Two-year safety of targeted lung denervation in patients with moderate to severe COPD

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Background: Targeted lung denervation (TLD) is a novel bronchoscopic therapy that ablates parasympathetic pulmonary nerves along the main bronchi and has been reported as feasible and safe through one-year follow-up *(Eur Resp J 2014 44*: *Suppl 58, P3720)*.

Aim: Evaluate two-year safety of TLD in COPD patients.

Methods: A first-in-human, prospective, multicenter, study in COPD patients ($FEV_1/FVC<0.70$; FEV_1 30-60% predicted) was performed (NCT01483534). Patients underwent TLD using a catheter based lung denervation system (Holaira, Inc., USA) delivered during two rigid bronchoscopies 30 days apart, in an outpatient setting. Two-year safety was determined by registration of all AEs in that time.

Results: Twelve patients (FEV_1 33.8±9.4 % predicted, age 62.9±11.4 yrs) were treated at a 20W energy dose and 10 (FEV_1 34.5±6.3 % predicted, age 64.4±8.9 yrs) at 15W. Eighteen patients completed 2-year follow-up. No deaths or unexpected AEs were reported. 21 serious AEs were observed; 11 COPD exacerbations, 2 respiratory infections, 2 cancers (stomach and pancreatic), 1 flu, 1 myocardial infarction, 1 chest pain, 1 drug reaction, 1 gastroenteritis, and 1 episode of gastroparesis. 13 were in the 15W group with 8 occurring in a single patient. Respiratory AE rates are similar between doses and trend toward fewer events over time.

Conclusion: TLD has an acceptable rate of AEs and no unexpected AEs in COPD patients out to 2 years.