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Lung Volume Reduction Surgery in Australia and New Zealand: Six Years On: Registry Report

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A M E R I C A N C O L L E G E O F
 C H E S T
P H Y S I C I A N S

Lung Volume Reduction Surgery in Australia and New Zealand*

Six Years On: Registry Report

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Background: Lung volume reduction surgery (LVRS) has been shown to improve lung function, exercise performance, and quality of life in highly selected individuals with severe emphysema; however, major questions regarding the efficacy and long-term outcomes of LVRS still remain unanswered. Pending the results of large randomized controlled trials (RCTs), the Australian and New Zealand LVRS Database was created to audit local clinical practice and patient outcomes.

Aims: To review patient selection, surgical activity, and patient outcomes related to LVRS in Australia and New Zealand.

Methods: Prospective data were voluntarily submitted by hospitals performing LVRS in Australia and New Zealand. Preoperative, surgical, perioperative, and follow-up variables were analyzed.

Results: Data were collected from 15 hospitals regarding 529 patients. Mean age (\pm SD) at surgery was 63 ± 7 years. Preoperatively, FEV₁ was $29 \pm 9\%$ predicted, total lung capacity (TLC) was $138 \pm 20\%$ predicted, residual volume (RV) was $250 \pm 64\%$ predicted, and 6-min walk (6MW) distance was 327 ± 111 m. There has been a reduction in the overall number of cases and hospitals performing LVRS since 1999. Improvements in lung function following LVRS (*ie*, FEV₁ increase of 38%, RV decrease of 27%, TLC decrease of 17%) and exercise capacity (*ie*, 6MW distance increase of 24%) appear to be maintained for approximately 3 years.

Conclusions: LVRS continues to be performed in Australia and New Zealand, predominantly in large tertiary teaching hospitals with similar outcomes to those described in the literature. It remains difficult to capture long-term lung function and survival outcomes in this population. Ongoing audit and RCTs are both required to resolve the confusion that still shrouds this procedure. (CHEST 2003; 124:1443–1450)

Key words: evidence based medicine; lung volume reduction; outcomes assessment; pulmonary emphysema; registry

Abbreviations: DLCO = diffusing capacity of the lung for carbon monoxide; LVRS = lung volume reduction surgery; RCT = randomized control trial; RV = residual volume; 6MW = 6-min walk; TLC = total lung capacity; VAT = video-assisted thoracoscopy; VC = vital capacity

In the 1990s, there was renewed interest in the surgical management of severe emphysema. This followed the reintroduction of lung volume reduction surgery (LVRS) by Cooper and colleagues,¹ building on the earlier work of Brantigan and Mueller² in the late 1950s. The operation was based on

the theory that reducing lung size would restore elastic recoil and radial traction on the terminal bronchioles, therefore improving lung function and chest wall mechanics. Favorable results were published in a number of case series,^{3–6} and a rapid uptake in the use of LVRS was subsequently seen in the United States, Europe, and Australia.

The short-term outcomes of LVRS have been repeatedly demonstrated. LVRS has the potential to improve lung function, exercise performance, and quality of life in highly selected individuals with severe emphysema.⁷ Published operative mortality rates vary from 0 to 19%,⁸ and postoperative morbidity is relatively high. Optimal patient selection is still unknown.

LVRS has remained controversial as major questions regarding its efficacy and long-term outcomes

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still remain unanswered. The degree of benefit in terms of symptomatic relief, improvement in lung function, exercise capacity, and quality of life varies between individual patients. There is also a lack of long-term results describing the duration of any improvement obtained. Aside from these clinical questions, economic and ethical issues have also been raised regarding whether health-care systems can afford to offer what must be regarded as an expensive palliative treatment for a very common, often "self-induced" disease.⁹⁻¹³

A few small randomized controlled trials (RCTs) have compared medical management with LVRS,^{14,15} and the results of these studies have been consistent with the earlier case series. Large multicenter RCTs are underway in the United States,¹⁶ Canada,¹⁷ and United Kingdom,¹⁸ and will compare LVRS with best medical management, including pulmonary rehabilitation. It is hoped that they will be able to answer many of these complex questions, further defining the role of LVRS in the management of emphysema.

In the absence of current clear clinical guidelines, the Australian and New Zealand LVRS Database, operating under the auspices of the Royal Australasian College of Surgeons' Australian Safety and Efficacy Register for New Interventional Procedures—Surgical, was created to audit local clinical practice and to monitor surgical activity and patient outcomes. Priority was given to the dissemination of data and facilitation of discussions among clinicians in an attempt to provide regional leadership to what had internationally developed into a sometimes confusing and at times a controversial management option. Comprehensive patient selection criteria have been developed using Australian and New Zealand data,¹⁹ and opportunities for the improvement in surgical and perioperative management have been identified.²⁰

This report presents the results of these audit activities as a summary of the ongoing assessment of safety and efficacy of LVRS in Australia and New Zealand over a 6-year period. It also highlights some of the practical difficulties with the administration and utilization of voluntary registries as part of an evidence-based approach.

MATERIALS AND METHODS

Data Collection

Hospitals performing LVRS in Australia and New Zealand voluntarily submitted data to the Australian and New Zealand LVRS Database on a standardized data collection form. Operational definitions were specified where possible and distributed to hospitals to further standardize reporting. A unique identifier

was created for each case submitted, comprising a two- to three-character hospital code and a case number. All data were entered onto an Access 97 database (Microsoft; Redmond, WA). Computer files were password secured with access available only to the director and coordinator of the Australian and New Zealand LVRS Database. Data were regularly collated and returned to each individual hospital for correction and updating.

Table 1 shows the variables collected. Values were recorded preoperatively, at 3 months, 6 months, 9 months, and 12 months postoperatively, and then yearly following LVRS. The best value for each time period was used if multiple test results were available.

Patient Selection

The individual hospitals contributing to the database were responsible for their own patient selection and independently determined patient suitability for LVRS. General inclusion and exclusion criteria for potential LVRS candidates have been suggested in the literature.^{5,7,19,21-23}

Data Analysis

The data set from September 1995 to August 2001 was analyzed. Patients who had LVRS following lung transplantation were excluded. Data analyses were conducted using SAS version 8.0 (SAS Institute; Cary, NC) and Excel 97 (Microsoft). Descriptive statistics are reported as mean \pm SD unless otherwise specified. A repeated-measures generalized linear model was used to describe the change in lung function ($n = 336$) and 6-min walk (6MW) distance ($n = 292$) over time following LVRS. The multivariate models were adjusted for age, gender, and hospital. Where data are not complete for the variable of interest, actual numbers included in the analysis are specified.

RESULTS

Surgical Activity Levels

Between September 1995 and August 2001, 14 centers in Australia and 1 center in New Zealand

Table 1—Data Collected

Preoperative
Demographics: age, gender
Lung function: FEV ₁ , VC, RV, TLC, DLCO
Exercise capacity: 6MW
Arterial blood gases on room air
Distribution of disease: as shown on CT chest, ventilation/perfusion scan
Surgical
Type of surgery (bilateral/single)
Approach (median sternotomy, thoracotomy, VAT)
Reinforcement technique
Perioperative
Intercostal catheter duration <i>in situ</i>
Length of hospital stay
Complications
Follow-up
Survival status
Lung function: FEV ₁ , VC, RV, TLC, DLCO
Exercise capacity: 6MW
Arterial blood gases on room air

contributed a total of 542 LVRS cases to the Australian and New Zealand LVRS Database. Thirteen patients who had LVRS following lung transplantation were excluded.

The number of cases performed per year dramatically increased from 1 case in 1995 to 128 cases in 1998. In 1999, the level of activity stabilized and then declined in 2000. Data for 2001 are incomplete (only available to August), but a trend toward a further decline in activity is clear (Fig 1).

Of the 15 hospitals performing LVRS, 4 hospitals contributed < 10 cases and 6 hospitals contributed > 40 cases, the largest being 152 cases (Fig 2). Thirteen centers were tertiary teaching hospitals, and 2 centers were private hospitals. All four lung transplantation centers (three Australian, one New Zealand) had an LVRS program, and together they performed 47% of the total number of reported cases. The number of hospitals performing LVRS reduced from 13 hospitals in 1998 to 7 hospitals in 2001.

Patient Selection

The preoperative characteristics of patients with LVRS are summarized in Table 2.

Distribution of Disease

Data regarding the distribution of disease on ventilation/perfusion scan were available in 450 cases. Three hundred eighty-one patients (84.7%) had apical disease, 40 patients (8.9%) had basal disease, 27 patients (6%) had diffuse disease, and 2 patients (0.4%) other distributions.

Preoperative Pulmonary Rehabilitation

Pulmonary rehabilitation was undertaken preoperatively in 424 of 439 cases (97%).

Surgery

Four hundred seventy-six of 509 patients (93.5%), in whom the type of surgery was reported had bilateral LVRS. There was a significant increase in the proportion of unilateral LVRS performed in the period from 1998 to 2000 compared with from 1995 to 1997 ($p = 0.045$).

A midline sternotomy was used in 49%, thoracotomy in 43%, and video-assisted thoracoscopy (VAT) in 8%. Bovine pericardial strips (Biovascular; Minneapolis, MN) were used for reinforcement in 57% of cases, and Gore-tex (Gore and Associates; Phoenix, AZ) was used in 35% of cases.

Although there were no postoperative complications in 43% of patients, major (life threatening) and minor postoperative complications were reported in 29% and 28% of cases, respectively. Of those with major postoperative complications, 23% had an air leak > 7 days, 22% had sepsis, 19% required reintubation for respiratory failure, 12% underwent tracheostomy, 15% had cardiac events, and 9% had other complications. In those patients with a survival time of at least 90 days, intercostal catheters were *in situ* for 9.8 ± 9.3 days and length of hospital stay was 17 ± 14 days.

Lung Function

FEV₁ percentage of predicted improved from 29 to 40% predicted at 3 months after surgery, then

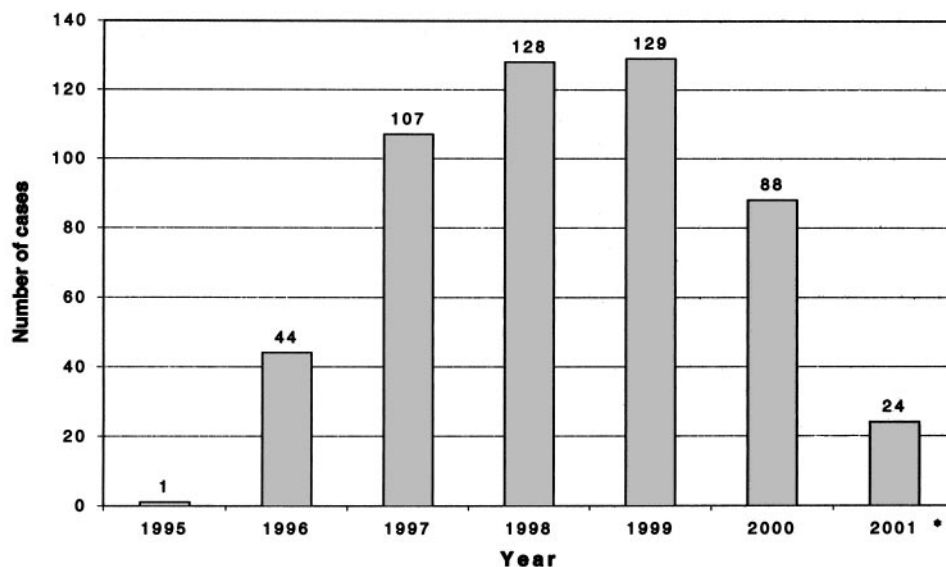


FIGURE 1. LVRS cases per year ($n = 513$). *2001 data annualized (16 cases to August).

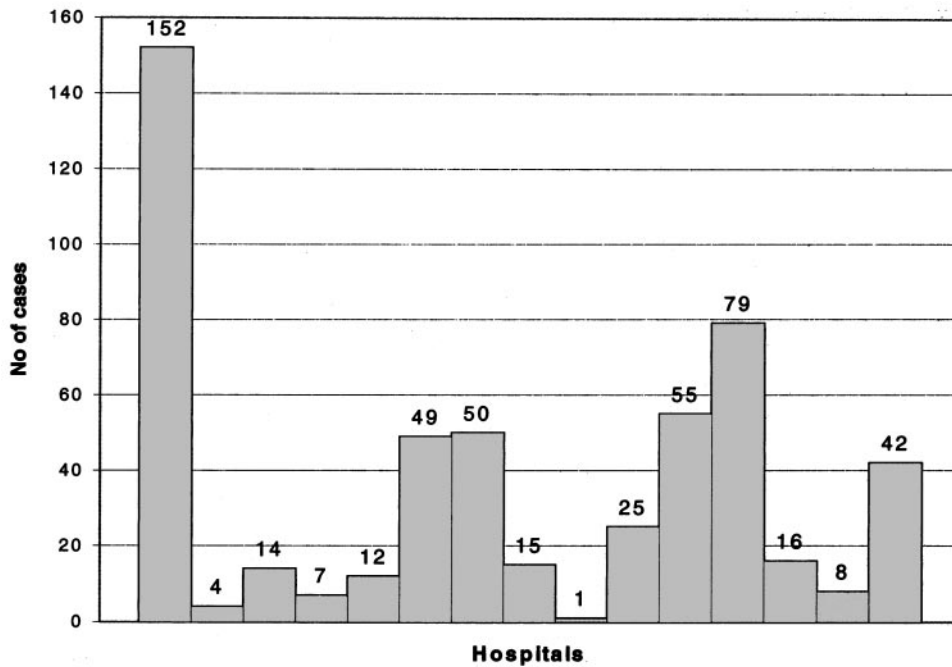


FIGURE 2. LVRS cases performed per hospital.

declined linearly at a rate of approximately 3% (0.10 L) per year ($p < 0.0001$) returning to baseline at 3 to 4 years. Vital capacity (VC) percentage of predicted improved in the first postoperative year, then also fell steadily by approximately 1.5% (0.14 L) per year ($p < 0.009$). RV percentage of predicted decreased from 250 to 183% predicted in the first 6 months, then increased at a rate of approximately 6%/yr thereafter ($p = 0.0007$). TLC percentage of predicted dropped from 138 to 115% in the first 3 months, then increased by approximately 1.5%/yr ($p = 0.006$).

Table 2—Preoperative Patient Characteristics*

Preoperative Characteristics	Data
Demographics	
Age, yr	63 ± 7
Male gender, %	58
Lung function	
FEV ₁ , L	0.76 ± 0.22
FEV ₁ , % predicted	29 ± 9
VC, L	2.41 ± 0.79
VC, % predicted	69 ± 16
DLCO, % predicted	37 ± 12
TLC, % predicted	138 ± 20
RV, % predicted	250 ± 65
Exercise capacity	
6MW distance, m	327 ± 111 (n = 477)
Arterial blood gas (air), mm Hg	
PaO ₂	68 ± 12 (n = 401)
PaCO ₂	42 ± 7 (n = 401)

*Data are presented as mean ± SD unless otherwise indicated.

6MW

There was a continued improvement in the 6MW distance for approximately the first year after LVRS. The distance walked appeared to remain above the baseline preoperative value for approximately 3 years. Overall, 6MW distance declined at a rate of 16 m per year ($p = 0.0002$) over the 5-year time period from the preoperative value.

Survival

Survival status was reported in 454 cases (85.8%). Three hundred ninety-six patients were alive, and 58 patients were dead. Thirty-day survival was 96.2%, and 90-day survival was 92.2%. Survival after surgery was 90.5%, 90.2%, 88.7%, and 79.4% at 1 year, 2 years, 3 years, and 4 years, respectively. Cause of death was specified in 48 cases. Respiratory failure accounted for 45% of deaths, sepsis accounted for 21%, and cardiac failure accounted for 17%.

DISCUSSION

Over the last 6 years, LVRS has been embraced in Australia and New Zealand as a palliative surgical therapy for a crippling medical condition. With widespread publicity, this procedure has generated significant medical, public, and patient interest. The Australian and New Zealand LVRS Database, and others like it, supply important information on cur-

rent LVRS practice and provide a benchmark against which any future trials or clinical case series can be compared.

In comparison with European countries, to the end of 1999, Australia had a greater number of reported cases of LVRS (Fig 3). Australia also had a greater number of institutions performing LVRS; at 4.1 LVRS cases per million population per year, the level of servicing for the population was only higher in Switzerland and Austria²⁴ (Fig 4). Similar US data are not available, but with the withdrawal of US Medicare funding for LVRS in 1993,²⁵ it is probable that US levels of activity are considerably lower.

The high level of Australian activity likely reflects the fact that 47% of cases were performed through lung transplant centers, usually in response to the significantly unsatisfied demand for suitable donor organs for the very large number of emphysema sufferers. In fact, the number of LVRS procedures performed throughout the last 6 years outstrips those performed for lung transplantation, another palliative surgical procedure for emphysema, by 4:1. Although Australia also has the world's highest level of servicing for lung transplantation,²⁶ LVRS is seen to represent a simpler, more accessible, low-cost alternative procedure.

Notwithstanding, the number of LVRS cases performed appears to have significantly waned in the last 2 years. The reasons for the downturn in LVRS procedures performed in Australia and New Zealand are multifactorial. There has possibly been some

diminution in the pool of ideal candidates, and there is always competition for diminishing resources; however, concern about the seemingly inevitable background morbidity and mortality of existing techniques, in the setting of a likely median duration of improvement of only 3 years, are the more significant issues.

Australian and New Zealand case selection, clinical results and survival outcomes closely follow those published results from large US centers.^{3,4,7,14} It is also notable that no significant "center effect" was demonstrable among the contributing groups, suggesting Australian and New Zealand centers have heeded the messages behind the US Medicare LVRS funding crisis.²⁵

In the current series, the vast majority of patients (93.5%) underwent bilateral LVRS, usually via an open technique. The choice of surgical approach (open vs VAT) related to the surgeon's experience and preference. Outcomes appear similar whatever the strategy, but further data are clearly needed.

One of the main limitations to our analyses is the voluntary nature of data reporting. Obtaining long-term follow-up data was challenging as individual centers had differing follow-up practices. There was considerable variability in the length of time patients were followed up for and the frequency and extent of physiologic and functional outcome testing performed. Long-term outcome data from this (and all other) LVRS studies is limited by the relatively small numbers of patients included in the analysis, the

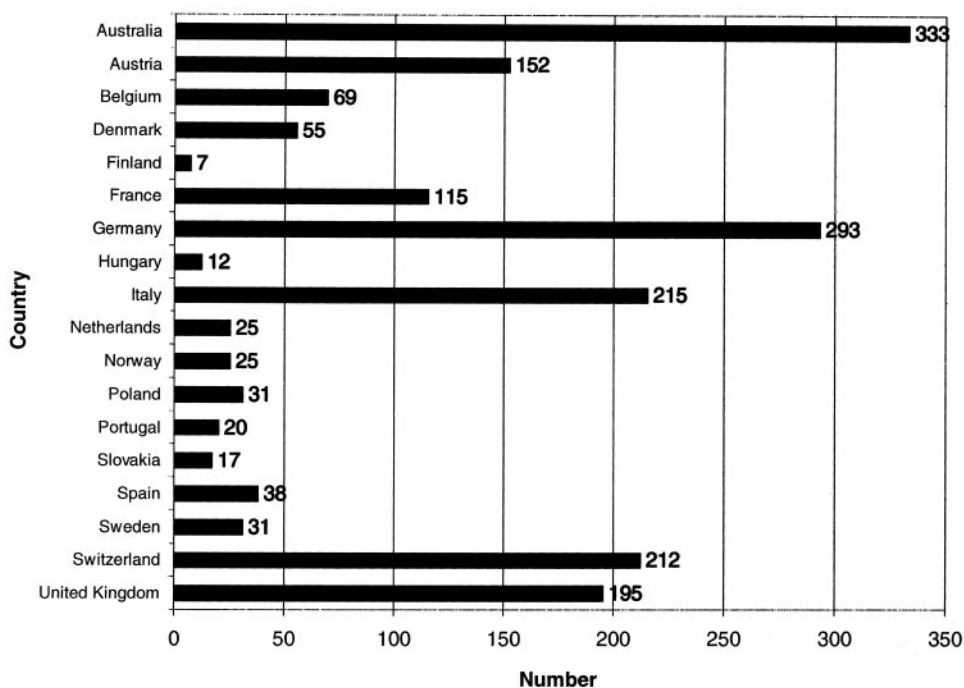


FIGURE 3. Reported cases of LVRS to end of 1999. European data are from Hamacher et al.²⁴

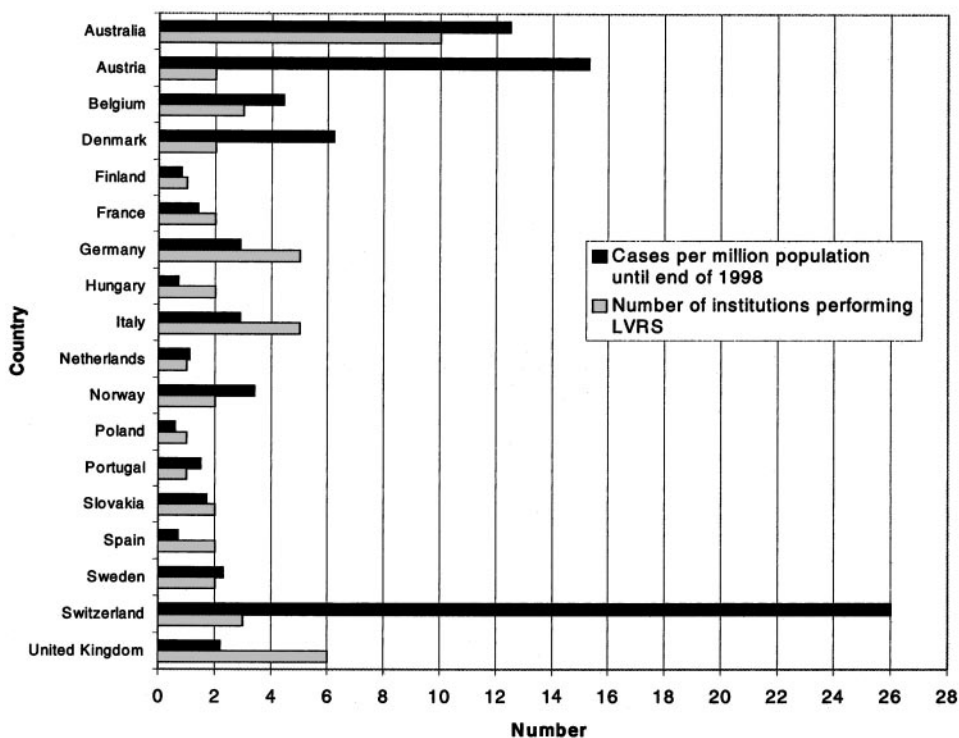


FIGURE 4. Comparison of Australia and European LVRS activity. European data are from Hamacher et al.²⁴

high proportion of patients unavailable for follow-up, and the lack of an adequate control group for comparison. In particular, this has the tendency for LVRS studies to underestimate long-term mortality.²⁷

Selection bias appears to have been less problematic for the Australian and New Zealand LVRS Database than is often experienced by voluntary registries. A survey undertaken in 1999 estimated that the Australian and New Zealand LVRS Database captured approximately 76% of all identifiable cases of LVRS in Australia and New Zealand.²⁸ We suspect that this has now improved to > 85% as the procedure has become more focused in the tertiary hospital setting. This represents a uniquely high level of cooperation with data transfer, and could be attributed to the relatively small medical community in Australia and New Zealand and the strong professional network links of key personnel with relevant professional bodies including the Royal Australasian College of Surgeons, Thoracic Society of Australia and New Zealand, and the Australian Physiotherapy Association.

The Australian and New Zealand LVRS Database has played a vital role in the evaluation and clinical evolution of LVRS in Australia and New Zealand. Although registries are inherently subject to greater bias than RCTs, they are still capable of generating reliable data and can reduce bias attributed to

surgical skill.²⁹ The existence of this registry has enabled individual hospitals to benchmark their own practice and outcomes (particularly mortality and morbidity) with other participating centers and with the published results. There is also the potential to compare registry reported mortalities with national death indexes to improve accuracy.³⁰

Fessler and Wise⁸ provided a detailed review of the duration of benefit following LVRS and suggested that it was probably incorrect to assume there to be a linear decline in FEV₁; however, in our analysis, we found that a linear model best described the change in lung function over time. Our results showed that FEV₁ percentage of predicted improved from 29 to 40% in the first 3 months postoperatively, then declined at a rate of 100 mL/yr, returning to baseline at 3 to 4 years. Brenner and coworkers³¹ reported an average loss of FEV₁ of 163 mL/yr in 180 patients who, like our group, had undergone a variety of LVRS procedures. The annual rate of decline of FEV₁ in patients with COPD has been reported to be up to 80 mL/yr.³² Despite these data, it remains difficult to make direct comparisons between groups of LVRS patients with emphysema, as there may be important differences in smoking history, age, medical management, severity of disease, and other factors. RCTs will ultimately provide the best comparisons.

There are prospects for improvements in morbid-

ity, mortality, and clinical outcomes, as the results of various large RCTs, such as the National Emphysema Treatment Trial, become available, and via the inevitable evolution to newer, less invasive LVRS technologies.^{33,34}

Although RCTs are the scientific “gold standard” for evaluating new therapies, it can be argued that observational studies may be preferable in the setting of evolving patient selection, operative, and perioperative management practices as is the case with LVRS.²⁹ Recently, the National Emphysema Treatment Trial research group published a report³⁵ regarding patients who were at high risk of death after LVRS. This patient population was characterized by an FEV₁ ≤ 20% predicted and diffusing capacity of the lung for carbon monoxide (DLCO) ≤ 20% predicted or a homogenous pattern of disease. Based on their findings, they have now stopped enrolling this group of patients in their clinical trial. Of the 1,033 patients who had been randomized from 17 centers, 140 patients (13.6%) were identified as high risk. In comparison, of our 529 patients, only 8 patients (1.5%) met these “high-risk” criteria. We believe that this large difference in inclusion criteria for LVRS is likely to be due to the fact that the Australian and New Zealand centers had already clinically defined this group correctly and deemed them unsuitable candidates for surgery on the basis of a high likelihood of increased morbidity and mortality.

So who is responsible for providing evidence regarding the efficacy of a new procedure? Despite an apparent keenness to develop an evidence base for clinical medicine from professional bodies, hospital administrators, and individual clinicians, practical issues essential for the ongoing functioning of a database such as ours are often overlooked. Funding support and potential clashes with privacy laws and institutional ethics committees across different international and state borders are all very real problems; however, from a practical standpoint, maintaining a database for regular audit is an inexpensive way to monitor activity and outcomes when compared to the financial burden and restriction of an RCT. In an Australian context, groups like Australian Safety and Efficacy Register for New Interventional Procedures—Surgical are only just starting to provide assistance for this type of project.³⁶

CONCLUSION

Over the last 6 years, there has been considerable LVRS activity in Australia and New Zealand. The early successes detailed elsewhere have been duplicated in a local setting. From a clinical perspective,

perioperative morbidity and mortality and limited long-term efficacy remain as challenges to overcome. From a broader perspective, health-care professionals have a responsibility to be accountable to patients and the taxpayer, by monitoring all outcomes of a new intervention. Although appropriately designed international RCTs are important, further direct Australian and New Zealand data are needed for LVRS to be relevant in our specific context. It is very clear that both emphysema and LVRS are here to stay.

APPENDIX: CONTRIBUTING HOSPITALS

Australia

The Alfred, Victoria; Austin & Repatriation Medical Centre, Victoria; Canberra Hospital, Australian Capital Territory; North Shore Private Hospital, New South Wales; The Prince Charles Hospital, Queensland; Queen Elizabeth Hospital, South Australia; Royal Adelaide Hospital, South Australia; Royal Melbourne Hospital, Victoria; Royal North Shore Hospital, New South Wales; Royal Perth Hospital, Western Australia; Sir Charles Gairdner Hospital, Western Australia; St. Vincent's Hospital, New South Wales; Strathfield Private Hospital, New South Wales.

New Zealand

Greenlane Hospital, Auckland.

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