Evaluation of the Safety and Effectiveness of the Spiration® Valve System for Single Lobe Treatment of Severe Emphysema in Patients with Alpha-1 Antitrypsin Deficiency

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STUDY OBJECTVES

Alpha-1 Antitrypsin Deficiency (AATD), an inherited disorder, raises the risk for lung disease and can often lead to emphysema. Many of these patients have severe gas trapping and limited exercise function due to dyspnea. We report on the 6-month results of the AATD arm of the EMPROVE study, a multicenter, prospective, randomized controlled trial undertaken at 31 centers in the US and Canada to assess the safety and effectiveness of the Spiration® Valve System (SVS) compared to standard medical care in patients with severe emphysema.

METHODS

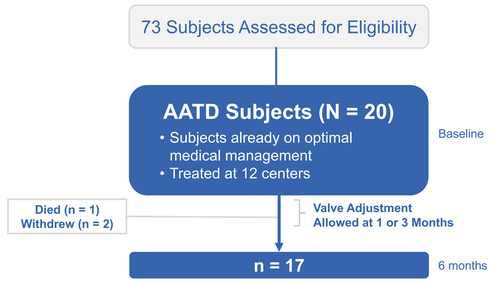
AATD patients were evaluated for enrollment in a separate treatment arm of the EMPROVE trial.

Key inclusion criteria:

- $FEV_1 \leq 45\%$
- TLC ≥ 100%
- RV ≥ 150% predicted

A total of 20 AATD subjects already on optimal medical management were treated with SVS valves at 12 centers.

SUBJECT FLOW



BASELINE CHARACTERISTICS

	AATD (N = 20) Mean ± S.D. or N (%)
Sex (male)	9 (45.0%)
Age (years)	59.4 ± 8.9
FEV_1 (L)	0.867 ± 0.211
FEV_1 (% pred)	29.4 ± 8.9
RV (L)	4.546 ± 1.273
RV/TLC Ratio	0.613 ± 0.109
Dyspnea (mMRC)	2.5 ± 0.7
COPD Assessment Test	20.9 ± 6.6
SGRQ Total	55.2 ± 16.0
Target Lobe Volume (L)	1.830 ± 0.445
Emphysema Severity (%)	62.0 ± 9.4
Emphysema Heterogeneity (% points)	24.7 ± 12.3

HRCT ASSESSMENT

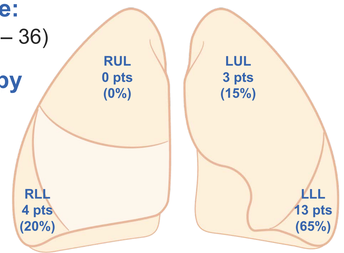
The most diseased lobe for treatment was selected based on HRCT assessment. The treated lobe had ≥ 40% emphysema involvement and ≥ 10% difference with the ipsilateral lobe (the right middle lobe was not considered in this analysis). The selected lobe had an intact fissure separation ≥ 90% with the ipsilateral lobe. HRCT analysis was performed by MedQIA (Core Lab) using Apollo software (VIDA Diagnostics).

PROCEDURE DATA

Average procedure time:
20.3 ± 8.6 Minutes (range 8 – 36)

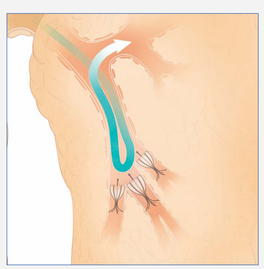
Follow-up bronchoscopy for valve adjustment:
3 of 20 Subjects (15%)

Lobes treated:
Upper lobes: 3 (15%)
Lower lobes: 17 (85%)



SPIRATION VALVE SYSTEM MECHANISM OF ACTION

Pretreatment with hyper-inflated left lower lobe (LLL)



Valves occluding airways

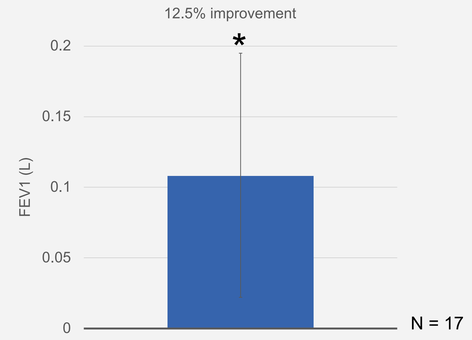
Posttreatment showing left lower lobe (LLL) atelectasis

Images provided by VIDA Diagnostics

RESULTS

IMPROVED LUNG FUNCTION

CHANGE IN FEV_1 @ 6 MONTHS



CHANGE IN TARGET LOBE VOLUME

@ 6 MONTHS

64% REDUCTION

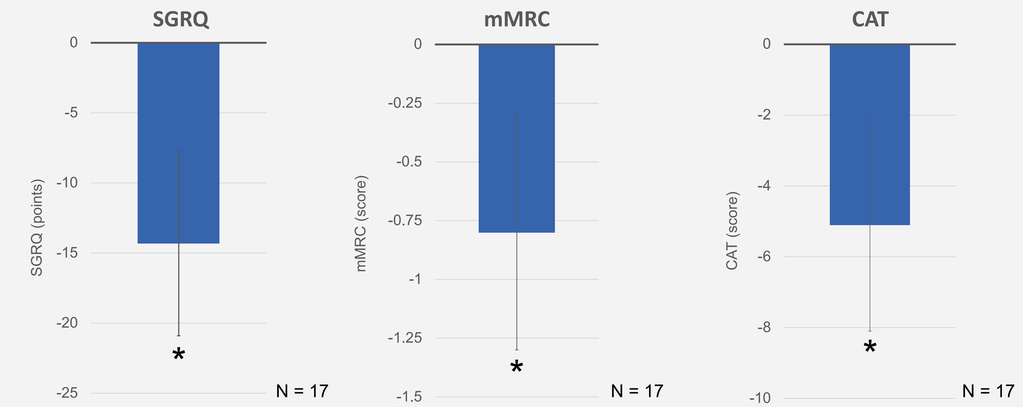
Difference: -1.157 L
95% BCI: (-1.604, -0.710)

Mean ± 95% Bayesian Credible Interval (BCI); *95% BCI > 0 = Statistically Significant

Images provided by VIDA Diagnostics

IMPROVEMENTS IN HEALTH STATUS, DYSPNEA AND COPD ASSESSMENT

CHANGE @ 6 MONTHS



Mean ± 95% BCI; *95% BCI < 0 = Statistically Significant

SAFETY

Through 6 months, there was one death.

Six (30%) of the AATD group (including the patient who died) had procedure/device-related serious adverse events, consisting of:

- acute COPD exacerbations (10%)
- pneumonia (5%)
- pneumothorax (15%)

CONCLUSIONS

Spiration Valve System placement resulted in statistical improvements in FEV_1, target lobe volume reduction, health status, dyspnea and COPD parameters in this underserved Alpha-1 Antitrypsin Deficient patient population.

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