Bronchial Rheoplasty for Chronic Bronchitis: Initial Results from a European Registry Study with RheOx®

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BACKGROUND

Chronic bronchitis (CB), defined by persistent cough and mucus hypersecretion is associated with poor quality of life (QoL), exacerbations and lung function decline. Bronchial Rheoplasty (BR) with RheOx® utilizes non-thermal pulsed electric fields to reduce airway goblet cell hyperplasia and improve CB symptoms. We present preliminary results from a European Registry study.

METHODS

The study was a post-market, observational, multi-center, open-label, single arm registry.
Fifty patients with significant disease burden have been enrolled at centers in Austria and Germany. Treatment involved bilateral BR approximately one month apart. Data collection included respiratory serious adverse events (SAE) and QoL using the COPD Assessment Test (CAT), and St. George's Respiratory Questionnaire (SGRQ). Responders were defined as those who improved by at least the minimally clinically important difference (MCID) for CAT (-2 points) and SGRQ (-4). Enrollment and follow-up is ongoing.

Safety: Respiratory SAEs

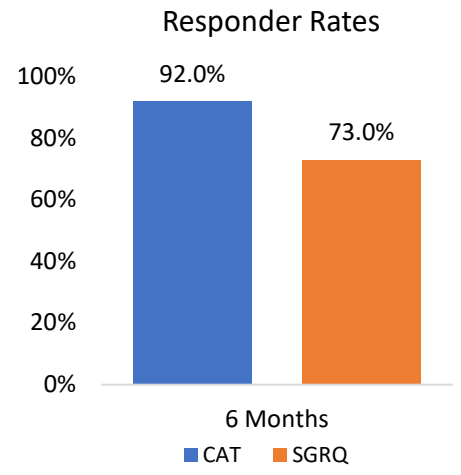
Respiratory SAEs

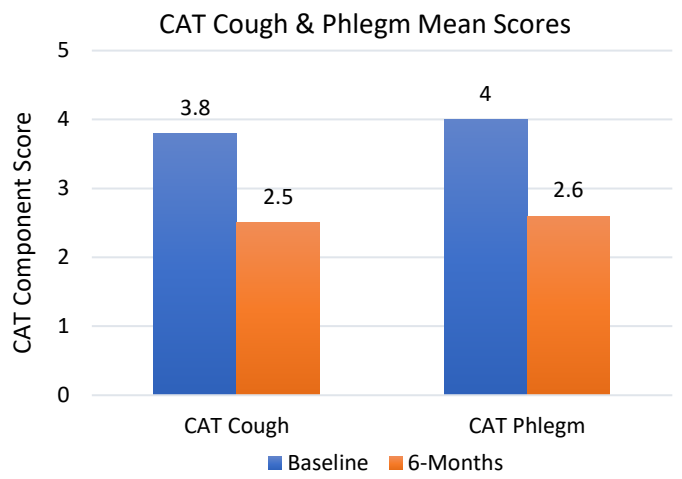
Event Type	Procedure Recovery* (N=50)	Through 6 Months (N=45)
COPD exacerbation	2	2
Lower airway obstruction	0	1
Mediastinal neoplasm NOS	1	0
Pneumonia NOS	0	1
Pneumonitis	0	1
Pneumothorax	0	2
Respiratory infection	1	0
Sputum increased	0	1
Thoracic pain	2	0

- Adverse event types and frequency similar to diagnostic bronchoscopy
- Relatively few respiratory SAEs among ~100 BR procedures performed
- Two device related SAEs (increased sputum, thoracic pain)

**Defined as the 30 days following either Rheoplasty procedure*

Quality of Life Outcomes: CB Patients





RESULTS

50 patients have been enrolled, 30 patients completed both BR procedures and a 6-month follow-up visit. Of these, 26 were identified as having predominantly CB phenotype [mean (SD) age 67.4 (8.8), post-BD FEV_1 59.9 (25.4), RV 160.7% (38.9), 6MWD 349.5 (123.9), SGRQ 53.0 (18.8)] and 4 were identified as predominantly non-CB phenotype [mean (SD) age 65.7 (6.2), post-BD FEV_1 36.5 (10.6), RV 207.4% (25.7), 6MWD 194.5 (55.9), SGRQ 73.5 (5.8)]. Two device related respiratory SAEs were reported through 6 months: increased sputum and thoracic pain. CB symptoms, as assessed by the mean CAT cough and phlegm scores, improved by greater than 30%. 92% of patients (24 of 26) were symptomatic responders, having symptom improvement that met or exceeded the CAT MCID.

CONCLUSION

This ongoing study provides post-market clinical experience with BR. The safety profile is very favorable, with few respiratory SAEs reported. Preliminary results suggest clinically meaningful symptom improvements through 6 months in CB patients, similar to prior trials. Enrollment and longer-term data collection continues. A sham controlled randomized clinical trial (RheSolve) is also underway

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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.