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.

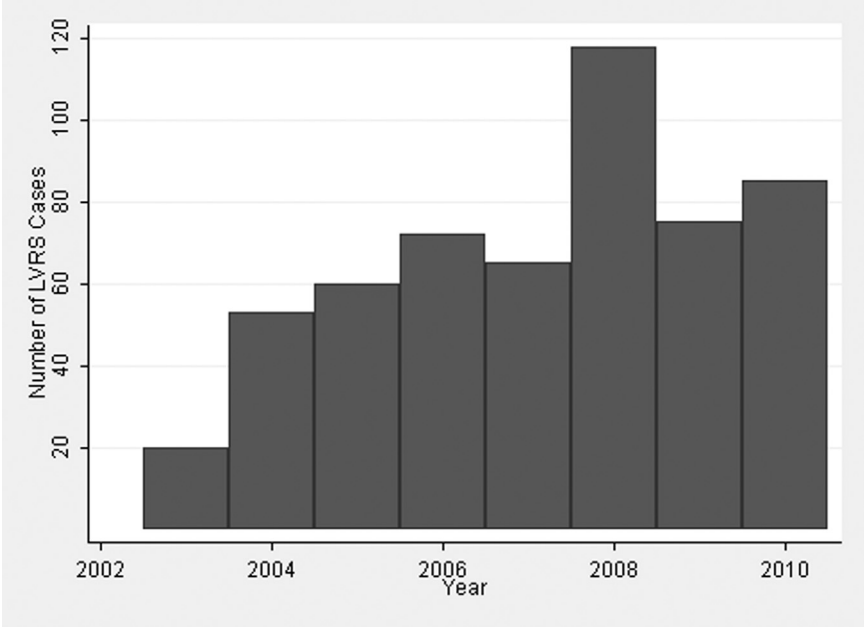

FIGURE 1. Yearly annual volume of LVRS reported in the STS Database from January 2003 to December 2010; 2011 volume is not shown, because yearly data were incomplete at the time of this study. *LVRS*, Lung volume reduction surgery.

In all analyses, missing observations in STS data were excluded from the denominator; however, patients with missing data were not excluded from the overall STS cohort. Only deidentified aggregate data were available from the STS Database; therefore, imputation could not be performed. Proportions of missing observations were reported with outcomes to aid interpretation. In addition, to account for missing data, mortality outcomes were analyzed under 2 other scenarios: one in which all missing patients were assumed to be alive and another in which all missing patients were assumed to be deceased. Statistical analyses were performed in STATA (StataCorp 2011. Stata Statistical Software: Release 12. StataCorp LP, College Station, Tex).

RESULTS

From January 2003 to June 2011, 585 patients underwent LVRS reported in the STS Database. The yearly annual volume of LVRS is shown in Figure 1. Patients in the STS Database were compared with the 608 NETT subjects who were randomized to surgery, of whom 538 were determined to be non–high risk and 139 had upper lobe predominant disease and low exercise tolerance.

When the preoperative characteristics of patients in the STS Database were compared with those of all NETT subjects, STS subjects were younger and a larger proportion was of a nonwhite race (Table 1). There were no patients in the STS Database with forced expiratory volume in 1 second or carbon monoxide diffusing capacity less than 20% of predicted, who would fall into the high-risk category deemed by the NETT. Although the majority of NETT subjects underwent LVRS via a median sternotomy approach, most STS subjects underwent the procedure with a thoracoscopic approach. Other approaches included cervical, subxiphoid, thoracotomy, and transverse sternotomy.

Overall, less than half of patients in the STS Database had major comorbidities (Table 2). Approximately 10% of patients in the STS Database had previous cardiothoracic surgery, whereas NETT enrollees with previous sternotomy or lobectomy were excluded. Some 1.5% of patients in the STS Database had a diagnosis of lung cancer, whereas the

TABLE 1. Quantitative comparison of preoperative and operative characteristics of patients undergoing lung volume reduction surgery in the National Emphysema Treatment Trial versus the Society of Thoracic Surgeons Database

	STS	NETT	Mean difference		
Characteristics	Mean	Mean	Mean $\lvert\Delta\rvert$	(95% CI)	*P* value*
Age, mean y	61.3	66.5	5.2	(−6.1 to −4.3)	<.001
Sex					.192
Male	54.6%	58.4%	3.7%	(−9.4 to 1.9)	
Female	45.4%	41.6%	3.7%	(−1.9 to 9.4)	
Race					.010
White	91.4%	95.6%	4.1%	(−6.9 to 9.7)	
Black	5.1%	3.1%	1.9%	(−0.3 to 4.2)	
Other	3.5%	1.3%	2.2%	(0.4-3.9)	
Pulmonary function tests					
FEV1 % predicted	31.1%	28.1%	3.0%	(1.6-4.4)	<.001
DLCO % predicted	37.8%	29.2%	8.6%	(6.9-10.2)	<.001
Surgical approach					<.001
Median sternotomy	35.8%	70.0%	34.2%	(−40.2 to −28.1)	
VATS	51.3%	30.0%	21.3%	(15.1-27.5)	
Other	12.9%	0%	12.9%	(9.6-16.3)	

CI, Confidence interval; *DLCO*, carbon monoxide diffusing capacity; *FEV1*, forced expiratory volume in 1 second; *NETT*, National Emphysema Treatment Trial; *STS*, Society of Thoracic Surgeons; *VATS*, video-assisted thoracic surgery. **P* values calculated using 2-sided *t* tests for continuous variables and chi-square tests for differences in proportions.

TABLE 2. Description of preoperative health status of patients undergoing lung volume reduction surgery in the Society of Thoracic Surgeons Database compared with the National Emphysema Treatment Trial selected cohort

Patient characteristics	STS %	NETT*
Comorbidities		
CHF	2.6	Excluded if "Congestive heart failure within 6 mo of interview and ejection fraction <45%"
Coronary artery disease	17.4	
Pulmonary hypertension	0.7	Excluded if "Pulmonary hypertension: mean P_{PA} on right heart catheterization ≥35 mm Hg (≥38 mm Hg in Denver) or peak systolic P_{PA} on right heart catheterization ≥45 mm Hg (≥50 mm Hg in Denver); right heart catheterization is required to rule out pulmonary hypertension if peak systolic P_{PA} on echocardiogram >45 mm Hg"
Systemic hypertension	45.1	Excluded if "Uncontrolled hypertension (systolic >200 mm Hg or diastolic >110 mm Hg)"
Peripheral vascular disease	2.6	
Diabetes	9.4	
Steroids	17.8	Excluded if "Daily use of more than 20 mg of prednisone or its equivalent as of randomization"
Previous cardiothoracic surgery	9.9	Excluded if "Previous sternotomy or lobectomy"
Lung cancer	1.5	Excluded if "Evidence of systemic disease or neoplasia that is expected to compromise survival over the duration of the trial" or "Pulmonary nodule requiring surgery"
Preoperative chemotherapy and radiation	1.0	
Smoking history		Included if "Nonsmoker (tobacco products) for 4 mo before initial interview and patient remains a nonsmoker throughout screening (by history)"
Current smoker	4.6	
Quit within 1 y previously	8.4	
Quit >1 y ago	52.5	
Never smoked	34.5	
ASA class		Surgical Patients' average daily Quality of Well-Being score:†
I	2.0	0.58 ± 0.12
II	6.8	Upper Lobe Predominant, Low Exercise Tolerant Quality of Well-Being score:
III	63.1	0.57 ± 0.12
IV	28.0	Surgical Patients' St George's Respiratory Questionnaire Score:‡
V	0.2	52.5 ± 12.6
ECOG/Zubrod score		Upper Lobe Predominant, Low Exercise Tolerant St George's Respiratory Questionnaire Score:
0, normal activity	9.1	
1, symptomatic but ambulatory	63.1	54.3 ± 12.1
2, symptomatic, <50% daytime in bed	20.4	
3, symptomatic, >50% <100% daytime in bed	4.5	
4, bedridden	2.9	

ASA, American Society of Anesthesiologists; *ECOG*, Eastern Clinical Oncology Group; *CHF*, congestive heart failure; *NETT*, National Emphysema Treatment Trial; *STS*, Society of Thoracic Surgeons; P_{PA}, pulmonary arterial pressure. *Referenced from Fishman and colleagues[4] (Appendix Table E1). †Quality of Well-Being score is on a scale from 0 to 1, with higher scores indicating better health. ‡St George's Respiratory Questionnaire score is on a scale from 0 to 100, with lower scores indicating better health.

NETT excluded enrollees with pulmonary nodules or evidence of neoplasia that could interfere with the trial.

The majority of patients in the STS Database had American Society of Anesthesiologists class III or IV and Eastern Clinical Oncology Group or Zubrod scores of 1 or 2, indicating that most patients were symptomatic and ambulatory or partially disabled. This parallels with the middle-range health-related quality of life scores reported by NETT subjects (Table 2).

The median time from surgery to evaluation of 30-day outcomes was 0.7 month in all NETT subjects, including the non–high-risk subset and 0.8 month in the subset with upper lobe predominant disease and low exercise tolerance.[4] Outcomes were assessed at 30 days postoperatively in the STS Database. Given the slight difference in time from surgery to evaluation of outcomes in NETT versus the STS Database, mortality within 60 days is reported for NETT subjects as a frame of reference.

Mortality within 30 days of LVRS was not significantly different between STS subjects and all NETT subjects (Table 3). When 30-day mortality rates were compared between STS subjects and the non–high-risk NETT subset (Table 4), as well as the NETT subset with upper lobe predominant disease and low exercise tolerance (Table 5), STS subjects had a 3% to 4% higher mortality rate that was statistically significant. Mortality assessed at 1.7 months postoperatively was 4.8% among non–high-risk NETT subjects and 2.9% among subjects with upper lobe

TABLE 3. Comparison of outcomes after lung volume reduction surgery in Society of Thoracic Surgeons Database versus National Emphysema Treatment Trial

Outcomes	STS* %	All NETT %	Difference % |Δ|	Difference (95% CI)	*P* value†
30-d mortality‡	5.6	3.6	2.0	(−0.5 to 4.5)	.113

CI, Confidence interval; *NETT*, National Emphysema Treatment Trial; *STS*, Society of Thoracic Surgeons. *Missing STS observations excluded. †*P* values from chi-square tests. ‡Referenced from Fishman and colleagues.[4]

predominant disease and low exercise tolerance, compared with the STS 30-day mortality rate of 5.6%.

When other outcomes were compared between STS subjects and non–high-risk NETT subjects randomized to surgery, there were no significant differences in rates of intensive care unit readmission, sepsis, arrhythmia requiring treatment, or myocardial infarction (Table 4). STS subjects had significantly lower rates of ventilator dependence lasting more than 48 hours postoperatively and reintubation.

Mortality data were missing for 83 (14%) of the patients in the STS Database. There were 213 to 214 (36%-37%) missing observations for each of the other outcome variables; missing observations were excluded from sample proportions. When all missing patients were assumed to be alive, rather than excluded, no significant differences in mortality were identified between patients undergoing LVRS in the STS Database versus the NETT (Appendix Tables E1 and E2). Mortality rates were significantly higher for patients undergoing LVRS in the STS Database compared with those in the NETT when all missing patients were assumed to be deceased (Appendix Tables E3 and E4).

DISCUSSION

This study of LVRS in the STS Database from 2003 to 2011 is the first longitudinal, population-level assessment

TABLE 4. Comparison of outcomes after lung volume reduction surgery in Society of Thoracic Surgeons Database versus non–high-risk National Emphysema Treatment Trial subset

Outcomes	STS* %	Non–high-risk NETT subset %	Difference % |Δ|	Difference (95% CI)	*P* value†
30-d mortality‡	5.6	2.2	3.4	(1.0-5.0)	.005
Readmittance to ICU§	7.8	11.7	3.9	(−8.8 to 1.0)	.156
Sepsis§	1.9	2.5	0.6	(−2.5 to 1.3)	.544
Arrhythmia§	16.2	18.6	2.4	(−7.5 to 2.6)	.350
MI§	1.1	1.0	0.1	(−1.3 to 1.4)	.910
Ventilator >48 h§	4.6	13.6	9.1	(−12.7 to −5.4)	<.001
Reintubation§	12.9	21.8	8.9	(−13.8 to −3.9)	<.001

CI, Confidence interval; *ICU*, intensive care unit; *MI*, myocardial infarction; *NETT*, National Emphysema Treatment Trial; *STS*, Society of Thoracic Surgeons. *Missing STS observations excluded. †*P* values from chi-square tests. ‡Referenced from Fishman and colleagues.[4] §Referenced from Naunheim and colleagues.[13]

TABLE 5. Comparison of outcomes after lung volume reduction surgery in Society of Thoracic Surgeons Database versus National Emphysema Treatment Trial subset with upper-lobe predominant disease and low exercise tolerance

Outcomes	STS* %	NETT, upper lobe disease ↓exercise tolerance %	Difference % |Δ|	Difference (95% CI)	*P* value†
30-d mortality‡	5.6	1.4	4.2	(1.4-7.0)	.039

CI, Confidence interval; *NETT*, National Emphysema Treatment Trial; *STS*, Society of Thoracic Surgeons. *Missing STS observations excluded. †*P* values from chi-square tests. ‡Referenced from Fishman and colleagues.[4]

of LVRS since the NETT. Our study demonstrates that since the NETT was published in 2003, surgeons have performed LVRS for a broader group of patients (including smokers, younger patients, and people with previous cardiac surgery); techniques have evolved (with greater use of thoracoscopic surgery); and outcomes differ in some areas while remaining the same in others.

The annual volume of LVRS in the STS Database increased substantially from 2003 to 2004 but did not steadily increase thereafter. This suggests that LVRS is underused, as reported in a study of Medicare claims from 2004 to 2005 in which there were only 258 claims for LVRS over 21 months.[10] When considering that emphysema is reported to affect 4.7 million Americans,[2] it appears that only a small proportion of these patients are pursuing LVRS as a treatment option. Reasons for this remain unclear. Overly restrictive patient selection criteria do not appear to be the cause. Overall differences in patient characteristics between the STS Database and the NETT demonstrate that patient selection was less restrictive in the STS Database. With underuse unlikely to be related to restrictive selection criteria, it may instead be related to restrictive referral patterns and limited access to this specialized surgery.

When compared with subjects in the NETT, more subjects in the STS Database underwent LVRS via a thoracoscopic approach, which is likely a consequence of an increase in surgeons' comfort with thoracoscopy and video-assisted thoracoscopic surgery.[17] The fact that 10% of patients in the STS Database had previous cardiothoracic surgery is a testament to surgeons' increased comfort with the technical aspects of the lung volume reduction procedure. The younger mean age of STS subjects may relate to increasing numbers of insurers offering coverage of LVRS,[18,19] following the Centers for Medicare & Medicaid Services (CMS) published criteria for expanded coverage of LVRS in 2003.[20] However, the CMS has restricted the types of facilities that are eligible for reimbursement of LVRS to those approved for the NETT, credentialed by the Joint Commission on Accreditation of Healthcare Organizations under their Disease Specific Certification Program for LVRS, and those approved by Medicare for lung or heart and lung transplants.[21] Although this

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policy maintains the quality of LVRS by requiring that the appropriate infrastructure is in place, it likely restricts access to this surgery that could benefit more than 1 million Americans. To address underuse of LVRS, perhaps an increase in the number of healthcare teams dedicated to treatment of advanced pulmonary disease is needed, similar to but distinct from healthcare teams dedicated to heart and lung transplantation or thoracic oncology.

In this study, 1.5% of patients in the STS Database were reported to have lung cancer. This may have been a result of miscoding of the surgical procedure as a lung volume reduction rather than a cancer resection, but the surgery also may have been performed for the dual purpose of lung volume reduction and cancer resection, as previously published.[22] Coding errors are always possible when collecting administrative data. However, given the stringent reporting requirements for reimbursement of LVRS,[18-21] there is a low likelihood that coding errors would be frequent enough to skew the results in our large sample size of more than 500 patients.

Outcomes after LVRS were similar between the STS Database and the NETT, with key exceptions. Lower rates of reintubation and prolonged ventilation in the STS Database may be related to nationwide efforts to improve these outcomes over the past decade. The STS, the American College of Surgeons-National Surgical Quality Improvement Program,[23] and the Physician Quality Reporting System in conjunction with CMS[24] use reintubation and prolonged ventilation as healthcare quality indicators. Hospitals throughout the country have developed quality-improvement programs to address these indicators, with increasing success.[25,26]

Analysis of outcomes further demonstrated that patients in the STS Database had a similar 30-day mortality rate when compared with all NETT subjects, but when compared with non–high-risk NETT subjects and those with upper lobe predominant disease and low exercise tolerance, STS subjects had a higher mortality rate. This may be related to differences in patient selection or surgical care outside of a clinical trial. Given that 30-day mortality has been demonstrated to be higher in patients undergoing bilateral resection, compared with unilateral resection,[27] the inclusion of patients in the STS Database who underwent unilateral LVRS was expected to have skewed the 30-day mortality rate in the STS Database to a rate lower than reported in the NETT; however, this was not the case.

As public attention to quality reporting increases and pay-for-performance policies are increasingly implemented, thoracic surgeons may be compelled to decide on thresholds for mortality. It may be unreasonable to expect the outcomes in practice to be as good as the best subgroup of outcomes in a randomized controlled clinical trial, but it is reasonable to expect a certain standard of care and decide on a threshold at which mortality risk cannot outweigh potential benefits.

This study measured outcomes with respect to an absolute benchmark set by the NETT. Current pay-for-performance models are based on both absolute and relative performance measurements.[28] Therefore, future investigation of relative performance measurements for LVRS would allow hospitals to compare their performance with others and potentially learn from high-performing outliers' patient selection, follow-up care, and other potential determinants of quality.

Although the less-restrictive patient selection demonstrated in the STS cohort may contribute to the higher mortality rate when compared with the selected NETT subjects, a small difference in mortality rates may not warrant restricting marginal non–high-risk candidates from access to this potentially life-saving procedure that has been shown to provide substantial improvements in quality of life.[4-9]

Study Limitations

It is worth mentioning that the mortality rates reported in the NETT were captured under a slightly narrower time window (0.7 month in all NETT subjects including the non–high-risk subset and 0.8 month in the upper lobe predominant low exercise tolerant subset) compared with the 30-day mortality in the STS Database. Given that the non–high-risk NETT subset mortality rates at 1.7 months remained below the STS 30-day mortality rate, it is unlikely that the 3% to 4% difference in mortality rates can be wholly attributed to the difference in time windows. Although there were differences in data collection between the STS Database and the NETT, as described, comparison remains informative with this limitation in mind.

This study also was limited by a lack of long-term data on outcomes of patients in the STS Database. Although 30-day outcomes were useful for assessing quality of care in the short term, previous studies have shown that the measurement of survival benefits and improvement in quality-adjusted life after LVRS requires long-term data collection.[5,9] Measurement of 90-day and 1-year outcomes after LVRS in quality-assessment databases such as that of the STS would facilitate future studies. This study of the STS Database also was limited by missing data, which comprised 14% to 37% of observations. Results should be interpreted while considering the proportion of missing observations (Appendix Table E1). Overall, the limitations of this study were largely due to limitations of observational data. The STS Database provides a national sample that is likely to be biased toward higher participation by major academic centers and hospitals with sufficient data-collection resources. This study was not designed to capture total national LVRS volume in the United States or to prescribe policy to address LVRS quality. Rather, the study was designed to provide a description that facilitates further investigation

into quality assessment and quality assurance for LVRS. As we have demonstrated, this goal was achieved, and the STS Database proved to be useful in providing an unadjusted assessment of volume and outcomes for LVRS.

Keeping thoracic surgeons apprised of unadjusted quality assessments is essential to involving surgeons in the identification of surgery-specific determinants of quality, the development of surgery-specific quality measures, and therefore the evolution of quality-improvement databases such as that of the STS. This study highlights the need to invest in future analyses that identify determinants of outcomes after LVRS so that future quality assessments can adjust for patient characteristics, payer status, location, and so forth. This is an iterative process that is best conducted with surgeons' involvement.

CONCLUSIONS

Overall, the major findings of this study demonstrate that mortality rates are higher in the STS Database than they were in selected NETT subjects and about the same compared with the overall NETT LVRS arm. Interpretation of differences in mortality rates is complicated by lack of consensus on appropriate benchmarks for mortality rates after LVRS. Our results and conclusions, like those of any observational study, are limited to description and interpretation of the available data. We maintain that the STS Database provides a geographically diverse national sample of outcomes after LVRS that may capture national trends. This study demonstrates the importance of patient selection and the need to develop consensus on appropriate benchmarks for morbidity and mortality rates after LVRS. Our study also underscores the need for primary care providers, pulmonologists, and thoracic surgeons to address the heavy burden of chronic lower respiratory disease in the United States by more frequently engaging a multidisciplinary team in discussions with patients regarding the treatment options for emphysema, taking into consideration individual patient risk factors and weighing risks and benefits in an evidence-based fashion. More dedicated centers for treatment of advanced respiratory disease are needed to improve access to LVRS, while refining preoperative evaluation and postoperative management of emphysema in a coordinated way.

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APPENDIX TABLE E1. Comparison of outcomes after lung volume reduction surgery in Society of Thoracic Surgeons Database versus National Emphysema Treatment Trial: Missing patients in the Society of Thoracic Surgeons Database assumed to be alive

			Difference		
Outcomes	STS* %	All NETT %	% |Δ|	(95% CI)	*P* value†
30-d mortality‡	4.8	3.6	1.2	(−0.1 to 3.5)	.306

CI, Confidence interval; *NETT*, National Emphysema Treatment Trial; *STS*, Society of Thoracic Surgeons. *Missing STS observations excluded. †*P* values from chi-square tests. ‡Referenced from Fishman and colleagues.[4]

APPENDIX TABLE E2. Comparison of outcomes after lung volume reduction surgery in Society of Thoracic Surgeons Database versus National Emphysema Treatment Trial subjects with upper-lobe predominant disease and low exercise tolerance: Missing Society of Thoracic Surgeons subjects assumed to be alive

		NETT, upper lobe disease ↓exercise	Difference		
Outcomes	STS* %	tolerance %	% |Δ|	(95% CI)	*P* value†
30-d mortality‡	4.8	1.4	3.4	(0.8-6.0)	.072

CI, Confidence interval; *NETT*, National Emphysema Treatment Trial; *STS*, Society of Thoracic Surgeons. *Missing STS observations excluded. †*P* values from chi-square tests. ‡Referenced from Fishman and colleagues.[4]

APPENDIX TABLE E3. Comparison of outcomes after lung volume reduction surgery in Society of Thoracic Surgeons Database versus National Emphysema Treatment Trial: Missing Society of Thoracic Surgeons subjects assumed to be deceased

			Difference		
Outcomes	STS* %	All NETT %	% |Δ|	(95% CI)	*P* value†
30-d mortality‡	19.0	3.6	15.4	(11.9-18.9)	<.001

CI, Confidence interval; *NETT*, National Emphysema Treatment Trial; *STS*, Society of Thoracic Surgeons. *Missing STS observations excluded. †*P* values from chi-square tests. ‡Referenced from Fishman and colleagues.[4]

APPENDIX TABLE E4. Comparison of outcomes after lung volume reduction surgery in Society of Thoracic Surgeons Database versus National Emphysema Treatment Trial subjects with upper-lobe predominant disease and low exercise tolerance: Missing Society of Thoracic Surgeons subjects assumed to be deceased

		NETT, upper lobe disease ↓exercise	Difference		
Outcomes	STS* %	tolerance %	% |Δ|	(95% CI)	*P* value†
30-d mortality‡	19.0	1.4	17.6	(13.8-21.3)	<.001

CI, Confidence interval; *NETT*, National Emphysema Treatment Trial; *STS*, Society of Thoracic Surgeons. *Missing STS observations excluded. †*P* values from chi-square tests. ‡Referenced from Fishman and colleagues.[4]

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