Estimated Growth of Lung Volume Reduction Surgery Among Medicare Enrollees*

1994 to 1996

Hugh F. Huizenga, MD, MPH; Scott D. Ramsey, MD, PhD; and Richard K. Albert, MD

**Objective:** To estimate the number of lung volume reduction surgery procedures performed on Medicare enrollees from 1994 to 1996.

**Design:** Statistical analysis of national Medicare claims data.

**Patients:** All Medicare enrollees with emphysema having claims records for pulmonary resection procedures from January 1, 1993, through December 31, 1996.

**Main outcome measure:** Estimated number of lung volume reduction procedures performed per month from July 1994 through December 1996.

**Results:** An estimated 1,212 lung volume reduction procedures were performed on Medicare enrollees between July 1994 and December 1995 (95% confidence interval, 1,012 to 1,408). Nearly one half of these procedures were performed in the last 3 months of 1995. At the time Health Care Financing Administration announced that it would suspend reimbursement for the procedure (December 1995), lung volume reduction surgery was being performed in 37 states. The number of claims per month decreased from a peak of 169 in December 1995, to 11 in March 1996. Average Medicare reimbursement per procedure was $31,398.

**Conclusions:** Lung volume reduction surgery for patients increased rapidly following its reintroduction in 1994. The growth of lung volume reduction surgery demonstrates that widespread adoption and utilization of a surgical procedure can occur in the absence of data from controlled clinical trials. Medicare expenditures for lung volume reduction surgery were an estimated $30 million to $50 million. Performing the surgery for all current Medicare patients who meet the appropriate clinical criteria would cost an estimated $1 billion.

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**Key words:** hospital charges; length of stay; lung volume reduction surgery; Medicare

**Abbreviations:** AHCPR = Agency for Health Care Policy Research; HCFA = Health Care Financing Administration; ICD = International Classification of Disease; LVRS = lung volume reduction surgery

The rapid growth of lung volume reduction surgery (LVRS) for patients since it was reintroduced in 1994 has engendered considerable controversy. After favorable results from a small study of patients with severe emphysema who underwent LVRS were reported at a national meeting in 1994, numerous institutions throughout the country began offering the procedure and actively recruiting patients. The Health Care Financing Administration (HCFA) announced in December 1995 that Medicare would no longer pay for LVRS on the grounds that insufficient safety and efficacy evidence was available for the procedure. Subsequently, HCFA and the National Heart, Lung, and Blood Institute announced that they would cosponsor a randomized controlled trial to evaluate the effectiveness of LVRS at selected academic centers. This trial, the National Emphysema Treatment Trial is just now beginning.

We sought to estimate the growth in utilization of LVRS among Medicare-eligible patients prior to HCFA’s suspension of payment. Because emphysema is a highly prevalent condition with few satis-
factory therapeutic options, LVRS may have a substantial economic impact on the Medicare program if it is proven to be effective compared with standard therapy. Examination of the historical rate of growth and expenditure for LVRS is important, since this information may predict future utilization and cost if the randomized trial establishes the value of LVRS in elderly patients with disabling emphysema.

**MATERIALS AND METHODS**

The primary goal of the analysis was to determine the number of LVRS procedures performed on Medicare enrollees prior to Medicare's suspension of payment for the procedure in December 1995. Because a specific *International Classification of Disease*, ninth edition (ICD-9-CM) procedure code was not established for LVRS until October 1995, we obtained computerized claims records for all pulmonary resection procedures performed on Medicare enrollees in the United States from January 1, 1993, through December 31, 1996. Claims were selected based on ICD-9-CM procedure codes for local excision of nonmalignant lung tissue (Table 1). Since the HCFA requires documentation of surgical procedures performed on Medicare enrollees, these lung resection codes were most likely to be assigned to LVRS procedures prior to the time that a specific code was created. To estimate the number of LVRS procedures performed before the specific code for LVRS was established, we compared the average number of claims per month for the codes listed in Table 1 during the months before and after LVRS was introduced into clinical practice.

We chose July 1994 as the initial month for tracking LVRS utilization. The first widely publicized report on LVRS was presented at a national meeting in April 1994. Choosing July 1, 1994 as the initial date allowed time for information dissemination after this meeting. The average number of procedures performed per month after July 1, 1994, less the average number of procedures performed per month for the 18-month period prior to July 1, 1994, was attributed to LVRS.

The analysis was restricted to claims in which COPD was the primary hospital admission diagnosis. In addition, cases in which a lobectomy or pneumonectomy was performed were excluded from the analysis. All claims using the specific procedure code for LVRS were attributed to the procedure.

Medicare LVRS claims for 1996 were also tracked to confirm the expected decline in use of the procedure after the HCFA payment moratorium. Charge and reimbursement data for LVRS claims submitted in 1996 (not available for previous years) were used to estimate expenditures for LVRS during previous years.

**Table 1—ICD Procedure Codes Used to Estimate the Number of LVRS Procedures Performed**

<table>
<thead>
<tr>
<th>ICD-9 Procedure Code Description</th>
<th>ICD Code No.</th>
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<tbody>
<tr>
<td>Plication of emphysematous bleb</td>
<td>32.21</td>
</tr>
<tr>
<td>LVRS*</td>
<td>32.22</td>
</tr>
<tr>
<td>Endoscopic excision or destruction of lesion or tissue of lung</td>
<td>32.28</td>
</tr>
<tr>
<td>Other local excision or destruction of lesion or tissue of lung (wedge, NOS)*</td>
<td>32.29</td>
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</tbody>
</table>

*This code became available in October 1995.

†NOS = not otherwise specified.

**RESULTS**

Between January 1, 1993, and June 30, 1994, HCFA recorded 528 claims for local lung excision procedures (Table 1), an average of 29.3 procedures per month. From July 1, 1994 through December 31, 1995, 1,322 claims were recorded for the same lung excision procedures (73.4 per month). This is an overall increase of 794 claims compared with the previous 18-month period, which can be attributed to LVRS. A total of 418 claims were recorded using the specific code for LVRS for the last 3 months of 1995. Based on these data, we estimate that approximately 1,212 LVRS procedures were performed on Medicare patients during the 18 months following its reintroduction in 1994 (95% confidence interval: 1,012 to 1,408 based on difference in mean number of procedures per month).

The number of claims per month increased rapidly during the period under study, particularly in the last 3 months of 1995. The average monthly volume of estimated LVRS claims rose from 48 per month during July 1994, through September 1995, to 164 per month during October 1995, through December 1995 (Fig 1). Overall, the last 3 months that HCFA allowed payment for LVRS account for nearly 50% of the estimated procedures performed. The highest monthly volume of procedures occurred in the last month that Medicare reimbursed for LVRS (169 cases—December 1995). Two hundred ten claims were submitted in 1996, probably reflecting delayed submission of claims for procedures performed in 1995. Most of these claims were submitted in January and February 1996. Only 11 claims were submit-
ted in March 1996. Over the last 6 months of 1996, only 12 claims were submitted.

Based on the 628 claims that were specifically coded as LVRS from October 1995 through December 1996, the procedure was being performed in 40 states. The mean age of patients undergoing the procedure was 68 years (range, 39 to age 89 years). Nearly one third of the patients were >70 years and 10% were >75 years. Ten percent of the patients were <60 years and presumably were disabled and therefore eligible for Medicare coverage. Seventy-two percent were male and 95% were white.

The mean and median length of stay estimates are comparable to those reported in several case series, although some centers have reported median lengths of stay as short as 8 days.2

Claims to Medicare for LVRS dropped substantially following HCFA's announcement that LVRS claims would no longer be reimbursed (Fig 1). The drop in claims identified as LVRS was accompanied by an increase in the performance of procedures categorized as "wedge resections" not otherwise specified (ICD-9-32.29). The number of cases per month in this category increased from an average of 7 per month for 1995 to an average of 39 per month during 1996. It is not clear whether these cases represent a separate trend in non-LVRS local excision procedures in patients with emphysema or are misclassified LVRS cases.

Charge and claims data from the 210 LVRS claims submitted in 1996 are summarized in Table 2.

The charge and reimbursement data are consistent with previously published literature that reports reimbursements ranging from $25,000 to $45,000 at major centers.2-4 While the median charges reimbursed are more representative of typical patient charges, from the perspective of a funding agency, the mean charges reimbursed are more indicative of the total LVRS reimbursement burden. Twenty percent of the claims submitted in 1996 received zero reimbursement from HCFA, consistent with the policy of not reimbursing for LVRS after December 1995. These claims were excluded in determining the mean and median reimbursement figures presented in Table 2.

Table 2—Mean and Median Charge and Length of Stay for LVRS Procedures Performed in 1996

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Charges submitted</td>
<td>$75,664.70</td>
<td>$42,692.20</td>
<td>$2,624–706,034</td>
</tr>
<tr>
<td>Charges reimbursed</td>
<td>$31,308</td>
<td>$17,754</td>
<td>$8,913–251,222</td>
</tr>
<tr>
<td>Length of stay, d</td>
<td>20.27</td>
<td>13</td>
<td>2–169</td>
</tr>
</tbody>
</table>

DISCUSSION

Early studies suggest that LVRS may be a promising therapy for patients with severe, disabling emphysema. As evidenced by the data, claims to Medicare for LVRS increased substantially prior to the HCFA's reimbursement moratorium for the procedure. In <2 years after its introduction, LVRS had been performed on 1,000 to 1,400 Medicare enrollees, and was being offered to Medicare patients in at least 37 states. The average reimbursement for allowed claims was $31,398.

Interpreting the rapid rate of rise in LVRS claims during the observation period (particularly the latter months of 1995) is problematic due to the limitations of administrative data. While the number of LVRS claims appears to be increasing rapidly at the end of 1995, this may in fact be due to more complete ascertainment of LVRS cases following introduction of the LVRS ICD-9 code in October 1995. In addition, the rate of LVRS procedures might have temporarily increased in anticipation of the Medicare reimbursement moratorium to enable patients without alternative insurance coverage to undergo the procedure. In either case, the data for the end of 1995 would overestimate the true trend of LVRS.

Conversely, the data reported herein may underestimate LVRS growth during 1995. Delays in coding claims and adopting new ICD-9 codes are common. Many LVRS claims may not have been accurately coded during this time, and the suspension of reimbursement added a potential disincentive to file claims for LVRS procedures using the specific procedure code.

This analysis also does not consider LVRS procedures that were reimbursed by private insurers. At the University of Washington, Medicare was the primary source of reimbursement for approximately 60% of all LVRS procedures performed.2 If the experience at the University of Washington is generalizable, it is likely that >2,000 LVRS procedures were performed nationally between July 1, 1994, and December 31, 1995. In 1996, the Agency from Health Care Policy Research (AHCPR) estimated that approximately 3,090 LVRS procedures had been performed in the United States, based on data received from 27 institutions responding to a request for information published in the Federal Register.5 It is not clear from this report how many of these patients were Medicare enrollees or the time period over which these cases were performed. If the average patient mix with respect to reimbursement is 40% Medicare and 60% non-Medicare, then the AHCPR estimate would be quite comparable to estimates reported herein.

It is likely, however, that both the AHCPR and
Medicare claims data estimates presented herein underestimate the true number of LVRS cases performed. We used a conservative approach to estimate LVRS procedures, relying on ICD-9 codes that were most likely to represent LVRS. Considerable coding variation practices exist among institutions and we may not have captured some LVRS procedures in our analysis. The AHCPR study relied on voluntary submissions from 27 individual centers and is thus likely a biased (and unrepresentative) sample. For example, the Medicare records identify claims from centers in 37 states, clearly comprising additional centers other than the 27 included in the AHCPR report.

The rapid growth of LVRS prior to the HCFA moratorium was fueled by a combination of clinical, regulatory, and economic factors. Traditional treatments for patients with severe emphysema have an extremely modest impact on quality of life, and do nothing to modify the course of the disease. Both patients and physicians have been eager to identify new and promising treatments for emphysema. Early LVRS case series showing promising results created tremendous anticipation that a “breakthrough” was at hand. (Evidence of the level of excitement among patients can be found on the Society for Thoracic Surgeons world wide web page entitled “Discussion Forum for LVRS.”)

Traditionally, new medical and surgical procedures such as therapeutic endoscopy, angioplasty, and LVRS have evolved within the medical community without extensive scrutiny from third-party payers. Procedures were developed, adopted, or abandoned over time based on their evaluation by the medical community. Unlike medications and medical devices, surgical procedures such as LVRS are not regulated by the Food and Drug Administration. Thus, other than through reimbursement moratoriums, federal, state, and private health insurers have little ability to regulate the growth of experimental surgical therapies. With increasing pressure to control health-care costs, health insurers are increasingly likely to exercise restrictions on reimbursement for new medical and surgical therapies as a means of controlling growth of health-care costs. Thus, to some extent, LVRS has pitted patients and some physicians, who believe LVRS to be beneficial, against health insurers, who have raised concerns over the economic implications of covering a new procedure that could affect tens of thousands of patients.

The cost of LVRS to the United States health economy was considerable prior to the Medicare reimbursement moratorium. Based on the average amount of reimbursement for definitive LVRS cases ($31,398), Medicare expenditures for LVRS exceeded $30 million during the 18-month period of this analysis, and overall national expenditures may have exceeded $100 million. Several private insurance carriers have suspended reimbursement for LVRS since the HCFA announced its moratorium for the procedure, while others have continued to reimburse for the procedure.

The HCFA has reason to be concerned about growth in LVRS. Approximately 1.65 million Americans suffer from emphysema. More than 20% of these patients are >65 years and thus are eligible for Medicare. If 10% of all Medicare patients with emphysema fit LVRS eligibility criteria, performing LVRS on these individuals would cost nearly $1 billion. LVRS may prove to be cost-effective compared with standard therapy for emphysema, but currently there are insufficient data to determine its cost-effectiveness.

Even if it proves to be cost-effective, LVRS is not likely to result in net cost savings for insurers, despite the potential for reduced use of medications and oxygen and potential for functional improvement. This is not to say that LVRS should not be performed. Very few medical interventions, short of selected immunizations, have been demonstrated to save money. The cost of the surgery may well be worth the potential improvements in patient quality of life. Before reimbursing for LVRS under Medicare, however, it is likely that the HCFA will require conclusive evidence demonstrating the magnitude and duration of benefits of LVRS in patients >65 years, particularly given that the mortality associated with LVRS in this age group may exceed 10%.

The National Emphysema Treatment Trial, if successfully completed, will help to answer critical questions about the clinical benefits and cost of LVRS. The trial may also serve to establish a standardized surgical technique for LVRS. This could benefit both payers and patients by minimizing the variation in practice among sites, since a great many centers are expected to begin offering LVRS if the clinical trial reveals that it confers benefits for patients with emphysema.

Conclusions

Utilization of LVRS among Medicare enrollees grew rapidly from the time the first studies were presented up to the time that HCFA suspended payment. We estimate that approximately 1,212 LVRS procedures were performed on Medicare enrollees in the 18 months prior to the reimbursement moratorium. Given the prevalence of emphysema, the cost of the procedure, and the clinical
demand for new therapies for emphysema, LVRS has the potential to become a significant component of national health-care expenditures.

REFERENCES
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