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Respiration  
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## From Bench to Bedside: Implementation of Endobronchial Valve Treatment for Patients with Advanced Emphysema in Routine Clinical Care

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Dear Editor,

The bronchoscopic lung volume reduction treatment using endobronchial valves (EBV) for patients with severe emphysema went through several developmental stages, starting in 2003 [1], with recently multiple positive randomized controlled trials being published [2], leading to the implementation of this therapy in the 2017 COPD (chronic obstructive pulmonary disease) GOLD [3] and National Institute for Health and Care Excellence (NICE) recommendations as well as FDA approval in 2018. Consequently, this treatment is becoming routine care in an increasing number of countries. Since the treatment is only suitable for a carefully selected group of severe emphysema patients, requires significant logistics, costs, and expert skills to perform and to handle its complications [4], its introduction and implementation on a national level should, in our opinion, be carefully guided to fully optimize outcomes and protect patients and physicians from failures. The question rises how to introduce and monitor such a new, promising intervention for a selected and vulnerable group of patients in clinical practice. In this perspective paper, we review the literature regarding the implementation of new interventions and conclude with recommendations from the literature and our clinical experience.

In the literature, no real guidance is given for the implementation of new interventions. The Dutch National Health Care Institute developed a guideline for the introduction of new interventions [5], advising a database development for the purpose of risk analyses, evaluation, and, if necessary, adjustment of processes after implementation. NICE has developed a guidance for the EBV treatment [6], advising a multidisciplinary team (MDT) for patient selection, that the treatment is only performed by trained clinicians, and, as the EBV treatment is associated with early and delayed complications that are manageable but could be potentially life-threatening if not promptly treated [4], to perform the treatment in high-volume expert centers only. “The more, the better” is also scientifically proven across a wide range of procedures [7,

8]. Finally, the FDA requires a full certified training program before a site can start any EBV treatment.

Based on these recommendations, we took the following steps for the introduction of the EBV treatment in the Netherlands.

### *Education and Specialized Treatment Centers*

The EBV treatment is only performed in a few centers with trained pulmonologists. The expert centers also need to have major COPD experience and do need to have access to other bronchoscopic and surgical treatment options to be able to opt for the ideal treatment for the patient. In the literature, no recommendations on minimal procedure volume numbers are reported, but to reach the experience level needed, we believe that at least 15–20 treatments per year per treating physician per center should be performed, but we will need to evaluate this in the future.

### *Registration Database*

We believe it is crucial to set up a registry to monitor EBV treatment outcomes in routine clinical practice, and to act accordingly. In the Netherlands, we started the BREATHE registry (NCT02815683) for this purpose. This registration has a monitoring purpose, can be used for risk analyses, the evaluation of results in clinical practice, and, if necessary, adjustment of processes. This will further optimize the treatment in terms of complications, patient selection, and clinical outcomes in the short and long term. Currently, a lot of countries have setup registries for the EBV treatment, such as the LIVE study in Germany (NCT01580215), the BreathGroup registry in Italy [9], and an UK registry (ISRCTN16371361). Perhaps, in the future, all could also be combined into one international registry to be able to monitor the treatment at a more global level.

### *Patient Selection by MDT*

Very careful patient selection is key in EBV treatment success. Therefore, besides our local MDT, we started a bi-weekly MDT meeting by videoconferencing with all (experienced and starting) centers in the Netherlands and 1 in Belgium to discuss patient selection, treatment challenges, and complications. These meetings include knowledge of COPD/emphysema, interventional pulmonology, radiology, surgery, rehabilitation, noninvasive ventilation, and transplantation. A nice example of a MDT structure for EBV treatment is described by Chew and Mahadeva [10].

In conclusion, we believe that new treatments reaching the market is not an endpoint but an important starting point. Therefore, it is important to guide the introduction of a new intervention, especially when it is only applicable to a selected group of patients and has known related treatment risks. According to the literature and our experience, important factors in this process are: education, specialized high-volume treatment centers, a mandatory registry, and the use of a MDT and multicenter meetings for patient selection.

### Disclosure Statement

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### Author Contributions

All authors contributed to the writing of the manuscript.

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