

BLVR at Henry Ford Hospital

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Lung Volume Reduction

Intended Physiologic Effects

- Increase elastic recoil
- Increase dynamic compliance
- Decrease air trapping, dead space and FRC
- Decrease diaphragm distension
- Decrease ventilation/perfusion mismatch

Intended Clinical Effects

- Improve PFT
- Improve exercise capacity
- Improve QOL
- Improve survival

Multicenter RCT

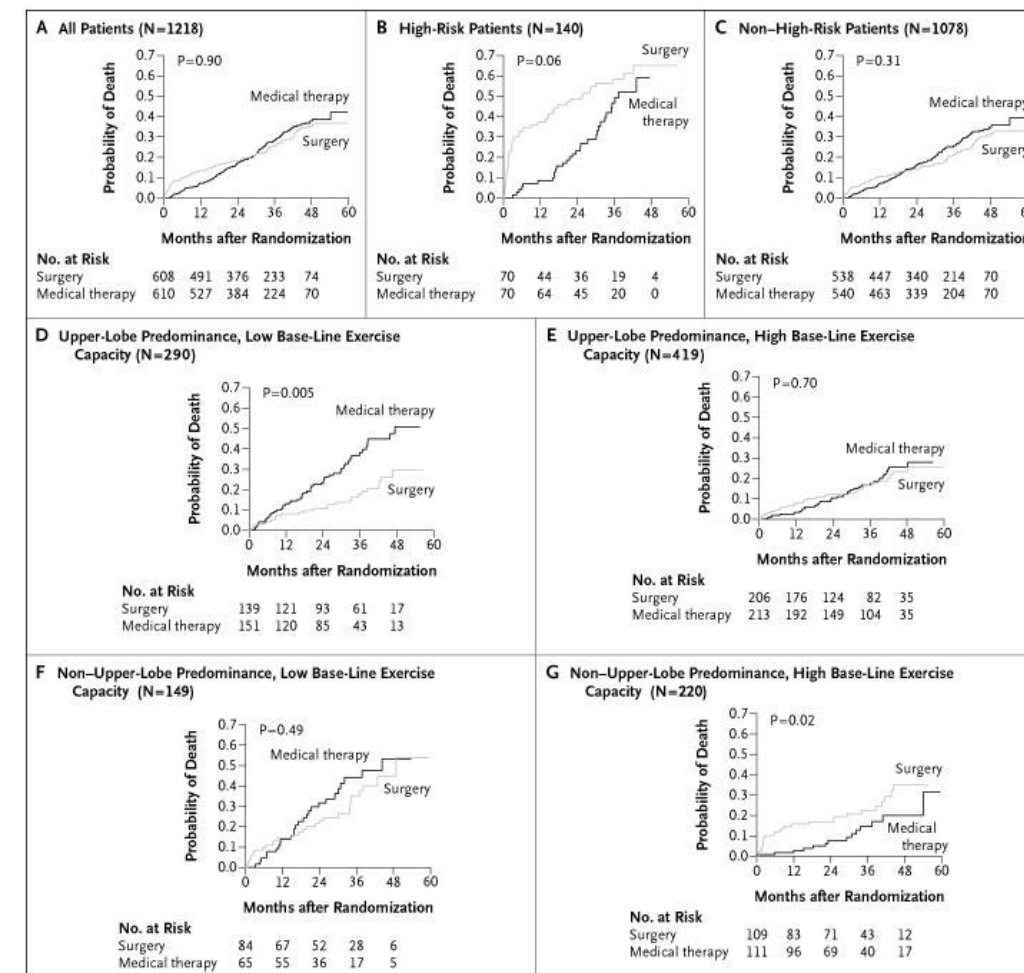
- 3277 pts evaluated → 1218 (37%) randomized
 - 608 surgery VS. 610 medical therapy
 - Mid sternotomy 70% / VATS 30%

Outcome

- Primary: Mortality and exercise capacity at 2 years
- Secondary: 6MWT, PFT, QOL, dyspnea scores

Inclusion:

- TLC $\geq 100\%$, RV $\geq 150\%$
- Cardiac clearance
- Pre-rehabilitation
 - FEV1 $\leq 45\%$
 - Resting PaCO2 ≤ 60 mm/Hg, PaO2 ≥ 45
- Complete 6-10 weeks of pulmonary rehabilitation

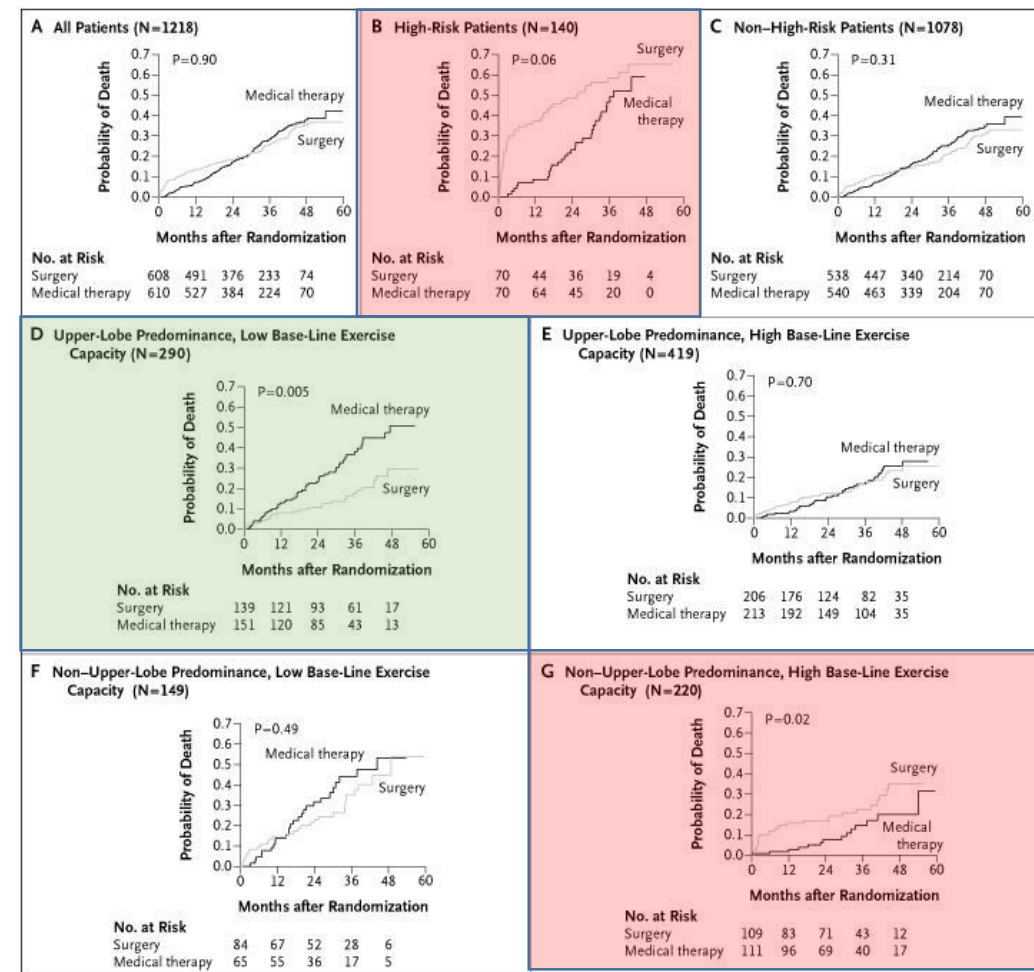


NETT – Results

- No survival benefit overall
- ↑ exercise capacity and QOL
 - ↑ mortality in high risk and non-upper lobe emphysema and high baseline exercise
 - Survival benefit in upper-lobe emphysema and low base-line exercise capacity

Complications

- Mortality 90 day → 7.9% (vs 1.3% for medical therapy)
- 58% any complication
- 90% prolonged air leaks (average 7 days)



LVRS in the US

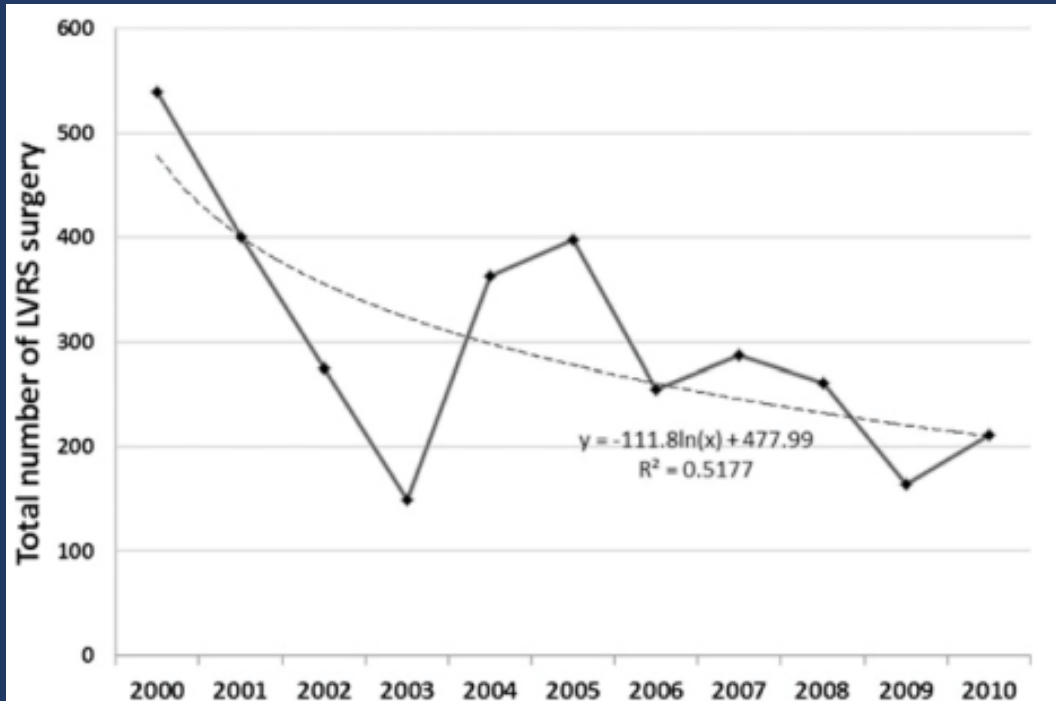


Figure 1 – Trends in LVRS in the United States from 2000 to 2010. Dotted line represents best fit. LVRS = lung volume reduction surgery.

- 3307 LVRS cases in 2000-2010
- In-hospital mortality 6.1%
- Tracheostomy 7.9%
- Hospital LOS 5-15d (median 9d)

TABLE 1] Variables Associated With Higher Mortality in People Undergoing LVRS

Age Group	Univariate, OR (95% CI)	Multivariate, OR (95% CI)
< 65 y	Reference	Reference
≥ 65 y	2.80 (1.50-5.22)	2.83 (1.51-5.32)
Individual comorbidities		
Interstitial lung disease	2.71 (1.29-5.67)	2.81 (1.33-5.93)
Malnutrition	3.02 (1.19-7.65)	2.74 (1.09-6.90)

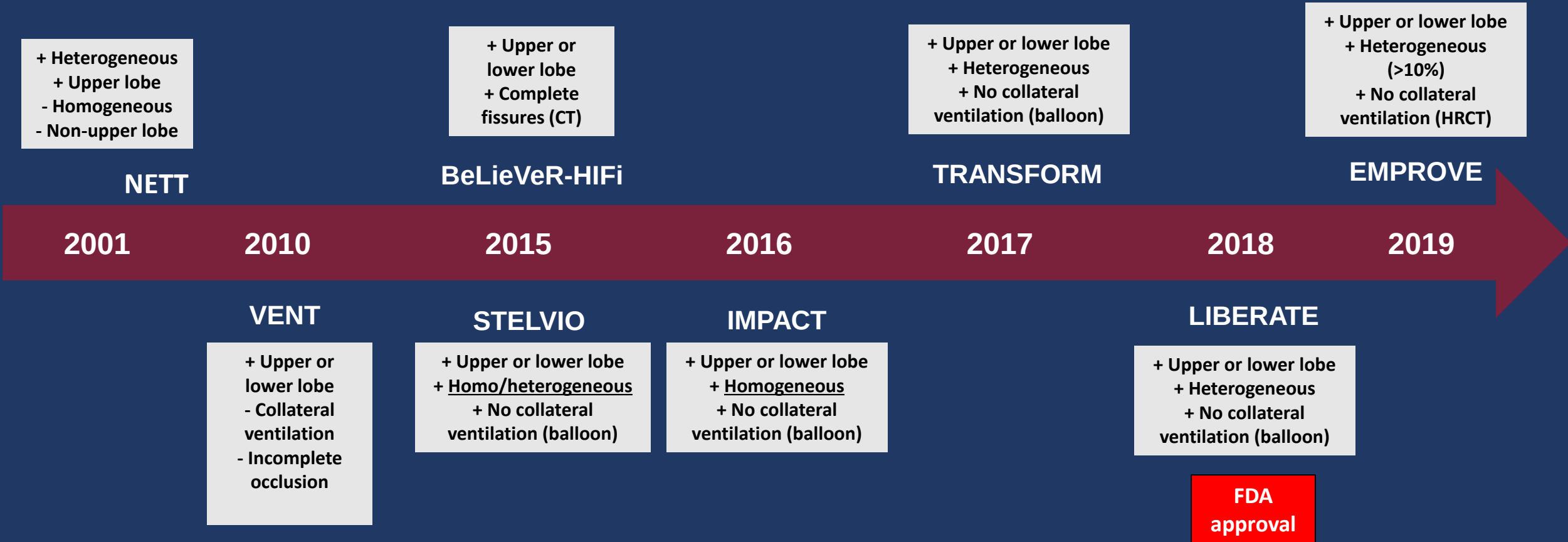
Should consider LQRS

- FEV1 <35%
- Hyperinflation RV >200%
- Upper lobe predominant emphysema
- No CO2 retention
- Low exercise capacity

Should not consider LQRS

- Highest risk patients
- FEV1 <20%
- DLCO <20%
- Homogeneous emphysema
- Caution in:
 - >65yo
 - ILD
 - Malnutrition

BLVR Literature Summary



BLVR – Summary of Results

		Improvement in (ITT group):		
RCT	Size & Follow-up period	Lung Function (FEV ₁ %) † MCID = 10%-15%	Exercise Capacity (6MWD) † MCID = 26 m	Quality of Life (SGRQ) † MCID = -4 pts
LIBERATE¹	N = 190 12 Mo	18.0%	39 m	-7.1 pts
TRANSFORM²	n = 97 6 Mo	29.3%	79 m	-6.5 pts
IMPACT³	n = 93 6 Mo	16.3%	28 m	-7.5 pts
STELVIO⁴	n = 68 6 Mo	17.8%	74 m	-14.7 pts*

1. Criner G et al. AJRCCM. 2018; 198 (9): 1151-1164
2. Kemp S et al. Am J Resp Crit Care Med 2017; (196)12: 1535-1543
3. Valipour et al. Am J Respir Crit Care Med. 2016; Vol 194, Iss 9, pp 1073-1082
4. Klooster K. et al. N Engl J Med. 2015; 373: 2325-2336

BLVR – Summary of Adverse Events



	Mortality		Pneumothorax		COPD with Hospitalization		Pneumonia		Respiratory Failure	
	EBV	SoC	EBV	SoC	EBV	SoC	EBV	SoC	EBV	SoC
LIBERATE (≤ 45 days)	3.1%	0%	27%	0%	7.8%	4.8%	0.8%	0%	1.6%	0%
TRANSFORM (≤ 45 days)	1.5%	0%	20%	0%	6.2%	3.1%	4.6%	0%	0%	0%
IMPACT (≤ 45 days)	0%	0%	23.3%	0%	16.3%	4.0%	0%	2.0%	0%	0%

Patient Selection Process – Inclusion



- Ex-smokers (≥ 4 months)
- PFT:
 - Post BD FEV1 15 – 45%
 - TLC $\geq 100\%$
 - RV $\geq 175\%$ (we may consider $>150\%$ in the future for selected cases)
- 6MWD
 - ≥ 100 - <500 meters after pulmonary rehabilitation program
- BMI <35 Kg/m²
- Completed pulmonary rehabilitation program (or is enrolled and completed 6-8 sessions)
- ABG: PaCO₂ <60 on room air, PaO₂ >45 on room air
- Stable on prednisone <20 mg/day

Patient Selection Process – Exclusion



- Any contraindication to bronchoscopy and/or general anesthesia
- Lung findings:
 - Concerning pulmonary nodule
 - Giant bullae (>1/3 hemithorax)
- Comorbidities:
 - Recent CV event (6 months)
 - Recent CVA (3 months)
 - Known uncontrolled PAH sPAP >45
- Prior lobectomy, LVRS, lung transplant, median sternotomy
- Careful consideration in:
 - CHF w/EF <45%
 - FEV 1 < 15%
 - DLCO <20%
 - Baseline 6MWD <100m
 - Lack of access to medical care

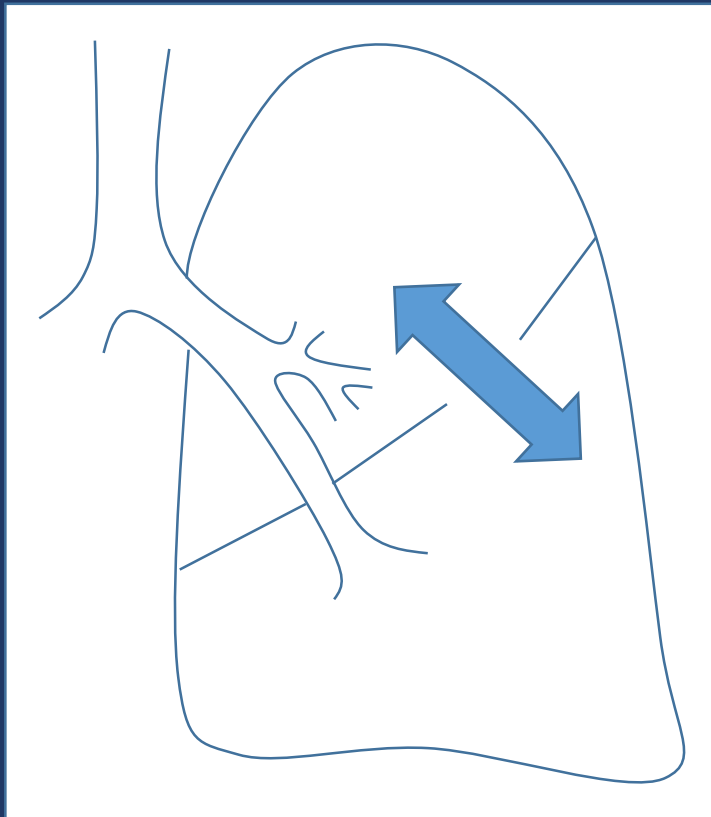
Patient Selection Process – Test Required



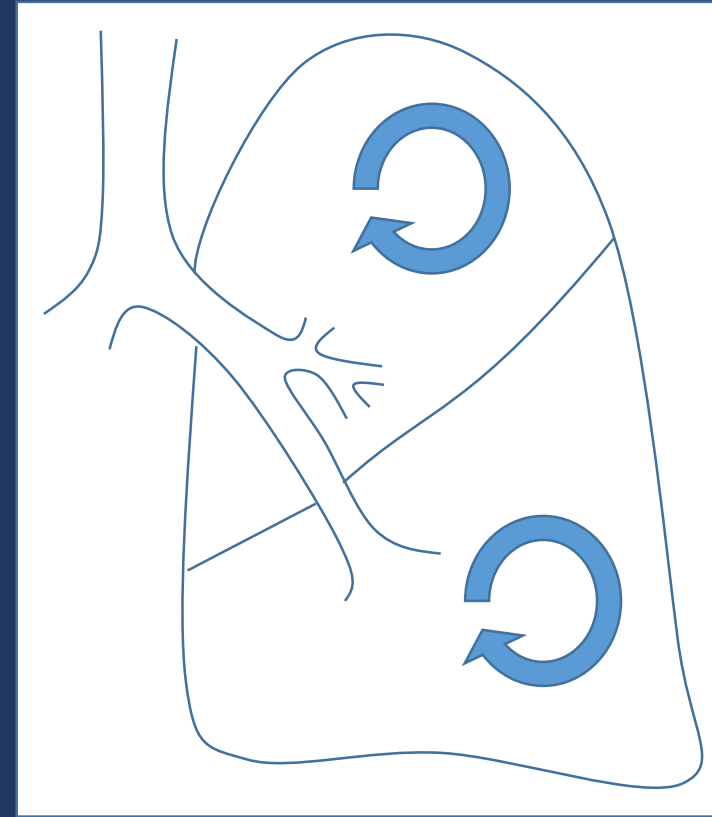
- These tests may be ordered by the referring pulmonologist or the BLVR team (within 1 year)
- Chest CT:
 - Chest CT with SD (super dimension protocol done at HFHS)
 - We can rule in with outside CT (minimum requirement HRCT inspiration only <1.5mm cuts, contrasted images are not analyzable) if done within 1 year. We do not rule out based upon outside images as quality may not be adequate.
- Complete PFT
- ABG
- 6MWT
- TTE
- A perfusion scan may be ordered on an individual basis after the BLVR clinic visit.

Collateral Ventilation

Collateral Ventilation (CV+)

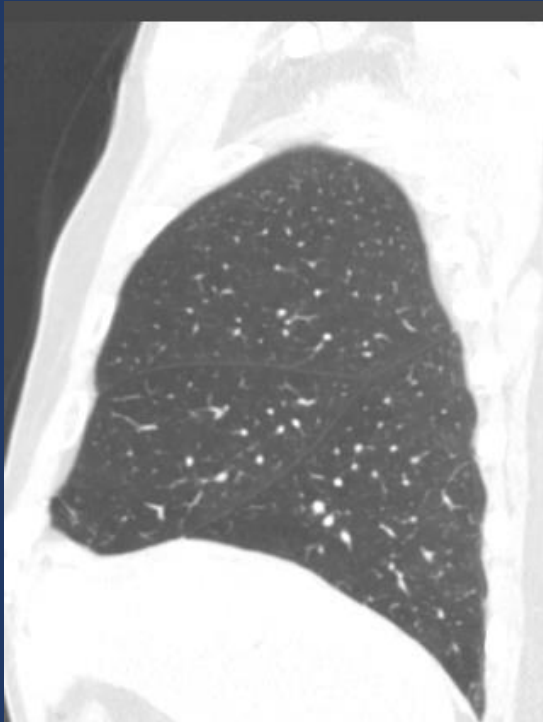


No Collateral Ventilation (CV-)

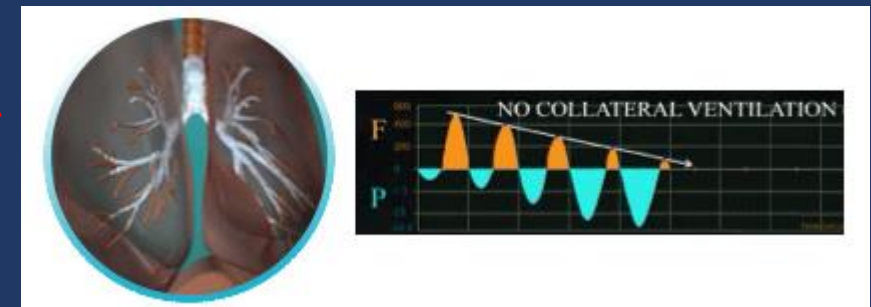
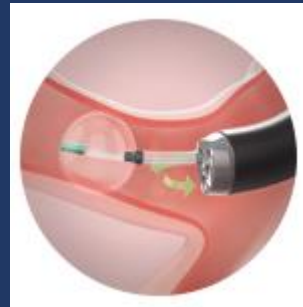


Collateral Ventilation – How to Assess?

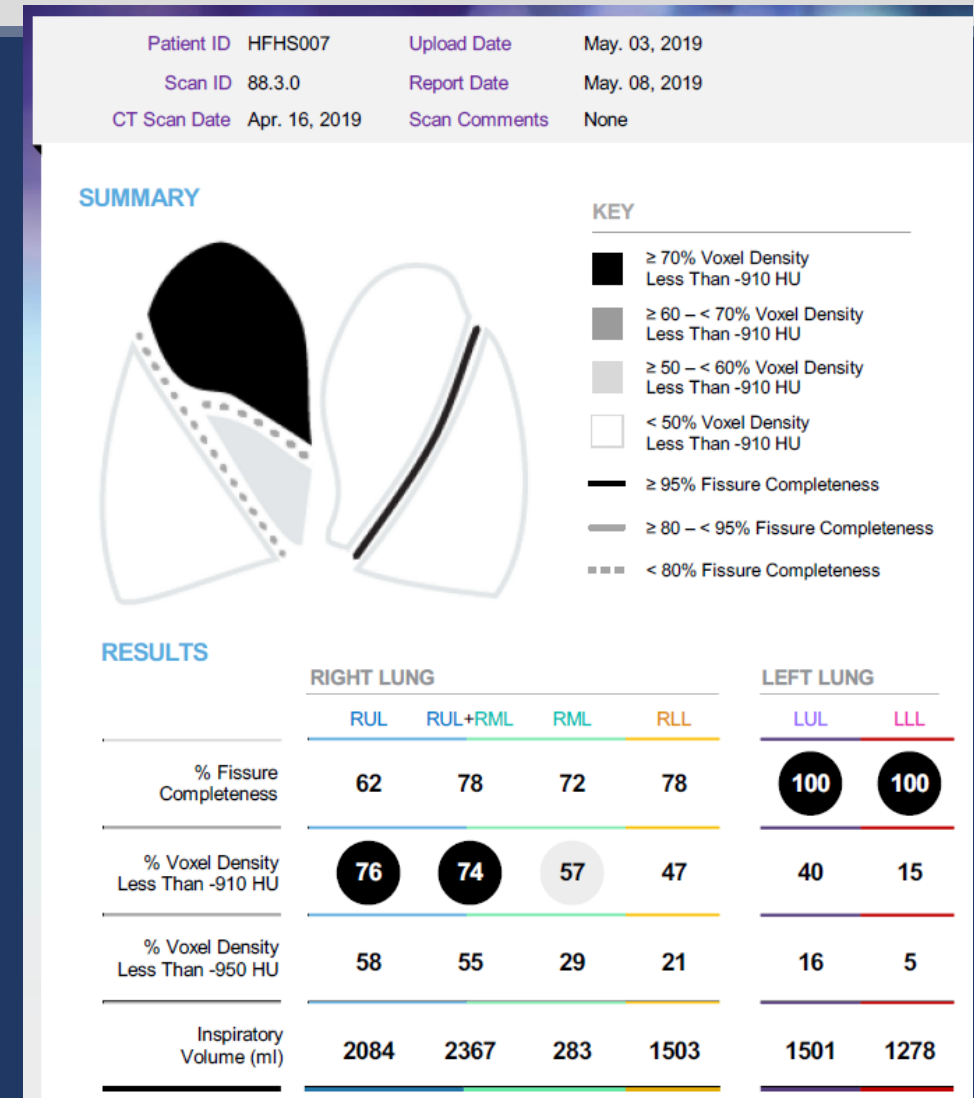
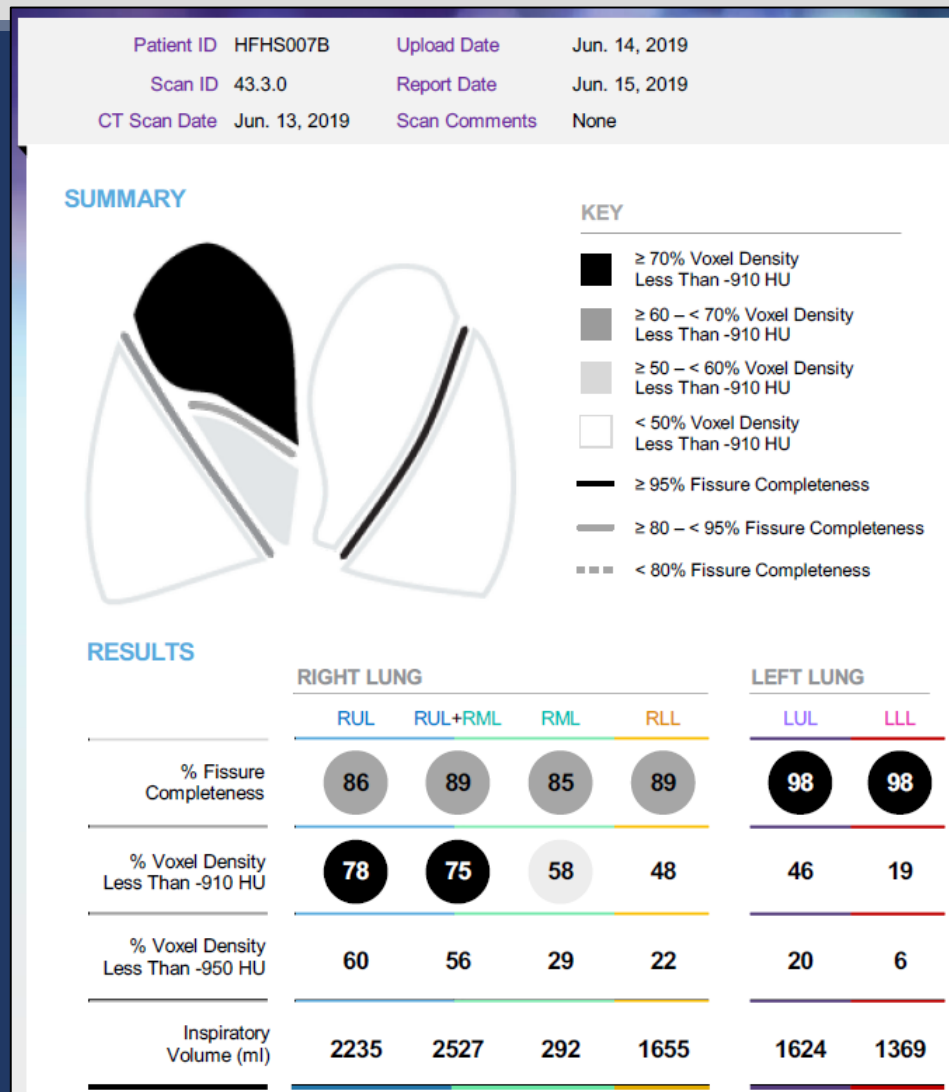
CT scan quantification of
fissure integrity



Chartis system for
collateral ventilation



Fissure integrity and Lobe Selection (QCT)



Target Lobe Selection



1. Little to No Collateral Ventilation
 - Fissure completeness $\geq 80\%$ preoperatively (StratX). Fissure $< 80\%$ rules out
 - Intraoperative confirmation with balloon (Chartis) that lobe is CV-
2. Higher Destruction
 - Emphysema score $\geq 45\%$ on QCT (Stratx)
 - Prefer lobe with greatest destruction
3. Larger Lobe Volume
4. Less Perfusion
 - Perfusion scan may be used when multiple valid target lobes are available
 - Consider if ipsilateral heterogeneity score is low
5. Greater Heterogeneity
 - Heterogeneity score $\geq 10\%$ (difference in emphysema score between the target and ipsilateral lobe)

Evaluation Process



1. Referral
2. Patient entered into database
3. Pre-clinic screen (Chart review and phone call). We will enter a “Pre-Clinic Screen” note on EPIC.
4. Complete pending tests if any (cPFT, TTE, ABG, 6MWD, HRCT)
5. BLVR clinic visit with same-day testing.
6. Chest CT → QCT analysis (usually 3-5 business days)
7. At this point we contact the patient to notify if they are a candidate or not
 1. Procedure scheduled vs. Patient not a candidate based on QCT (ie. Fissure integrity <80% or low emphysema score)
8. Insurance approval (fully covered by Medicare, others needs prior authorization)
9. Procedure (average referral to procedure time 11 weeks)
10. Hospital admission (5d)
11. 45d clinic visit with repeat cPFT and 6MWD
12. 6 month clinic visit

BLVR at HFH (as of 10/21/19)



	2019												
BLVR	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec	Totals
Referral	5	5	4	11	10	5	10	22	11	28			111
Clinic visits	0	1	1	4	4	6	7	9	9	13			54
Procedures	0	0	0	1	4	1	2	2	3	4			17
Removal/Replace Valve							1						1

Who and How to Refer?

- Patient with confirmed COPD/emphysema
- Optimized medical therapy
- Completed or enrolled in pulmonary rehabilitation
- Quit smoking (at least 4 months)
- Can tolerate bronchoscopy under general anesthesia
- cPFT showing
 - FEV₁ 15-45%
 - RV $\geq$ 175%
 - TLC $\geq$ 100%

- Jill Bunn RN (161063)
- Rebecca Priebe NP (313) 623-6336
- Rolando Peralta MD

Box 5: When to refer for LVR procedures for COPD (surgery or endobronchial valve placement)

At the end of pulmonary rehabilitation, a person with COPD's condition should have been optimised as far as is going to be possible.

At this point, and at subsequent clinical reviews:

1. Think about whether LVR is a possible intervention if the following criteria are met:

- FEV₁ <50%
- limited by breathlessness (typically MRC breathlessness score of 4 or 5)
- person does not smoke
- able to walk at least 140 m in six minute walk test.

2. If yes, offer a respiratory review to further assess whether

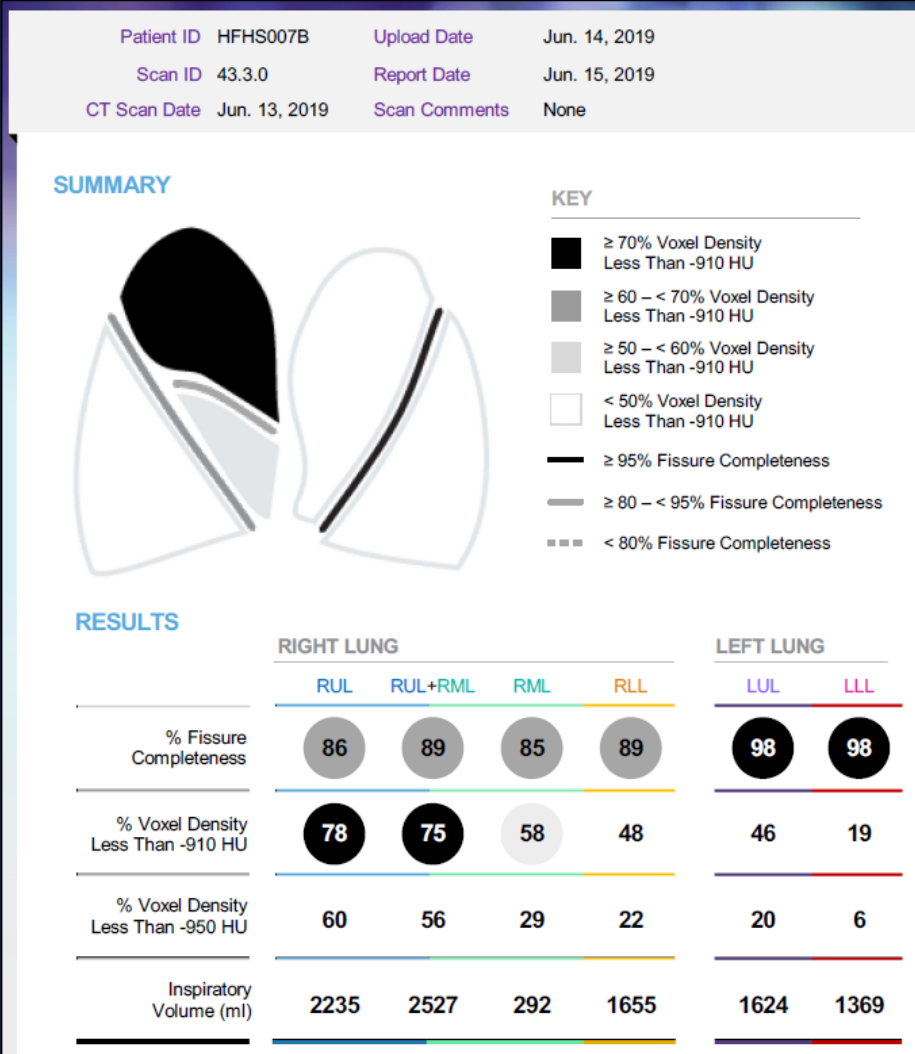
- lung function shows hyperinflation **and**
- unenhanced computed tomography scan of the chest shows emphysema **and**
- treatment of comorbidities has been optimised.

3. If yes, refer to a specialist LVR team to consider technical suitability for LVR.

Patient GL-HFHS007

CV negative
RUL occlusion

- FEV1 41% → 57%
- RV 239% → 165%
- BODE 6 → 1
- 6MWD 195 → 380



Thank you!

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