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### 390. Treatment beyond inhalers: endoscopic lung volume reduction

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**P3526****Late-breaking abstract: Prevalence of emphysema heterogeneity measured with thoracic computed tomography soft in combination with collateral ventilation assessment to plan endoscopic volume reduction**

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Functional improvements after endoscopic volume reduction in severe emphysema were related to lobar heterogeneity and integrity of fissures in a post-hoc analysis of VENT data, NEJM 2010;363:1233. In 101 consecutive patients referred for endoscopic volume reduction, irrespective of CT findings, with FEV<sub>1</sub> <50% pred. and in NHYA IV, we prospectively measured PFT's, arterial gases, % of lobar destruction as defined by the % of volume < -950 Hounsfield unit with Myriam, Intrastense, Paris, France and in patients with heterogeneous disease collateral ventilation with lobar balloon Chartis, Pulmonx, USA. Patients, 75 males, were 59.1±11.4 yr old, FEV<sub>1</sub> 29.1±9.8% pred., FVC 66.8±22.1%, TLC 146.5±23.4%, PaO<sub>2</sub> 8.84±1.5, PaCO<sub>2</sub> 5.5±1.22 kPa, KCO 39.6±20.6% pred., % of destruction was 30±17 in left upper lobe, 24±18 left lower lobe, 35±21 right upper lobe, 24±20 right middle lobe and 26±20 right lower lobe. In patients with severe emphysema, lobar heterogeneity defined by at least 1 lobe with > 50% destruction and a difference > 10% in destruction within lobes was found in 43 cases, 22 instances in left side, 31 right side, 15 both sides with no collateral ventilation in 83%. The first patients with no collateral ventilation treated with valves experienced major improvements in 80% in terms of FEV<sub>1</sub>, FVC and weight gain. We conclude that in patients with severe emphysema, heterogeneity was found in 43% of cases. From this single centre experience, endoscopic volume reduction seemed to result in meaningful improvements in 0.43x0.83x0.80 corresponding to 29% of cases. Funds from 2008-2010 innovative hospital grants.

**P3527****6-month follow-up in patients with advanced upper lobe predominant heterogeneous emphysema treated with endobronchial lung sealant therapy**

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**Objective(s):** Responses to AeriSeal® Emphysematous Lung Sealant System (ELS) therapy in patients with advanced upper lobe predominant heterogeneous (ULP) emphysema are summarized out to 6 months of follow-up.

**Methods:** 14 patients with ULP emphysema received ELS treatment in a multi-center study conducted at 8 sites across Europe and Israel. Ten (10) of these

patients underwent a second treatment session after 12 weeks in the contralateral upper lobe to complete bilateral therapy. Pulmonary function, functional capacity, and quality of life assessments were performed at 3 and 6 months following treatment.

**Results:** Upper lobe ELS therapy in this cohort (8 male, age 63±6 yrs) was associated with improvements in pulmonary function, functional capacity, and quality of life. Three (3) and 6 month improvements in FEV<sub>1</sub> (+17.4±33.1%; 20.3±33.3%), FVC (11.3±24.7%; 12.3±24.2%), RV/TLC ratio (-7.5±11.1%; -6.2±7.4%), MRCD (-0.3±0.83U; -0.4±0.77U), 6MWT (+22.4±105.9m; +31.6±80.6m), and SGRQ (-9.5±11.3U; -6.3±9.6U) were reported. Clinically significant improvements in spirometry were observed in 9 of 14 patients at 6 month follow-up. Physiological responses were best in those patients (n=10) who received bilateral upper lobe split dose therapy (ΔFEV<sub>1</sub> = +24.8±36.8%; ΔFVC = +17.6±25.6%). **Conclusions:** ELS therapy in patients with advanced ULP emphysema improves lung function, functional capacity and quality of life out to at least 6 months. Improvements in spirometry following bilateral upper lobe therapy can be equivalent to those observed following lung volume reduction surgery.

**P3528**

**Physiological consequence of lower vs upper lobe lung volume reduction in patients with advanced emphysema**

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**Objective(s):** Lower lobe lung volume reduction in patients with advanced emphysema is associated with less benefit than upper lobe therapy. We present computer modeling results that explain these observations, and can help direct treatment site selection in patients undergoing lung volume reduction therapy.

**Methods:** The model considers alveoli as discrete units with an exponential pressure-volume relationship of the form  $(V(P_{tp}) = V_{max} - Ae^{-kP_{tp}})$ . Gravitational effects on transpulmonary pressure (P<sub>tp</sub>), the extent of tissue destruction, airway closure effects, and extent of heterogeneity were incorporated as independent variables for predicting RV and RV/TLC.

**Results:** Gravitational effects on P<sub>tp</sub> are the major determinant of regional RV and overall RV/TLC. In upper lobe heterogeneous emphysema, changes in P<sub>tp</sub> from volume reduction distend the remaining alveoli at end exhalation. However, RV and RV/TLC are reduced due to a decrease in the total number of diseased alveoli following treatment. In lower lobe heterogeneous emphysema, volume reduction distends already stretched upper lobe alveoli attenuating treatment effects on gas trapping. This phenomenon was more pronounced in homogeneous disease. Potential benefits of lower lobe volume reduction could be completely negated by upper lobe alveolar distention, resulting in no improvement, or even worsening of RV and RV/TLC despite alveolar resection.

**Conclusions:** Gravitational effects largely explain why lower lobe volume reduction therapy is less therapeutic than upper lobe therapy. In patients with homogeneous emphysema, lower lobe therapy can actually worsen gas trapping despite resection of diseased tissue.

**P3529**

**Effect of fissure integrity on the efficacy of bronchoscopic lung volume reduction therapy using a peripheral acting tissue sealant in patients with advanced upper lobe predominant emphysema**

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**Objective(s):** Results from the VENT Study (Sciurba F et al, NEJM 2010) indicate that endobronchial valve therapy is most effective in patients with upper lobe predominant heterogeneous (ULP) emphysema who have intact fissures. This study examines how fissure integrity affects the response to endobronchial volume reduction performed with the AeriSeal Emphysematous Lung Sealant System (ELS), a peripheral-acting tissue sealant.

**Methods:** Lung volumes, tissue density, and disease heterogeneity were assessed by CT scanning in 27 patients (age 62.6±7.5 yrs, 19 male) with advanced ULP emphysema before and after ELS therapy. Post-treatment changes in lobar and total lung volumes were correlated with fissure integrity and with physiological, functional and quality of life outcomes out to 6 months.

**Results:** ELS therapy reduced lobar volumes independent of fissure integrity. In ULP patients treated on the side of a complete fissure (n=12), lobar volume reduction was 530±323 mL, vs 406±330 mL on the side of an incomplete fissure (n=15; p=0.304). Improvements in pulmonary function (Complete vs Incomplete: ΔFEV<sub>1</sub> = +8.5% vs 8.9%), functional capacity (ΔMRCD = -1.1U vs -0.5U; Δ6MWD = +43.3m vs +41.0m), and quality of life (ΔSGRQ = -6.0U vs -7.9U) were similar in ULP patients with and without complete fissures although overall reductions in RV/TLC (ΔRV/TLC = -6.7% vs -1.8%) were greater in those with complete fissures.

**Conclusions:** Fissure integrity had minimal impact on the overall response to endobronchial lung volume reduction therapy performed using ELS in patients with advanced ULP emphysema.

**P3530**

**Efficacy of bronchoscopic thermal vapor ablation and lobar fissure completeness**

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**Background:** Bronchoscopic thermal vapor ablation (BTVA) ablates emphysematous tissue through a localized inflammatory response followed by contractive fibrosis and atelectasis leading to permanent lung volume reduction that should not be influenced by collateral ventilation.

**Objectives:** To determine the correlation of clinical data from a trial of BTVA to computed tomography (CT) assessment of fissure integrity.

**Methods:** Single arm study (n= 44) of patients with heterogeneous upper lobe predominant emphysema with FEV<sub>1</sub> <45% predicted. Patients received BTVA to the RUL or LUL in a single setting. Primary efficacy outcomes: FEV<sub>1</sub> and SGRQ at 6 months. Efficacy: lobar volume reduction (LoVR) from thin section multislice CT, spirometry, body plethysmography, 6MWD and mMRC dyspnea score. The treated lobar fissure was analyzed visually in non-enhanced pre-interventional CT. Incompleteness of small fissure, upper half of right large fissure, and three thirds of left large fissure were estimated in 5% increments and the relative amount of fissure incompleteness calculated. Pearson correlation coefficients were calculated for the association between fissure incompleteness and change in efficacy outcomes (baseline to 6 months).

**Results:** Mean age 62 years, 50% men. FEV<sub>1</sub> 0.85 L (31% predicted), SGRQ 59 units, 6MWD 300m. Calculated relevant fissure incompleteness was 13% (median range 0-63%). 38/44 patients (86%) had incompleteness in the relevant fissure. Correlation coefficients (r) for the association of incompleteness to outcomes are as follows: FEV<sub>1</sub> 0.17, LoVR -0.27, SGRQ -0.10, 6MWD 0, RV -0.18, RV/TLC -0.14.

**Conclusion:** BTVA induced LoVR and improvements in clinical outcomes are independent of fissure integrity.

**P3531**

**Associations of efficacy outcomes following bronchoscopic thermal vapor ablation (BTVA) for the treatment of heterogeneous emphysema**

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**Background:** The associations among various COPD efficacy endpoints are variable; however, the degree of correlation is often important in examining the consistency of the results across measures that are not considered redundant.

**Objectives:** Determine the correlations of improvements in lung function and CT analysis of lobar volume reduction (LoVR) to health outcomes following treatment of heterogeneous emphysema with BTVA.

**Methods:** Single-arm trial of BTVA in patients with upper lobe predominant emphysema. Patient criteria: FEV<sub>1</sub> 15% - 45% predicted, age 40-75 years, RV > 150%, TLC > 100%, 6 minute walk distance (6MWD) > 140 m, DLCO > 20%, previous pulmonary rehabilitation. Primary efficacy endpoints: FEV<sub>1</sub> and St. George's Respiratory Questionnaire total score (SGRQ) at 6 months. Other endpoints: body plethysmography, mMRC dyspnea, 6MWD. Pearson correlation coefficients were calculated for the association of changes from baseline to 6 months of physiologic measures and LoVR to health outcomes.

	SGRQ	BODE	mMRC	6MWD
FEV1	-0.26	-0.62	-0.57	0.22
FVC	-0.07	-0.56	-0.53	0.37
RV	0.13	0.72	0.70	-0.25
TLC	0.15	0.63	0.59	-0.06
FRC	0.25	0.80	0.75	-0.26
IC	-0.21	-0.52	-0.50	0.33
LoVR	0.32	0.51	0.48	0.03

**Results:** 44 patients received BTVA. Mean age: 63 years, men 50%, FEV<sub>1</sub> 0.86 (31% predicted), RV 237% predicted, DLCO 35% predicted, SGRQ 59 units, 6MWD 300 m, mMRC 2.9.

**Conclusion:** Physiologic and CT LoVR outcomes correlate strongest with the BODE score and the perception of dyspnea. The variable degree of correlation among the health outcomes indicates the need to examine multiple efficacy variables in emphysema and reinforce that the measures are not redundant.

**P3532**

**Efficiency of the endo-bronchial volume reduction treatment for heterogeneous lower lobe predominant emphysema**

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**Background:** Patients with severe chronic obstructive pulmonary disease (COPD) have limited treatment options. Exercise capacity and health related quality of life (HRQL) of these patients are affected by the progress of respiratory failure. Thus, there is a need for new treatments that can palliate. Endo-bronchial volume reduction treatment (EBVRT) which is a minimally invasive method has been come up. Endobronchial valves (EBV) that allow air to escape from a pulmonary lobe but not enter. It can induce a reduction in lobar volume that may thereby improve lung function and exercise tolerance in patients with advanced emphysema.

**Method:** To evaluate the safety and effectiveness of the EBVRT of lower lobe predominant heterogeneous emphysema. Functional capacity was evaluated with spirometry, 6minute walk distance (6MWD). SGRQ were applied to evaluate the HRQL.

**Result:** Five patients with heterogeneous lower lobe predominant emphysema (two left, three right lower lobe) were treated with EBV. Most of the patients were male (80%). The mean age was 65 years. Valves were placed into left lower lobe (n=2) and right lower lobes (n=3). Valves were placed in airways with 100% technical success. There were no procedure-related deaths and complications. At the third month, there was an increase of 4.6% in the forced expiratory volume 1 second (FEV1) and 2.3% increase of 6MWD were observed. Also, there was a decrease of 2.3% in the SGRQ score was observed.

**Conclusion:** EBVRT for heterogeneous lower lobe predominant emphysema patients induced modest improvements in lung function, exercise tolerance, and HRQL. EBVRT is a new safety method for the patients with severe COPD.

**P3533**

**Multistage endobronchial valve treatment of emphysema**

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Of 59 patients with emphysema treated with endobronchial valves (EBV) at our institution, nine were submitted to multistage strategies with placement of additional valves at varying intervals to complement initial treatment or compensate for the natural decline associated with aging in this chronic disorder. All had severe emphysema with heterogeneity > 15% as measured by parenchymal density <-950HU. Three types of multistage strategies were used: bilateral (left/right), replacement (removal and reinsertion of valves), and progressive (nonlobar to lobar exclusion, upper/lower). Advantages of multistaging include protection from abrupt physiological changes and pneumothorax. Also, in the absence of clear clinical signs to predict response, multistaging allows a change in treatment approach, and clearly demonstrates the safety of EBVs.

Multistage endobronchial valve treatment of patients with severe emphysema

Patient No.	BODE*	1st treatment	Interval (months)	2nd treatment	Initial strategy	Final strategy
<b>Progressive</b>						
16	6	R B1 L B1+2	29	L B1+2, B3, B4+5	BNLE	LE
33	2	R B1	9	R B2, B3	NLE	LE
37	7	L B8	6	L B9	NLE	NLE
45	4	R B1, B2	10	R B3, B6	NLE	LE+Segment
<b>Replacement</b>						
20	3	R B1, B2, B3	40**	R B1, B2, B3	LE	LE
<b>Bilateral</b>						
10	6	R B1, B2, B3	80	L B1+2, B3, B4+5	LE	BLE
23	9	L B1+2, B3, B4+5	15	R B1, B2, B3	LE	BLE
29	7	R B1, B2, B3	41	L B1+2, B3, B4+5	LE	BLE
31	8	L B6, B8+9+10	12	R B8, 9, 10+B4+5	LE	BLE

BNLE = Bilateral nonlobar exclusion; BLE = Bilateral lobar exclusion; LE = lobar exclusion; NLE = nonlobar exclusion; R = right lobe; L = left lobe. \*Celli BR et al. N Engl J Med 2004; 350:1005-1012. \*\*Valves were completely removed for one month.

Multistage strategies should be considered in all valve patients as part of their routine follow-up.

**P3534**

**Management of severe COPD patients using bronchoscopic valve lung volume reduction: Preliminary results**

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**Background:** Despite of a modern level of anesthesiology, reanimation and surgical technics lethality after LVRS remains on range 2,5-4% and level of complications in some clinics reaches 20%.

**Aim:** To fulfil a technique of bronchoscopic valve lung volume reduction (BLVR) in management of COPD patients, to develop indications and contra-indications.

**Materials and methods:** 9 patients are undergone BLVR. Mean age was 56 y. All have severe dyspnoe from 3 up to 4 points on scale MRC, FEV1 - 25±3%, TLC - 134±23%, RV - 287±34%, a distance in 6-m test - 245±45 m. Criteria of inclusion in BLVR program were similar to those at a LVRS. Procedures were performed under local anesthesia with intravenous potentiation. Intervention carried out on one lung in 8 cases. 1 patient undergone consecutive bilateral BLVR. The unilateral valve of manufacture of "Medlung" (Russia) was established in a bronchial tube of the most amazed lobe or segmentary bronchial tubes of adjacent lobes for prevention of air bypass. The quantity of valves on one procedure varied from 1 up to 2. Average duration of procedure was 35±12 minutes.

**Results:** All patients were discharged. Average hospital period was 4 days. 1 patients had severe allergy bronchitis in site of valve. 2 patients had severe COPD exacerbation. 6 patients had marked reduction of dyspnoe, improving quality of life, increasing of physical tolerance, keeping up to 12 months after BLVR, including FEV1 - 30±3%, TLC - 102±3%, RV - 247±14%.

**Conclusions:** Preliminary results testify to efficiency, safety and expediency of BLVR in management of carefully selected severe COPD patients. We consider BLVR as a treatment option before LVRS and LT.

**P3535**

**Endoscopic lung volume reduction (ELVR) with the "endobronchial Miyazawa valve" (EMV) in patients with severe emphysema, a prospective pilot study**

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**Introduction:** The ELVR represent a new minimally invasive palliative option for the treatment of severe emphysema. The EMV is a new device with different characteristics compared to the others (a simple all in silicone structure, with a large opening, inexpensive, and without special delivery system) and is little studied. We believe this unidirectional valve is effective in reducing lung hyperinflation and improving lung function and dyspnea of a subtype of emphysema patients. We report here the data at one month for the first two patients

**Method:** Patients are affected from severe (FEV1<40%) heterogeneous emphysema and major hyperinflation (RV>130%). The Outcomes are the adverse effects, lung functions, exercise capacity and quality of life. The EMVs have been inserted through a rigid bronchoscope in the target segmental or lobar bronchi supplying the most hyperinflated parts of the lung in order to achieve an unilateral treatment with lobar exclusion.

**Results:** Baseline to 1 month after insertion. The patients A and B have improved in quality of life (St George's respiratory questionnaire A -9,B -18 points, pulmonary function (FEV1 A 0.51 to 0.62L and B 0.9 to 1.4L, RV A 4.49 to 2.53L and B 5.6 to 5.2L DLCO A 38 to 55.2% B 25 to 33% of predicted value) and exercise capacity (6 min. walk test A +65m. B +120m.). No atelectasis was visible on radiological control but signs of air trapping were reduced.

**Adverse effects:** Two episodes of bronchospasm in the first patient well controlled by medical therapy, and none in the second.

**Conclusion:** Our preliminary encouraging experience describe a new tool for the therapy of selected emphysema patients.

**P3536**

**Comparison between Chartis® pulmonary assessment system detection of collateral ventilation vs. corelab CT fissure analysis in predicting atelectasis in emphysema patients treated with endobronchial valves**

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**Introduction:** Accuracy of the Chartis® Pulmonary Assessment System in identifying responders after endobronchial valve (EBV) treatment is the subject of a recently concluded multi-center European Study. The Chartis system quantifies collateral ventilation (CV) by sealing a lung compartment and measuring its air pressure and flow. When the resistance value >10, the patient is "CV Negative;" when the resistance value ≤10, the patient is "CV Positive;". Fissure analysis



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prediction of LVR response is based on "completeness" or "incompleteness" of the target lobe fissure. In this study, the predictive value of the HRCT vs. Chartis assessment is compared.

**Objective:** To determine whether the accuracy of CV assessment is comparable to fissure analysis from HRCT in predicting clinically significant LVR following EBV treatment.

**Methods:** Baseline and 30-day follow-up HRCTs of EBV treated patients were evaluated by an independent, blinded core lab(s). A Chartis assessment was conducted prior to the baseline core lab reading. The baseline HRCT fissure results and the Chartis assessments were compared for a "matched" prediction, and reviewed against the LVR in the treated lobe as measured by 30-day HRCT.

**Results:** Data for 31 patients is available to date. Analysis of up to 75 patients is expected for ERS. In 31 patients, Chartis and CT matched 24 times (77.4%). Chartis and CT did not match 7 times (22.6%).

**Conclusion:** Accuracy of the Chartis<sup>®</sup> System is comparable to Corelab review of HRCT, and may be used in lieu of fissure analysis to predict clinically meaningful LVR following EBV treatment.

### P3537

#### Bronchoscopic assessment of collateral ventilation predicts outcome of endoscopic lung volume reduction with valves

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**Background:** Collateral Ventilation (CV) is a cause of failure of endoscopic lung volume reduction (ELVR) with endobronchial valves (EBV). The Chartis system (PulmonX, USA) measures CV in the target lobe of ELVR to predict outcome and aid patient selection.

**Aims:** To test this hypothesis we correlated Chartis values with outcome of ELVR with EBV.

**Methods:** In 15 patients with severe heterogeneous emphysema we measured CV with Chartis in the target lobe of ELVR and achieved complete lobar exclusion with Zephyr EBV. We measured lung function, 6MWD, SGRQ and radiological outcome at baseline and one month.

**Results:** In 2 patients a valid Chartis signal was not obtained, 3 patients showed high CV (Chartis value <10 = CV+ve) and 10 patients low CV (Chartis value >10 = CV-ve). The CV-ve group compared to the CV+ve group showed significant improvement of obstruction ( $\Delta FEV1$  0,23±0,13L vs. -0,05±0,18L; p=0,018) and hyperinflation ( $\Delta RV$  -1,00±0,62L vs. 0,02±0,78L; p=0,037).  $\Delta$ 6MWD was 58,6m vs. 43,3m (ns) and  $\Delta$ SGRQ was -10,5 vs. -2,0 (ns). 10/15 patients had a response to EBV (8 CV-ve, 2 without valid Chartis signal). Atelectasis developed in 8/15 patients (6 CV-ve, 2 without valid Chartis signal). Of the 5/15 non-responders ( $\Delta FEV1$  <0,112L;  $\Delta$ SGRQ <-4; no atelectasis), 3 were CV+ve and 2 CV-ve.

**Conclusions:** In our patient cohort Chartis adequately predicted outcome of ELVR with EBV in 11/15 patients. In 2 patients a valid Chartis measurement could not be obtained. 2 patients, although the Chartis reading was interpreted as CV-ve, were non-responders. Despite these limitations, Chartis in our preliminary experience seems a valuable tool to select patients for ELVR with EBV.

### P3538

#### One year follow-up of intrabronchial lung volume reduction in alpha-1-antitrypsin deficiency and severe emphysema

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**Introduction:** In patients with alpha-1-antitrypsin (AAT) deficiency, severe emphysema mainly localized to the lower lobes can develop. Volume reduction surgery (LVRS) is not recommended in these patients.

**Objectives:** One-way valves in selected bronchi can reduce the size of hyperinflated lung areas, and we decided to make a pilot study of intra-bronchial volume reduction (IBVR) in patients with AAT deficiency and severe lower lobe disease.

**Methods:** In patients aged 40-80 years, with RV >150% and FEV1sec 15-45% of predicted, and predominantly lower lobe disease, IBVR with installation of 3-4 valves in one selected lower lobe was performed.

**Results:** Five patients were included. There were no complications. An immediate improvement, both subjectively and objectively, occurred and remained during the six months the patients have been followed. FEV1sec increased from a mean of 0.76 to 1.2 L (57%) and RV decreased from 5.7 L to 4 L (42%).

**Conclusion:** IBVR seems to be a safe, reversible, and simple method to improve lung function in selected patients with AAT deficiency. Further studies are warranted.

### P3539

#### Endobronchial identification of persistent peripheral bronchopleural fistula with digital chest tube monitoring followed by treatment with endobronchial one-way valve implantation

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**Introduction:** Bronchopleural fistula (BPF) is associated with high morbidity and

mortality and causes prolonged hospital stay and costs. Surgery remains the treatment of choice, however, many patients are at high risk or unwilling to undergo thoracotomy.

**Objectives:** To present a standardized approach of endoscopic diagnosis and treatment of persistent peripheral BPF.

**Methods:** 10 patients with persistent air leaks (presence of chest tube >7 days) underwent bronchoscopy with balloon occlusion technique and digital monitoring of airflow in order to identify the peripheral source of bronchopleural fistula. Endobronchial one-way valve implantation (Spiration Inc., Olympus) was performed on a segmental or subsegmental level to block ventilation to the BPF.

**Results:** Mean chest tube drainage time prior to the intervention was 22±13 days. The source of the BPF was endoscopically identified in all cases. Bronchoscopic valve implantation (1.6±0.8 valves per patient) was performed successfully in all patients. Using digital chest tube monitoring air flow immediately decreased from 1026±695ml/min to 56±71ml/min (p < 0,001), indicating successful cessation of the leakage. 2 patients underwent additional chemical pleurodesis. The chest tube was removed 8±5 days after bronchoscopy. There was no evidence of recurrence during a mean follow-up time of 2 months.

**Conclusion:** Using a standardized approach in endobronchial diagnosis followed by endobronchial one-way valve implantation results in a high responder rate in patients with peripheral BPF.

### P3540

#### Bronchoscopic injection of absolute ethanol in patients with persistent air leak from chest tube drainage

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**Background:** Chest tube drainage (CTD) has indicated for the treatment of pneumothorax, hemothorax and after thoracic surgery. But, in the case of incomplete lung expansion and/or persistent air leak from CTD, medical or surgical thoracoscopy or, if that is unavailable, limited thoracotomy should be considered. We evaluate the efficacy of bronchoscopic injection of absolute ethanolamine to control persistent air leak in patients with CTD.

**Methods:** Patients who had persistent or prolonged air leak from CTD were included consecutively. We directly injected 1.0 ml aliquots of ethanolamine into a subsegmental or its distal bronchus where is probably air leakage site, 1 to 20 times using injection needle through a fiberoptic bronchoscope.

**Results:** 15 patients (all men) were enrolled. There were 14 spontaneous pneumothorax (5 idiopathic, 6 chronic obstructive pulmonary disease (COPD) and 3 post-tuberculosis) and 1 empyema associated with broncho-pleural fistula in the study. Of 14 patients with ethanolamine injection therapies, five had previous surgical therapy, wedge resection for bullae, but the others didn't have. Twelve were successfully treated by an ethanolamine injection therapy alone. But three (idiopathic, COPD and post-tuberculosis) were failed and followed by a surgery (2 cases) or pleurodesis (1 case). Minor complications such as fever, chest pain and transient pneumonic infiltrations occurred after the therapy. With successful, the time to discharge was about 3 days (median).

**Conclusions:** Bronchoscopic ethanolamine injection therapy may be partially useful in controlling air leakage and reducing the hospital stay in patients with CTD.

### P3541

#### Results of BODE index in the European multicenter study for the treatment of advanced emphysema with bronchial valves

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The BODE index evaluates the risk of mortality in patients with COPD. The VENT study (un-blinded, randomized with a medical control arm) reported that at 6 months, 40.6% of subjects treated with the Zephyr<sup>®</sup> (Pulmonx) valve in a single lobe, achieved at least a 1-point improvement in the BODE index as compared with only 18.6% of controls. We reported positive results of a blinded and randomized sham bronchoscopy controlled study evaluating the IBV<sup>®</sup> Valve System (Spiration) treating both upper lobes in subjects with advanced emphysema but, without the goal of lobar atelectasis.

**Methods:** BODE was calculated at baseline and 3-months (blinded study period) in subjects in whom all necessary data was available.

**Results:** With the exception of 1 subject in the treatment group (TG), blinding was maintained. BODE improvement was -0.32±1.4 and -0.33±1.1 in the TG and CG respectively (p = NS).

Approximately half of the TG had improvements that may reflect treatment and positive study effects. In contrast with the not-blinded VENT control arm, 36% of the CG had improvements that could only be explained by positive study effects and/or placebo.

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Groups	BODE improve -1 or >	BODE decline +1 or >	No change
Treatment (N=31)	15 (48.4%)	8 (25.8%)	8 (25.8%)
Control (N=33)	12 (36.4%)	7 (21.2%)	14 (42.4%)
Total (N=64)	27 (42.2%)	15 (23.4%)	22 (34.4%)

**Conclusions:** In this blinded study, there were BODE improvements for the TG and CG. Comparison with the VENT study suggests more BODE responders if there is a blinded CG arm. Well designed blinded and randomized studies are possible, may benefit patients in both groups and are needed to evaluate these therapies.

**P3542****High resolution computed tomography (HRCT) measurements of lobar volume reduction associated with bronchoscopic thermal vapor ablation (BTVA) in patients with heterogeneous emphysema**

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**Background:** High resolution computed tomography (HRCT) may be used to assess the extent of lobar volume reduction associated with bronchoscopic lung volume reduction (LVR).

**Objectives:** Analysis of HRCT profiles of patients before and after BTVA in the treatment of heterogeneous emphysema during a clinical trial.

**Methods:** HRCT scanning was used as a key inclusion criterion for a single-arm trial of BTVA in patients with heterogeneous emphysema. Patients were included if they had a CT determined heterogeneity index (HI) >1.2 (HI = tissue to air ratio (TAR) lower lobe/upper lobe), FEV<sub>1</sub> 15%-45% predicted, age 40-75 years, RV >150%, TLC >100%, 6 minute walk distance (6MWD) >140 m, DLCO >20%, previous pulmonary rehabilitation.

**Results:** 44 patients (mean age 62yrs, FEV<sub>1</sub> 31% predicted, residual volume 237%, DLCO 35%) received unilateral upper lobe BTVA. HRCT assessed lobar volume reduction post BTVA was 48% after 3 months and 46% after 6 months. HRCT findings at baseline, 3 and 6 months according to the treated upper lobe were as follows:

	RUL (n=24)			LUL (n=20)		
	Baseline	3 months	6 months	Baseline	3 months	6 months
Lung tissue (g)	134±35	126±42	102±28*	114±36	117±74	92±39*
Lung volume (ml)	1589±513	820±613*	813±650*	1365±421	636±358*	649±383*
TAR (%)	9±1	242±747	318±887	8±1	99±287	80±267*

\*p<0.05 vs. baseline.

At 6 months, HI decreased from 1.67 to 0.99 (right lung) and 1.76 to 1.04 (left lung) (p<0.05).

**Conclusion:** HRCT analysis demonstrates significant lung volume reductions following BTVA. Reductions of tissue mass at 6 months are consistent with lung remodeling.