

Ελάττωση του πνευμονικού όγκου  
(Lung Volume Reduction)  
στο εμφύσημα  
Θωρακοσκοπική επέμβαση

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ΓΝΝΘΑ “Η Σωτηρία”

LVRS vs. medical therapy

BLVR vs. medical therapy

## LVRS vs. BLVR

| NCT identifier | Sponsor                                | Device        | Patients | Centres | Countries | Key inclusion criteria   | Primary endpoint          | Status     | Estimated primary completion |
|----------------|--|---------------|----------|---------|-----------|--|---------------------------|------------|------------------------------|
| ISRCTN19684749 | National Institute for Health Research | Valve vs LVRS | 76       | 1       | UK        | FEV <sub>1</sub> 20-60% of predicted; RV >170%; absence of collateral ventilation; heterogeneous emphysema | Change in iBODE at 1 year | Recruiting | March, 2018                  |

LVRS

Open vs. VATS

# VATS vs Μέση Στερνοτομή

Θνητότητα (90 ημέρες): VATS 4,6% - ΜΣ 5,9%, P=0,67

Διεγχειρητική απώλεια αίματος: P=0,55

Ανάγκες για μετάγγιση: P=0,99

Μέσος εγχειρητικός χρόνος: **ΜΣ** < VATS, P<0,001

Διεγχειρητική υποξαιμία: VATS 5,3% - **ΜΣ** 0,8%, P=0,004

Διεγχειρητικές επιπλοκές: VATS 13,8% - **ΜΣ** 7%, P=0,02

Μέση διάρκεια νοσηλείας: **VATS** 9 ημ. - ΜΣ 10 ημ., P=0,01

Ανεξάρτητη επιβίωση στις 30 ημέρες: **VATS** 80,9% - ΜΣ 70,5%, P=0,0

Λειτουργικά αποτελέσματα παρόμοια στους 12 & 24 μήνες

Κόστος νοσηλείας: **VATS** < ΜΣ, P=0,03

Συνολικό κόστος στους 6 μήνες: **VATS** < ΜΣ, P=0,005

- Αύξηση της πίεσης ελαστικής επαναφοράς - αύξηση της εκπνευστικής ροής
- Μείωση της υπερέκπτυξης - βελτίωση της μηχανικής του διαφράγματος/θωρακικού τοιχώματος
- Μείωση της ανομοιογένειας αερισμού/αιμάτωσης, καλύτερη ανταλλαγή αερίων
- Συγχρονισμός της κίνησης του πνεύμονος με το θωρακικό



**Cochrane**  
**Library**

**Cochrane Database of Systematic Reviews**

## **Lung volume reduction surgery for diffuse emphysema (Review)**

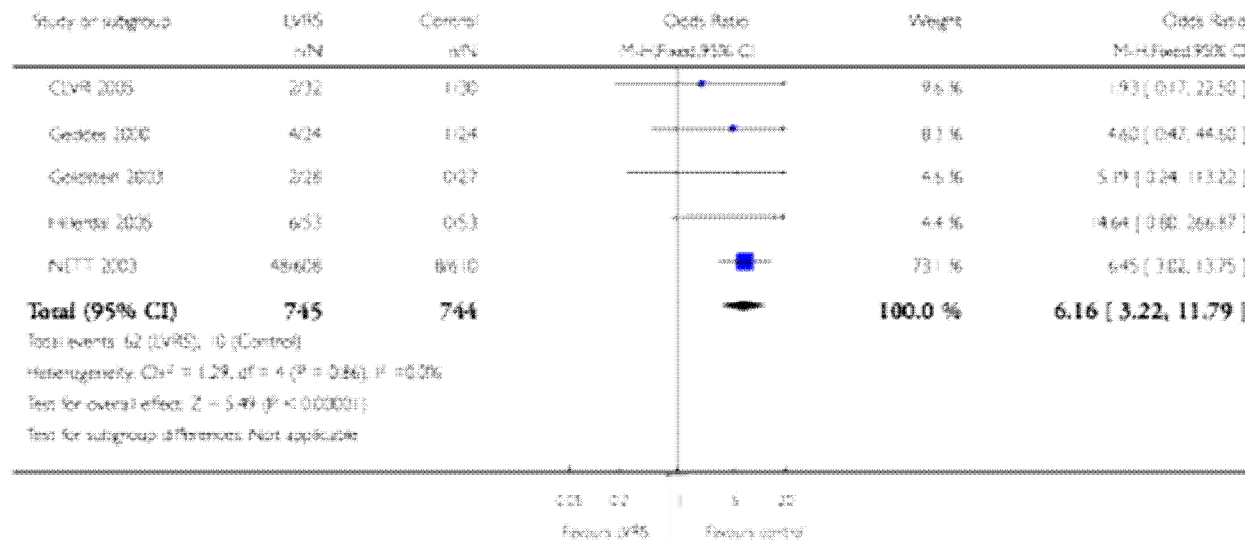
**van Agteren JEM, Carson KV, Tlong LU, Smith BJ**

**Analysis 1.1. Comparison 1 Surgery versus control, Outcome 1 Early mortality (90 days).**

Review: Lung volume reduction surgery for diffuse emphysema

Comparison: 1 Surgery versus control

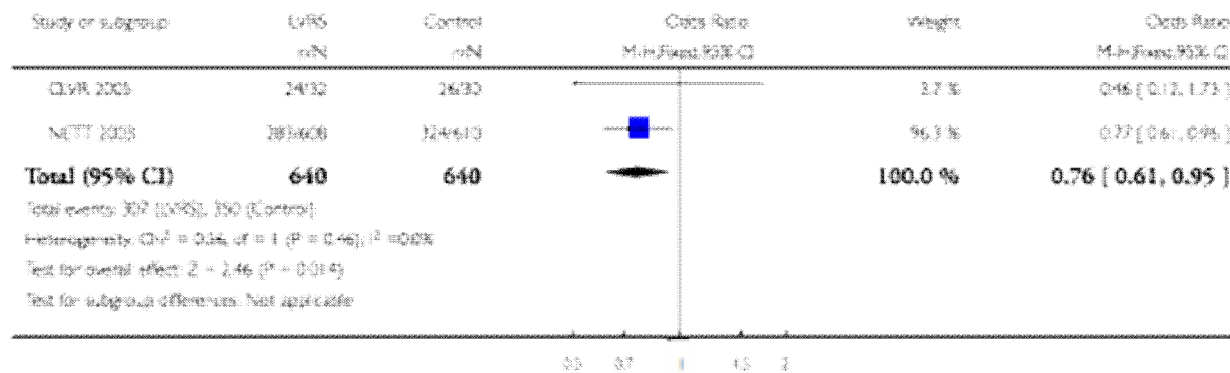
Outcome: 1 Early mortality (90 days)

**Analysis 1.2. Comparison 1 Surgery versus control, Outcome 2 Long-term mortality (> 36 months).**

Review: Lung volume reduction surgery for diffuse emphysema

Comparison: 1 Surgery versus control

Outcome: 2 Long-term mortality (&gt; 36 months)

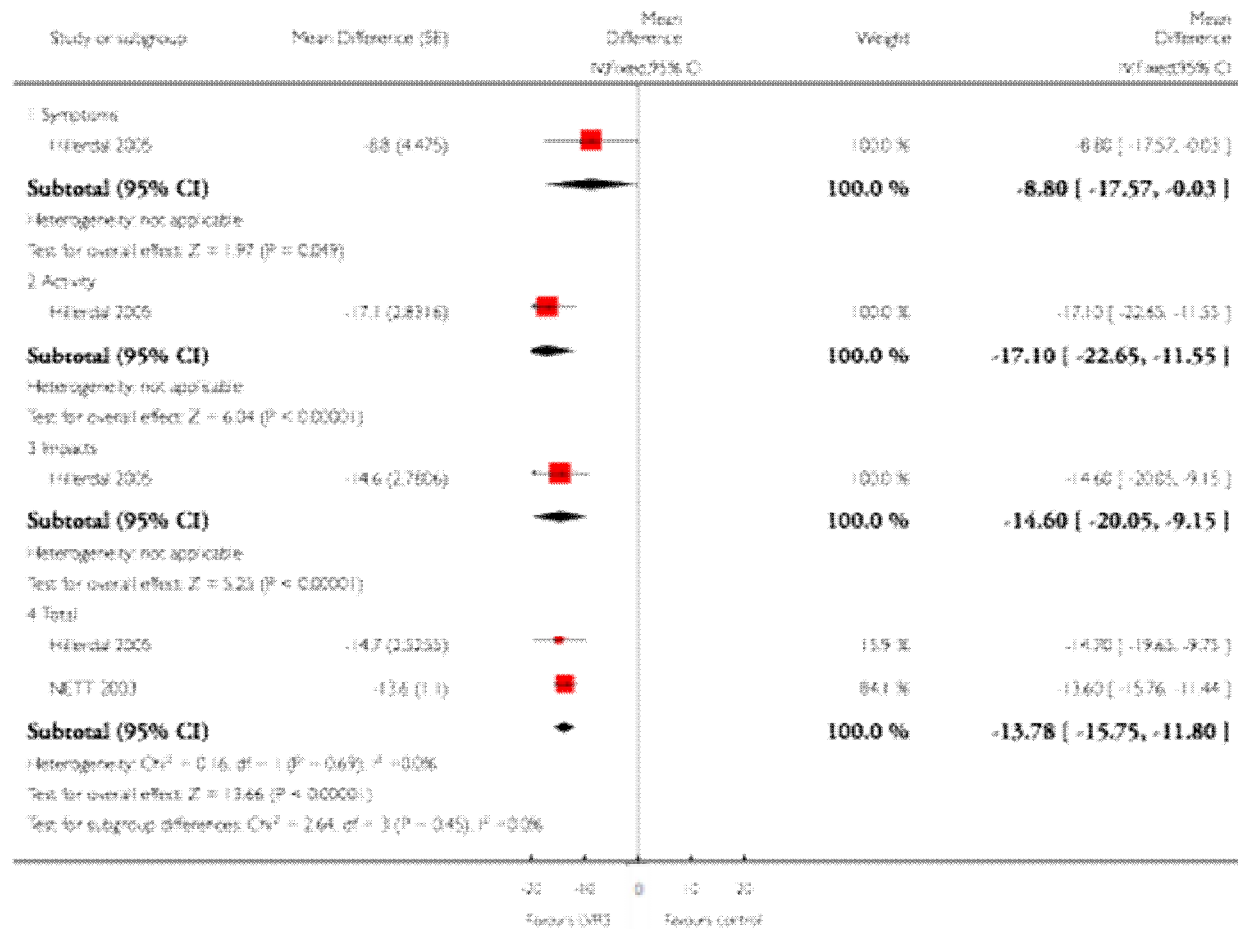


**Analysis 1.6. Comparison 1 Surgery versus control, Outcome 6 Change in SGRQ (end of follow-up).**

Review: Lung volume reduction surgery for diffuse emphysema

Comparison: 1 Surgery versus control

Outcome: 6 Change in SGRQ (end of follow-up)

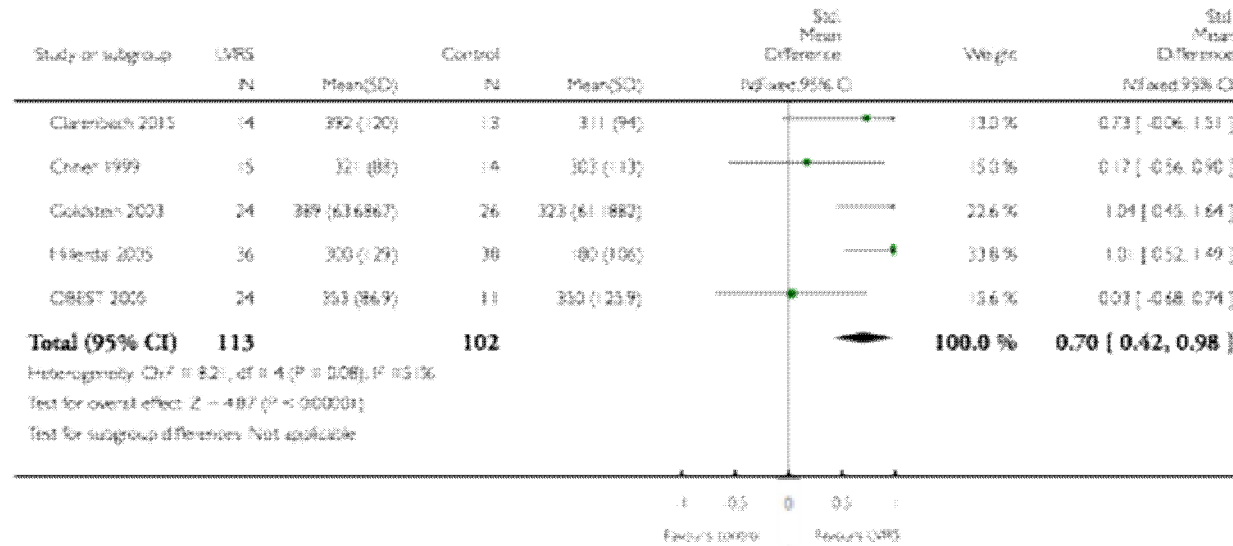


**Analysis 1.11. Comparison 1 Surgery versus control, Outcome 11 Walking Distance (Mtrs, end of follow-up).**

Review: Lung volume reduction surgery for diffuse emphysema

Comparison: 1 Surgery versus control

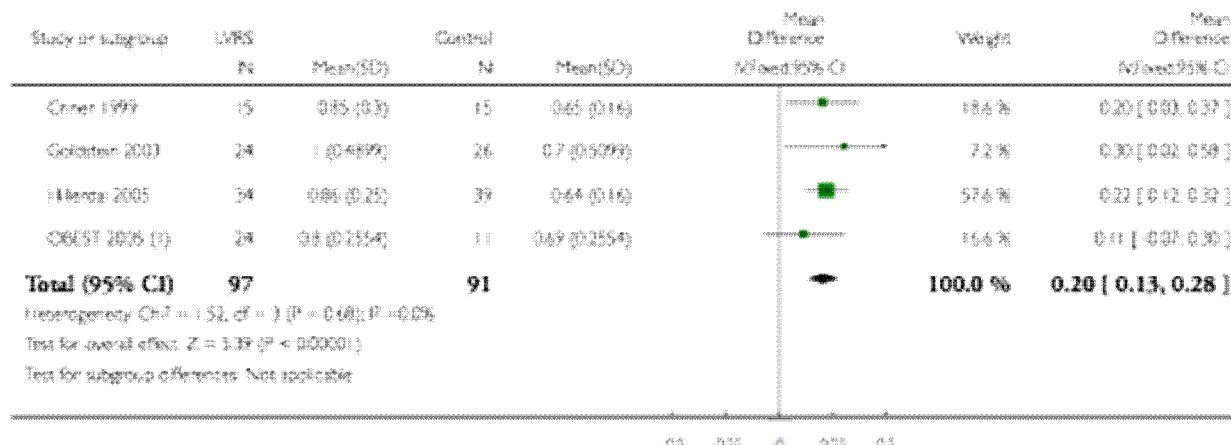
Outcome: 11 Walking Distance (Mtrs, end of follow-up)

**Analysis 1.12. Comparison 1 Surgery versus control, Outcome 12 FEV1 (L, end of follow-up).**

Review: Lung volume reduction surgery for diffuse emphysema

Comparison: 1 Surgery versus control

Outcome: 12 FEV1 (L, end of follow-up)





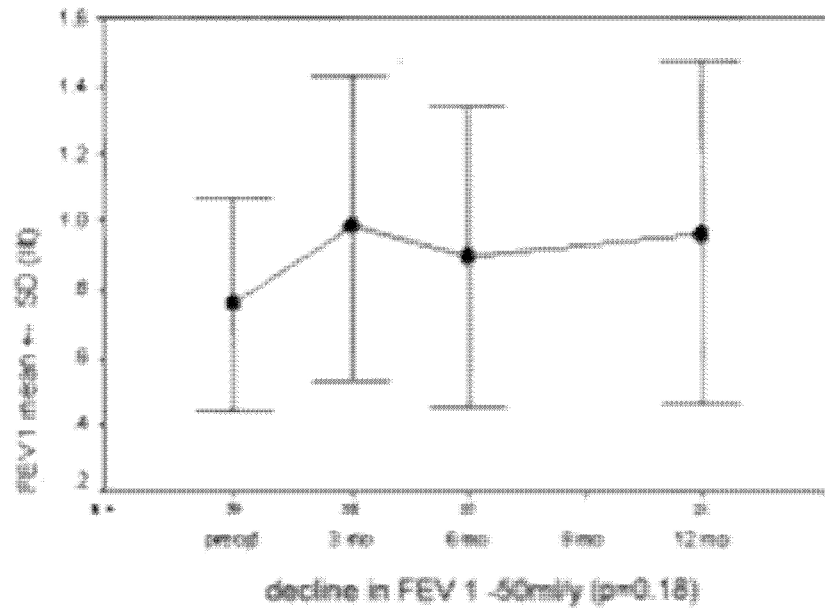
| Outcomes                                       | Anticipated absolute effects* (95% CI)   |   | Relative effect (95% CI) | No. of participants (studies) | Quality of the evidence (GRADE) | Comments  |
|--|--|---|--------------------------|-------------------------------|---------------------------------|---|
|  | Risk with control  | Risk with surgery   |                          |                               |                                 |   |
| Early mortality (90 days)                      | 13 per 1000  | 77 per 1000 (42 to 138)   | OR 6.16 (3.22 to 11.79)  | 1489 (5 RCTs)                 | ⊕⊕⊕○ MODERATE <sup>e</sup>      |   |
| Long-term mortality (> 36 months)              | 547 per 1000   | 478 per 1000 (424 to 534)   | OR 0.76 (0.61 to 0.95)   | 1280 (2 RCTs)                 | ⊕⊕⊕○ MODERATE <sup>e</sup>      | Substantial differences in follow-up between the 2 trials measuring this construct  |
| Change in total scores SGRQ (end of follow-up) | End of treatment control group mean SGRQ scores ranged from 57 units to 62.1 units             | Mean SGRQ score in the LVRS group was -13.78 units lower (-15.75 to -11.78)                             | -                        | 1326 (2 RCTs)                 | ⊕⊕⊕○ MODERATE <sup>e</sup>      | Lower score indicates better quality of life. A difference of 4 units or more is thought to be clinically important             |
| Walking distance (end of follow-up)            | Control group walking distance ranged from 303 to 350 metres (in the 4 studies reporting 6MWD) | Standardised mean walking distance in the LVRS group was 0.70 standard deviations higher (0.42 to 0.98) | -                        | 215 (5 RCTs)                  | ⊕⊕○○ LOW <sup>e,d</sup>         | Four studies reported 6MWD test and 1 shuttle walking test. 0.7 standard deviations equates to approximately 70 metres for 6MWD |
| FEV <sub>1</sub> (end of follow-up)            | Control group FEV <sub>1</sub> ranged from 0.64 L to 0.7 L FEV <sub>1</sub>                    | Mean FEV <sub>1</sub> in the LVRS group was 0.2 L higher (0.13 to 0.28)                                 | -                        | 188 (4 RCTs)                  | ⊕⊕○○ LOW <sup>e,f</sup>         |   |

Όλοι οι ασθενείς θα πρέπει να έχουν υποβληθεί σε εντατική  
**φυσικοθεραπεία του αναπνευστικού** πριν παραπεμφθούν για  
χειρουργική εκτίμηση

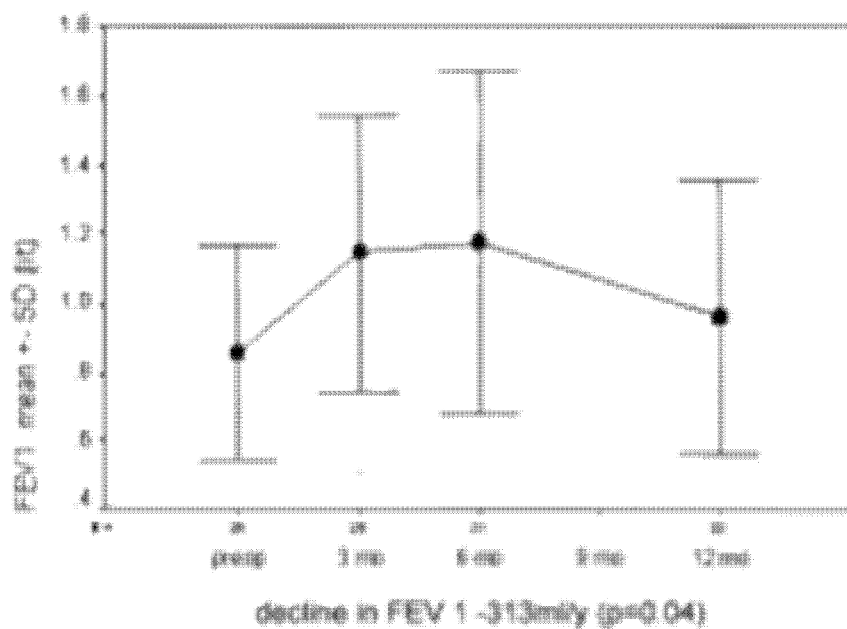
Ασθενείς υψηλού κινδύνου, είναι εκείνοι με **χαμηλές αναπνευστικές  
απεδρείες (< 20%)** και **ομοιογενές εμφύσημα**

Σημαντικότερο το όφελος σε αυτούς με **εμφύσημα κυρίως των άνω  
λοβών** και με **χαμηλή ικανότητα άσκησης**

change in FEV1 after unilat LVRS

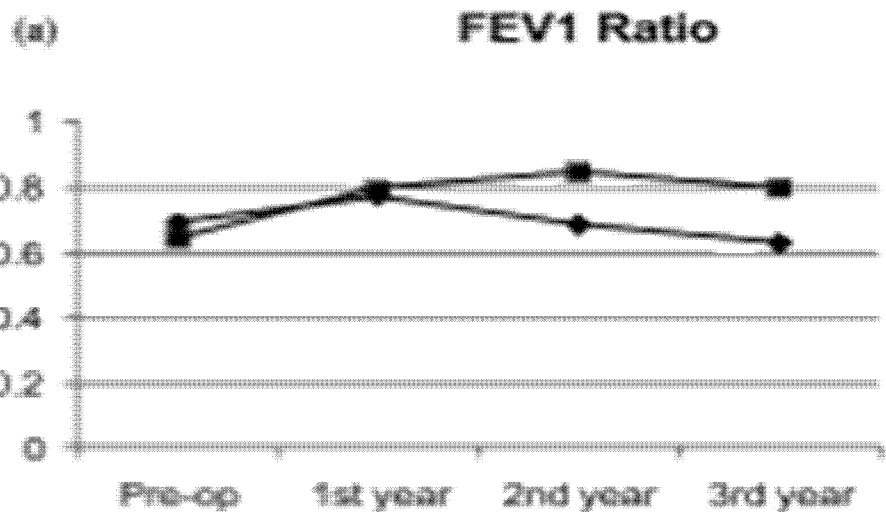


change in FEV1 after bilat LVRS

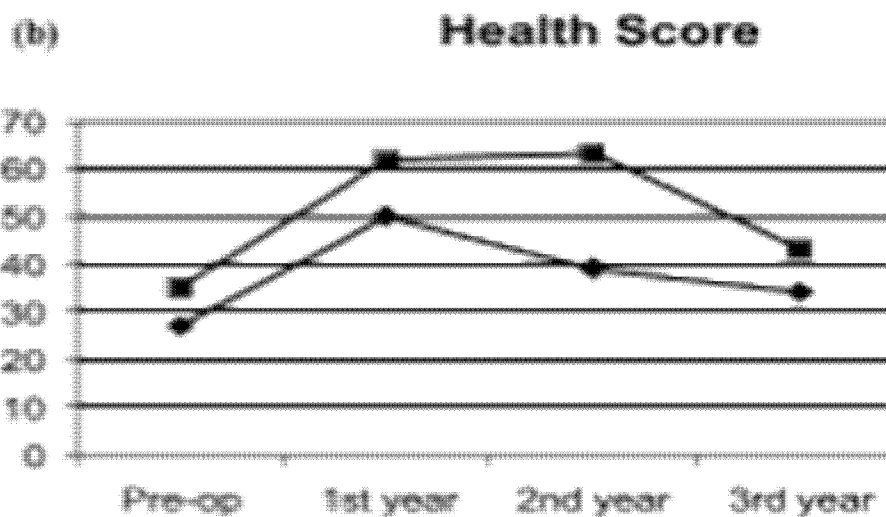


Perioperative course

|                           | Mean (SD)  |             | P-value |
|---------------------------|------------|-------------|---------|
|                           | Unilateral | Bilateral   |         |
| Lung resected (g)         | 80 (41)    | 118 (46)    | 0.0003  |
| ITU stay (days)           | 2 (13)     | 7 (9)       | 0.04    |
| Postoperative stay (days) | 16 (10)    | 28 (22)     | 0.004   |
| Postoperative ventilation | 2/39 (5%)  | 11/26 (42%) | 0.0002  |
| 30 day mortality          | 1/37 (3%)  | 2/26 (8%)   | 0.34    |



◆ Unilateral  
■ Sequential



◆ Unilateral  
■ Sequential

**Intra-group comparison following second operation in sequential cohort**

|                            | 1st op.     | 2nd op.     | Change       | P-value     |
|----------------------------|-------------|-------------|--------------|-------------|
| <b>FEV<sub>1</sub></b>     | <b>0.77</b> | <b>0.83</b> | <b>+3.1%</b> | <b>0.37</b> |
| <b>TLC</b>                 | <b>6.91</b> | <b>6.8</b>  | <b>-2.1%</b> | <b>0.87</b> |
| <b>MBC (dynamic index)</b> | <b>2.87</b> | <b>2.97</b> | <b>+3.5%</b> | <b>0.36</b> |
| <b>Health score</b>        | <b>62</b>   | <b>63</b>   | <b>+1.6%</b> | <b>0.72</b> |

**Table I. Baseline comparison of patients in the laser and staple-treated surgical groups**

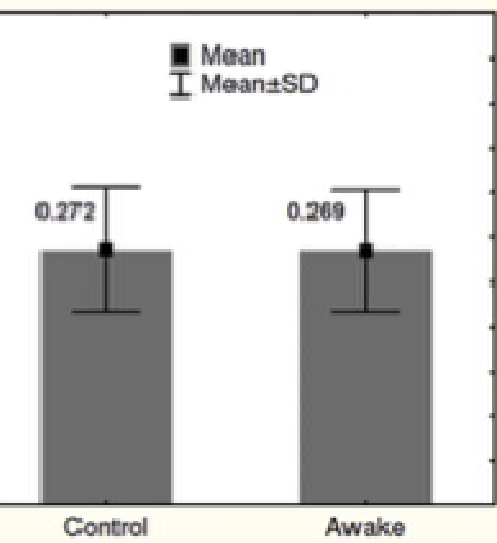
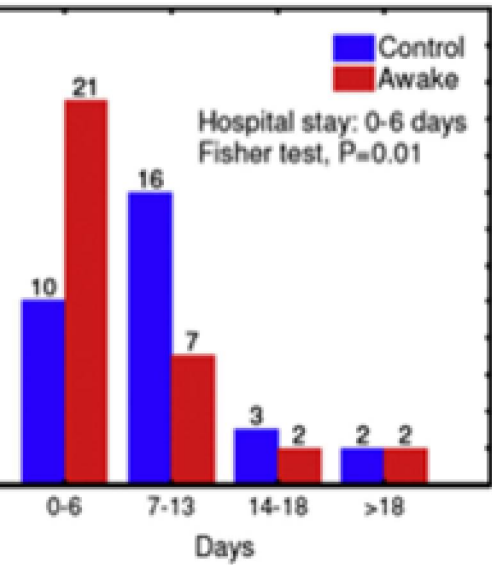
|  | Laser       | Staple      | <i>P</i> Value |
|--|-------------|-------------|----------------|
| No. of patients                        | 33          | 39          | <i>NS</i>      |
| Male (No.)                             | 26          | 32          | <i>NS</i>      |
| Age (yr)                               | 69 ± 6      | 66 ± 8      | <i>NS</i>      |
| FEV <sub>1</sub> (L)                   | 0.7 ± 0.2   | 0.7 ± 0.2   | <i>NS</i>      |
| FVC (L)                                | 2.1 ± 0.7   | 2.1 ± 0.7   | <i>NS</i>      |
| RV (L)                                 | 5.1 ± 1.1   | 5.4 ± 0.2   | <i>NS</i>      |
| TLC (L)                                | 7.6 ± 1.4   | 7.9 ± 1.3   | <i>NS</i>      |
| DtCO <sub>50</sub> (ml/min/mm Hg)      | 5.4 ± 3.0   | 8.6 ± 19    | <i>NS</i>      |
| P <sub>a</sub> O <sub>2</sub> (mm Hg)  | 65 ± 12     | 66 ± 12     | <i>NS</i>      |
| P <sub>a</sub> CO <sub>2</sub> (mm Hg) | 43 ± 7      | 44 ± 8      | <i>NS</i>      |
| SGaw (L/sec/cm H <sub>2</sub> O/L)     | 0.03 ± 0.01 | 0.03 ± 0.01 | <i>NS</i>      |
| Smoking (pack-years)                   | 62 ± 20     | 68 ± 24     | <i>NS</i>      |
| CT emphysema score <sup>6</sup>        | 60 ± 21     | 56 ± 21     | <i>NS</i>      |
| Dyspnea grade <sup>7</sup>             | 3.1 ± 0.6   | 3.1 ± 0.7   | <i>NS</i>      |
| Oxygen use (No. of patients)           | 25          | 27          | <i>NS</i>      |

**Table II. Comparison of the complications for the two procedures**

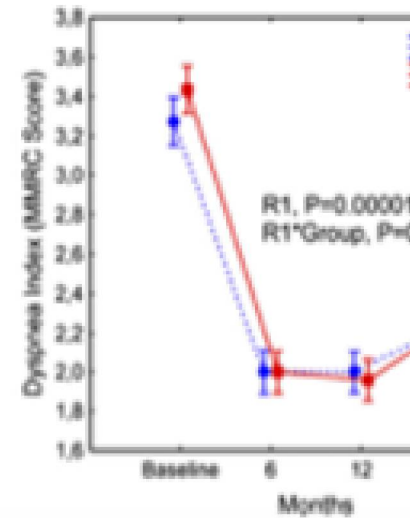
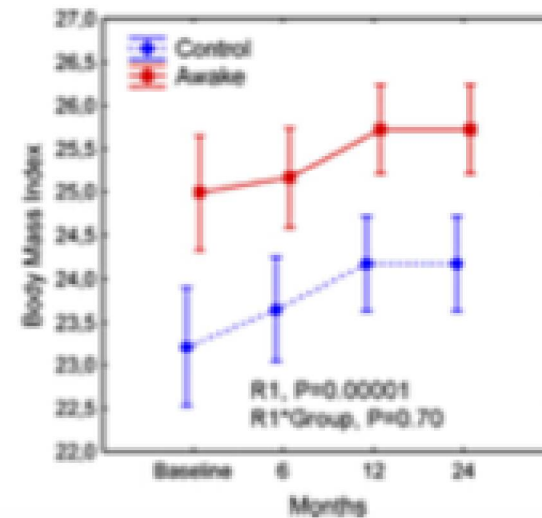
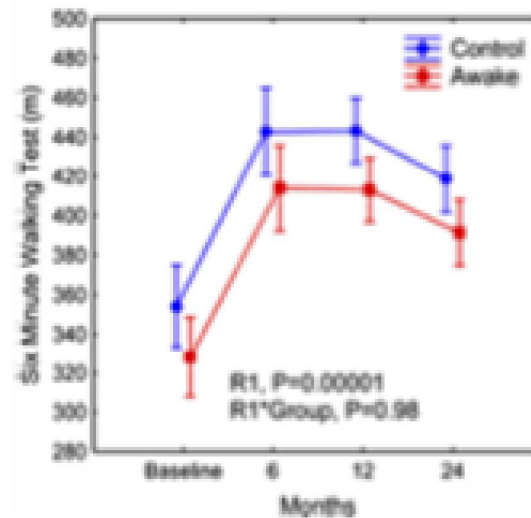
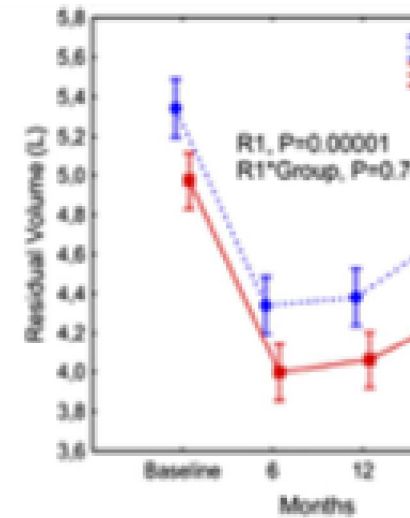
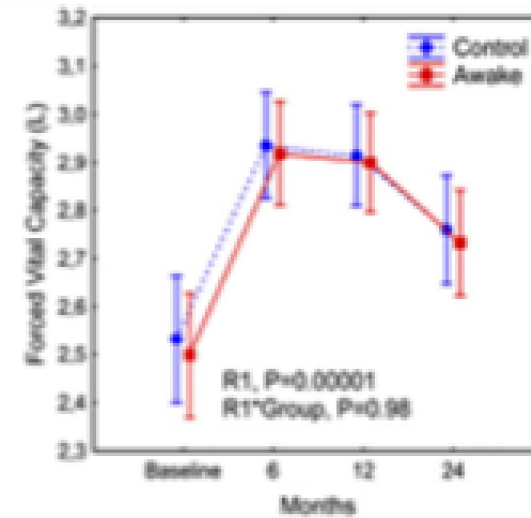
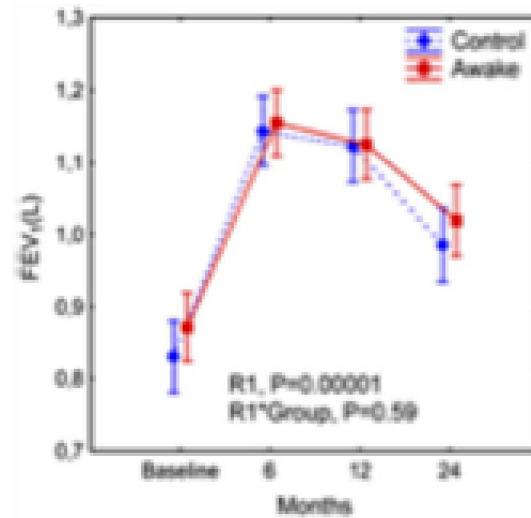
|                            | Laser<br>( <i>n</i> = 33) | Staple<br>( <i>n</i> = 39) | <i>p</i> Value |
|----------------------------|---------------------------|----------------------------|----------------|
| Hospital days (mean ± SD)  | 11 ± 12                   | 13 ± 11                    | <i>NS</i>      |
| Air leak >7 days (No.)     | 11 (33%)                  | 19 (48%)                   | <i>NS</i>      |
| Death (No.)                | 0                         | 1 (2.5%)                   | <i>NS</i>      |
| Respiratory failure (No.)  | 0                         | 1 (2.5%)                   | <i>NS</i>      |
| Operating time (hr)        | 2.1 ± 0.7                 | 1.9 ± 1.0                  | <i>NS</i>      |
| Take back (No.)            | 1 (3%)                    | 1 (2.5%)                   | <i>NS</i>      |
| Ileus (No.)                | 1 (3%)                    | 0                          | <i>NS</i>      |
| Deep vein thrombosis (No.) | 0                         | 1 (2.5%)                   | <i>NS</i>      |
| Delayed pneumothorax (No.) | 6 (18%)                   | 0                          | 0.005          |

- MOS-36 improvement: Laser 8/33, Staple 26/39, *p*=0.003
- Mean FEV1 improvement (6 months): Laser 0,09L, Staple 0,22L, *p*=0,01

# Primary outcomes



# Secondary outcomes



- Θωρακοσκοπική προσέγγιση προτιμάται έναντι της ανοικτής (όποτε αυτό είναι δυνατό)
- Μονόπλευρη εκτομή - σε δεύτερο στάδιο ετερόπλευρη εκτομή (εφόσον αυτό υπαγορεύεται από συμπτώματα και επιτρέπεται από φυσιολογική κατάσταση του ασθενούς)

**σας ευχαριστώ**