

Economic Considerations of Lung Volume Reduction Surgery and Bronchoscopic Valves



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KEYWORDS

• Emphysema • Lung volume reduction surgery • Bronchial valve • QALY • Cost-effective

KEY POINTS

- Chronic obstructive pulmonary disease (COPD) is associated with a substantial burden to the health care system and society, as it relates to direct medical costs and indirect costs.
- In select patients with predominantly upper lobe disease and low exercise tolerance, lung volume reduction surgery can be a cost-effective procedure.
- In select patients without collateral ventilation bronchial valve, therapy can be a cost-effective procedure.
- As surgical and bronchoscopic techniques are refined, length of stay, complication rate, and correct patient selection will improve cost-effectiveness of these lung volume reduction procedures

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) remains a leading cause of chronic morbidity and is the third leading cause of mortality within the United States.¹ For heavy current or former smokers, the prevalence of COPD is approximately 20%, impacting at least 16 million people in the United States.² It contributes to a significant reduction in quality of life with substantial economic, societal, and personal costs.

Prevention of COPD exacerbations and the high costs associated with hospital admission remain a major quality goal of the US health care system. For many patients, the disease can be well controlled with medications alone, while for patients with the most severe disease, lung transplant is an effective, although extremely expensive and highly resource-limited option. For patients with significant disease who are not

candidates for transplant, treatments focused on reducing dead space and improving ventilation-perfusion matching have shown to be efficacious. This can be done surgically, by resecting the diseased lung, or via 1-way valves that prevent airflow into the diseased area but do allow air to return. These 2 procedures, lung volume reduction surgery (LVRS) and bronchoscopic lung volume reduction (BLVR), have different costs and effectiveness. The economic impacts of these therapies, relative to each other and to best medical practice, is the focus of this article.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE ECONOMIC BURDEN

COPD is associated with a substantial economic burden to the health care system and society as a whole. Understanding the cost of the disease is important for health care decision makers to

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inform policy and guide resource-allocation toward interventions that have the most impact on overall disease-related health care costs and the greatest improvement in patient quality of life. In 2009, US costs attributable to COPD totaled \$50 billion, with direct cost estimated at \$29.6 billion and indirect costs estimated at \$20.4 billion.³

Direct costs to the health care system include those related to the detection, treatment, prevention, and rehabilitation of the disease. The direct costs of COPD on the US health care system are substantial. The 2017 Agency for Healthcare Research and Quality group data report total expenditures of COPD at \$79 billion, in comparison to cancer at \$106 billion, diabetes at \$104 billion, and hypertension at \$46 billion.⁴ COPD consistently ranks among the top 5 most expensive chronic diseases.⁵

Patients with poorly controlled disease have significantly higher costs because of more primary care interactions, more emergency room visits, and increased hospital and intensive care unit admissions.⁶ Although total treatment costs are highly correlated with disease severity, within each stage it is still hospitalization expenses that remain the highest portion of costs⁷ (see **Table 1** for direct cost breakdown). Targeting interventions that reduce hospitalizations will therefore have the most impact on direct costs.

When considering the economic impact of disease on society, it is also important to understand the indirect costs of the disease. Indirect costs are those costs borne by the patient and society because of the disabling effects of the disease and include loss of productivity, loss of salary, caregiver time and lost productivity, and use of disability benefits. As work productivity and disability benefits are among the largest drivers of indirect costs, the percentage of patients who are working age has a large impact on the societal burden of the disease. In the *Confronting COPD in North America and Europe* survey, researchers found 82% of COPD patients in the United States are of working age.⁸ Patients of working age were asked how often their COPD affected their capacity to work. The results found a dramatic impact on productivity, with over 50% of the population reporting that the disease affected their work productivity. Thirty-five percent of respondents were completely prevented from working during the previous year; 18% were limited in the work they were able to do, and an additional 5% had absences from work. The Health and Retirement Study evaluated the impact of the COPD on Americans older than 50 years with regards to employment status and the collection of disability benefits.⁹ These researchers found having COPD resulted in a 9% decrease in likelihood of being employed, a 3.9% increase in probability of collecting Social Security Disability Insurance (SSDI), and a 1.7% increase in likelihood of collecting Supplemental Security Income (SSI). This negative impact on employment exceeds nearly all other major chronic health conditions including heart disease, cancer, hypertension, and diabetes. Only stroke patients experience a comparable decline in employment productivity. Moreover, the associations of COPD with collecting SSDI and SSI are the largest of any of the chronic disease conditions evaluated. At the time of this study, the average wage loss was \$38,844, SSDI average annual benefit \$14,507, and SSI average annual benefit \$6008, for a total societal economic loss of nearly \$60,000 per patient. Further compounding the issue is that these are almost certainly underestimates of the broader societal and patient impact, as many indirect costs are difficult to capture. In many cost-effectiveness studies, these costs described previously, as well as costs of out-of-pocket expenses such as nonprescription medication, travel costs to and from health care visits, economic value of the care provided by family members, and time spent by the patient receiving treatment, are not included. Overall, this may lead to potential underestimation of the total economic burden.

Table 1
Direct costs (costs in Canadian dollars, 2004)

	Price
Intensive care unit (ICU) stay	\$1446/d
Non-ICU stay	\$626/d
General practitioner visit	\$54/visit
Emergency room visit	\$123/visit
Specialist visit	Varies
Oxygen	\$383/month
Medications	\$1175
Rehabilitation	\$56/outpatient
Mean hospitalization for exacerbation (in the United States)	\$18,120 ³⁶

Adapted from Miller JD, Malthaner RA, Goldsmith CH, et al. A randomized clinical trial of lung volume reduction surgery versus best medical care for patients with advanced emphysema: a two-year study From Canada. *Ann Thorac Surg* 2006;81(1):314-321; with permission; Additional data from AbuDagga A, Sun SX, Tan H, Solem CT. Exacerbations among chronic bronchitis patients treated with maintenance medications from a US managed care population: an administrative claims data analysis. *Int J Chron Obstruct Pulmon Dis*. 2013;8:175-185.

HISTORY OF LUNG VOLUME REDUCTION SURGERY AND COSTS

LVRS was first described in 1957, when Brantigan and colleagues^{10,11} reported their initial results with multiple wedge resections of emphysematous lung. The procedure showed promise of significant functional improvement, but was abandoned due to perioperative mortality that approached 20%. In 1995 and 1996, Cooper and colleagues reported their results, demonstrating an initial 82% improvement in forced expiratory volume in 1 second (FEV1) with significant symptomatic improvement, with a 90-day mortality of only 4%.¹² Despite these promising results, in 1995, Medicare made the decision not to reimburse LVRS.

The denial of coverage in light of the promising data from Cooper and colleagues is what ultimately led to the National Emphysema Treatment Trial (NETT). This trial confirmed a significant improvement in quality of life and survival for certain subgroups undergoing LVRS, while also identifying patients for whom the procedure was harmful.¹³ For non-high-risk patients, there was an improvement in survival, exercise capacity, and quality of life, with the greatest benefit seen in those patients with upper lobe predominant disease and low exercise capacity. As a result of the NETT data, LVRS achieved limited approval by the Centers for Medicare and Medicaid Services (CMS) for select hospital programs and specific patient populations.

Cost-Effectiveness

As part of the NETT report, a companion study evaluating cost-effectiveness was performed. The study included both the direct costs, specifically surgical costs, hospital days, and medications, along with indirect costs such as transportation and time spent by patients and family members related to the care of their disease. **Table 2** shows the breakdown of costs of LVRS compared with best medical care. The study found that after excluding the highest risk patients, who were unlikely to benefit from surgery, the incremental cost-effectiveness ratio (ICER) for LVRS was \$190,000 per quality-adjusted life year gained (QALY).¹⁴ With statistical modeling to 10 years, the ratio decreased to \$53,000 per QALY gained. The patients with upper lobe predominant disease with low exercise capacity had overall greatest improvement in survival and quality of life, with projected 10-year cost of \$21,000 per QALY gained.

In 2006, the data from the multicenter Canadian randomized controlled trial comparing LVRS

versus best medical care were published.¹⁵ The researchers found that the LVRS group had a 0.21 improvement in QALY compared with best medical care, and the cost difference was \$28,119. For the 2-year study period data, ICER was \$133,900 per QALY gained.

Drivers of Cost-Effectiveness

Although the authors from the NETT group looked at direct and indirect costs, it was the direct cost that overwhelmingly drove the cost of care, and of direct costs, number of hospitalization days was the single largest cost driver.¹⁴ The surgery group has 23.3 days in the hospital in the first 6 months, compared with 3 days for the medical group, with an associated total direct medical cost per patient in the surgery group of \$62,753 in the first 12 months, compared with \$12,932 over the first year per patient in the medical group. These numbers reversed in year 2, with the medical group having higher costs and more hospital days. Further reducing perioperative morbidity and postsurgical length of stay could thus improve the cost-effectiveness ratio for surgery patients, especially the upper lobe-predominant, lower exercise capacity group.

Surgical Approach and Cost

Among the NETT surgical patients, both median sternotomy and video-assisted thoracoscopic surgery (VATS) approaches were utilized; although sternotomy was the dominant approach (359 sternotomy vs 152 VATS). In a nonrandomized comparison of these 2 cohorts, there was no difference in perioperative morbidity or mortality, but there was a shorter length of stay, earlier return to independent living, and overall lower cost for the VATS group.¹⁶ As hospitalization is the largest cost, understanding the main determinants of length of stay is key to reducing the costs associated with LVRS. Although the largest driver of length of stay (LOS) in both groups was air leaks, the rates of air leak at 7 days between the 2 groups were similar (46% sternotomy vs 49% VATS). In a randomized cohort comparing the groups, VATS patients had a median LOS of 6 fewer days than sternotomy patients (9 days vs 15 days). Finally, within the randomized cohort, total cost for VATS was \$6500 less per patient over the first 6 months compared with sternotomy.

Improvement in Long-Term Outcomes

Apart from lowering costs, improvements in effectiveness also significantly impact the cost-effectiveness ratio. The NETT follow-up was a median of 2.4 years,^{13,17} and the long-term

Table 2
Costs of lung volume reduction surgery (data adjusted to 2020 US dollars)

		Lung Volume Reduction Surgery	Best Medical Care
	Surgery (including bronchoscopy and tracheostomy)	\$4882	\$0
Index hospitalization	Length of stay	30,248	0
	Total index hospitalization	35,130	0
2 y of follow up costs	Hospitalizations	7509	12,670
	Rehabilitation	3616	2759
	Oxygen	2899	4125
	Medications	1225	1459
	Outpatient visits	1589	1561
	Total follow-up costs	16, 838	22,574
Total Costs		\$51, 968	\$22,574

Adapted from Miller JD, Malthaner RA, Goldsmith CH, et al. A randomized clinical trial of lung volume reduction surgery versus best medical care for patients with advanced emphysema: a two-year study From Canada. *Ann Thorac Surg* 2006;81(1):314-321; with permission.

projections assumed that the differences in outcomes persisted to 3 years. However, in 2006, a long-term analysis of the outcomes found that the benefits persisted for up to 5 years.¹⁷ Excluding high-risk patients, there was an 18% relative risk reduction of death for LVRS patients at 5 years, and 15% of LVRS patients had a clinically significant improvement in quality of life at 5 years compared with only 7% of medical patients.¹⁷ Among upper lobe-predominant, low-exercise participants, there was a 43% reduction in mortality at 5 years, while 19% had a clinically significant quality-of-life improvements, compared with 0% of the medically treated patients. For the upper lobe-predominant high exercise capacity subgroup, there was a significant palliative benefit, with 23% of LVRS patients having significant quality-of-life improvements persisting to 5 years, compared with only 13% of the medical subgroup.

Utilizing an additional 2 years of data, Ramsey and colleagues performed an updated cost-effectiveness analysis to NETT cost analysis.¹⁸ They found that the 5-year cost for LVRS patients compared with medical patients was \$140,000 per QALY gained, which compared favorably with the \$190,000 per QALY based on observed 3-year data. For the upper-lobe, low exercise capacity group, the ratio improved from \$98,000 per QALY to \$77,000 per QALY gained. The other groups also showed improved ICERs. See details in [Table 3](#).

HISTORY OF ENDOBRONCHIAL THERAPY AND COSTS

BLVR refers to several different non-surgical interventional techniques for treating severe

emphysema. The first and most widely used is the bronchial valve, which is designed to allow 1-way airflow through the airways. The clinical applicability and use of bronchoscopic valves for COPD began in 2007 with publication of a small multi-center study with 30 patients utilizing the Spiration valve, which showed significant improvement in patient-reported quality of life.¹⁹ In 2010, the Emphysema Palliation (VENT) Trial²⁰ evaluated efficacy of the Zephyr valve placement and showed significant clinical improvement, with the most dramatic improvements seen in patients with a complete fissure. Three subsequent trials, STELVIO, TRANSFORM, and LIBERATE, showed similar clinical improvements with placement of EBV.²¹⁻²³ The IMPACT trial evaluated Zephyr valve placement in patients with homogenous emphysema without collateral ventilation, which again showed clinical improvement, but demonstrated that the primary determinant of clinical benefit from EBV is the absence of collateral ventilation, rather than the pattern of emphysema.²⁴ In June 2018, the US Food and Drug Administration (FDA) approved the Zephyr endobronchial valves as the first bronchoscopic treatment for emphysema in the United States.²⁵

Following the success of the Zephyr trials, The REACH and EMPROVE trials re-evaluated the Spiration valve on a larger scale and found statistically significant improvements in clinical markers of lung function.^{26,27} In December 2018, the FDA approved the Spiration IBV for treatment of emphysema.²⁸ In December 2018, the National Institute for Health Care Excellence in the United Kingdom followed suit to recommend the use of bronchial valves for use in emphysema patients.²⁹

Table 3
Projected and observed cost-effectiveness ratios for LVRS vs maximal medical therapy for observed and projected years of follow-up from initial randomization, using observations up to 3 years and 5 years after randomization

Incremental Cost-Effectiveness Ratio	All Patients	Upper Lobe Emphysema, Low Exercise Capacity	Upper Lobe Emphysema, High Exercise Capacity	Non-upper Lobe Emphysema, Low Exercise Capacity
Observed up to 3 y	\$190,000	\$98,000	\$240,000	\$330,000
Observed up to 5 y	140,000	77,000	170,000	225,000
Projected at 10 y based on 3 y of follow-up	58,000	21,000	54,000	Dominant
Projected at 10 y based on 5 y of follow up	\$54,000	\$48,000	\$40,000	\$87,000

From Ramsey SD, Shroyer AL, Sullivan SD, Wood DE. Updated Evaluation of the Cost-effectiveness of Lung Volume Reduction Surgery. *CHEST* 2007;131(3):823-832; with permission.

Shortly thereafter, the 2019 GOLD Report detailed guidelines for the appropriate use of bronchoscopic interventions in select patients with advanced emphysema.³⁰

Cost-Effectiveness

Cost analyses for the valves have been performed utilizing data from the original VENT and STELVIO trials. Within the VENT study, researchers evaluated the subgroup of patients who met the current clinical recommendations for bronchial valve therapy: emphysema diagnosis with high heterogeneity, complete fissures isolating the target lobe, and lobar exclusion. They captured direct medical costs obtained from 2014 German Diagnosis Related Group (G-DRG) reimbursement rates.³¹ The analysis incorporated procedure costs (assuming an average of 3 valves per procedure) and included all clinical events during the 12-month follow-up with Markov modeling used to project costs for years 2 to 10. They found in the 5-year model, EBV costs were \$30,313 versus control \$15,256, and QALY in the EBV group was 2.88 versus control 2.66. The calculated ICERs were \$67,722 and \$36,757 per QALY gained for the 5 year and 10-year models, respectively^a. In a separate study, data from the STELVIO trial were used to calculate direct medical costs from the hospital perspective, derived from Dutch health insurance price levels in 2016.³² The analysis included an expected 5-day LOS, assumed average of 4.5 valves per procedure, and included

all clinical events within the first 6 months, with a Markov simulation model to determine long-term economic value at 5 and 10 years. The authors found with a 5-year modeling analysis a cost of \$46,937 per QALY gained and for 10-year modeling a cost of \$25,876 per QALY gained^b.

Drivers of Cost-Effectiveness

Hartman and colleagues³³ reviewed the breakdown of costs in the valve group compared with the control group. Most of the total costs that came from the EBV group were from the initial bronchoscopy and the associated products used. Furthermore, in the instance in which there was a complication that required intervention with repeat bronchoscopy (35%), there was an even larger expense associated with the total cost. In this study, with just 6 months of follow-up data, there did not appear to be a huge difference in the COPD exacerbation rates among the control group and EBV group, which is a large limitation in the study, because as was seen in the NETTs trial, the benefit of intervention was most seen in the second year after the procedure.¹⁴ Longer-term follow-up with data of both the control group and the EBV group would likely lead to larger differences for COPD-specific complications from standard medical therapy compared with EBV placement. Also, with provider experience in use of placement of EBVs, it is likely the complication rates will decrease, thus, further improving the cost-effectiveness ratio for EBV patients.

^aCosts reported here are converted from 2014 Euros to the 2020 US dollar.

^bCosts reported here are converted from 2016 Euros to the 2020 US dollar.

Table 4
Variation in cost analysis among studies (data adjusted to 2020 US dollars)

Study	Years of Data	Cost per QALY Gained
US NETT 2003 ¹⁶	3 y	\$272,270
US NETT 2003 ¹⁶ (subgroup with most clinical benefit: upper lobe emphysema, with low exercise capacity)	3 y	140,434
Canadian RCT 2006 ⁹	2 y	134,365
Ramsey et al, ¹⁸ 2007 NETT update	5 y	196,149
Ramsey et al, ¹⁸ 2007 NETT update (subgroup with most clinical benefit: upper lobe emphysema, with low exercise capacity)	5 y	107,822
German EBV Study ¹⁹ modeling projections for 5 y	12 months	69,611
Dutch EBV Study ²⁰ modeling projections for 5 y	6 months	\$46,498

Data from Refs. ^{14,15,20,32,33}

COST-EFFECTIVENESS COMPARISON OF LUNG VOLUME REDUCTION SURGERY AND ENDOBRONCHIAL VALVES

Within a health care system with limited budgets, it is important for medical care payers to determine the value of each novel therapy, as each approved reimbursement of a new cost increasing technology could potentially displace payments for other areas of health care. In the instance of LVRS versus BLVR, it also ensures that therapies are applied to the most suitable patients, as the clinical outcomes vary largely depending on the type of emphysema. In selecting COPD patients who are most likely to benefit from LVRS, data would suggest that those with predominantly upper-lobe emphysema and low exercise capacity have the greatest improvement in terms of survival and functional outcomes compared with medical therapy. Conversely, the optimal COPD patient to benefit from a valve placement is one with a complete fissure and thus no collateral ventilation to the lobe that the provider is aiming to occlude. An important difference from LVRS is that the bronchial valve clinical trials demonstrated equal clinical effectiveness in both upper and lower lobe-predominant emphysema.³³

A direct comparison of the ICERs for LVRS and BLVR is challenging. The data were collected from different time periods and in different health care systems. The LVRS data are from early 1997 to 2003, from US and Canadian health care systems, while the BLVR cost analysis was done from 2014

to 2016 in European health care systems. Table 4 includes costs adjusted to US dollars and accounted for inflation to demonstrate anticipated cost per QALY gained in 2020. Additionally, because bronchial valve placement therapy for COPD is a relatively new technique, there has been no true 5- and 10-year cost analysis follow-up done, only projections based on assumed efficacy. As the data from LVRS demonstrated, 5- and 10-year modeling can be dramatically different from the true long-term outcomes (see [Table 4](#)).¹⁸ As of now, however, the data would suggest the clinical benefit of EBV therapy lasts for at least a 5-year follow-up.³⁴ Perhaps most challenging is the changing nature of the costs of a given procedure. As discussed previously, most of the LVRS patients in the analysis had a median sternotomy; however, the current preferred surgical approach is VATS, which is associated with lower overall costs than sternotomy.¹⁶ Similarly, as providers become more comfortable with the bronchoscopic technique, it is likely that the complication rates and LOS will improve and, subsequently, costs will decrease. Finally, the LVRS studies were done before implementation of various national quality improvement programs that have led to great improvements in health care quality indicators, including lower rates of reintubation and prolonged ventilation.

FUTURE MEDICAL COSTS

Akuthota and colleagues³⁵ performed an analysis from their pulmonary function test laboratory

database from 1996 to 2006 searching patients with GOLD III and IV COPD. They estimated up to 15% of the general population of advanced emphysema patients are potential candidates for LVRS.

However, the limited number of CMS-approved sites for performing LVRS and hesitation on the side of patients and referring providers has limited the number of procedures to less than 1000 per year in the United States. In a review of the STS Database from January 2003 to June 2011, Decker and colleagues³⁵ noted only 538 patients underwent LVRS in 8.5 years, with a high of 118 cases in 2008. Future growth in treatment of patients with advanced (GOLD III and IV) emphysema will likely be in treatment with BLVR. This endoscopic approach is not limited to the CMS-approved sites for LVRS. Data from the VENT trial would suggest that 37% of patients with advanced emphysema had complete fissures eligible for treatment.

Based on US Centers for Disease Control and Prevention (CDC) and severity data, it is estimated there are 1.5 million severe emphysema patients in the United States. Of these, 80% are predicted to have sufficient hyperinflation for volume reduction. Of these, another 20% would be ineligible for treatment because of comorbidities, lung destruction, or lung morphology. Another 50% would be ineligible due to collateral ventilation. Thus, approximately 500,000 patients would be eligible for treatment with BLVR. The advanced emphysema population is growing by 1% to 2% a year, and the average life expectancy for these patients is about 10 years, meaning approximately 10% to 12% of the prevalent base is comprised of patients newly diagnosed with severe emphysema each year.

The biggest challenge in predicting future cost is that most of these patients are not currently referred for treatment, and many are not under the care of a pulmonologist. Ideally, patients would be sent to a center offering pulmonary rehabilitation, surgery, and bronchial valves for workup that included radiological, nuclear medicine, blood gas, exercise and pulmonary function assessments, and personalized care recommendations. Because BLVR was only recently approved by the FDA and similar international bodies, it will take many years to begin making the necessary changes to referral patterns to get patients to routinely be referred to COPD centers of excellence.

SUMMARY

Prevention of COPD exacerbations and hospitalizations remains a major quality goal for health care systems. In patients with severe emphysema-related COPD, hospitalizations remain the primary driver of the high cost of care. In the United States,

it is estimated that the total societal economic loss associated with COPD is nearly \$60,000 per year. In properly selected patient cohorts, both LVRS and BLVR have proven cost-effective.

The data show LVRS has the greatest clinical benefit and cost-effectiveness in patients with upper lobe predominant emphysema and low exercise tolerance. In addition, this cohort had the lowest 30-day mortality rate, at 2.9% in the NETT trial.³⁶ LVRS remains clinically effective and reduces costs in patients with upper lobe-predominant emphysema and high exercise capacity. Recent trials show BLVR is clinically effective and cost-effective in emphysema patients with low exercise capacity and complete fissures irrespective of whether the disease is upper lobe predominant or homogenous.

At first pass, one could conclude that homogenous patients should be approached with BLVR and upper lobe predominant patients approached with minimally invasive (VATS) LVRS. The ICER for upper lobe predominant emphysema patients with low exercise capacity observed for 5 years and projected for 10 years was \$48,000 compared with an ICER of \$87,000 in non-upper-lobe predominant emphysema patients with low exercise capacity.

A challenge arises in trying to effectively identify patients with a complete fissure. Each trial showed an approximate 20% incidence of collateral ventilation based on bronchoscopic investigation of patients with HRCT examinations, suggesting complete fissures. The need to cross-over these 20% of patients to evaluation for LVRS will add to the overall cost of care. An encouraging finding in the studies was the retained eligibility for surgical LVRS in patients requiring removal of the endobronchial valves.

The less-invasive nature of BLVR and the embracement of the technology by pulmonary medicine physicians will hopefully increase referrals of advanced emphysema patients for lung volume reduction at multidisciplinary centers.

CLINICS CARE POINTS

- Upper lobe-predominant emphysema patients with low exercise capacity after formal pulmonary rehabilitation should be managed with bilateral VATS LVRS.
- Non-upper lobe emphysema patients without collateral ventilation should be managed with BLVR.
- Any procedure performed on a cohort of patients at higher risk for complications and

poor tolerance of adverse outcomes requires a multidisciplinary approach to optimal patient selection.

- Proper patient selection and perioperative patient management play a more significant role in outcomes for this patient population than nuances of procedural technique.

DISCLOSURE

The authors report nothing to disclose.

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