Cost-Effectiveness of Lung Volume Reduction Surgery

The Health Industry Forum

October 24, 2007 - Washington DC

The National Emphysema Treatment Trial
National Emphysema Treatment Trial (NETT)

Multicenter, randomized clinical trial comparing medical treatment with lung volume reduction surgery (LVRS) to medical treatment alone in patients with severe emphysema
Rationale

- Epidemiology of Emphysema
  - 2,000,000 affected
  - 32.4 cases per 1,000 in people over age 65.
  - Highest prevalence is in the white, low income, mid-west
  - 18,000 deaths in 1999.

- Clinical Management
  - Delay progressive decline in lung function
  - Prevent exacerbations
  - Improve survival and QOL
  - Surgery?
CMS LVRS Coverage History

- Prior to December 1995
  - LVRS coverage decisions left to local contractors

- September 1995
  - NHLBI workshop called for a controlled trial

- December 1995
  - HCFA issued a national coverage decision.
    - No reimbursement based on inadequacy of evidence and potential for extensive morbidity and mortality
NETT Treatment groups

- All patients
  - Pulmonary rehabilitation + optimal medical treatment

- Treatment Groups (randomized)
  1. Medical therapy
  2. LVRS
     - Median sternotomy
     - VATS
NETT Endpoints

- **Primary**
  - Survival
  - Maximum exercise capacity

- **Secondary**
  - Identify selection criteria for LVRS
  - LVRS effect on
    - Pulmonary function
    - Health related quality of life
    - Symptoms
  - Cost effectiveness
NETT Recruitment and Enrollment

Estimated inquiries: 
N = 31,000

Screened: 
N = 3,777 (12%)

Randomized: 
N = 1,218 (4%)
Results
Mortality: High Risk Subgroup

LVRS: Mortality increased

P = 0.06

N Engl J Med 2001; 345: 1075-83
Mortality: Non High Risk Patients

LVRS: No survival effect
Surgical Morbidity: Place of Residence (non high risk patients)

1 month*
- Home: 23.6%
- Hospital Rehab: 0.4%

2 months*
- Home: 9.3%
- Hospital Rehab: 0.4%

4 months*
- Home: 2.9%
- Hospital Rehab: 0.8%

*P<0.001

- Red = Surgical
- Yellow = Medical
Improved more than 10 watts in exercise capacity at 24 months

<table>
<thead>
<tr>
<th></th>
<th>Surgery % Imprvd</th>
<th>Medical % Imprvd</th>
<th>Odds-ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>15%</td>
<td>3%</td>
<td>6.27*</td>
</tr>
<tr>
<td>High-risk</td>
<td>7%</td>
<td>2%</td>
<td>3.48</td>
</tr>
<tr>
<td>Non high-risk</td>
<td>16%</td>
<td>3%</td>
<td>6.78*</td>
</tr>
</tbody>
</table>

* P < 0.001
### Change in Quality of Well-Being: Non high-risk survivors

**Quality of Well Being**

<table>
<thead>
<tr>
<th></th>
<th>6 Months</th>
<th>12 Months</th>
<th>24 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change from baseline</td>
<td>-0.8</td>
<td>-0.6</td>
<td>-0.4</td>
</tr>
<tr>
<td>No. of patients</td>
<td>439</td>
<td>422</td>
<td>366</td>
</tr>
<tr>
<td>Mean</td>
<td>0.02</td>
<td>-0.03</td>
<td>0.00</td>
</tr>
<tr>
<td>S.D.</td>
<td>0.12</td>
<td>0.12</td>
<td>0.13</td>
</tr>
</tbody>
</table>

- **= Surgical**
- **= Medical**

![Box plot showing change in quality of well-being over time for surgical and medical patients.](chart.png)
Subgroups
Predictors of differential outcome

**YES**
- FEV\(_1\) % predicted
- Homogeneity of emphysema
- D\(_L\)CO % predicted
- Maximum exercise capacity
- Upper-lobe predominance

**NO**
- Age
- Race
- Gender
- PaCO\(_2\)
- Hyperinflation
- RV % predicted
- RV / TLC
- VE / VCO\(_2\)
- Perfusion ratio
- QOL
Overall and Subgroup Treatment Effects

All Patients
- Mortality RR = 1.01
- Exercise OR = 6.27
- SGRQ OR = 4.90

Non High Risk Patients
- Mortality RR = 0.89
- Exercise OR = 6.78
- SGRQ OR = 5.06

High Risk Patients
- Mortality RR = 1.82
- Exercise OR = 3.48
- SGRQ OR = ∞

Upper Lobe
- Low Exercise
  - Mortality RR = 0.47
  - Exercise OR = ∞
  - SGRQ OR = 8.38
- High Exercise
  - Mortality RR = 0.98
  - Exercise OR = 5.81
  - SGRQ OR = 5.67

Non Upper Lobe
- Low Exercise
  - Mortality RR = 0.81
  - Exercise OR = 1.77
  - SGRQ OR = 7.35
- High Exercise
  - Mortality RR = 2.06
  - Exercise OR = 0.90
  - SGRQ OR = 1.35
### Costs and Outcomes for LVRS vs. Medical Therapy at 3 Years

<table>
<thead>
<tr>
<th></th>
<th>LVRS</th>
<th>Medical</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>531</td>
<td>535</td>
</tr>
<tr>
<td>Cost</td>
<td>$98,952</td>
<td>$62,560</td>
</tr>
<tr>
<td>QALYs</td>
<td>1.463</td>
<td>1.271</td>
</tr>
</tbody>
</table>

P<0.001 for costs and QALYs

Future costs and QALYs discounted at 3% per year after year 1
## Cost-Effectiveness of LVRS vs. Medical Therapy

<table>
<thead>
<tr>
<th></th>
<th>All Patients</th>
<th>Emphysema Subgroups</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Upper-lobe, low exercise capacity</td>
<td>Upper-lobe, high exercise capacity</td>
</tr>
<tr>
<td><strong>Observed at 3 years</strong></td>
<td>$190,000</td>
<td>$98,000</td>
</tr>
<tr>
<td><strong>Lifetime (projected)</strong></td>
<td>$54,000</td>
<td>$48,000</td>
</tr>
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CMS Coverage Decision

- Trial results announced spring 2003
- Coverage decision for LVRS was made by CMS August 20, 2003
- Coverage began January 1, 2004
LVRS is reasonable and necessary only if preceded and followed by a program of pulmonary rehabilitation – as per NETT.

LVRS is reasonable and necessary only when performed at NHLBI-certified NETT facilities and those accredited by CMS for lung transplantation.
“If the technology is effective, we would find a way to pay for it. There is no dollar value per life per year at which Medicare would decline to pay.”

August 16, 2003 NY Times
Sean Tunis, MD
Chief Medical Officer, CMS
What is the Economic Value of Information Gained From the NETT?

- **Value of Information Theory**
  - Gathering information via clinical trials is costly, but…
  - Making the wrong clinical decision is also costly
    - e.g., LVRS for patients where it is ineffective or harmful
  - We invest in clinical trials in part to improve clinical care
    - Increase likelihood of using effective treatments
    - Reduce chance of adopting ineffective/harmful therapies
## Costs Associated with Conducting the National Emphysema Treatment Trial

<table>
<thead>
<tr>
<th>Expense</th>
<th>Expenditure ($2003-millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study costs (investigators, support staff, clinical study coordinators, etc)</td>
<td>$37.2</td>
</tr>
<tr>
<td>Participant travel costs (paid from study funds)</td>
<td>$0.1</td>
</tr>
<tr>
<td>Patient evaluation and preparation costs, including the pre-trial rehabilitation program*</td>
<td>$2.7</td>
</tr>
<tr>
<td>Post-therapy rehabilitation</td>
<td>$1.0</td>
</tr>
<tr>
<td>Trial-related treatment costs*†</td>
<td>$18.1</td>
</tr>
<tr>
<td><strong>Total Estimated Expenditure</strong></td>
<td><strong>$59.2</strong></td>
</tr>
</tbody>
</table>
## Value of Information From the NETT

<table>
<thead>
<tr>
<th>Threshold WTP/QALY</th>
<th>WTP $50,000/QALY</th>
<th>WTP $100,000/QALY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incremental net benefit</td>
<td>$305,000/QALY</td>
<td>$305,000/QALY</td>
</tr>
<tr>
<td>Expected net benefit of sampling</td>
<td>$3.41 billion</td>
<td>$7.23 billion</td>
</tr>
<tr>
<td>Probability of change in decision</td>
<td>0.04</td>
<td>0.24</td>
</tr>
</tbody>
</table>
Linda Watson, who has advanced emphysema, underwent lung volume reduction surgery (LVRS) to improve her quality of life. In a nationwide study, physicians from Columbia University and NewYork-Presbyterian Hospital, along with their colleagues from other leading medical centers, demonstrated that LVRS can significantly improve breathing in certain patients. This is the first breakthrough in the treatment of advanced emphysema in decades. So now, more people like Linda can live better lives. To learn more, call 877-NYP-WELL or visit nyp.org.

Can a unique surgical procedure transform the treatment of emphysema?

N=324