Risk analysis for thoracoscopic lung volume reduction: a multi-institutional experience

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Abstract

Objective: Most reports of thoracoscopic lung volume reduction (TLVR) are relatively small and early experiences from a single institution, factors which limit both the statistical validity and the applicability to the population at large. In order to address these shortcomings we undertook an analysis of the TLVR experience at five separate institutions to assess operative morbidity and identify predictors of mortality.

Methods: Questionnaires were sent to four groups of surgical investigators at five institutions actively performing TLVR. Data was requested regarding preoperative, operative and postoperative parameters. Twenty-five potential predictors of mortality were analyzed and seven proved to be at least marginally significant ($P \leq 0.10$). These parameters were entered into a stepwise logistic regression analysis to identify independent predictors.

Results: The 682 patients (415 males, 267 females, mean age 64.0 years) underwent unilateral (410) or bilateral (272) TLVRs. Overall, operative mortality was 6% with half of the deaths resulting from respiratory causes. The remaining patients were discharged to home (88%), a rehabilitation facility (4%) or a ventilator facility (2%). There were 25 perioperative factors chosen representing clinically important indices such as spirometry, oxygenation, functional status, clinical and demographic variables. Univariate analysis identified seven variables as predictors of mortality ($P \leq 0.10$) and these were entered into a stepwise logistic regression analysis. Only age, 6-min walk, gender (male 8%, female 3% mortality) and the procedure performed (unilateral 4.6%, bilateral 8%) were independent predictors while preoperative steroid therapy, preoperative oxygen administration, and time since smoking cessation dropped out of the model. The specific institution, learning curve (early vs. late experience), type of lung disease, spirometric indices and predicted maximum VO$_2$ were not significant predictors.

Conclusion: This experience suggests that unilateral and bilateral lung volume reduction procedure can be performed with acceptable morbidity and mortality. Although age, gender, exercise capacity and the procedure performed are all independent predictors of mortality, the risk of operative death did not appear excessive in this fragile patient subset. © 2000 Elsevier Science B.V. All rights reserved.

Keywords: Lung volume reduction; Pulmonary emphysema; Postoperative complications; Emphysema; Treatment outcome

1. Introduction

At the end of 1995, the Health Care Finance Administration (HCFA) decided to halt reimbursement for lung volume reduction operations in the United States. This was based partially on a health technology assessment report which reported a ‘substantial mortality’ of at least 6% with no reported long-term results demonstrating efficacy [1]. Lung volume reduction (LVR) is undertaken in a fragile subset of patients with little physiologic reserve and thus the potential operative morbidity is significant. Although the majority of series report operative deaths in the 3–8% range [2–6], mortality in excess of 10% has also been published [7,8]. Identifying clinical predictors of mortality could allow physicians the opportunity for better patient selection with potentially lower mortality. The risk analyses performed previously have been undertaken on small patient cohorts, usually from a single institution. This limits the statistical power of the analysis and its applicability outside a given institution. In order to address these short-
comings we undertook an analysis of TLVR performed by four surgical groups at five separate institutions in an attempt to identify significant independent predictors of operative mortality.

2. Materials and methods

Each of the participating institutions have been involved in the intramural prospective collection of data regarding lung volume reduction patients. In order to harvest and combine these separate prospective databases, questionnaires were sent to the five participating centers (Allegheny University, Saint Louis University, Southern Illinois University, University of Pennsylvania, University of Pittsburgh) utilized by the four surgical groups. The specific information requested in these questionnaires has been previously published [9] and included demographic, clinical, spirometric and functional preoperative data. Additional information regarding operative mortality and morbidity was also requested. Only those patients undergoing lung volume reduction surgery for end-stage emphysema using a thoracoscopic approach were included. Patients with giant bullae and patients who required conversion from a thoracoscopic approach to thoracotomy were not included in this study. Patient selection criteria were similar among the centers and have been described in previous publications by the authors [3,10–12].

In summary, patients selected to undergo surgery have both the radiographic and spirometric criteria for the diagnosis of end-stage emphysema. Inclusive criteria consisted of evidence of severe air flow obstruction with an FEV$_1$ in the range of 15–35% of predicted and a residual volume (RV) usually in excess of 200% of predicted as measured by body plethysmography. The chest X-rays and CT scans had to demonstrate changes of hyperinflation. Quantitative ventilation/perfusion lung scanning was performed to identify variable areas of perfusion within the lung fields. The ideal patient was felt to have heterogeneous disease with focal zones of hypoventilated and hypoperfused lung, most commonly in the apices. However, several institutions did perform LVR in patients with diffuse disease. Exclusion criteria included tobacco usage within 3 months prior to evaluation, pulmonary artery systolic pressure >50 mmHg, significant obesity (>1.25 ideal body weight or cachexia (<0.75 ideal body weight) ventilator dependence and radiographic, clinical or spirometric evidence of chronic bronchitis, bronchiectasis or bronchospasm. All patients were referred for 6 weeks of preoperative pulmonary rehabilitation although not all patients were able to successfully complete this regimen and some others refused. The preoperative clinical parameters recorded and analyzed included age, gender, race, body mass index, number of pack years of smoking, interval since smoking cessation in years, work status (working vs. retired/disabled), preoperative oxygen usage (none vs. continuous or intermittent), preoperative steroid usage (at the time of surgery), ability to complete preoperative rehabilitation, documented alpha-1-antitrypsin disease and the nature of emphysema (heterogeneous vs. homogeneous distribution as assessed by the surgeon). Spirometric and functional data included the actual functional vital capacity (FVC), percent predicted FVC, actual forced expiratory volume in one second (FEV$_1$), percent predicted FEV$_1$, actual residual volume (RV), percent predicted RV, preoperative partial pressure of oxygen (pO$_2$), preoperative partial pressure of carbon dioxide (pCO$_2$), preoperative maximum oxygen consumption (VO$_2$) and the preoperative 6-min walk distance. These 22 preoperative parameters were to be tested for significance. In addition, three surgical parameters were assessed for their effect on mortality. These included the surgical group performing the operation, the extent of LVR (unilateral vs. bilateral), and the surgical learning curve. This latter parameter was tested by dividing the operative experience of each group into equal halves chronologically (early and late half of the experience) and then summing the four ‘early’ and four ‘late’ patient cohorts to produce cumulative patient cohorts representing the early and late phases of the learning curve.

The choice of whether to undertake a unilateral or bilateral procedure was made by each surgeon and the criteria changed with time. Initially most surgeons performed a unilateral procedure alone. With increased experience, individual surgeons felt comfortable performing bilateral procedures as the operation of choice. However, unilateral procedures continued to be performed in specific cases in which there were contraindications to a bilateral procedure (prior thoracotomy, prior empyema, prior pleurodesis, predominantly asymmetric or unilateral disease).

Hospital mortality was defined as any death within 30 days of the operation or any death which occurred during hospitalization either within the acute care facility or in a ventilator or rehabilitation facility prior to the patient being discharged home. The cause of death was also recorded.

Data were analyzed using StatView for Windows (SAS Institute, Inc., Cary, NC, Version 5.01). Statistical analysis consisted of a Mann–Whitney test for continuous variables and a chi square contingency table, or Fisher’s exact test, for discrete variables. Means are expressed with ±1 standard deviation. A $P$ value of less than 0.05 was considered significant while a $P$ value of less than 0.10 and greater than 0.05 was considered marginally significant. Both significant and marginally significant variables were then entered into a stepwise logistic regression analysis to identify significant independent predictors of operative mortality.

3. Results

3.1. Preoperative profile

Between February 1993 and July 1998, there were 682
thoracoscopic lung volume reduction (TLVR) procedures performed by one of four surgical groups at one of the five participating institutions. Patients included 415 males and 267 females with a mean age of 64 years (range 36–87). Bilateral TLVR was performed in 272 patients and in 410 patients the TLVR was unilateral. Of these 410 unilateral procedures, 72 of the procedures were the first of two staged operations; the contralateral TLVR operation was performed at an interval between 1 and 43 months (mean 9.5 months) after the initial TLVR. For purposes of risk analysis, only the primary unilateral TLVR in staged patients was considered. This was done since all patients who were staged had to survive the initial procedure. In addition, the second procedure was excluded since only staged patients would have the additional risk factor of a previous TLVR. Two of 72 staged patients died after the second procedure (operative mortality 2.7%). In each of the four surgical groups, the operative experience was divided into that occurring during the first half of the 68-month interval (‘early’ cases) and that occurring during the second half of the period (‘late’ cases) so that potential differences resulting from a learning curve could be assessed.

3.2. Operative mortality

There were 41 patients who died either within 30 days of the procedure or prior to eventual discharge to home (see Fig. 1). The most common cause of death was due to respiratory compromise (adult respiratory distress syndrome in three, pneumonia in four and progressive respiratory failure in 13) which accounted for 49% of (20/41) of the deaths. In ten patients (24%) a cardiac cause of death (nine acute myocardial infarction, one sudden death) was identified. In five patients (12%) non-pulmonary sepsis (four gastrointestinal sepsis, one fungal empyema) was the cause of death while multi-organ failure was the reported cause of death in an additional five patients. The final patient died of progressive pulmonary hypertension. The deaths occurred from 6 h to 228 days following surgery with a median death interval of 25 days. Seventeen of the 41 deaths (41%) occurred more than 30 days after surgery.

3.3. Risk analysis

Survivors and non-survivors were compared with regard to the 25 perioperative parameters listed previously. Table 1 depicts the clinical parameters. Significant univariate predictors of operative mortality included age (63.8 in survivors ±8.2 vs. 68.3 ± 7.6 in non-survivors, P = 0.0005), male gender (60% in survivors, 80% in non-survivors, P = 0.008), preoperative oxygen utilization (61% survivors, 71% non-survivors, P = 0.02) preoperative utilization of steroids (38% survivors, 54% non-survivors, P = 0.05) and years since smoking cessation (6.3 ± 5.7 in survivors, 8.6 ± 6.7 in non-survivors, P = 0.02). No significant differences could be seen with regard to body mass index, pack years of smoking, work status, ability to complete rehabilitation, presence of alpha-1 antitrypsin disease or the heterogeneity of emphysema as graded by the surgical investigators.

Table 2 depicts the spirometric and functional variables which were subjected to univariate analysis. Only the preoperative 6-min walk (885 ± 322 feet survivors, 740 ± 415 feet non-survivors, P = 0.002) proved to correlate with mortality. No spirometric or oxygenation indices were predictive. Finally, the three surgical variables (site of surgery, early vs. late experience, unilateral vs. bilateral procedure) were evaluated and are depicted in Figs. 1–3. Fig. 1 depicts the operative mortality of the four groups of surgical investigators (note that two institutions are included for one surgical group). There were no significant differences among the centers and operative mortality. Similarly, an analysis of the ‘learning curve’ was performed by
combining the operative mortalities during the first half of the study interval for all four surgical groups and comparing it to that from the second half of the interval (Fig. 2). There was no significant difference in these mortalities. The only surgical factor which appeared to carry even marginal significance was the unilateral vs. bilateral nature of the procedure (Fig. 3). Patients undergoing unilateral procedure sustained a 4.6% operative mortality vs. an 8% mortality for bilateral procedures, yielding a $P$ value of 0.06.

The seven significant or marginally significant univariate predictors were then entered into a stepwise logistic regression analysis. Four of the variables were found to be significant independent predictors (Table 3). A low 6-min walk distance, male gender, bilateral surgery and advanced age all proved to be significant independent predictors for operative mortality. The time interval from smoking cessation and the preoperative usage of either oxygen or steroids proved not to be predictive of mortality in this logistic regression analysis.

### 4. Discussion

The 1994 report which reintroduced lung volume reduction to the thoracic surgical community described a bilateral lung volume reduction performed through a median sternotomy and reported excellent functional results with a 0% operative mortality [13]. This was indeed ‘too good to be true’ and as Cooper and others enlarged their operative experience and broadened the selection criteria, operative mortalities became substantial in this fragile, high-risk patient subset. Thoracic surgeons experienced in video-assisted thoracic surgical techniques felt that perhaps this discipline might hold the key to a less invasive approach to lung volume reduction with lower morbidity. The purpose of this manuscript was to critically appraise the operative mortality of the thoracoscopic approach with the hopes of identifying predictors of mortality. As with any surgical procedure, the motivation behind this analysis is to optimize patient selection with the hopes of minimizing operative mortality in the future.

It is not surprising that approximately half the deaths occurring following TLVR are due to respiratory causes such as pneumonia, ARDS, and progressive respiratory insufficiency. Given the severely compromised respiratory status of this patient population, it would be surprising to find otherwise. However, 24% (10/41) of the patient population succumbed to significant cardiac morbidity including acute infarction and/or sudden death. This is not terribly surprising considering the advanced age, heavy smoking history and preponderance of males in this series. Indeed, Thurnheer reported a 15% incidence significant coronary occlusion in asymptomatic patients undergoing routine angiography during LVR evaluation [14]. For this reason, non-invasive evaluation of coronary ischemia has become routine at those institutions performing TLVR and the significant coronary artery disease is felt to be a contraindication to up-front surgery.

An additional 12% (5/41) of patients died directly due to sepsis from significant gastrointestinal complications (four

### Table 2

<table>
<thead>
<tr>
<th>Spirometry and function</th>
<th>Survivors ($n = 641$)</th>
<th>Non-survivors ($n = 41$)</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVC actual (l)</td>
<td>2.4 ± 0.8</td>
<td>2.43 ± 0.9</td>
<td>NS</td>
</tr>
<tr>
<td>FVC predicted (%)</td>
<td>67 ± 17</td>
<td>66 ± 22</td>
<td>NS</td>
</tr>
<tr>
<td>FEV actual (l)</td>
<td>0.72 ± 0.25</td>
<td>0.74 ± 0.29</td>
<td>NS</td>
</tr>
<tr>
<td>FEV predicted (%)</td>
<td>26.9 ± 8.2</td>
<td>26.8 ± 9.1</td>
<td>NS</td>
</tr>
<tr>
<td>RV actual (l)</td>
<td>5.2 ± 1.3</td>
<td>5.3 ± 1.6</td>
<td>NS</td>
</tr>
<tr>
<td>RV predicted (%)</td>
<td>244 ± 56</td>
<td>241 ± 62</td>
<td>NS</td>
</tr>
<tr>
<td>Preop $pO_2$ (mmHg)</td>
<td>67 ± 12</td>
<td>67 ± 11</td>
<td>NS</td>
</tr>
<tr>
<td>Preop $pCO_2$ (mmHg)</td>
<td>42 ± 7</td>
<td>41 ± 6</td>
<td>NS</td>
</tr>
<tr>
<td>Preop 6-min walk (ft)</td>
<td>885 ± 322</td>
<td>740 ± 415</td>
<td>0.002</td>
</tr>
<tr>
<td>Preop VO$_2$ (ml/min per kg)</td>
<td>246 ± 65</td>
<td>239 ± 67</td>
<td>NS</td>
</tr>
</tbody>
</table>

Fig. 2. Operative mortality compared in the early and late portions of the learning curve ($P = NS$).

Fig. 3. Operative mortality of unilateral and bilateral TLVR ($P = 0.06$).
patients) or from multi-organ failure incited by such a complication (one patient). Although the reasons for this clinical association of end-stage emphysema and life-threatening gastrointestinal complications are not immediately obvious, it is clear that such complications occur frequently in the postoperative period following LVR and account for 10–20% of the operative mortality in many series [4,6,7,11]. Most LVR patients experienced significant ileus in the early postoperative period and vigorous attempts should be made to promote intestinal motility.

One additional point should be made regarding the time of operative mortality. It is clear from our analysis that the standard definition of operative mortality must be scrutinized in this patient population. Approximately 40% of the deaths occurred more than 30 days after surgery, often in a site (rehabilitation or ventilator facility) other than the hospital. These deaths must certainly be considered operative mortalities and future reports should likely note both the 30- and 90-day mortality and deaths in medical facilities other than the primary hospital should be included if the patient was discharged or transferred to that site without an intercurrent stay at home.

Much of the literature dealing with risk analysis in LVR patients concerns identifying predictors of long-term clinical success as opposed to predictors of operative mortality. However, there are several articles which have examined this latter topic and the results are not entirely consistent. The earliest to do so was the work of Fujita and Barnes who reviewed the clinical experience of Wakabayashi who utilized primarily laser pneumoplasty in order to achieve lung volume reduction [15]. Although the clinical benefits of laser lung reduction have since been demonstrated to be inferior to that of stapled lung reduction [16], the patient population and operative risk appear quite similar. These investigators found that increased age, male gender, \( FEV_1 < 700 \text{ ml} \) and \( pCO_2 > 55 \) all were univariate predictors of increased morbidity and mortality. The Massachusetts General experience reported by Szekely and colleagues suggested that a resting \( pCO_2 > 45 \text{ mmHg} \) or the inability to walk 200 m on the 6-min walk test were the best predictors of poor outcome [8]. Argenziano and his co-authors reviewed the Columbia experience and evaluated whether ‘high-risk’ variables such as severe hypercapnea, steroid dependence, inability to complete preoperative rehabilitation, and profound pulmonary dysfunction (\( FEV_1 < 500 \text{ ml} \)) predicted higher operative mortality or inferior long-term survival [17]. They found no significant differences between their high-risk and low-risk patients. McKenna and his co-investigators have reported no differences in operative mortality in patients undergoing unilateral or bilateral TLVR but did report that high-risk patients (age \( > 75 \text{ years} \), \( pO_2 \leq 50 \), and \( FEV_1 \leq 500 \text{ ml} \)) had a lower one year survival when unilateral as opposed to bilateral TLVR was performed [4]. Finally, O’Brien and colleagues found no increased mortality in hypercapnea patients undergoing LVR [18].

When compared to these prior articles, our report carries the advantages of a cooperative study from multiple institutions. This produced a large cohort of patients with a diverse profile including those with and without alpha-1-antitrypsin disease, patients with both homogeneous and heterogeneous disease, and both unilateral and bilateral procedures.

Although several earlier reports have identified preoperative blood gases as a significant indicator for operative mortality, we could not confirm this finding. Neither \( pO_2 \) or \( pCO_2 \) were predictive of mortality when analyzed as either a continuous or categorical (\( pCO_2 > 50 \)) variable.

It is not surprising that advanced age carries some increased risk of operative mortality in our study. A subanalysis of our data demonstrates that patients equal to or greater than 70 years of age have an 11.1% mortality (21/189) which is significantly higher (\( P = 0.0005 \)) than the 4.1% found in patients younger than 70 years of age (20/473). Significantly higher operative mortalities are found in elderly patients in many cardiac and thoracic procedures and is likely the result of a lower physiologic reserve in advanced age. Of note, however, is the fact that the eldest patient in our series was an 87-year-old female who underwent an uncomplicated unilateral TLVR and was discharged in 6 days, surviving for 28 months after surgery. Obviously, age alone is not an absolute contraindication, but its effect must be weighed against the relative physiologic status of the patient and the potential overall benefit from the surgery.

The reason for a survival difference on the basis of gender is not immediately obvious. A prior report has suggested there is an increased risk of long-term mortality for males with significant chronic lung disease, however, this does not

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### Table 3
Stepwise logistic regression analysis

<table>
<thead>
<tr>
<th></th>
<th>Univariate ( P ) value</th>
<th>Logistic regression chi-square</th>
<th>Logistic regression ( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.0005</td>
<td>6.35</td>
<td>0.01</td>
</tr>
<tr>
<td>Male gender</td>
<td>0.008</td>
<td>6.16</td>
<td>0.01</td>
</tr>
<tr>
<td>6-min walk</td>
<td>0.002</td>
<td>7.84</td>
<td>0.005</td>
</tr>
<tr>
<td>Bilateral procedure</td>
<td>0.06</td>
<td>9.16</td>
<td>0.003</td>
</tr>
<tr>
<td>Preop oxygen</td>
<td>0.02</td>
<td>3.41</td>
<td>NS</td>
</tr>
<tr>
<td>Preop steroids</td>
<td>0.05</td>
<td>2.77</td>
<td>NS</td>
</tr>
<tr>
<td>Smoking quit</td>
<td>0.02</td>
<td>1.99</td>
<td>NS</td>
</tr>
</tbody>
</table>

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\( P \) values for statistical significance.
explain the immediate effect found in operative mortality [19]. Technically, the operation is usually less difficult in males due to the larger thoracic cavity. A higher risk of mortality has also been noted previously in one large patient cohort undergoing laser lung reduction [15]. It may be that men have a higher incidence of comorbidity such as heart disease, but our analysis doesn’t confirm this supposition. Although seven of the ten cardiac heart-related deaths in our study occurred in males (an incidence of 70%), men accounted for 61% of our surgical population and this does not seem to be disproportionate to the risk of cardiac death observed. Further study will be required to identify why males appear to be at a greater risk.

The 6-min walk has been previously identified as a risk factor by Szekely and colleagues who noted that patients able to walk 200 m or less had an elevated mortality [8]. Our own experience was similar with an 11.1% mortality in those unable to walk 200 m vs. 4.5% in those who could (P = 0.05). A lower 6-min walk distance would suggest that an operative candidate who is more severely compromised may not tolerate the rigors of surgery as well as a patient in better physiologic condition.

Perhaps the most interesting predictor proved to be the extent of procedure performed, (e.g. unilateral vs. bilateral). When we first examined this issue, we feared that the learning curve could prove to be a significant complicating factor since each of the institutions began with unilateral procedures and thus many of the mistakes were made and lessons learned on this early population. However, when the learning curve (early vs. late) was utilized as an independent predictor, it proved not to be significant. It appears that a unilateral procedure may be easier to tolerate than a bilateral one. Argenziano and colleagues noted that bilateral LVR carried a 7.4% mortality as opposed to 3.6% in the unilateral group [20]. They noted that most ‘major complications including reintubation, tracheostomy, pneumonia, sternal dehiscence, and reoperation for air leak were less common in patients undergoing unilateral LVRS.’ Similarly, Cooper reported his experience with bilateral and unilateral procedures and reported a 4 and 0% operative mortality, respectively. In both of these series, the number of patients within the series was too small to demonstrate statistical significance, but the real possibility of a type II error certainly exists.

The rationale behind proceeding with a bilateral LVR is twofold. First, McKenna has suggested that patients undergoing bilateral TLVR had a superior 1-year actuarial survival due to significantly increased respiratory improvement [4]. However, reports by our own group and the above-mentioned paper by Argenziano suggest no significant difference in long-term survival whether one or two sides are operated upon [9,20].

The second reason to perform the bilateral LVR is the supposition that greater spirometric, oxygenation, and functional improvements can be achieved if both sides are operated upon. While there is indeed objective data which demonstrates greater spirometric improvement with the bilateral procedure as measured by FEV1, there is conflicting evidence as to whether a bilateral LVR is better than a unilateral LVR with regard to functional or oxygenation outcomes [2,4,10]. Both Cooper [2] and Argenziano [20] found similar improvements in functional capacity as measured by the improvement in the 6-min walk. Kotloff found bilateral LVR to yield superior 6-min walk improvement [11]. Cooper also noted an identical improvement in the pO2 level in bilateral and unilateral LVR patients. Finally the analysis of our own series with regard to functional results demonstrates that there are superior spirometric increases for bilateral TLVR, but that unilateral TLVR produces virtually identical improvements in oxygenation and 6-min walk [21]. Thus, while the bilateral LVR appears to be the standard of care whether performed thoracoscopically or by using an open approach, questions should be raised regarding the optimal role of unilateral LVR, especially in view of the increased mortality risks suggested by the above analysis.

This report could be criticized for being retrospective in nature, however, it should be pointed out that all data was collected in a prospective fashion for the respective databases at each of the five institutions.

This paper demonstrates that TLVR can be performed with acceptable rates of morbidity and mortality. Whether or not thoracoscopy is less morbid than the sternotomy approach cannot be concluded from this study; the overall mortality and morbidity of TLVR appears similar to that reported for open LVR in the literature. The National Emphysema Treatment Trial currently underway in the United States is designed to answer the question of the optimal approach.

Although this study identified no absolute contraindications to TLVR, it did demonstrate increased operative risk in patients who are older, male, and have poor functional capacity as demonstrated by a low 6-min walk. In view of the increased risk associated with bilateral procedures, such patients could be considered for unilateral TLVR. Whether or not this will prove to be the optimal approach must await the results of future studies.

References


