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Pulmonx's Zephyr Data Bring NICE Thumbs-Up For Endobronchial Valves

by Reed Miller

The UK's National Institute for Health and Care Excellence (NICE) is now recommending insertion of endobronchial valves used to treat severe emphysema, and the Interventional Procedures Advisory Committee that wrote the recommendations points out that most of the support for this procedure comes from trials of Pulmonx' Zephyr "duckbill" endobronchial valve.

New *guidance* from UK's National Institute for Health and Care Excellence (NICE) supporting endobronchial valves to treat severe emphysema is especially encouraging news for *Pulmonx Corp.*

Most of the evidence supporting the new recommendations come from four clinical trials of Pulmonx' *Zephyr* "duckbill" endobronchial valve and the Interventional Procedures Advisory Committee (IPAC) that wrote the recommendations that the other device they evaluated, *Olympus Corp.*'s *Spiration* umbrella-shaped implant does not appear to be equivalent in safety and efficacy. (Also see "*US Market In Pulmonx' Sights Nine Years After Zephyr First Failure*" - Medtech Insight, 24 Oct, 2017.)

"Different studies used different types of endobronchial valves," the IPAC concludes in its evidence review. "Most of the evidence comes from one of the valves (Zephyr, Pulmonx). The devices do not seem to be equivalent in safety and efficacy."

IPAC considered data from 1,673 patients across one systematic review and metaanalysis of five Zephyr trials with 703 patients and three Spiration trials with 372 patients, the 97-patient randomized *TRANSFORM* trial of Zephyr, and four case series with Zephyr, one case series with Spiration, and one series of patients treated with either or both device.

The systematic review and metaanalysis IPAC reviewed includes the *BeLieVeR-HiFI*, *STELVIO*, *IMPACT*, *VENT-EU*, and *VENT-US* randomized trials, showing treatment with significantly improves lung function, exercise tolerance and quality of life in emphysema patients whose lungs have areas with little or no collateral ventilation, as identified by the Pulmonx' *Chartis* imaging system.

Six-month six- results from 97 patients TRANSFORM trial, the first multicenter randomized trial to evaluate Zephyr guided by Chartis in patients with heterogeneous emphysema, showed patients treated with Zephyr were significantly more likely to show clinically significant improvements in lung-function and exercise capacity than patients treated with medical management only.

The evidence supporting Spiration is not so encouraging. The 277-patient *IBV Trial* of Spiration showed a statistically significantly lower percentage change in FEV1 (forced expiratory volume in one second) scores in patients treated with Spiration than patients treated with standard medical care. A *73-patient European randomized trial* found no difference in FEV1 scores between patients treated with Spiration versus standard medical care at the three-month follow-up. A *2012 trial in 22 patients* showed Spiration statistically significantly improved FEV1 scores in patients treated unilaterally but not in patients treated bilaterally.

Olympus is sponsoring the *EMPROVE* trial comparing the Spiration device to medical management in 172 patients with emphysema and the 200-patient *VAST* trial, comparing Spiration to standard chest-tube drainage management in patients with persistent air leaks.

About 1.2 million people in the UK have diagnosed chronic obstructive pulmonary disease and about 400,000 of them have emphysema, according to the British Lung Foundation.

Over the past decade, more than 50,000 Zephyrs have been implanted in more than 12,000 patients around the world. The Global Initiative for Chronic Obstructive Lung Disease and the independent Cochrane Airways Group recommend considering endobronchial intervention for severe emphysema patients when medical therapy has failed, and the healthcare systems in Germany, Switzerland, and The Netherlands support endobronchial valves in eligible patients with severe emphysema.

The US FDA is currently considering a PMA for Zephyr based on the results of *LIBERATE*, a 190-patient randomized pivotal trial comparing Zephyr guided with Chartis to optimal medical management in patient with emphysema. Chartis earned a 510(k) in 2009. The company is also seeking a 510(k) for its *StratX* cloud-based service for analysis of computed tomography scans of the lung.

From the editors of Clinica