Alveolar-pleural fistulas (APFs) 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 ailereak. 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

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

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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.

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Footnote

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References
1. Williams NS, Lewis CT. Bronchopleural fistula: a review
fistula--present-day study of an old problem. A review of
3. Chee CB, Abisheganaden J, Yeo JK, et al. Persistent air-
leak in spontaneous pneumothorax--clinical course and
2015;100:1181-6.
Endobronchial valves in the treatment of persistent
air leak, an alternative to surgery. Arch Bronconeumol
2015;51:10-5.
Spontaneous pneumothorax in chronic obstructive
pulmonary disease: complications, treatment and

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