Lung volume reduction surgery since the National Emphysema Treatment Trial: Study of Society of Thoracic Surgeons Database

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Objectives: The National Emphysema Treatment Trial demonstrated that lung volume reduction surgery is an effective treatment for emphysema in select patients. With chronic lower respiratory disease being the third leading cause of death in the United States, this study sought to assess practice patterns and outcomes for lung volume reduction surgery on a national level since the National Emphysema Treatment Trial.

Methods: Aggregate statistics on lung volume reduction surgery reported in the Society of Thoracic Surgeons Database from January 2003 to June 2011 were analyzed to assess procedure volume, preoperative and operative characteristics, and outcomes. Comparisons with published data from the National Emphysema Treatment Trial were made using chi-square and 2-sided *t* tests.

Results: In 8.5 years, 538 patients underwent lung volume reduction surgery, with 20 to 118 cases reported in the Society of Thoracic Surgeons Database per year. When compared with subjects in the National Emphysema Treatment Trial, subjects in the Society of Thoracic Surgeons Database were younger ($P < .001$), a larger proportion underwent the procedure thoracoscopically ($P < .001$), and forced expiratory volume in 1 second was 31% versus 28% of predicted ($P < .001$). When mortality was compared between subjects in the Society of Thoracic Surgeons Database and all subjects in the National Emphysema Treatment Trial randomized to surgery, there were no significant differences. However, mortality was 3% higher in subjects in the Society of Thoracic Surgeons Database when compared with the non–high-risk National Emphysema Treatment Trial subset ($P = .005$).

Conclusions: This study demonstrates the importance of patient selection and the need to develop consensus on appropriate benchmarks for mortality rates after lung volume reduction surgery. It underscores the need for dedicated centers to increasingly address the heavy burden of chronic lower respiratory disease in the United States in a multidisciplinary fashion, particularly for preoperative evaluation and postoperative management of emphysema. (J Thorac Cardiovasc Surg 2014;148:2651-8)

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Chronic lower respiratory disease is the third leading cause of death in the United States,[1] with chronic obstructive pulmonary disease (COPD) taking approximately 126,000 lives every year.[2] At least one third of these COPD cases are related to a diagnosis of emphysema.[3] Contemporary treatment options for emphysema include oxygen therapy, beta agonists and anticholinergics, oral and inhaled steroids, pulmonary rehabilitation, lung transplantation, experimental endobronchial therapies, and lung volume reduction surgery (LVRS). LVRS has been reported to improve long-term survival and quality of life in appropriately selected patients with emphysema,[4-9] but LVRS practice patterns and outcomes have not since been evaluated nationally, outside of a clinical trial.

The National Emphysema Treatment Trial (NETT),[4,5] which first published results in 2003, randomized 1218 patients with emphysema to LVRS or best medical therapy and examined the primary end points of survival and maximal exercise performance, with secondary end points of pulmonary function, patient symptom severity, and quality of life.[4] The NETT had a large enough subject enrollment to identify the subgroup of patients with emphysema with heterogeneous, upper lobe predominant disease, and low exercise capacity who have the best short- and long-term outcomes after bilateral LVRS, with significant improvements in survival and exercise capacity. The trial also identified that people with a forced expiratory volume in 1 second

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Abbreviations and Acronyms
CMS = Centers for Medicare & Medicaid Services
COPD = chronic obstructive pulmonary disease
LVRS = lung volume reduction surgery
NETT = National Emphysema Treatment Trial
STS = Society of Thoracic Surgeons

of 20% or less than predicted and those with a homogeneous distribution of emphysema or carbon monoxide diffusing capacity of 20% or less than predicted were at high risk of death after LVRS.[4] The NETT thus defined selection criteria for patients with emphysema who are appropriate candidates for LVRS by identifying those who are at high risk for poor outcomes. Since closure of the trial, multiple meta-analyses of LVRS outcomes have been performed using NETT data, but there have been few subsequent studies reporting LVRS outcomes in the post-NETT era. Approximately 10 years after the trial results were published, it is worthwhile to evaluate LVRS practice patterns and outcomes on a national level.

Despite the published benefits of LVRS as a treatment option for emphysema, the procedure is reportedly underused.[10] Reasons for this are unclear, because COPD and emphysema comprise a significant burden of disease in the US population. The National Heart, Lung, and Blood Institute projected that COPD costs $29.6 billion in direct healthcare expenditures and $20.4 billion in indirect morbidity and mortality expenditures annually.[11] In this study, we report on comprehensive LVRS data from the Society of Thoracic Surgeons (STS) Database beginning in 2003, when the NETT was first published. The STS Database provides a geographically diverse national sample, which unlike Medicare claims data, includes patients aged less than 65 years. This is a valuable advantage of STS data because approximately half of patients with emphysema in the country are aged 45 to 64 years.[2] By examining the outcomes of LVRS in the STS Database and comparing outcomes with results of the NETT, our study assesses the performance of LVRS compared with the clinical benchmark set by a landmark clinical trial. This study has implications for future identification of determinants of LVRS quality and development of LVRS-specific quality benchmarks.

MATERIALS AND METHODS

Study Design and Data Sources

This study involved a retrospective review of de-identified aggregate statistics on patients who underwent LVRS reported in the STS Database from 2003 to 2011. Previously published data from the NETT[4,5,12,13] were studied for statistical comparison. The University of Wisconsin Institutional Review Board approved this study.

Study Populations

Subjects in the NETT who were randomized to surgery underwent bilateral stapled wedge resection. These patients were subdivided into a non–high-risk group and a subgroup of non–high-risk patients with upper lobe predominant disease and low exercise tolerance.

Patients included in the analysis of patients in the STS Database underwent bilateral or unilateral resection. Both groups were included because of the lack of distinction between unilateral and bilateral LVRS in certain versions of the STS General Thoracic Surgery Database Major Procedure Collection Form.[14] Patients with the following procedure codes were included:

Major Procedure Collection Form Version 2.2 (Last revised 2012): "Removal of lung, excision-plication of emphysematous lung(s) for lung volume reduction (LVRS) (32491)"; "Thoracoscopy with resectionplication for emphysematous lung (bullous or non-bullous) for lung volume reduction-LVRS, unilateral including any pleural procedure (32672)." Version 2.081 (Last revised 2009): "Removal of lung, excision-plication of emphysematous lung(s) for lung volume reduction (LVRS) (32491)." Versions 2.06 (2004) and 2.07 (2005): "Lung volume reduction."

Analysis

The STS Database yearly annual volume of LVRS was calculated to depict nationwide trends in volume over time, without attempt to capture total national volume. Meta-analysis was required to estimate differences between sample means and proportions using null hypothesis significance testing with t tests and chi-square tests, respectively. This allowed for estimation of confidence intervals around calculated differences in event rates, while accounting for sample size. Confidence intervals around estimated differences were calculated using the Z statistic, with alpha = 0.05, assuming normal distribution. Preoperative and operative characteristics were compared between patients in the STS Database who underwent LVRS and patients in the NETT who were randomized to surgery. Preoperative characteristics included age, sex, race, and pulmonary function tests, which included percent of predicted forced expiratory volume in 1 second and carbon monoxide diffusing capacity. Operative characteristics accounted for the surgical approach to lung volume reduction: median sternotomy, video-assisted thoracoscopic surgery, or other.

Descriptive statistics on health status indicators and comorbidities of patients in the STS Database were calculated. Published data on the overall health status and comorbidities of subjects in the NETT were not directly comparable. Therefore, a descriptive comparison was made on the basis of related health indicators and NETT cohort selection criteria. STS health status indicators and comorbidities included congestive heart failure, coronary artery disease, pulmonary hypertension, systemic hypertension, peripheral vascular disease, diabetes, steroid use (defined as systemic steroid therapy, inhaled steroid therapy, or preoperative protocol within 30 days before the procedure),[14] previous cardiothoracic surgery, lung cancer, smoking history, American Society of Anesthesiologists class, and Eastern Clinical Oncology Group/Zubrod score. Related health status indicators in the NETT included the Quality of Well-Being Score and the St George's Respiratory Questionnaire score; the Quality of Well-Being score, which ranges from 0 to 1, with higher values indicating better health-related quality of life;[15] and St George's Respiratory Questionnaire score, which ranges from 0 to 100, with lower values indicating better health-related quality of life.[16]

Outcomes within 30 days of surgery were compared between patients in the STS Database and non–high-risk subjects in the NETT. These outcomes included readmission to the intensive care unit, sepsis, arrhythmia requiring treatment, myocardial infarction, ventilator dependence beyond 48 hours postoperatively, and reintubation. Mortality within 30 days of surgery was compared between patients in the STS Database and (1) all subjects in the NETT, (2) the non–high-risk NETT subset, and (3) the NETT subset with upper lobe predominant disease and low exercise tolerance.