



# Βρογχοσκοπικές Θεραπείες ΧΑΠ και άσθματος;;



## BLVR/BT/TLD: *Επιλογή ασθενών και μέθοδοι*

Γρ. Στρατάκος MD, FCCP

Επ. Καθηγητής Πνευμονολογίας

Μονάδα Επεμβατικής Πνευμονολογίας,

1<sup>η</sup> Πνευμονολογική Κλινική ΕΚΠΑ, ΝΝΘΑ «Σωτηρία»

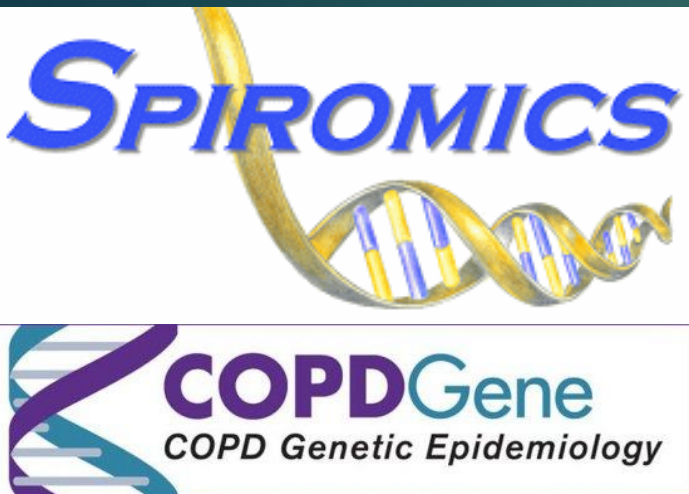
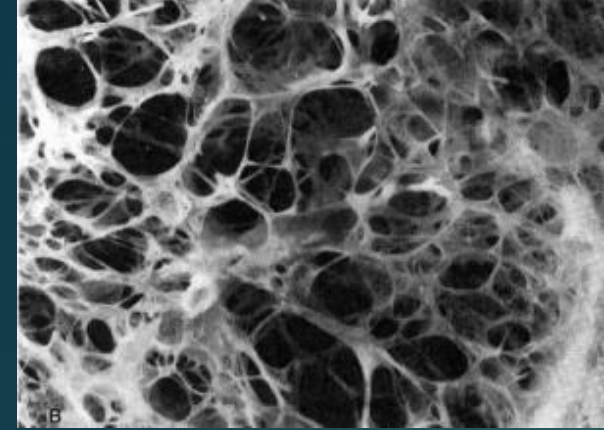




# (Βαρύ) Πνευμονικό Εμφύσημα

# Ένας ορισμός για το εμφύσημα...

- ▶ Όλοι οι ασθενείς είχαν YT όπου υπολογίστηκε το ποσοστό των voxels με τιμές λιγότερο από **-950 Hounsfield units**.
- ▶ Η ομάδα αυτή συγκρίθηκε με σημαντικά κλινικά χαρακτηριστικά (outcomes)
- ▶ Οι ασθενείς με **>5% εμφυσηματικό πνεύμονα (<-950 Hounsfield units)**, είχαν περισσότερες παροξύνσεις, χειρότερο St George's RQ και μεγαλύτερη θνητότητα.
- ▶ Η συσχέτιση αυτή ίσχυε μόνο για τους ασθενείς με αποφρακτικό σύνδρομο ( **$FEV_1/FVC < 70\%$**  με GOLD criteria).



Association between Emphysema and Chronic Obstructive Pulmonary Disease Outcomes in the COPD Gene and SPIROMICS Cohorts: A Post Hoc Analysis of Two Clinical Trials.

*Am J Res Crit Care Med*, 2018;198: 265–267

**FEV1/FVC < 70, > 5% (-950HU)**

που δεν έχουν «ειδικού» τύπου νόσο:

- ▶ A<sub>1</sub>AT deficiency
- ▶ Bullous Disease
- ▶ Paraseptal Emphysema
- ▶ CPFE

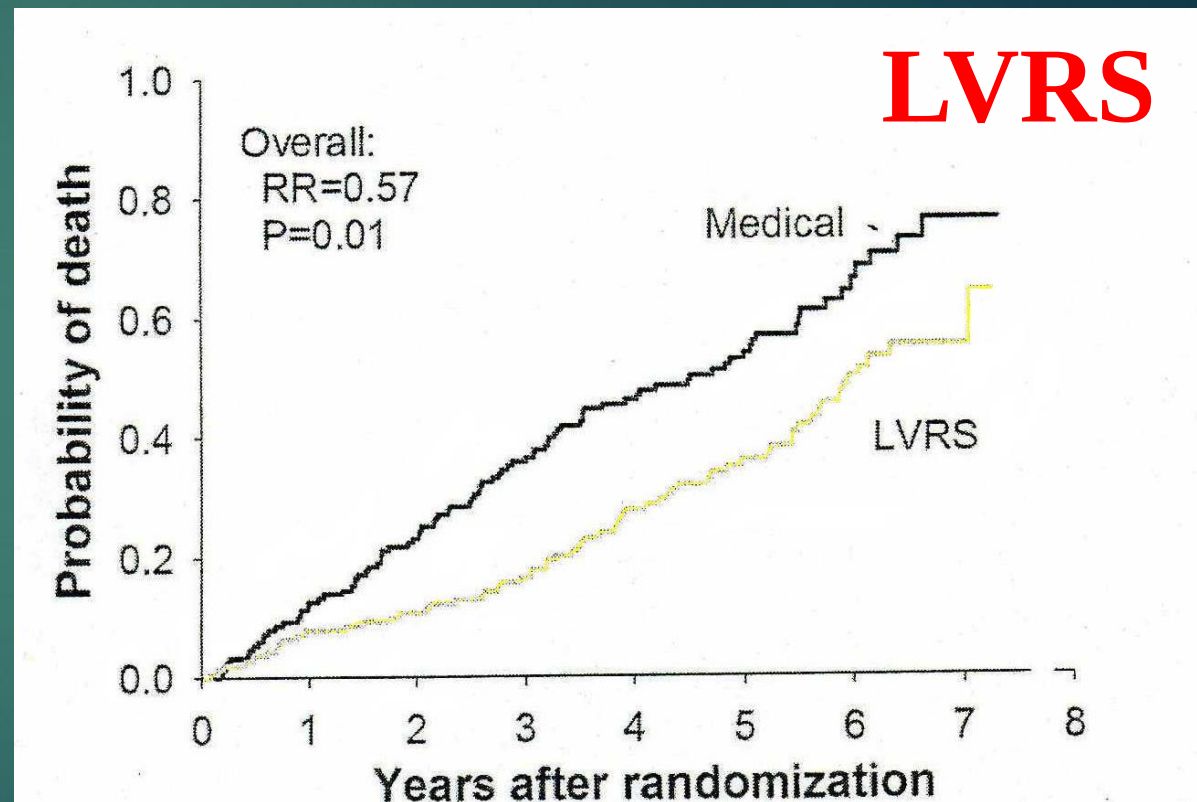




Κεντρολοβιώδες με εντόπιση στους άνω λοβούς  
DLCO > 20% και μειωμένη αντοχή στην άσκηση :

Low exercise capacity :post rehab baseline max work of  $\leq 25$  watts for women and  $\leq 40$  watts for men.

**National  
Emphysema  
Treatment  
Trial  
1218 pts**

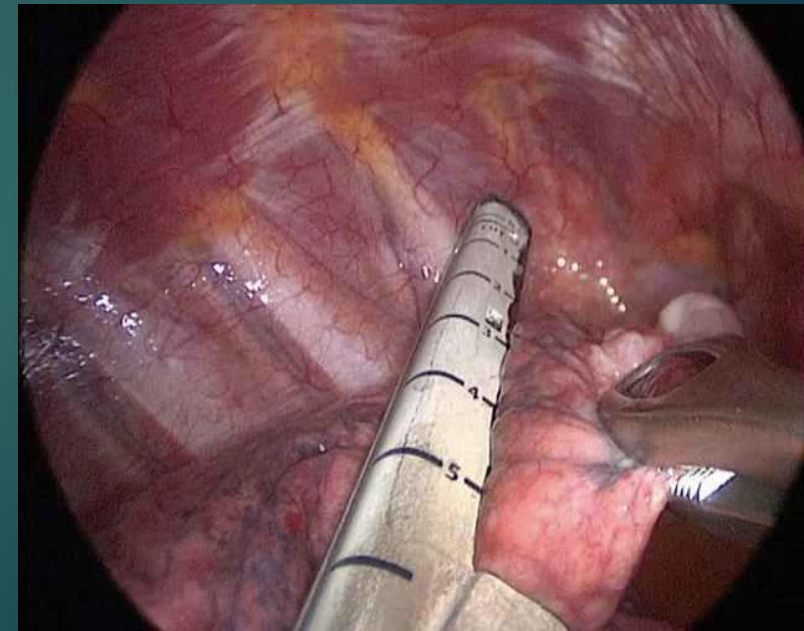


**Ann Thorac Surg 2006;82:431-3**

# Lung Volume Reduction Surgery Since the National Emphysema Treatment Trial: Study of Society of Thoracic Surgeons Database

*J Thorac Cardiovasc Surg.* 2014 December ; 148(6): 2651–2658.

- Μεταξύ 2003 και 2011 (8.5 χρόνια) μόνο 538 ασθενείς <65 ετών χειρουργήθηκαν στις ΗΠΑ (20-118/έτος)  
*Υπολογισμός ασθενών  $4.7 \times 10^6$*
- FEV<sub>1</sub> 31% pred κατά MO (έναντι 28% της NETT)
- Περισσότεροι ασθενείς έγιναν θωρακοσκοπικά
- Η θνητότητα σε ασθενείς όχι υψηλού κινδύνου ήταν παρ'όλα αυτά 3% μεγαλύτερη της NETT (p<0.005)

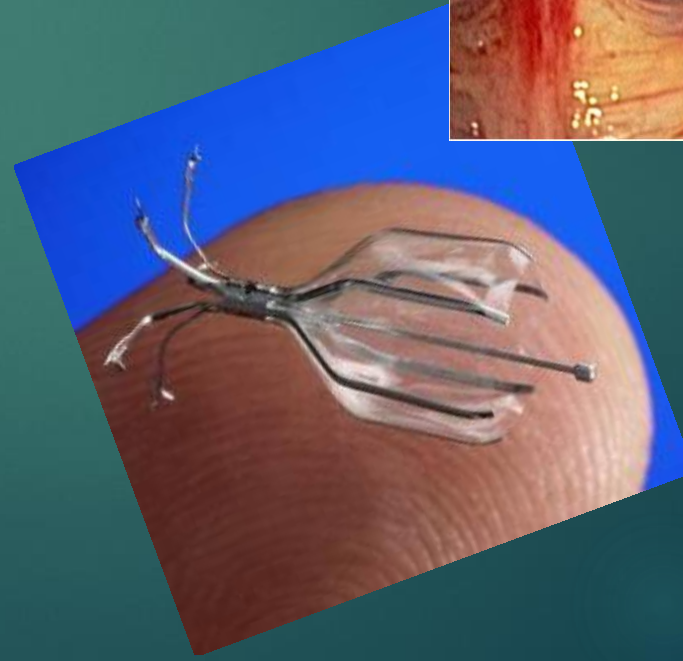
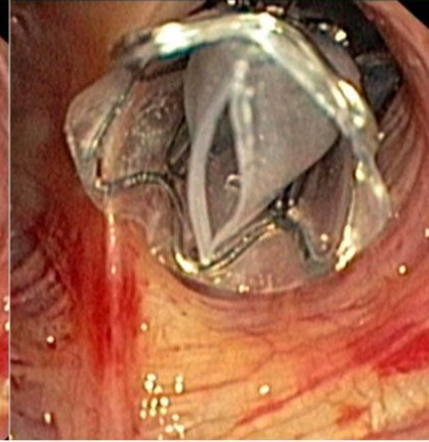
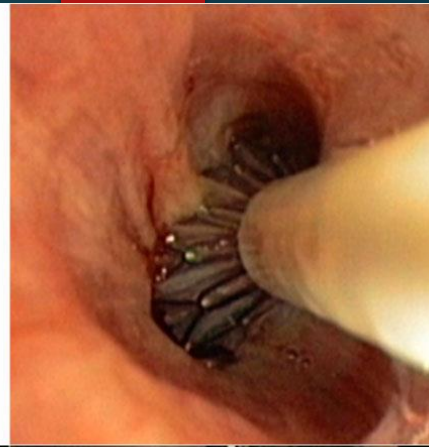
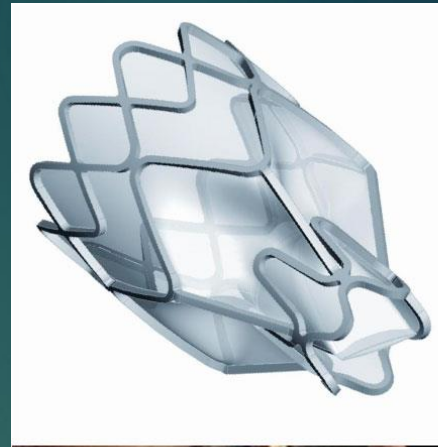


- 33 pts 2009-2014. DLCo <20% The 90-day mortality was 0%.
- FEV1 % at 3 months increased from 23% to 29% ( $p < 0.001$ ).
- Dlco increased from 15% to 24% ( $p < 0.001$ ), and median hyperinflation decreased from 76% to 63% ( $p < 0.001$ ).
- A prolonged air leak exceeding 7 days occurred in 48.5%, and 6 required reoperation for fistula closure
- Selected patients with severely impaired DLCo of less than 20% can cautiously be considered as potential candidates if hyperinflation is severe and the lungs show areas with advanced destruction as targets for resection.

# Endoscopic LVR

## Α. Τροποποίηση αεραγωγών και ροής Endobronchial valves

- **Emphasis-Zephyr (Pulmonx):** One-way Valve
- **Spiration:** Umbrella



# Pulmonx valves



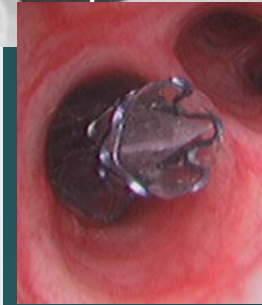
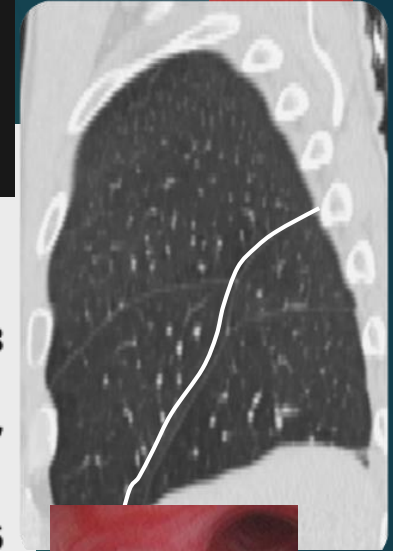
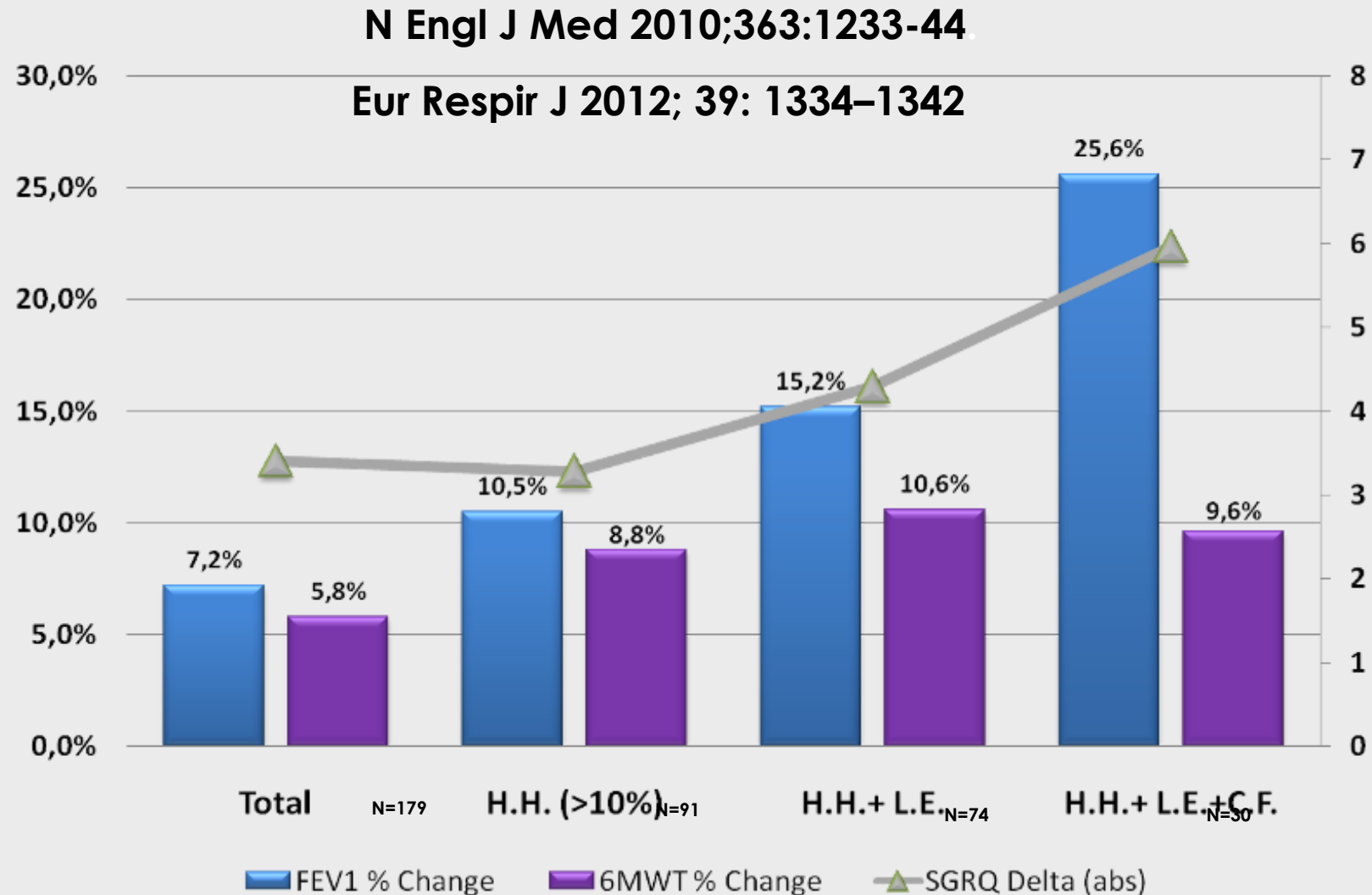
|                                    | Primary Safety Endpoint<br>6 months |              |         | Additional Safety Analysis<br>12 months (cumulative) |              |         |
|------------------------------------|-------------------------------------|--------------|---------|------------------------------------------------------|--------------|---------|
|                                    | Control<br>n=101                    | EBV<br>n=220 | p value | Control<br>n=101                                     | EBV<br>n=220 | p value |
| Major Complication Composite (MCC) | 1.1%                                | 6.1%         | 0.0748  | 4.6%                                                 | 10.4%        | 0.1724  |
| Death                              | 0.0%                                | 2.8%         | 0.1867  | 3.5%                                                 | 3.7%         | 1.0000  |
| Empyema                            | 0.0%                                | 0.0%         | ----    | 0.0%                                                 | 0.0%         | ----    |
| Massive Hemoptysis                 | 0.0%                                | 0.5%         | 1.0000  | 0.0%                                                 | 0.5%         | 1.0000  |
| Distal Pneumonia                   | NA                                  | 1.4%         | ----    | NA                                                   | 4.2%         | ----    |
| Pneumothorax/<br>air leak > 7 days | 1.1%                                | 1.4%         | 1.0000  | 1.2%                                                 | 1.9%         | 1.0000  |

nal medical treatment



# VENT Responder Summary

(Delta Treatment & Control @ 6mons)



H.H. – High Heterogeneity, L.E. – Lobar Exclusion Achieved, C.F. – Low Collateral Flow

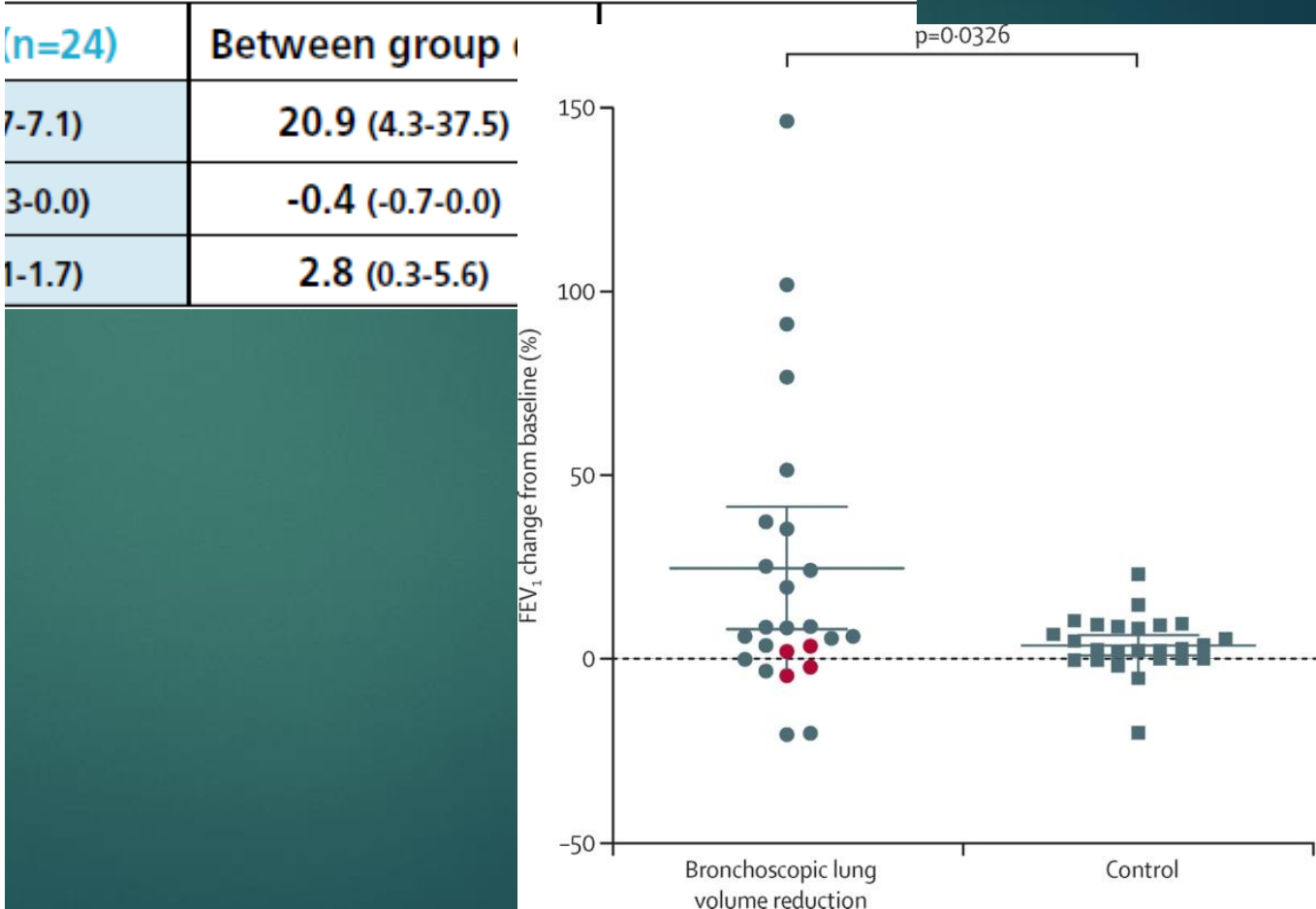
Lancet 2015; 386: 1066–73

Bronchoscopic lung volume reduction with endobronchial valves for patients with heterogeneous emphysema and intact interlobar fissures (the BeLieVeR-HiFi study): a randomised controlled trial

|                                  | BLVR       |                                   | Control<br>(n=24) | p value* |
|----------------------------------|------------|-----------------------------------|-------------------|----------|
|                                  | All (n=23) | CV-positive<br>excluded<br>(n=19) |                   |          |
| FEV <sub>1</sub>                 | 9 (39%)    | --                                | 1 (4%)            | 0.0044   |
| >15% Improvement                 | --         | 9 (47%)                           | 1 (4%)            | 0.0022   |
| RV                               | 11 (48%)   | --                                | 7 (29%)           | 0.24     |
| 0.35 L reduction <sup>28</sup>   | --         | 11 (58%)                          | 7 (29%)           | 0.07     |
| 6MWD                             | 12 (52%)   | --                                | 4 (17%)           | 0.012    |
| 26 m Improvement <sup>28</sup>   | --         | 12 (63%)                          | 4 (17%)           | 0.004    |
| Endurance cycle time             | 10 (43%)   | --                                | 2 (8%)            | 0.008    |
| 105 s Improvement <sup>28</sup>  | --         | 9 (47%)                           | 2 (8%)            | 0.005    |
| SGRQc                            | 11 (48%)   | --                                | 11 (46%)          | 1.0      |
| 4 points reduction <sup>28</sup> | --         | 11 (58%)                          | 11 (46%)          | 0.5      |
| CAT                              | 13 (57%)   | --                                | 7 (29%)           | 0.080    |
| 2 points reduction <sup>28</sup> | --         | 13 (68%)                          | 7 (29%)           | 0.015    |

Data are n (%). CV-positive=collateral ventilation using Chartis system. BLVR=bronchoscopic lung volume reduction. FEV<sub>1</sub>=forced expiratory volume in 1 s. RV=residual volume. 6MWD=6 min walking distance. SGRQc=St George's respiratory questionnaire for chronic obstructive pulmonary disease (COPD). CAT=COPD assessment test score. \* Fisher's exact test (this analysis does not include imputed values).

Table 5: Responder rates according to lung function, health status, and exercise criteria



**Table 3. Serious Adverse Events during 6 Months of Follow-up.\***

| Event                                                                                                           | EBV Group<br>(N = 34) | Control Group<br>(N = 34) | P Value† |
|-----------------------------------------------------------------------------------------------------------------|-----------------------|---------------------------|----------|
|                                                                                                                 | no. (%)               |                           |          |
| Total no. of serious events                                                                                     | 23                    | 5                         | <0.001   |
| Pulmonary events                                                                                                |                       |                           |          |
| Death                                                                                                           | 1 (3)‡                | 0                         | 1.00     |
| COPD exacerbation with hospitalization                                                                          | 4 (12)                | 2 (6)                     | 0.67     |
| Pneumonia                                                                                                       | 2 (6)                 | 1 (3)                     | 1.00     |
| Pneumothorax                                                                                                    | 6 (18)                | 0                         | 0.02     |
| Resolved ≤14 days after onset, without drainage                                                                 | 1 (3)                 | 0                         | 1.00     |
| Resolved ≤14 days after onset, with drainage                                                                    | 2 (6)                 | 0                         | 0.49     |
| Required temporary valve removal                                                                                | 1 (3)§                | NA                        | NA       |
| Required permanent valve removal because of recurrent pneumothorax                                              | 1 (3)                 | NA                        | NA       |
| Required permanent valve removal, after temporary removal and reimplantation, because of recurrent pneumothorax | 1 (3)                 | NA                        | NA       |
| Other EBV-related events requiring permanent removal of all valves                                              |                       |                           |          |
| Torsion of the bronchus                                                                                         | 2 (6)¶                | NA                        | NA       |
| Pneumonia distal to valve                                                                                       | 1 (3)                 | NA                        | NA       |
| Increased sputum, dyspnea, or coughing without patient-perceived treatment benefit                              | 2 (6)                 | NA                        | NA       |
| Other EBV-related events requiring valve replacement                                                            |                       |                           |          |
| Valve migration                                                                                                 | 2 (6)                 | NA                        | NA       |
| Valve expectoration                                                                                             | 0                     | NA                        | NA       |
| Valve dislocation due to formation of granulation tissue                                                        | 1 (3)                 | NA                        | NA       |
| Increased sputum, dyspnea, or coughing                                                                          | 1 (3)                 | NA                        | NA       |
| Stroke                                                                                                          | 1 (3)                 | 2 (6)                     | 1.00     |

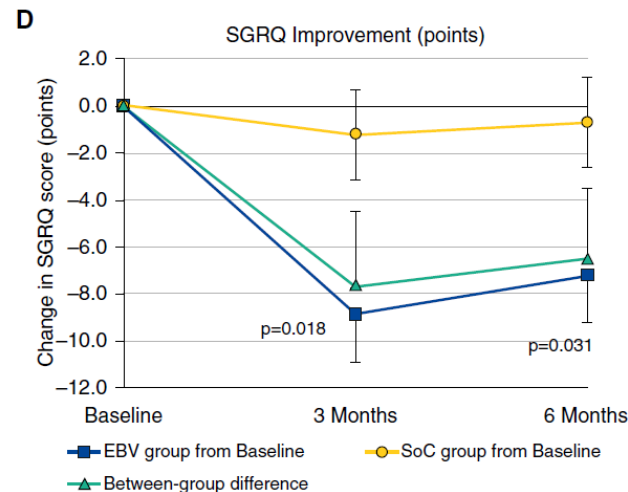
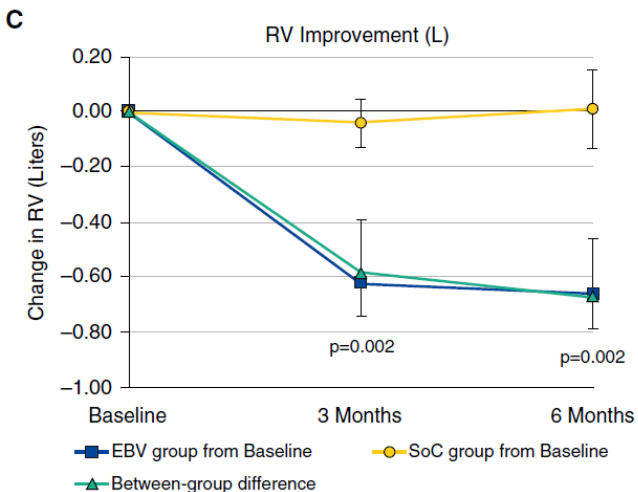
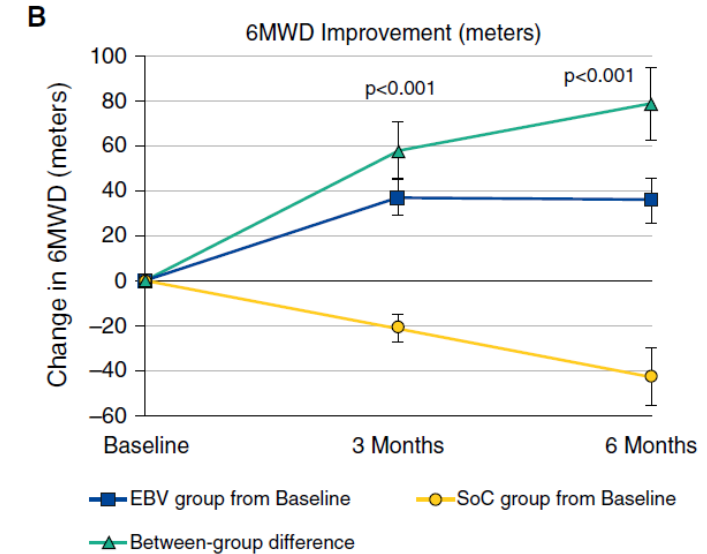
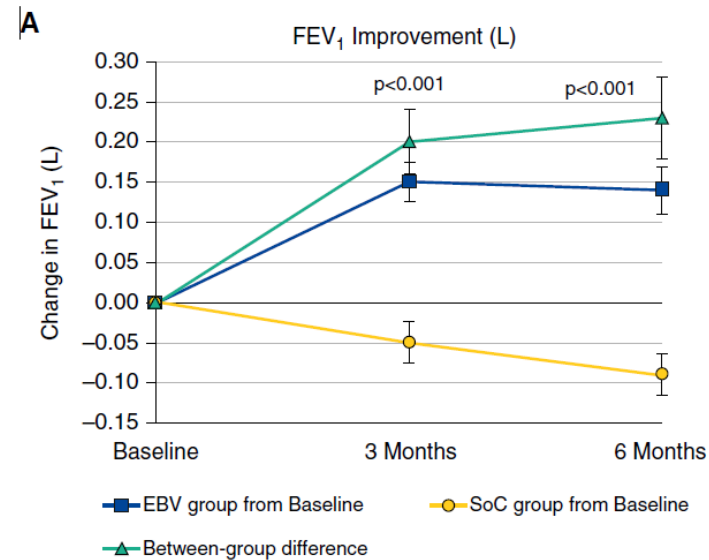


**N Engl J Med 2015;373:2325-35**

# A Multicenter Randomized Controlled Trial of Zephyr Endobronchial Valve Treatment in Heterogeneous Emphysema (TRANSFORM)

Am J Respir Crit Care Med 2017;196:1535–1543

97 pts (65 vs32)  
55.4% of EBV and 6.5% of  
SoC subjects had an FEV<sub>1</sub>  
improvement of  $\geq 12\%$ .

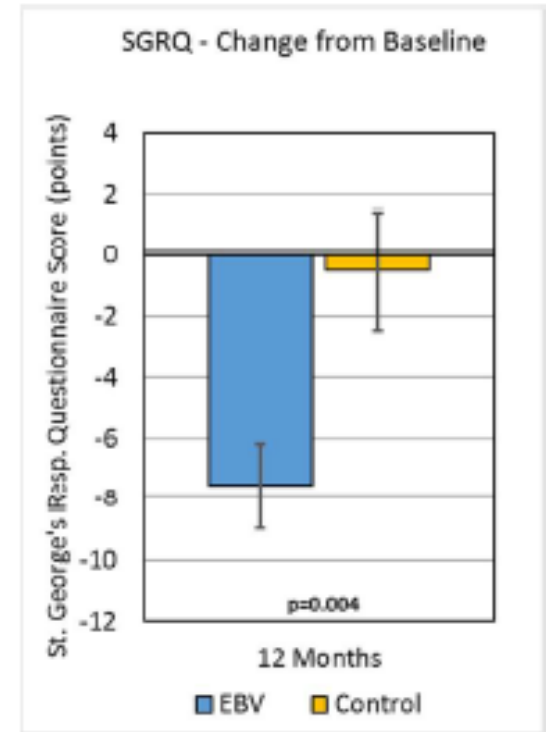
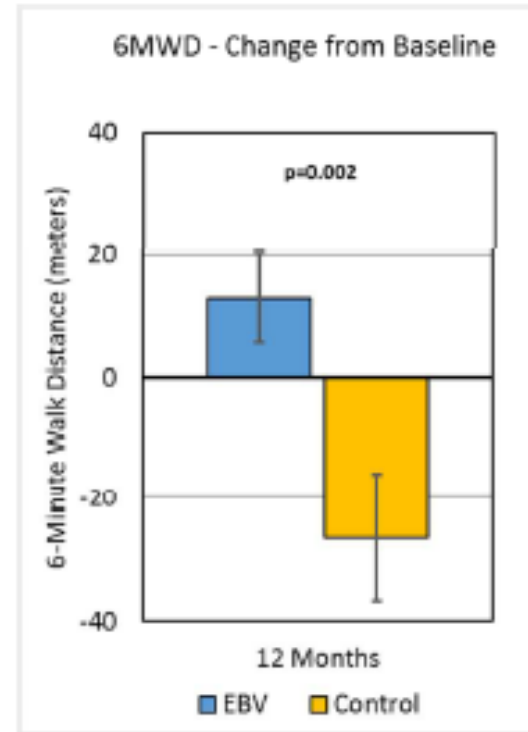
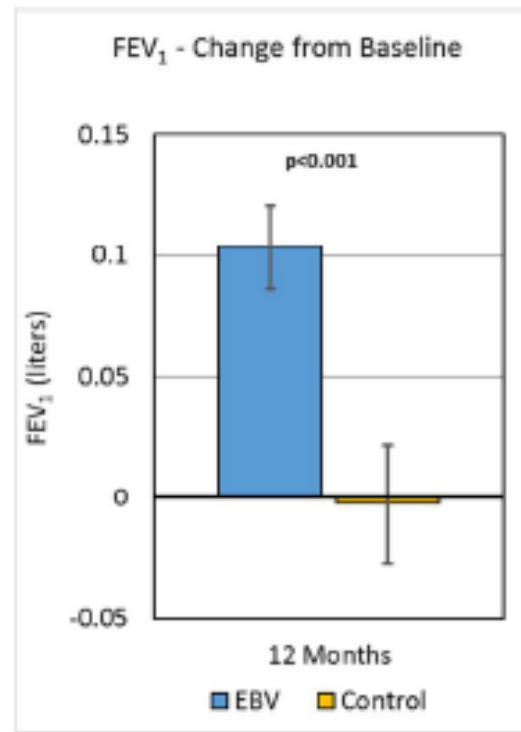
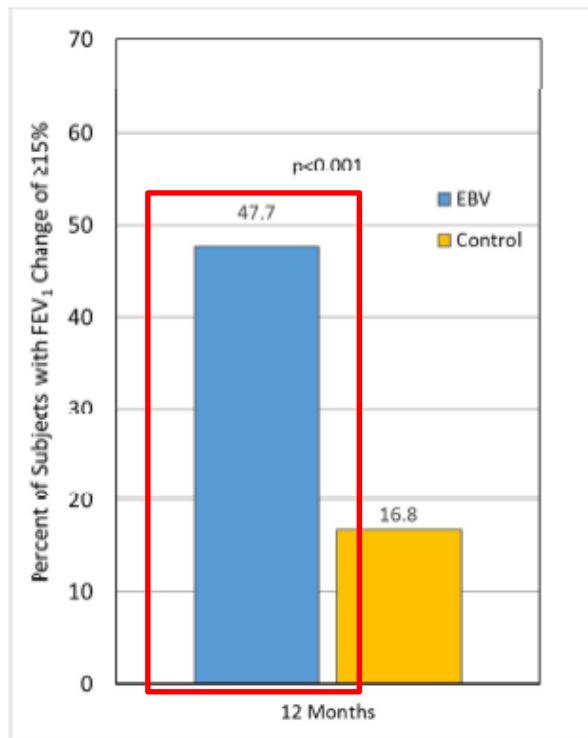


# LIBERATE STUDY:

Multicenter RCT to evaluate effectiveness and safety of Zephyr® Endobronchial Valve EBV® out to 12-months.

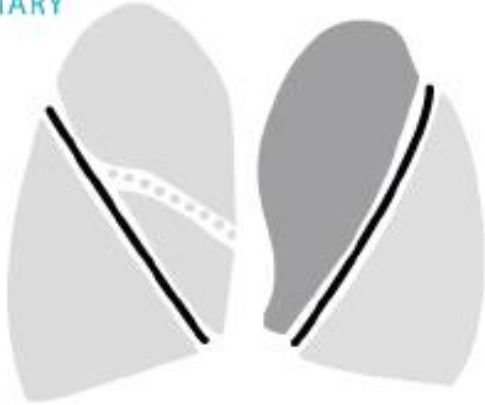
Heterogeneous emphysema with little to no collateral ventilation (CV) in the treated lobe. **190 subjects, 128 EBV and 62 controls.**

Pneumothorax was the most common serious adverse in 34/128 (26.6%) of EBV subjects. Four deaths occurred in the EBV group during this phase, and one each in the EBV and SoC groups between 46 days and 12-months.



Patient ID: NIK01.01.1951      Upload Date: April 12, 2018  
 Scan ID: 68.188      Report Date: April 13, 2018  
 CT Scan Date: Nov. 21, 2017      Scan Comments: None

## SUMMARY



## KEY

- ≥70% Voxel Density Less Than -910 HU
- 60-70% Voxel Density Less Than -910 HU
- 50-60% Voxel Density Less Than -910 HU
- <50% Voxel Density Less Than -910 HU
- ≥95% Fissure Completeness
- 80-95% Fissure Completeness
- .... <80% Fissure Completeness

## RESULTS

## RIGHT LUNG

## LEFT LUNG

|                                   | RUL  | RUL+RML | RML  | RLL  | LUL  | LLL  |
|-----------------------------------|------|---------|------|------|------|------|
| % Fissure Completeness            | 73.9 | 98.6    | 78.3 | 98.6 | 97.7 | 97.7 |
| % Voxel Density Less Than -910 HU | 52   | 53      | 56   | 51   | 60   | 53   |
| % Voxel Density Less Than -950 HU | 22   | 22      | 22   | 27   | 27   | 26   |
| Inspiratory Volume (ml)           | 1747 | 2300    | 553  | 1718 | 2077 | 1505 |

# STRAT-X

## assessment system

FEV1<50%, TLC> 100%,  
 RV>150%, RV/TLC >0.58,  
 DLCO > 20%, 6MWT 150-400m  
 &MRC ≥3

With complete Fissures and no  
 collateral ventilation

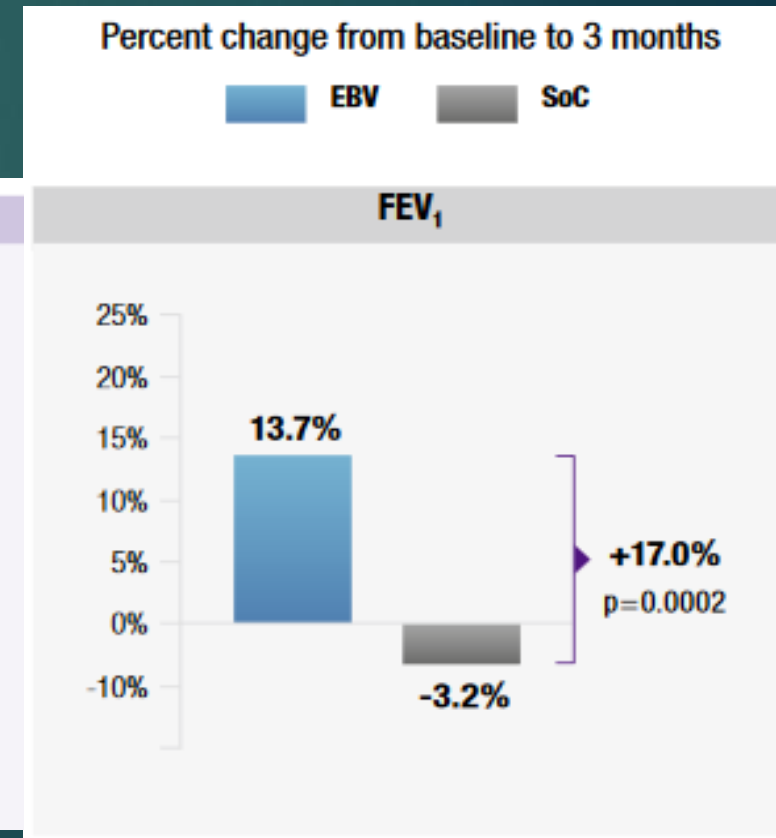
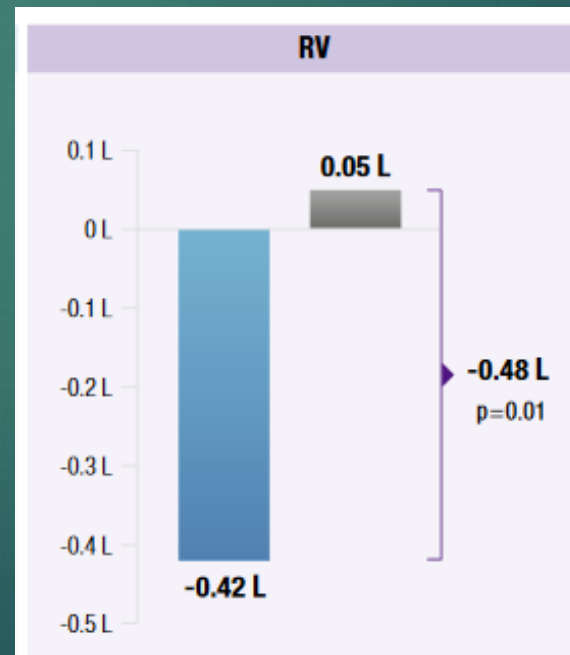
Optimal pharmacological and non pharmacological  
 treatment

# ΟΜΟΙΟΓΕΝΕΣ ΕΜΦΥΣΗΜΑ: IMPACT - RCT

93 ασθενείς με σοβαρό, ομοιογενές εμφύσημα και απουσία παράπλευρου αερισμού στον λοβό-στόχο.

These data indicate that EBV therapy can benefit substantially more patients than previously believed.

EBV-treated pts experienced improved exercise tolerance, with a 40-meter increase over the control group in the 6MWD, and improved QuoL, with a 10-point improvement in the SGRQ score over the control group.



Valipour A, et al. Am J Respir Crit Care Med. 2016.

# Endoscopic LVR

## Inferior Results

### **Spiration** Intrabronchial Valves (IBV)



Multicentre European study for the treatment of advanced emphysema with bronchial valves

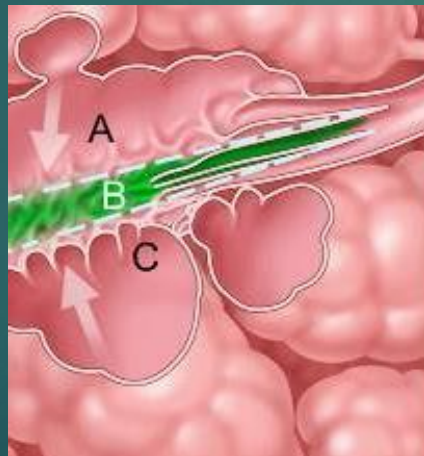
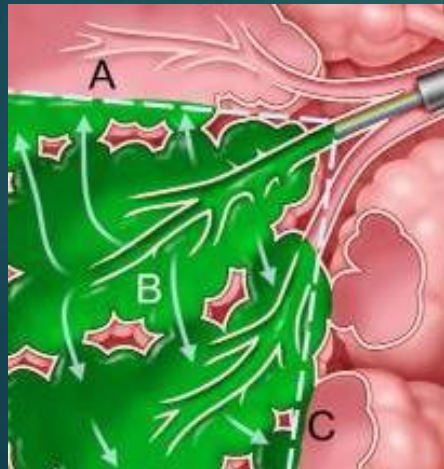
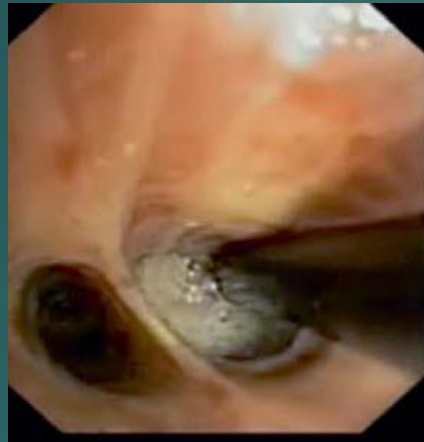
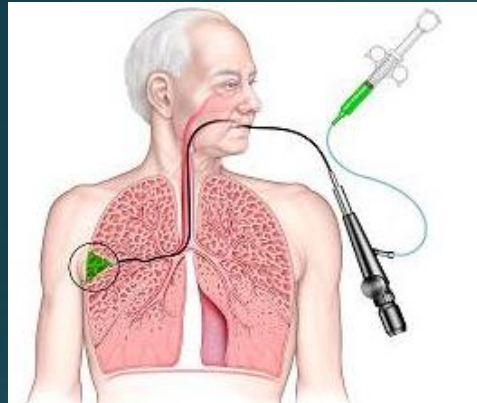


Eur Respir J 2012; 39: 1319–1325

Treatment with bronchial valves without complete lobar occlusion in both upper lobes was safe, but not effective in the majority of patients

# Β. Τροποποίηση πνευμονικού παρεγχύματος :

## 1. Polymer sealant LVR



**Chest 2007;131:1108–1113.**

Criner G et al. BLVR in Advanced Upper lobe Emphysema: Phase 2 Results.

Am J Respir Crit Care Med 2009; 179:791-798

Bilateral upper lobes treatment (8 subsegments).

Increase of FEV<sub>1</sub> by 15% FVC 9% TLC 6% and SGRQ in 12 weeks. NO significant complications.

Rafaely Y et al. BLVR in Advanced Homogeneous emphysema. Eur Respir J 2010;36:20-27

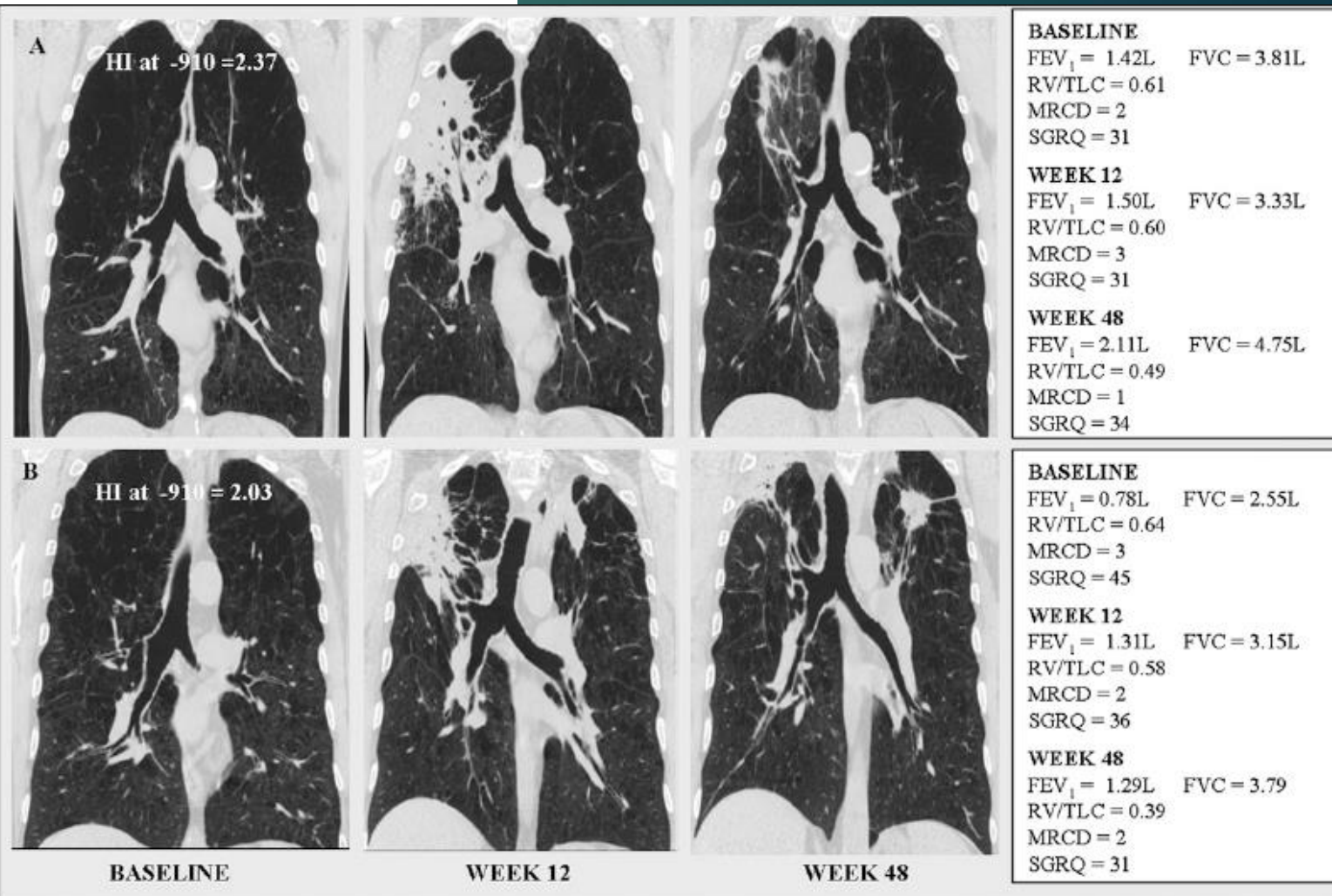
17 pts, (Upper lobes or apical of the lower lobes) 29-47% increase >12% in FEV<sub>1</sub> and FVC 65-75% improvement of SGRQ No deaths. 20% AE COPD



# Bilateral Endoscopic Sealant Lung Volume Reduction Therapy for Advanced Emphysema

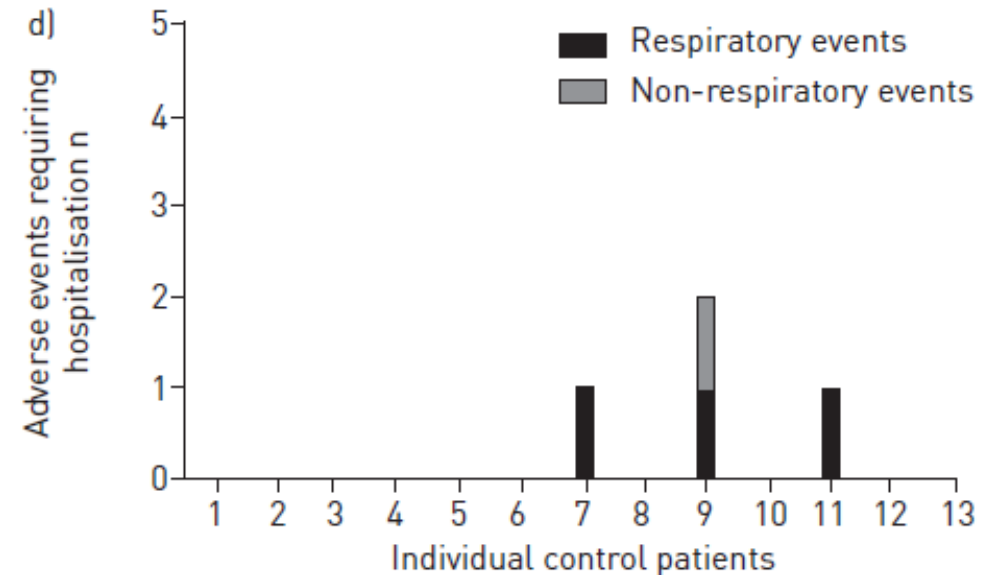
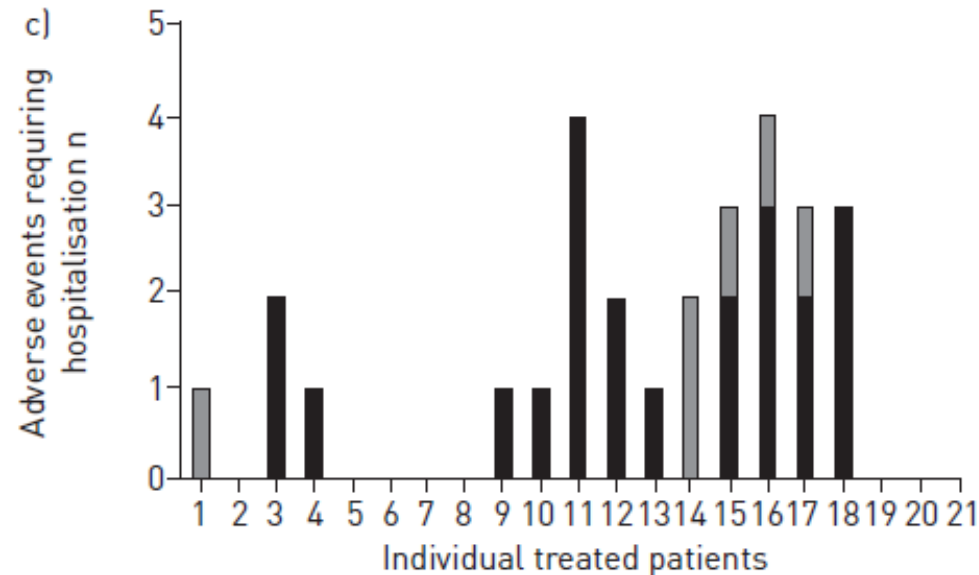
Mordechai R. Kramer, MD, FCCP; Yael Refaely, MD; Nimrod Maimon, MD; Dror Rosengarten, MD; and Oren Fruchter, MD

**CHEST 2012;  
142(5):1111–1117**





## A randomised trial of lung sealant *versus* medical therapy for advanced emphysema

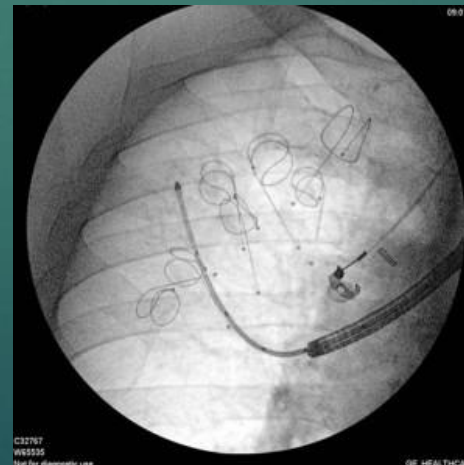
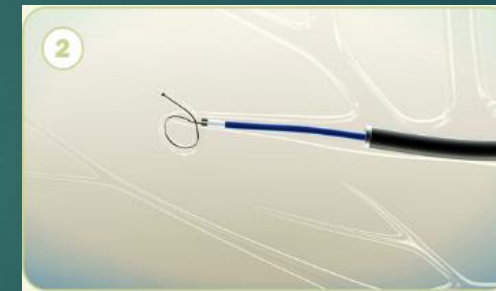
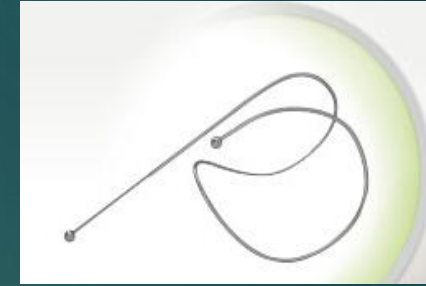


|                               | Δ from baseline | 6m Treatment G        | 6m Control G | p    |
|-------------------------------|-----------------|-----------------------|--------------|------|
| Subjects n                    |                 |                       |              |      |
| FEV <sub>1</sub> <sup>#</sup> |                 |                       |              |      |
| SGRQ <sup>¶</sup>             |                 |                       |              |      |
| mMRC <sup>+</sup>             |                 |                       |              |      |
| 6MWD <sup>§</sup>             |                 |                       |              |      |
| FEV <sub>1</sub> (% ; mL)     |                 | 26±42 %;<br>174±317mL | 3±11; 31±145 | 0.03 |
| SGRQ(U)                       |                 | -13±15                | -3±6         | 0.02 |
| MRC(D)(U)                     |                 | -0.6±1.2              | -0.5±0.7     | 0.61 |
| 6MWT(m)                       |                 | 16±52                 | -17±46       | 0.08 |

Data are p  
George's R  
6-min walki  
FEV<sub>1</sub> from l  
[25]; §: MCI

# Modifying the pulmonary parenchyma: Endobronchial coils made from nitinol– Pneum RX<sup>®</sup>

- Introduction under fluoroscopy.
- Not affected by collateral ventilation.
- 10 coils per lobe for volume reduction.
- Not in extreme destruction of the parenchyma-improve elastic properties of the lung.
- **Once introduced difficult if not impossible to remove.**



## RESET trial: randomized, 22 pts vs 23 controls

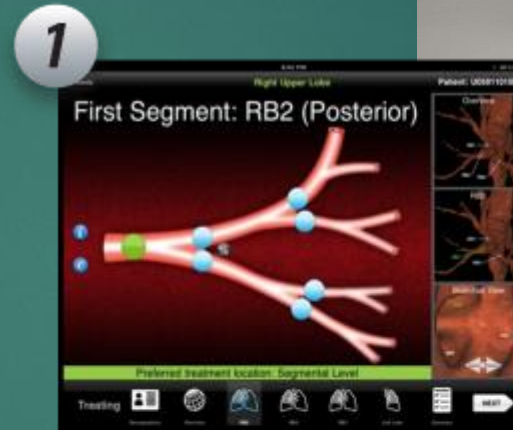
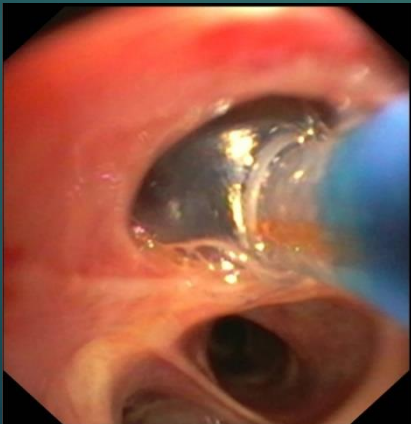
|                   | Treatment              | Usual care               | Between group difference in change from baseline | P value |
|-------------------|------------------------|--------------------------|--------------------------------------------------|---------|
| Primary outcome   |                        |                          |                                                  |         |
| SGRQ              | -8.11(-13.83 to -2.39) | 0.25 (-5.58 to 6.07)     | -8.36 (-16.24 to -0.47)                          | 0.04    |
| Secondary outcome |                        |                          |                                                  |         |
| TLC (L)           | -0.24 (-0.38 to -0.10) | -0.13 (-0.27 to 0.01)    | -0.11 (-0.29 to 0.07)                            | 0.22    |
| RV (L)            | -0.51 (-0.73 to -0.30) | -0.20 (-0.42 to 0.02)    | -0.31 (-0.59 to -0.04)                           | 0.03    |
| 6 MWT             | 51.15 (27.65 to 74.66) | -12.39 (-36.61 to 11.83) | 63.55 (32.57 to 94.53)                           | <0.001  |
| %change in FEV1   | 14.19 (6.84 to 21.55)  | 3.57 (-4.02 to 11.17)    | 10.62 (1.12 to 20.12)                            | 0.03    |
| mMRC              | -0.24 (-0.57 to 0.09)  | -0.09 (-0.44 to 0.26)    | -0.15 (-0.60 to 0.30)                            | 0.5     |

No between-group difference in serious adverse events

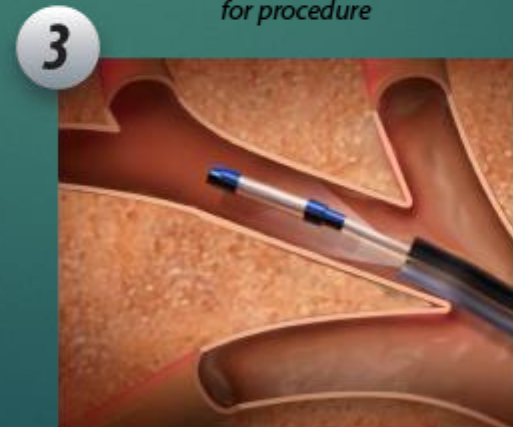
*Lancet Respir.Med.* 2013; 1: 233–40.

# Modifying the pulmonary parenchyma: Bronchoscopic Thermal Vapor Ablation InterVapor® System

- Steam administration (5-10 cal/gr) with endobronchial catheter with balloon at segments of targeted lobe.
- Thermal damage that causes scarring and atelectasis.
- Not affected by collateral ventilation.



IP3 identifies airway targets for procedure



InterVapor catheter is placed into position



Occlusion balloon is inflated and heated water vapor is delivered



Bronchoscope is inserted into target segment airway

### Vapor Ablation in the Presence of Incomplete Fissures: 12-Month Results from the STEP-UP Randomized Controlled Study

ULP- E, 45 patients, 24 control, one lobe treated per session.

|                       | Bronchoscopic vapour ablation group | Control group        | Difference between groups (95% CI) | p value |
|-----------------------|-------------------------------------|----------------------|------------------------------------|---------|
| FEV <sub>1</sub> (mL) | 70.5<br>(SD 179.9)                  | -32.2<br>(SD 114.3)  | 102.6<br>(30.5 to 174.8)           | 0.0060  |
| FVC (mL)              | 110.2<br>(SD 395.4)                 | -128.3<br>(SD 409.2) | 238.5<br>(28.6 to 448.3)           | 0.0269  |
| Residual volume (mL)  | -159.1<br>(SD 572.4)                | 78.3<br>(SD 470.0)   | -237.4<br>(-499.2 to 24.5)         | 0.0747  |
| FRC (mL)              | -163.6<br>(SD 564.5)                | 82.6<br>(SD 417.4)   | -246.2<br>(-490.0 to -2.5)         | 0.0477  |
| 6MWT (m)              | 8.8<br>(SD 66.5)                    | 5.1<br>(SD 73.4)     | 3.6<br>(-33.3 to 40.6)             | 0.8442  |

FEV<sub>1</sub>=forced expiratory volume in 1 s. FVC=forced vital capacity. FRC=functional residual capacity. 6MWT=6 min walk test.

Table: Change in secondary endpoint measures at 12 months after vapour ablation

47 patients: 23 to treatment and 24 to usual care . SGRQ response at 90 days after treatment was greater in the treatment group than it was in the usual care group (between-group difference in change from baseline **-8.36 points** [95% CI -16.24 to -0.47]; p=0.04).

# Lung Volume Reduction with Vapor Ablation in the Presence of Incomplete Fissures: 12-Month Results from the STEP-UP Randomized Controlled Study

*Respiration* 2016;92:397–403

- 78% of treated patients were found to have 1 or more incomplete fissures adjacent to a treated lobe and were considered to be CV+

**Table 1.** Results for primary efficacy endpoints for patients with incomplete fissures

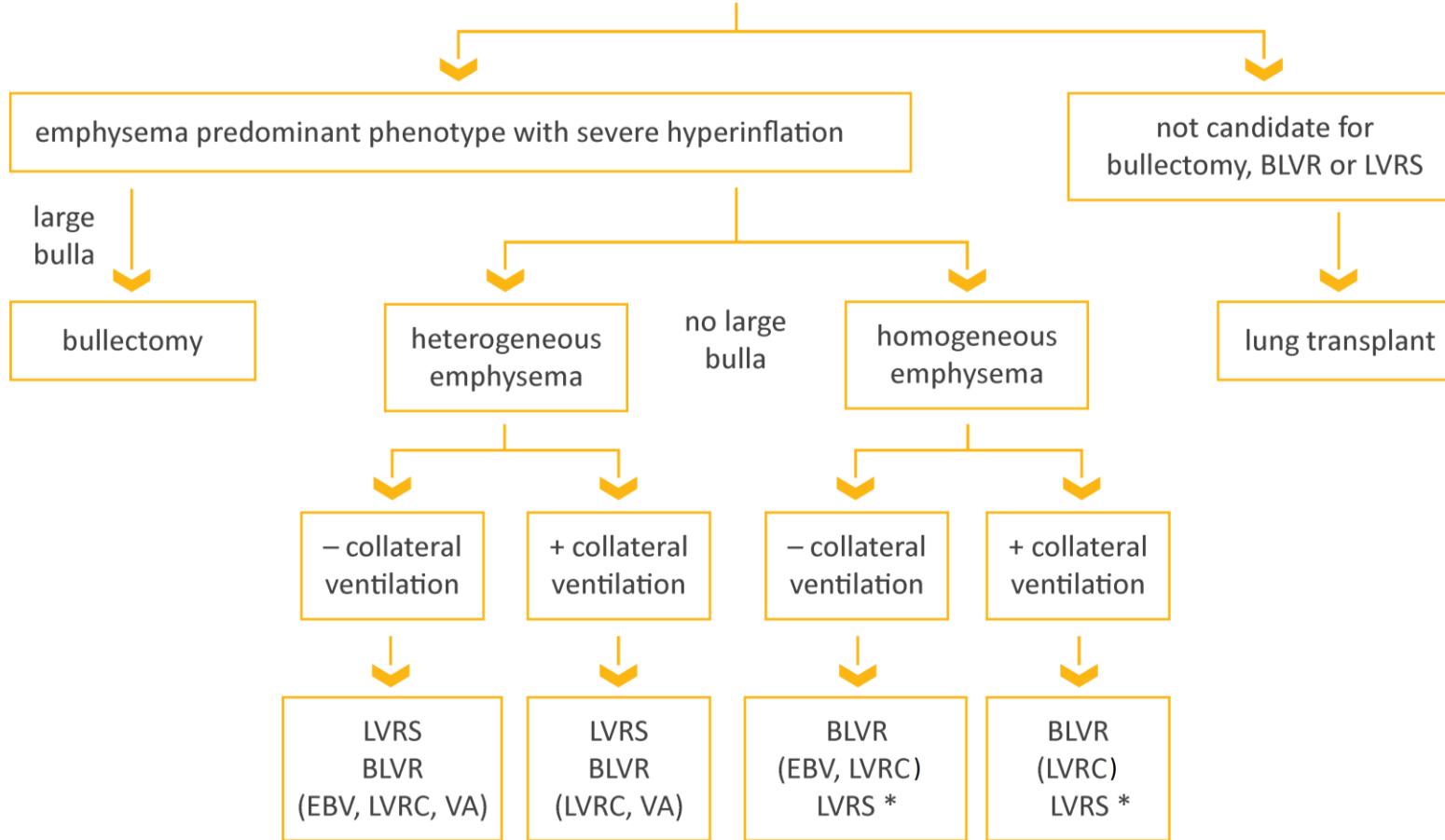
|                                      | Bronchoscopic vapor ablation group | Control group | Difference between groups (95% CI) | p value |
|--------------------------------------|------------------------------------|---------------|------------------------------------|---------|
| Patients with incomplete fissures, n | 35                                 | 19            |                                    |         |
| Δ FEV <sub>1</sub> , %               |                                    |               |                                    |         |
| 3 months                             | 7.9                                | −1.2          | 9.1 (0.1 to 18.1)                  | 0.0056  |
| 6 months                             | 7.6                                | −3.4          | 10.9 (3.6 to 18.4)                 | 0.0024  |
| 12 months                            | 9.2                                | −5.4          | 14.6 (3.1 to 26.7)                 | 0.0137  |
| Δ SGRQ-C (points)                    |                                    |               |                                    |         |
| 3 months                             | −7.7                               | −2.2          | −5.5 (0.5 to −11.5)                | 0.0697  |
| 6 months                             | −6.8                               | −0.6          | −6.1 (1.3 to −13.7)                | 0.1089  |
| 12 months                            | −9.4                               | −1.0          | −8.4 (0.7 to −17.5)                | 0.0712  |

# Vapor Ablation in the Presence of Incomplete Fissures: 12-Month Results from the STEP-UP Randomized Controlled Study. Adverse events

**Table 3.** SAEs and hospital admissions

|                          | Treatment group ( <i>n</i> = 35)        |                                           | Control group ( <i>n</i> = 19) |                                  |
|--------------------------|-----------------------------------------|-------------------------------------------|--------------------------------|----------------------------------|
|                          | 0–180 days after treatment <sup>1</sup> | 181–365 days after treatment <sup>1</sup> | 0–180 days after randomization | 181–365 days after randomization |
| COPD exacerbation        | 3 (9)                                   | 0                                         | 1 (5)                          | 2 (11)                           |
| Pneumonia or pneumonitis | 8 (23)                                  | 0                                         | 1 (5)                          | 1 (5)                            |
| Pneumothorax             | 1 <sup>2</sup> (3)                      | 0                                         | 0                              | 0                                |
| Hemoptysis               | 0                                       | 0                                         | 0                              | 0                                |
| Death                    | 1 (3)                                   | 0                                         | 0                              | 0                                |
| Any respiratory SAE      | 9 (26)                                  | 0                                         | 2 (11)                         | 3 (16)                           |

## Advanced COPD



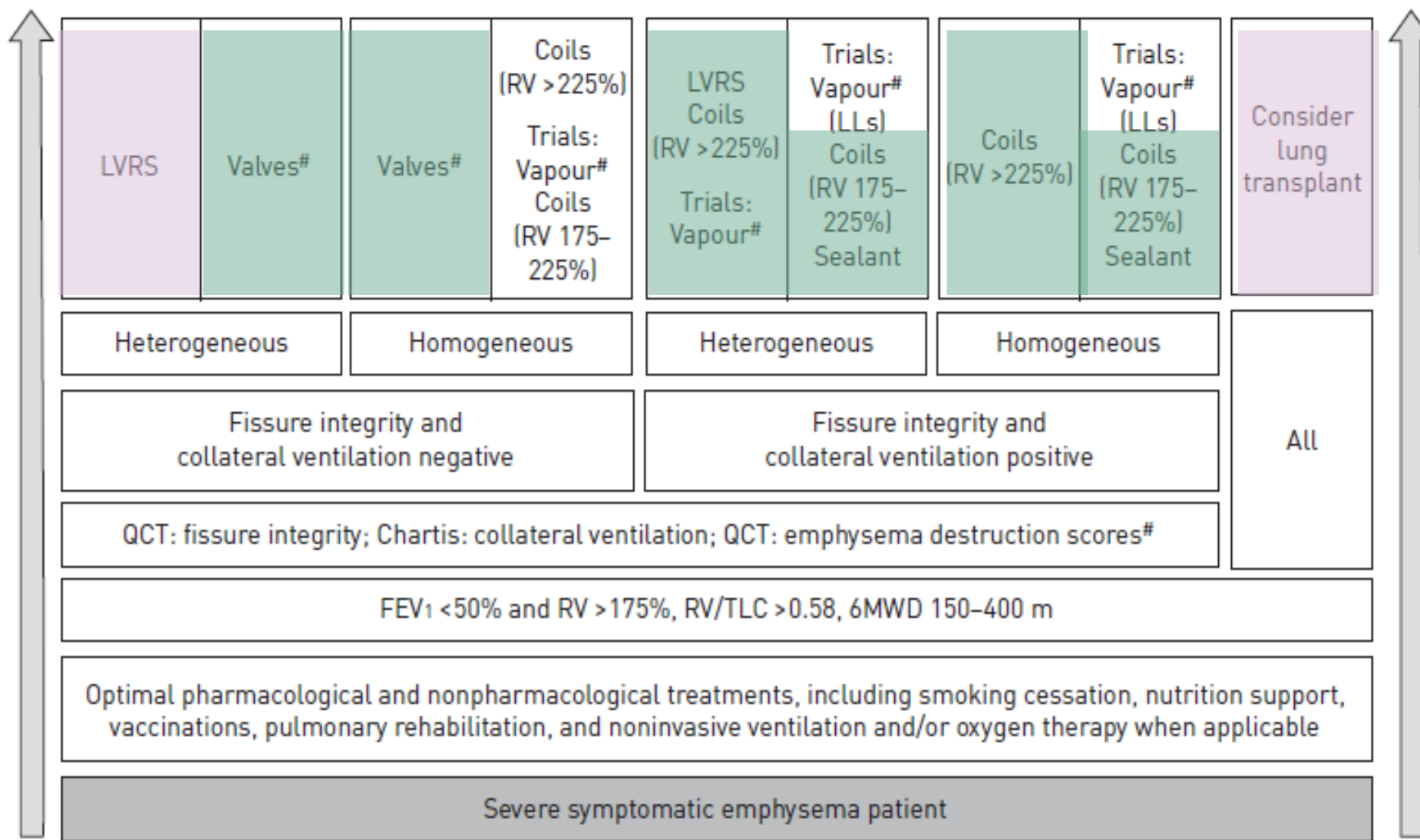
Definition of Abbreviations: BLVR, Bronchoscopic Lung Volume Reduction, EBV, endobronchial Valve, LVRS, Lung volume reduction surgery, LVRC, Lung volume reduction coil, VA, Vapor ablation

\*at some but not all centers

FIGURE 4.5



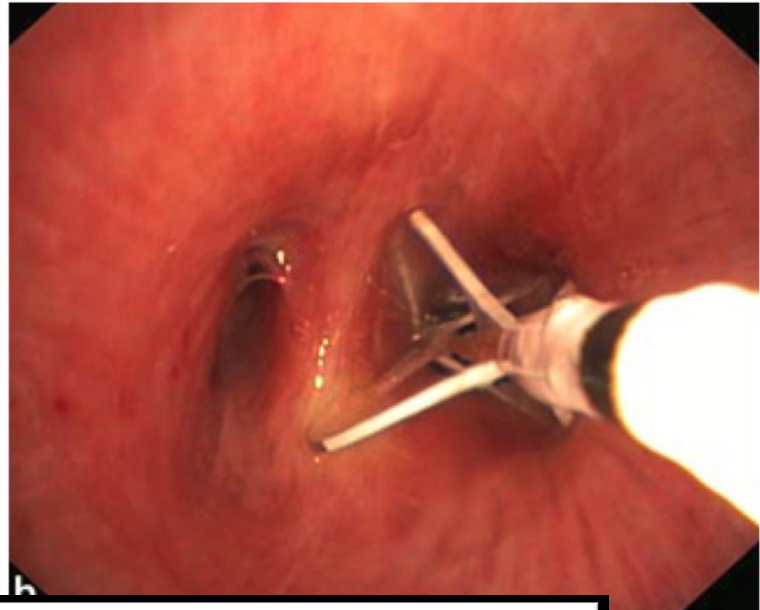
## BRONCHOSCOPIC LUNG VOLUME REDUCTION | D-J. SLEBOS ET AL.

Number 78  
December 2017**Optimal  
treatment**



# Μη ελεγχόμενο Βρογχικό Άσθμα

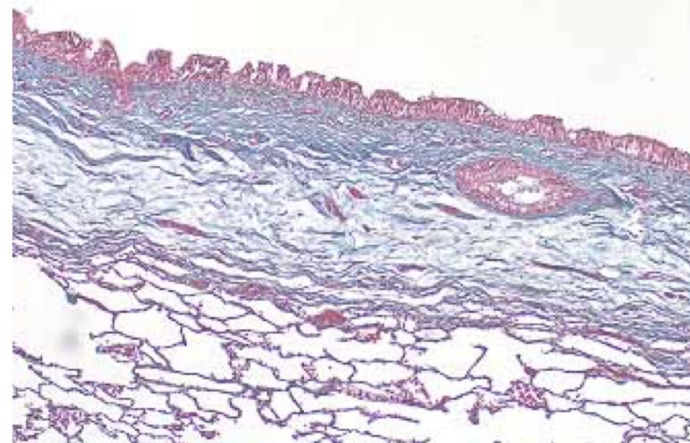
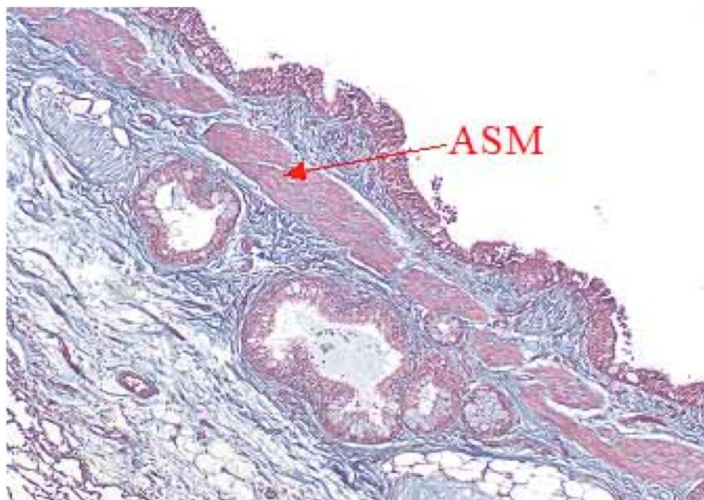
# Radiofrequency ... Ablation for ASTHMA

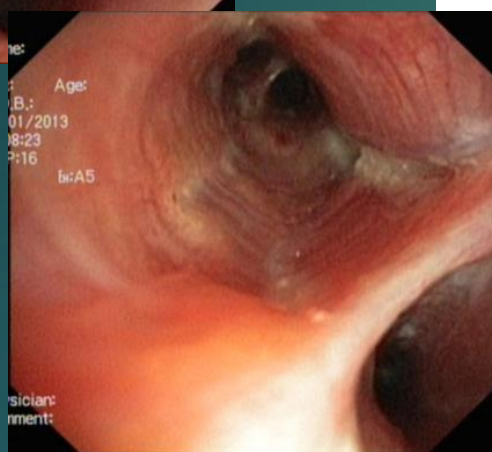
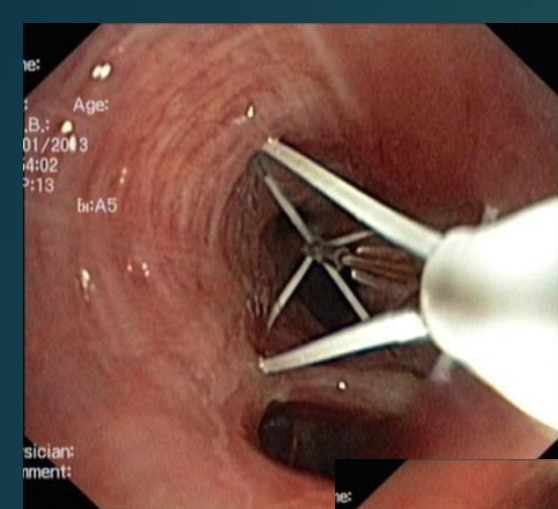


Single use catheter  
4 expandable electrodes



Radiofrequency generator  
Monopolar 450 – 500 kHz

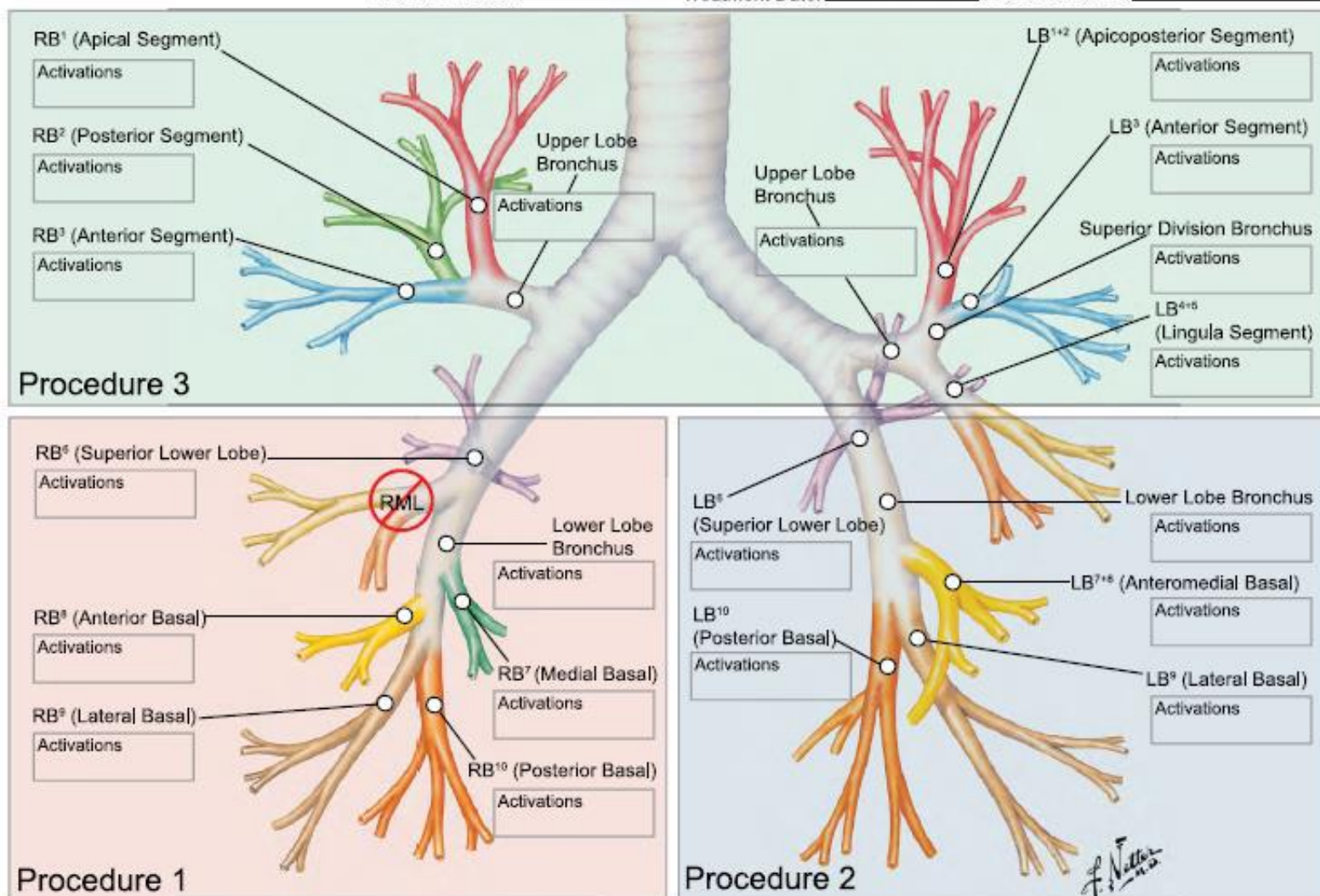




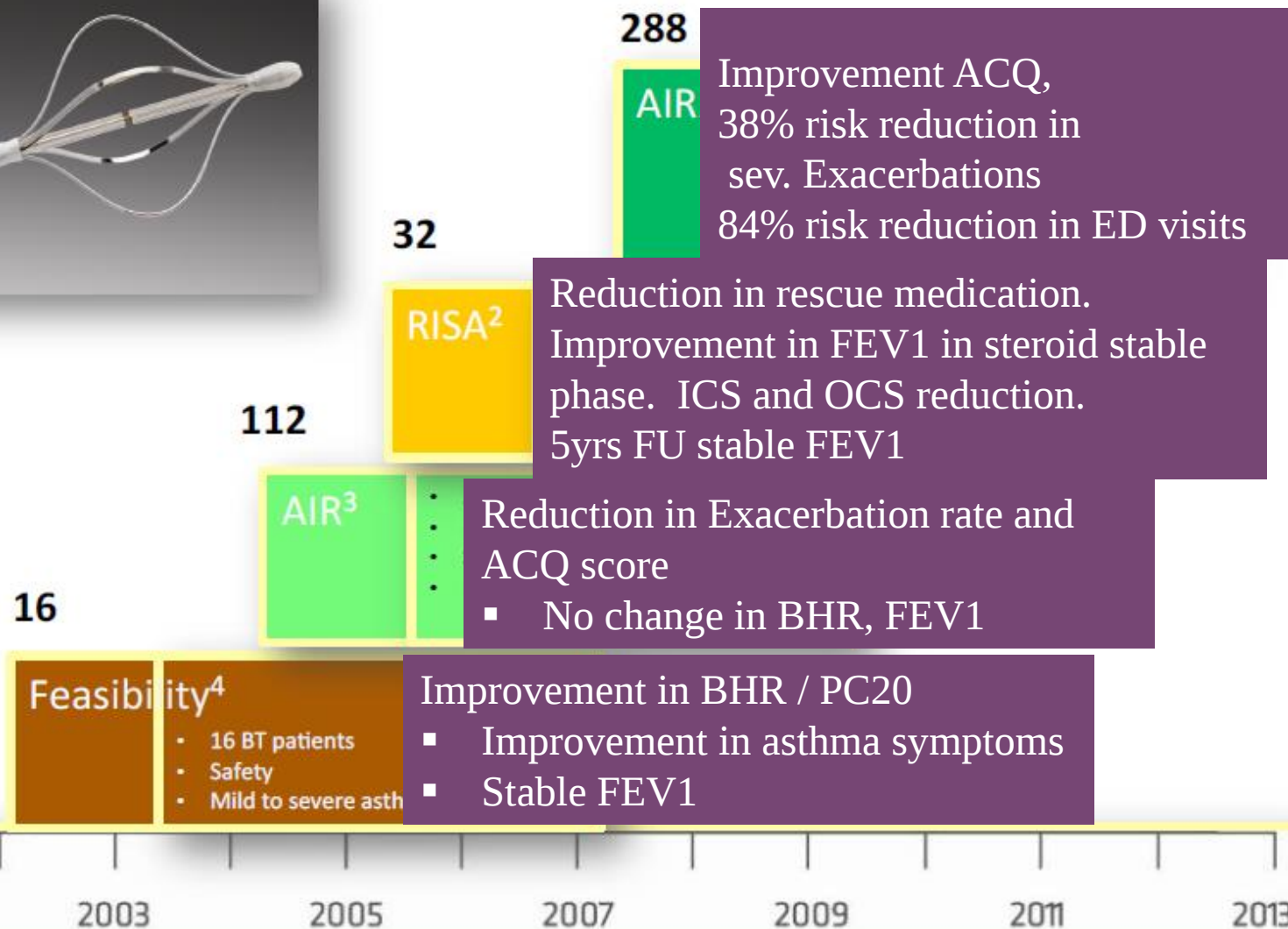
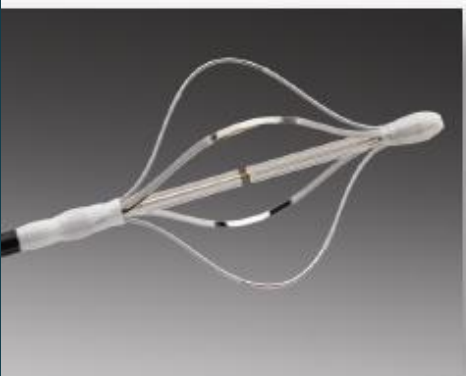
40 – 100  
activations/register

45 – 60 minutes / BT

Patient ID: \_\_\_\_\_ Procedure 1: Right Lower Lobe Procedure 2: Left Lower Lobe Procedure 3: Right & Left Upper Lobes  
Treatment Date: \_\_\_\_\_ Treatment Date: \_\_\_\_\_ Treatment Date: \_\_\_\_\_



## Clinical trials thermoplasty



- ▶ Πρόκληση θερμότητας ως 65°C
- ▶ Ενέργεια 18 W
- ▶ Εφαρμογή για 10 sec σε κάθε θέση. Στοχεύει τους βρόγχους από το επίπεδο των λοβαίων ως αυτούς με d: 3mm
- ▶ Μείωση της μάζας των λείων μυϊκών ινών κατά 50%
- ▶ Όχι πλήρης καταστροφή τους
- ▶ Δεν επηρεάζει το περιβρογχικό πνευμονικό παρέγχυμα

# PAS2: FDA 3 yrs FU

284 subjects enrolled from April, 2011 to Oct, 2014

- Comparison of the first 190 PAS2 subjects with poorer asthma control to the 190 BT-treated subjects in the AIR2 trial
- 5 years FU completed in 2020



Eur Respir J 2017; 50: 1700017



ORIGINAL ARTICLE  
ASTHMA



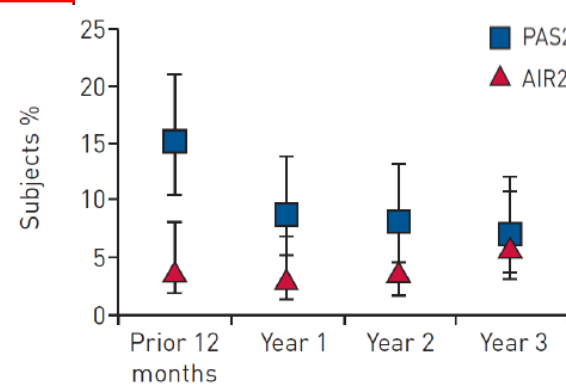
rossMark

**Long-term outcomes of bronchial thermoplasty in subjects with severe asthma: a comparison of 3-year follow-up results from two prospective multicentre studies**

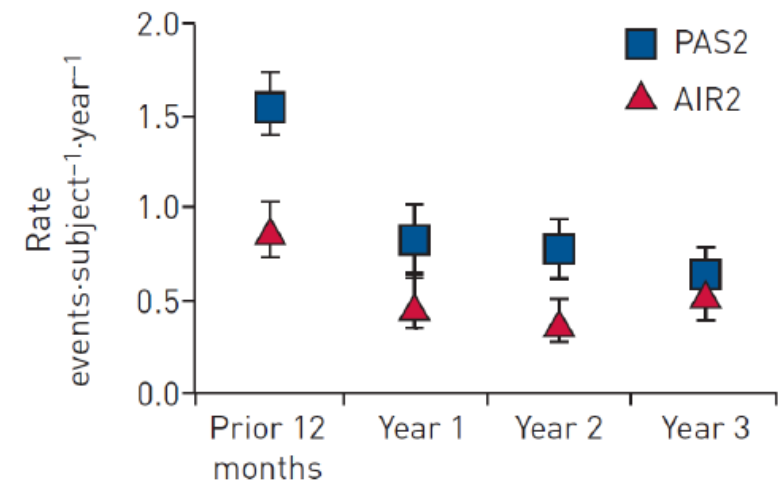
|                                      | PAS2                                  | AIR2                                |
|--------------------------------------|---------------------------------------|-------------------------------------|
| Characteristic                       | N=190                                 | N=190                               |
| Age (years)                          | 45.87 ± 11.39 (190)                   | 40.69 ± 11.89 (190)*                |
| Female                               | 61.6% (117/190)                       | 57.4% (109/190)                     |
| Body Mass Index [kg/m <sup>2</sup> ] | 32.50 ± 7.72 (190)                    | 29.29 ± 6.16 (190)*                 |
| AQLQ                                 | 4.17 ± 1.33 (190)                     | 4.30 ± 1.17 (190)                   |
| Severe Asthma<br>(ERS/ATS)           | 94.7% (180/190)                       | 82.1% (156/190)*                    |
| ICS (µg/day)                         | 2301.04 ± 807.46 (189)                | 1960.74 ± 745.19 (190)*             |
| LABA (µg/day)                        | 106.87 ± 39.36 (189)                  | 116.8 ± 34.39 (189)*                |
| SABA (puffs/day)                     | 2.38 ± 1.48 (182)                     | 2.24 ± 1.29 (168)                   |
| OCS (% and mg/day)                   | 18.9% (36/190)<br>9.13 ± 2.66 (35)    | 4.2% (8/190)*<br>11.88 ± 15.51 (8)  |
| Omalizumab<br>(% and mg/day)         | 15.8% (30/190)<br>266.83 ± 88.67 (30) | 1.1% (2/190)*<br>350.00 ± 35.36 (2) |

- No mortality
- (S)AEs in treatment period, treatable/predictable
- No long term complications
- HRCT: 3% bronchiectasies
- No device related complications
- Pulmonary function tests: stable FEV1

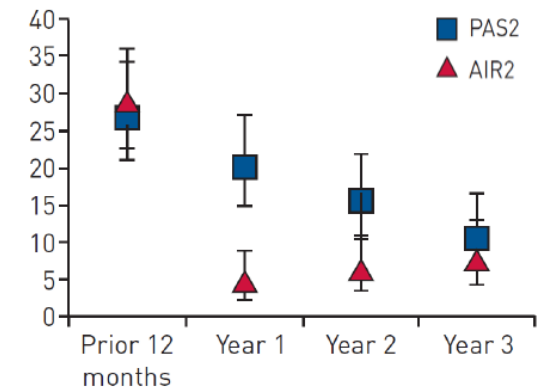
Hospitalizations



Rate

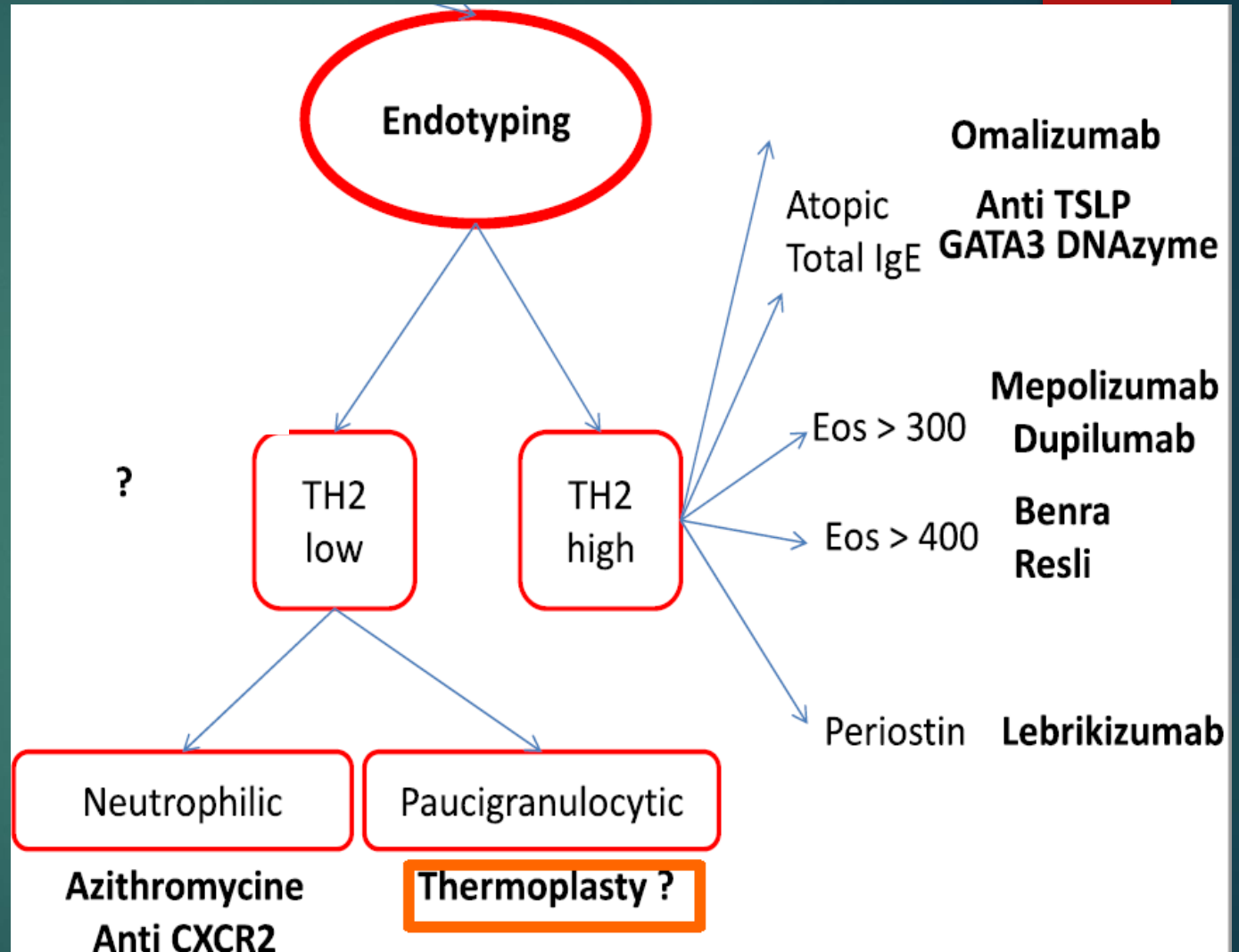


ED visits



# Επιλογή ασθενών

- 21 is a minimum age for BT
- Sedation as per local experience and skills
- Treat patients who have responded but only partially to Omalizumab
- BT can be performed safely in any patient with  $FEV_1 > 50\%$  pred
- No evidence supporting re-treatment



# Take Home message



## **BLVR for Pulm. Emphysema**

- ▶ Ασθενείς με απόφραξη και υπερδιάταση (TLC>100% RV>175%), με σοβαρό εμφύσημα (-910HU score). Ελέγχεται η ομοιογένεια/ετερογένεια και η ακεραιότητα των μεσολοβίων.
- ▶ CV (-) Valves
- ▶ CV(+) Coils, Sealant, Vapor
- ▶ Ανταπόκριση σε 50-75% των ασθενών
- ▶ Βελτίωση FEV<sub>1</sub>, RV, TLC
- ▶ Βελτίωση αντοχής στην άσκηση κ QoL

## ▶ **RF Bronchial Thermoplasty for ASTHMA**

### ▶ RCTs: AIR/RISA/AIR2:

Κλινική Βελτίωση ACQ/AQLQ

- ▶ Μείωση ρυθμού παροξύνσεων
- ▶ Βρογχική Υπεραντιδραστικότητα και FEV<sub>1</sub> παραμένουν σταθερά
- ▶ Την περίοδο της επέμβασης παρατηρούνται παροξύνσεις

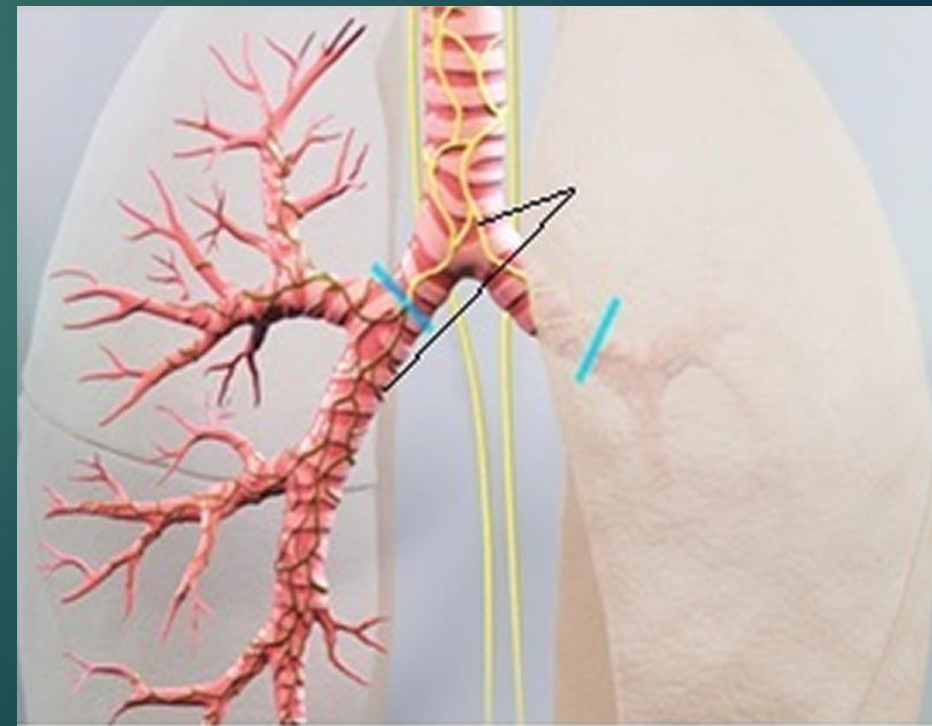
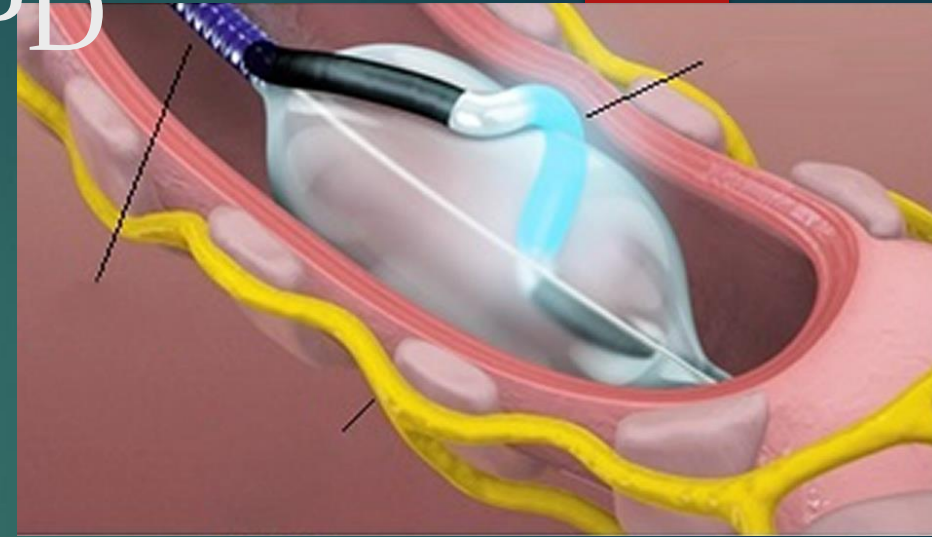
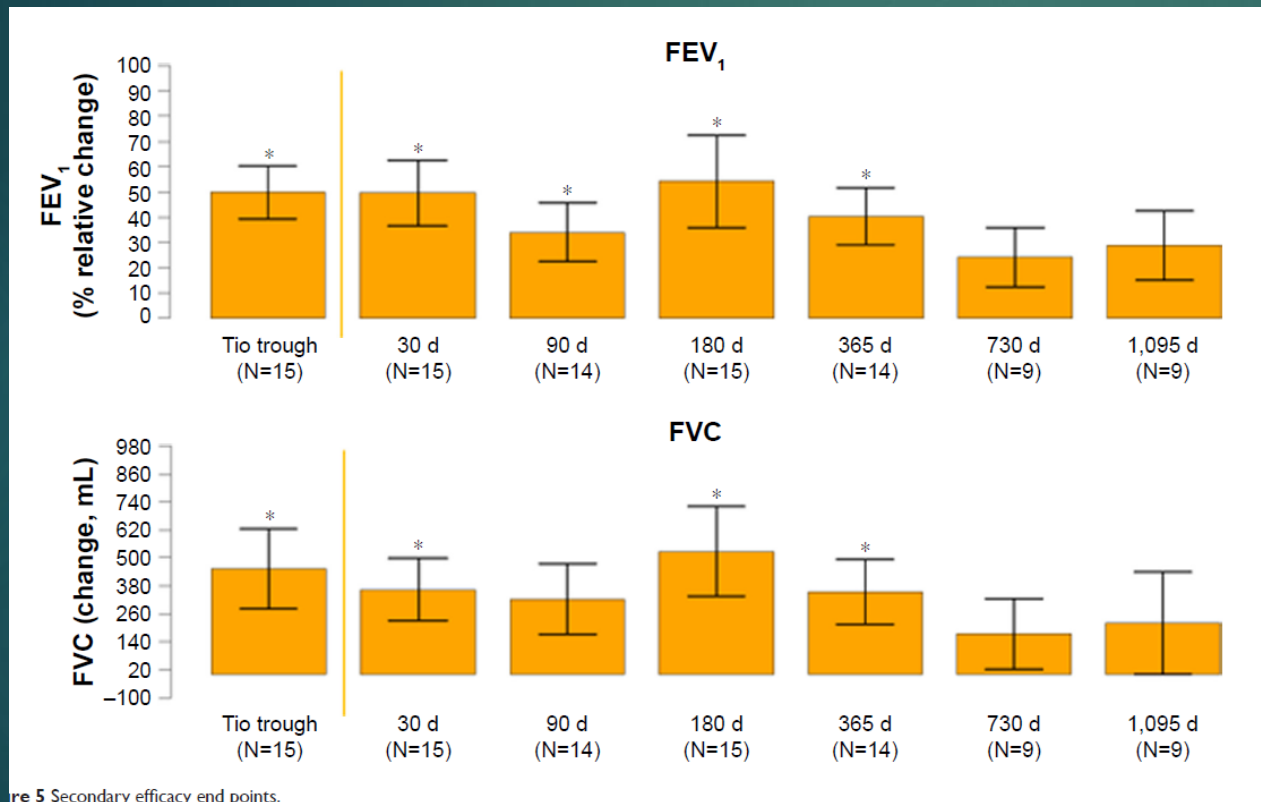
### ▶ **Μηχανισμός δράσης της BT?**

### ▶ **Ποιοι ασθενείς ωφελούνται περισσότερο?**

- ▶ ■ TASMA study: AMC, UMCG, Royal Brompton
- ▶ ■ ASTMATERM study: France

# Total Lung Denervation for COPD

- ▶ Feasible and safe (no complications in 3 yrs)
- ▶ Comparable effect to Tiotropium for FEV1



PERSPECTIVE  
PRECISION MEDICINE FOR AIRWAY DISEASES



## Treatable traits: toward precision medicine of chronic airway diseases

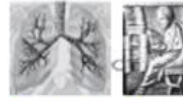
Alvar Agusti<sup>1</sup>, Elisabeth Bel<sup>2</sup>, Mike Thomas<sup>3</sup>, Claus Vogelmeier<sup>4</sup>,  
Guy Brusselle<sup>5,6</sup>, Stephen Holgate<sup>7</sup>, Marc Humbert<sup>8</sup>, Paul Jones<sup>9</sup>,  
Peter G. Gibson<sup>10</sup>, Jørgen Vestbo<sup>11</sup>, Richard Beasley<sup>12</sup> and Ian D. Pavord<sup>13</sup>

Athens  
welcomes

6th European Congress  
for Bronchology  
and Interventional Pulmonology



Organized by



Hellenic Training Association  
for Interventional  
Pulmonology



National & Kapodistrian  
University of Athens



endorsed by



HELLENIC  
THORACIC  
SOCIETY

EUROPEAN  
RESPIRATORY  
SOCIETY

Ευχαριστώ

ECBIP

April 22- 24  
2021

