



Healthcare
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SHTG
Advice on health
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Endobronchial valves for lung volume reduction in patients with severe or very severe emphysema

Plain Language Summary | SHTG Recommendation 02 | November 2020

What is emphysema?

Emphysema is a lung condition. In people with emphysema, tiny air sacs in the lungs are damaged and stale air becomes trapped in them. This trapped air fills up the lungs leaving less room for oxygen-rich air to enter with the next breath. Common symptoms include breathlessness, a chronic chesty cough, regular chest infections, and wheezing. The main cause of emphysema is long-term cigarette smoking.

Most people with emphysema also have chronic bronchitis. Having one or both of these respiratory conditions is referred to as having chronic obstructive pulmonary disease (COPD).

What are endobronchial valves?

Endobronchial valves are devices that are inserted into airways in the lungs of people with severe or very severe emphysema/COPD. The valves prevent inhaled air from entering diseased parts of the lung, while allowing trapped air to leave. This one-way flow of air causes damaged air sacs to collapse, leaving more space for healthy lung tissue to absorb oxygen. After having endobronchial valves inserted, patients continue taking all the medications prescribed for their emphysema.

There are currently two endobronchial valves available: the Zephyr® Endobronchial Valve System (duck-bill shaped) and the Spiration® Valve System (umbrella shaped). Most people have three to five valves inserted at a time.

Why is this topic important?

Emphysema and COPD are chronic, progressive, and ultimately fatal. COPD is the second most common lung disease in the UK.

Current treatments for people with emphysema/COPD do not work for everyone, so some patients are offered surgery to remove damaged sections of the lungs. The surgery is invasive and carries substantial risk. Endobronchial valves offer a less invasive option for these patients.

What we did

We assessed the published evidence on whether endobronchial valves are safe and effective for reducing lung volume in people with severe or very severe emphysema/COPD. We also looked at whether endobronchial valves offer good value for money and at patient experiences.

What we found

Zephyr® valve

Seven studies with 987 participants compared the Zephyr® valve with standard medical care (six studies) or a fake procedure (one study). When analysed together, these studies demonstrated that the Zephyr® valve led to improvements in lung function, quality of life, and distance a person could walk in 6 minutes, in patients who had no collateral ventilation*. These benefits of the Zephyr® valve need to be balanced against significant increases in the risk of having a serious complication or a collapsed lung with this device.

*Collateral ventilation is where people have extra connections between air sacs in the lung, allowing air to bypass the airways where valves are placed.

Spiration® valve

Four studies with 629 participants compared the Spiration® valve with either standard medical care (two studies) or a fake procedure (two studies).

When all four studies were analysed together, the Spiration® valve did not appear to provide any benefits to patients. If the analysis only included two studies where the participants had no collateral ventilation, there were improvements in lung function and quality of life with the Spiration® valve. There was no significant increase in the risk of a collapsed lung with this device.

Comparing valves

One analysis of 10 studies compared the Zephyr® and Spiration® valves with each other (instead of with medical care). There were no significant differences between the two valves in effectiveness or safety.

Patient views and experiences

Patients described living with emphysema/COPD in terms of the effects of breathlessness:

- 83% felt breathless when washing or dressing,
- 76% felt breathless when walking around the house,
- 96% felt breathless when walking outside on level ground, and
- 99% described themselves as walking slower than other people their age.

Patients had a strong desire to act to improve their breathing and quality of life, even if that meant having a procedure with known risks. Patients valued having endobronchial valves as a treatment option. One study found that patients preferred endobronchial valves to surgery.

Value for money

One study assessed whether the Zephyr® valve offered good value for money. The study found the Zephyr® valve was associated with both an increased quality of life and higher costs than medical care. The Zephyr® valve only offered good value for money over the long-term (10 years or more). Limitations in how this study was done mean we are not certain about these results.

We did not find any studies that assessed the value for money of the Spiration® valve.

Organisation issues/context

Guidance and a draft policy document in NHS England recommend the use of endobronchial valves for treatment of severe or very severe emphysema.

We calculated there were approximately 160-170 people with severe or very severe emphysema/COPD in Scotland who could be eligible for endobronchial valves each year.

What SHTG considered when developing advice for NHSScotland

- Based on comments from clinical experts the Council agreed that for individual, carefully selected patients endobronchial valves can be a very effective treatment with significant effects on breathing and quality of life.
- The Council discussed the lack of options available to specialists working in hospitals for treating patients with worsening emphysema/COPD who are already taking the most appropriate medications.
- The Council discussed the differing quantity and strength of evidence available for the Zephyr® and Spiration® valves, and the lack of studies on value for money. The

recommendation was designed to allow for clinical choice in valve selection and development of new valves.

- The Council noted the importance of a clear, nationally agreed process for referring patients that involved all relevant healthcare providers, to ensure equity of access to endobronchial valve procedures for eligible patients.
- It was agreed that responsibility for selection of patients for endobronchial valve procedures should be restricted to national centres of excellence. Once consistent patient selection is established, doctors could offer these procedures regionally.
- The Council noted new evidence would soon be available from the CELEB trial that compares endobronchial valves with surgical lung volume reduction.

What is our advice to NHSScotland?

All patients referred to hospital who have severe or very severe emphysema, and significant disability despite taking the most appropriate medications, should undergo a detailed assessment by a team of experts to determine suitability for lung volume reduction.

Endobronchial valves should be available to all suitable patients. Procedures should be provided at a small number of centres via a national referral pathway to ensure equity of access. Patients should not be considered for endobronchial lung volume reduction if they have collateral ventilation or if they lack suitable target areas within the lungs.

Individual patient- and procedure-associated risk must be discussed with the patient as part of a shared decision on endobronchial lung volume reduction.

The value for money of endobronchial valve implantation remains uncertain for the Zephyr® valve and there are no data for the Spiration® valve. Patient outcome data should be collected for all valve procedures.

Future work

Studies comparing the Zephyr® and Spiration® valves with each other, and studies comparing endobronchial valves with surgery, are required. Studies are also needed to assess the value for money of endobronchial valves for the NHS in Scotland.

This plain language summary has been produced based on SHTG Recommendation 02 - November 2020.