

CASE STUDY

InterVapor®



Treating Physician: Dr. Franz Stanzel
Hospital / Country: Lungenklinik Hemer, Germany

Patient Background

Age / Gender: 76 years / male
Disease: COPD Stage IV, severe emphysema, heterogenous, upper lobe predominant
Clinical History: Smoker 1970-2010
Referral Pathway: Issues with daily activities, shortness of breath

Procedure

Basis of decision to treat with BTVA* (InterVapor®):

This patient was first treated in the STEP UP clinical trial; he then returned several times to get (sub-) segmental Vapor treatment. He had positive collateral ventilation (CV+).

First-Treatment

2014, Oct 1
RB1 - subsegment a

2015, Jan 6
LB1

Additional Treatments

2016, June 1 : RB2
2017, July 6 : LB3
2018, Oct 25 : RB1 - subsegment b

IMAGES



2014 - Placment of the InterVapor catheter prior treatment



2018 - View into submegment after InterVapor treatment

Quality of life changes: The patient's quality of life improved after each procedure; since this is a progressive disease, over the course of four years he had a little decline which was resolved after a new treatment.

Adverse Events: None

CONCLUSION

PHYSICIAN PERSPECTIVE ON OUTCOMES:

The treating physician, Dr. Stanzel, states that the patient improved after every treatment but over time declined again (also getting older, now turning 77 in 2019). InterVapor offers the ability for a repeated, stepwise disease control post initial treatment and provides additional improvement as the patient begins to decline with a progressive disease. Note that all other ELVR therapies are one shot fixes and the patients will decline due to the nature of the disease.

The patient had a relatively little decline in FEV₁ after 4 years (1.02 to .92), 6MWT went down 120M after 3 years and RV stayed relatively stable over 4 years (.36L increase). Note that the volume of the most diseased segment on the left (LB1) was reduced from 1203 ml to 292 ml.

It is feasible and safe to treat patients multiple times. This particular patient was limited to only upper lobe treatment options.

PULMONARY FUNCTION CHANGES

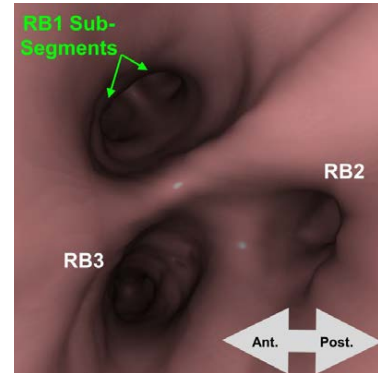
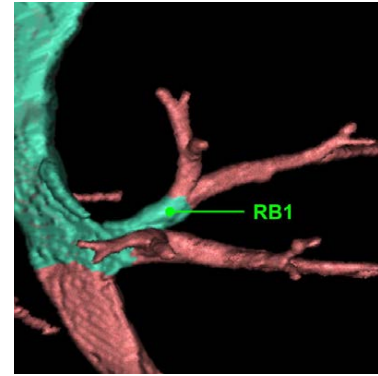
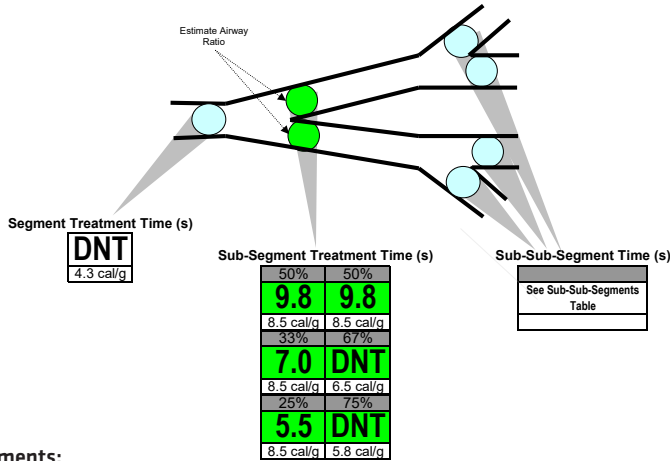
RIGHT UPPER LOBE SEGMENT: RB1 (LAST TREATMENT)

Segment volume:	1723 ml
Segment mass:	95 g
Percent of lobe:	58%
Emphysema (%-950)	67%

Target Vapor Dose:	8.5 cal/g
Vapor Dose Lower Limit:	7.5 cal/g
Vapor Dose Upper Limit:	8.5 cal/g

Preferred treatment location: **Sub-Segmental Level**

A sub-segmental treatment is preferred because a segmental treatment would result in an out of range dose.



Comments:

An RB1 sub-segment was treated on 1-Oct-2014. Only the untreated RB1 sub-segment is available for treatment.

Note: Never apply InterVapor twice to the same region. DNT=Do Not Treat

The STEP-UP trial protocol is designed to start conservatively. The first treatment targets the most diseased segment accounting for 50% on average of the first lobe. The second treatment 3 months later, "steps-up" to 60% on average and also targets the most diseased segments of the second lobe.

FEV1

19.9.14:	1.02 l*
12.10.15:	1.11 l
2.12.15:	1.14 l
15.2.16:	1.32 l*
11.7.17:	1.05 l
24.10.18:	0.92 l

Comment: Good improvement until 2016* (+30% from Step-Up baseline) declining again with progression of disease and old age.

6 Min Walk Test

26.9.14:	295 m
18.12.14:	390 m
1.4.15:	340 m
12.10.15:	320 m
24.10.18:	195 m

Comment: Clinically meaningful improvement at 1 year after Baseline of Step-Up.

RV

19.9.14:	5.61 l (214%)
1.4.15:	5.39 l
15.2.16:	5.49 l
11.7.17:	4.92 l
24.10.18:	5.97 l

Comment: Good improvement over time but sharp decline in 2018, no data as yet post 5th treatment in October 2018

Bronchoscopic Thermal Vapor Ablation (BTVA®) treatment included in the

2019 GOLD Guidelines

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