Bronchial Rheoplasty for Chronic Bronchitis: 2 Year Results from a US Feasibility Study with RheOx®

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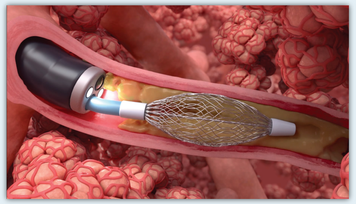
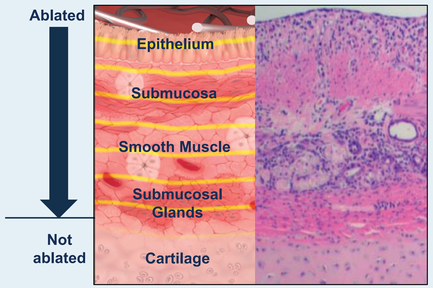
INTRODUCTION

Chronic bronchitis, a form of COPD, defined by persistent cough and mucus hypersecretion is associated with poor quality of life, exacerbations, and lung function impairment. Despite pharmacotherapy, patients often remain highly symptomatic. Bronchial Rheoplasty (BR) uses the investigational RheOx® System to deliver non-thermal pulsed electric fields to induce non-necrotic epithelial and submucosal cell death, and repopulated epithelium with reduced airway goblet cell hyperplasia. Previously reported one-year results from this U.S. multi-center, single-arm study in chronic bronchitis patients demonstrated a favorable safety profile and improved symptoms. Two-year results from the study are reported here.





METHODS

21 patients with CB were enrolled in a prospective, multi-center study at 8 centers in the U.S.

KEY INCLUSION CRITERIA

- ✓ Chronic bronchitis defined clinically as a productive cough for three months in two successive years
- ✓ Post-BD FEV_1 30% to 80% predicted
- ✓ 10 pack-years or greater smoking history
- ✓ SGRQ ≥ 25 points and CAT ≥ 10 points
- ✓ Sum of CAT Q1 and Q2 (cough and mucus) ≥ 7
- ✓ ≥ 1 prior exacerbation of any severity

KEY EXCLUSION CRITERIA

- ✗ Active respiratory infection or COPD exacerbation within 6-weeks of study enrollment
- ✗ Previous lung surgery
- ✗ History of arrhythmia
- ✗ Other lung disease including primary diagnosis of asthma
- ✗ Emphysema ≥ 20% as quantified on baseline HRCT scan (low attenuation area less than -950HU)

All patients underwent bilateral BR procedures under general anesthesia. Right-sided airways were treated first; the left side was treated one month later. Patients were followed for 2 years.

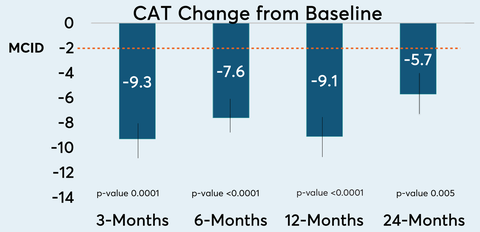
Outcomes at 2-years included assessment of serious adverse events (SAEs), symptoms using the COPD Assessment Test (CAT) and quality of life using the St. George's Respiratory Questionnaire (SGRQ), exacerbation rates, and spirometry. Moderate (requiring steroid or antibiotic treatment) and severe (requiring hospitalization) exacerbations were tabulated excluding the 30-day post-procedure recovery periods. Baseline exacerbations were captured in the year prior to treatment.

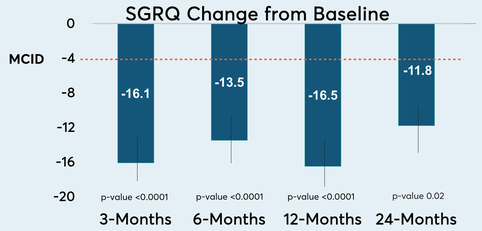
RESULTS

BR was successfully performed in all 21 patients (mean age 66.1 ± 5.3, post-BD FEV1 53.3 ± 15.8, SGRQ 60.1 ± 15.5, CAT 26.9 ± 4.9). Baseline exacerbation rates: moderate+severe 1.19 events/pt-yr, severe 0.14 events/pt-yr, and moderate 1.05 events/pt-yr.

SAFETY:
There were no device or procedure-related serious adverse events. There were no significant changes in pulmonary function through 24 months. Four SAEs were reported in 2 patients between the 12-month and the 2-year visit including COPD exacerbation (2 events in 1 patient), pulmonary embolism (1 event), and worsening dyspnea (1 event).

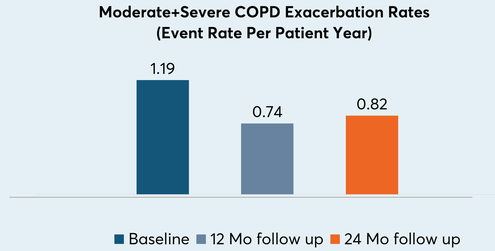
PATIENT REPORTED OUTCOMES:
significant improvements from baseline to 24 months were observed in both the CAT (-5.7 points) and SGRQ (-11.8 points).





RESULTS

COPD EXACERBATIONS :
A 31% reduction in the moderate or severe COPD exacerbation rate during year 2 (0.816 events/patient-year) compared to the year prior to treatment (1.19 events/patient-year) was observed. 2 severe exacerbations and 13 moderate exacerbations were reported between 12 and 24 months.



CONCLUSION

This interim update assessed longer term outcomes of bronchial rheoplasty in the initial US feasibility study cohort of 21 chronic bronchitis patients. The results suggest that the improvements in chronic bronchitis symptoms and health related quality observed through 1 year persist through 2 years. A randomized controlled clinical trial is currently underway to confirm these findings.

RheOx® system has CE certification. RheOx system is an investigational device in the United States. Limited by Federal (or United States) law to investigational use.

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