



# Editorial: the movement towards airway valves for the treatment of persistent air leaks

Amit K. Mahajan, Sandeep J. Khandhar

Department of Surgery, Section of Thoracic Surgery and Interventional Pulmonology, Inova Fairfax Hospital, Falls Church, VA, USA

Correspondence to: Amit K. Mahajan, MD, FCCP, DAABIP. Department of Surgery, Section of Thoracic Surgery and Interventional Pulmonology, Virginia Commonwealth University School of Medicine, Inova Fairfax Hospital, 3300 Gallows Rd, Falls Church, VA 22042, USA.

Email: amit.mahajan@inova.org.

Comment on: Dugan KC, Laxmanan B, Murgu S, *et al.* Management of Persistent Air Leaks. *Chest* 2017;152:417-23.

Received: 17 November 2017; Accepted: 08 December 2017; Published: 31 December 2017.

doi: 10.21037/shc.2017.12.05

View this article at: <http://dx.doi.org/10.21037/shc.2017.12.05>

Alveolar-pleural fistulas (APF) are pathologic communications between the alveoli and pleural space. These communications can occur from pneumothoraces, pulmonary infections, trauma, malignancies, and complications of thoracic surgery. Development of an APF may result in a persistent airleak (PAL), which allows air entering the lungs to continuously pass into the pleural space. The presence of an APF or a PAL is associated with significant morbidity, increased mortality, and prolonged hospitalizations (1-3).

Dugan *et al.* thoroughly reviewed the management of APFs and PALs in the August 2017 edition of the *Chest Journal* (4). They describe the etiology of APFs and dissect the treatment options for PALs, ranging from conservative to invasive. Dugan *et al.* highlight a number of minimally invasive options for the treatment of PALs, which include chemical pleurodesis, autologous blood patch placement, and airway valve insertion. Neither chemical pleurodesis nor autologous blood patches are commonly utilized in clinical practice for the treatment of PALs due to the absence of large studies describing their safety or effectiveness. Yet, the use of unidirectional airway valves has emerged as a more desirable option for the treatment of PALs despite only a limited number of small, single institution studies and case reports describing their effectiveness. These airway valves are used most commonly used following thoracic surgical procedures and spontaneous pneumothoraces in patients with severe emphysema. These valves are typically removed bronchoscopically six weeks after cessation of the airleak. Currently, a large, randomized controlled trial,

the Spiration Valves Against Standard Therapy (VAST), is ongoing in hopes of proving safety and effectiveness data.

Unidirectional airway valves were originally developed as a non-surgical alternative to lung volume reduction surgery (LVRS). Two different valve designs were tested in studies for bronchoscopic LVRS; the Zephyr EBV (Pulmonx) and the Spiration valve (Olympus Corporation of the Americas). Unfortunately, initial bronchoscopic LVRS trials utilizing the Spiration valves and the Zephyr EBVs did not meet predetermined study endpoints and failed to obtain United States Food and Drug Administration (FDA) approval. Fortunately, extrapolation from these trials and other bronchoscopic LVRS studies led to FDA approval of the Spiration valve system under the Humanitarian Device Exemption (HDE) for the treatment of PALs following thoracic surgery. Compelling data driving HDE approval stemmed from results of a 58 patient United States Investigational Device Exemption (IDE) study for the treatment of severe emphysema. Four patients in this study were treated with Spiration valves for PALs under the IDE compassionate use exemption. All four patients experienced immediate improvement or resolution of their PALs after valve placement. Based on these clinical results, along with *ex vivo* calf and human lung testing, unidirectional airway valves gained approval for this indication.

Under the HDE, indications for use of Spiration valves for APFs include PALs following lobectomy, segmentectomy, or LVRS. An airleak present on postoperative day 7, unless present only during forced exhalation or cough, is an indication for the placement

Spiration valves. Additionally, a PAL present on day 5 can be treated using Spiration valves if it is continuous, present during normal inhalation phase of inspiration, or present upon normal exhalation and accompanied by subcutaneous emphysema or respiratory compromise. While the HDE indication for Spiration valve placement recommends waiting 5–7 days to establish that an airleak is persistent, physicians are regularly placing these valves prior to the recommended time period following surgery. This practice is based on the desire to avoid the increased morbidity associated with PALs. While airway valves do not always completely eliminate a PAL, they typically reduce leak severity. This is useful for patients who are unable to tolerate waterseal and require continuous wall suction. By reducing the severity of the airleak, patients may be able to return home with an indwelling chest tube where the APF can heal over time. After the airleak has resolved, the chest tube can be removed in the outpatient setting.

The use of airway valves for PALs resulting from bleb or bullae rupture in patients with underlying emphysema has become increasingly common (5,6). Pneumothoraces in patients with chronic obstructive pulmonary disease (COPD) carry a significantly higher complication and mortality rate than those without COPD (7). In our experience, patients with underlying emphysema who suffer from PALs tend to have prolonged hospital stays compared to young, healthy individuals with spontaneous pneumothoraces. Based on this observation, we opt for early placement of Spiration valves to decrease flow through the APF in order to reduce the hospital length of stay. Although this practice pattern is an off-label use since these PALs do not result from a post-thoracic surgery complication, we believe this use is justified as it improves patient care and reduces the risk of hospital related morbidity. Along these lines, we believe that such a practice is rapidly evolving into the standard of care for patients suffering from PALS due to bleb or bullae rupture with underlying emphysema. In fact, we believe that this off-label indication for Spiration valve use may become more commonly utilized than the post-thoracic surgery on-label indication, if it has not already done so.

The use of Spiration airway valves for the treatment of post-surgical PALs and PALs following rupture of blebs or bullae in patients with underlying emphysema is quickly gaining favor compared to other treatment options. While these valves are approved for the treatment of post-thoracic surgery PALs, their off-label uses are becoming increasingly common. As data emerges regarding Spiration valve safety

and effectiveness for the treatment of PALs, this therapeutic option will hopefully make conservative therapy and surgical intervention a thing of the past.

## Acknowledgments

*Funding:* None.

## Footnote

*Provenance and Peer Review:* This article was commissioned by the editorial office, *Shanghai Chest*. The article did not undergo external peer review.

*Conflicts of Interest:* Both authors have completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/shc.2017.12.05>). The authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

*Open Access Statement:* This is an Open Access article distributed in accordance with the Creative Commons Attribution-NonCommercial-NoDerivs 4.0 International License (CC BY-NC-ND 4.0), which permits the non-commercial replication and distribution of the article with the strict proviso that no changes or edits are made and the original work is properly cited (including links to both the formal publication through the relevant DOI and the license). See: <https://creativecommons.org/licenses/by-nc-nd/4.0/>.

## References

1. Williams NS, Lewis CT. Bronchopleural fistula: a review of 86 cases. *Br J Surg* 1976;63:520-2.
2. Malave G, Foster ED, Wilson JA, et al. Bronchopleural fistula--present-day study of an old problem. A review of 52 cases. *Ann Thorac Surg* 1971;11:1-10.
3. Chee CB, Abisheganaden J, Yeo JK, et al. Persistent air-leak in spontaneous pneumothorax--clinical course and outcome. *Respir Med* 1998;92:757-61.
4. Dugan KC, Laxmanan B, Murgu S, et al. Management of Persistent Air Leaks. *Chest* 2017;152:417-23.
5. Reed MF, Gilbert CR, Taylor MD, et al. Endobronchial Valves for Challenging Air Leaks. *Ann Thorac Surg*

- 2015;100:1181-6.
6. Cordovilla R, Torracchi AM, Novoa N, et al. Endobronchial valves in the treatment of persistent air leak, an alternative to surgery. *Arch Bronconeumol* 2015;51:10-5.
  7. Videm V, Pillgram-Larsen J, Ellingsen O, et al. Spontaneous pneumothorax in chronic obstructive pulmonary disease: complications, treatment and recurrences. *Eur J Respir Dis* 1987;71:365-71.

doi: 10.21037/shc.2017.12.05

**Cite this article as:** Mahajan AK, Khandhar SJ. Editorial: the movement towards airway valves for the treatment of persistent air leaks. *Shanghai Chest* 2017;1:65.