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Improving Lung Function in Severe Heterogenous Emphysema with the Spiration Valve System: Still a Great Need to “EMPROVE”

To the Editor:

We read with keen interest the results of a randomized controlled trial of the Spiration Valve System in patients with severe emphysema by Criner and colleagues (1). We congratulate the authors for presenting a well-designed study on an important clinical question. It has been previously reported that use of endobronchial valves in severe emphysema leads to improvement in FEV₁ compared with placebo, similar to the results found in the present study (2). However, some important points regarding the reported results need careful consideration and further discussion.

Although the authors report significant improvement in FEV₁ compared with baseline on 6-month follow-up in the valve group, the overall responder rate is only 37%; that is, only approximately one-third of all patients who received the valve actually demonstrated benefit in airflow. Similarly, although the patient-centered outcomes (i.e., dyspnea and quality of life) improved in the valve group, they did so in only 53% and 54% of subjects, respectively, at 6 months. We feel that this response rate is extremely low by any standard, especially considering the high cost and potential complications associated with valve placement. Therefore, it would be desirable to interpret these results in the proper perspective, based on cost benefit.

Considering the patient population in which endobronchial valve therapy is being considered (i.e., those with severe airflow limitation, limited exercise capacity, and receiving long-term oxygen therapy), it may be worthwhile to identify predictors of nonresponse in the endobronchial valve therapy group in an attempt to identify patients most likely to derive benefit from this intervention. This may have important implications for rationalizing clinical practice of emphysema management. ■

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Reply to Jain *et al.*

From the Authors:

We thank Dr. Jain and colleagues for their comments about our study. We wholeheartedly agree that refining the patient population most likely to benefit from this or any other therapy is the goal of personalized patient care. The cost of care, especially in the case of patients with emphysema, is also of prime importance. However, we would like to emphasize that despite the severity of the patient group studied in EMPROVE (patients with severe and irreversible airflow obstruction [FEV₁, 28–30% predicted], hyperinflation [residual volume, 207–213% predicted], and >60% emphysema severity in the targeted lobes), patients with valve treatment were sevenfold more likely to achieve >15% improvement in FEV₁ at 1 year compared with the control group receiving optimal medical therapy (1). In addition, as pointed out by Dr. Jain, more than half the subjects exceeded the minimally important changes in dyspnea and quality of life. This was balanced against the complication of pneumothorax, a treatable consequence of endobronchial valve treatment with total lobar occlusion in subjects with fissure integrity. We believe it is also important to consider the alternative therapies used to treat patients at this stage of their disease and their symptom

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