may improve lung function, exercise tolerance, and symptoms in patients with emphysema and severe lung hyperinflation.

Objective To determine the effectiveness and safety of endobronchial coil treatment.

Design, Setting, and Participants Randomized clinical trial conducted among 315 patients with emphysema and severe air trapping recruited from 21 North American and 5 European sites from December 2012 through November 2015.

Interventions Participants were randomly assigned to continue usual care alone (guideline based, including pulmonary rehabilitation and bronchodilators; n = 157) vs usual care plus bilateral coil treatment (n = 158) involving 2 sequential procedures 4 months apart in which 10 to 14 coils were bronchoscopically placed in a single lobe of each lung.

Main Outcomes and Measures The primary effectiveness outcome was difference in absolute change in 6-minute-walk distance between baseline and 12 months (minimal clinically important difference [MCID], 25 m). Secondary end points included the difference between groups in 6-minute walk distance responder rate, absolute change in quality of life using the St George's Respiratory Questionnaire (MCID, 4) and change in forced expiratory volume in the first second (FEV_1; MCID, 10%). The primary safety analysis compared the proportion of participants experiencing at least 1 of 7 prespecified major complications.

Results Among 315 participants (mean age, 64 years; 52% women), 90% completed the 12-month follow-up. Median change in 6-minute walk distance at 12 months was 10.3 m with coil treatment vs −7.6 m with usual care, with a between-group difference of 14.6 m (Hodges-Lehmann 97.5% CI, 0.4 m to ∞; 1-sided $P = .02$). Improvement of at

least 25 m occurred in 40.0% of patients in the coil group vs 26.9% with usual care (odds ratio, 1.8 [97.5% CI, 1.1 to ∞]; unadjusted between-group difference, 11.8% [97.5% CI, 1.0% to ∞]; 1-sided $P = .01$). The between-group difference in median change in FEV_1 was 7.0% (97.5% CI, 3.4% to ∞; 1-sided $P < .001$), and the between-group St George's Respiratory Questionnaire score improved −8.9 points (97.5% CI, −∞ to −6.3 points; 1-sided $P < .001$), each favoring the coil group. Major complications (including pneumonia requiring hospitalization and other potentially life-threatening or fatal events) occurred in 34.8% of coil participants vs 19.1% of usual care ($P = .002$). Other serious adverse events including pneumonia (20% coil vs 4.5% usual care) and pneumothorax (9.7% vs 0.6%, respectively) occurred more frequently in the coil group.

Conclusions and Relevance Among patients with emphysema and severe hyperinflation treated for 12 months, the use of endobronchial coils compared with usual care resulted in an improvement in median exercise tolerance that was modest and of uncertain clinical importance, with a higher likelihood of major complications. Further follow-up is needed to assess long-term effects on health outcomes.

Trial Registration clinicaltrials.gov Identifier: NCT01608490