



# Management of persistent air leaks: a shifting paradigm

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An air leak is commonly defined as being persistent when it extends beyond 5–7 days. A leak is indicated by the detection of bubbles in the water seal chamber of a collection system connected to a pleural drain. Abnormal communication between the airways and the pleural space results in an air leak. When the source of air entering the pleural space is at the level of the segmental bronchus or more proximal, it is termed a bronchopleural fistula (BPF). An alveolar-pleural fistula (APF) is a more distal communication. Etiologies of these fistulae include pulmonary infection, mechanical ventilation, chest trauma, thoracic surgery, and pneumothorax. The advent of digital drainage systems that allow more precise quantification of an air leak has led to reduced chest tube duration and hospital length of stay (LOS) (1). Although mortality is not clearly increased with post-surgical persistent air leak (PAL), it still leads to increased rates of intensive care unit (ICU) re-admission, pneumonia, and hospital LOS (2).

Management of PAL remains controversial due to the lack of guidelines addressing newer management modalities. The American College of Chest Physicians (ACCP) 2001 guidelines on the management of spontaneous pneumothorax recommend surgical evaluation for pleurodesis via video-assisted thoracoscopic surgery (VATS) and advised against bronchoscopic interventions for PAL (3). The 2010 British Thoracic Society (BTS) guidelines on the subject simply recommend early thoracic surgical opinion for PAL (4). These guidelines do not address options for patients who are poor surgical candidates. This ambiguity has led to variable practice patterns depending on local expertise and resources.

Mahajan *et al.* review the evolution of unidirectional

airway valves, which provides insight on the currently approved indications (5). In the United States, the Spiration valve (Olympus Corporation of the Americas) is approved under the Food and Drug Administration (FDA) Humanitarian Device Exemption (HDE) category for the treatment of PAL following thoracic surgery. This category applies to situations where fewer than 4,000 individuals are affected per year. Mahajan *et al.* also clearly delineate the FDA approved indications, which are PAL on postoperative day 5 that is continuous, present during inspiration with tidal breathing, or present during expiration with tidal breathing and accompanied by subcutaneous emphysema or respiratory compromise (5). An air leak that is still present on postoperative day 7 also meets criteria, unless it only occurs with forced exhalation or cough.

We agree with Kaneda in that the treatment objectives for pneumothorax should be recovery of respiratory function, cessation of air leak, and prevention of recurrence (6). Future studies in this area should utilize this framework when selecting their methodology and outcome measures. Kaneda also highlights Endobronchial Watanabe Spigots (EWS) as an alternative minimally invasive treatment option for PAL (6). Although both EWS and unidirectional endobronchial valves reduce airflow across a pathologic fistula, the valve may also reduce infection risk by allowing retained distal secretions to move proximally and be expelled. The other potential advantage of the Spiration valve is that it is available in four sizes versus the three sizes of EWS permitting improved size-matching between the airway and the valve.

Collateral ventilation may enable a continued air leak, albeit one that is less vigorous, regardless of which endobronchial

intervention is selected. In the largest study of Spiration valves to date (N=75 patients), Gilbert *et al.* demonstrated resolution or diminution of air leak in 56% of patients (7). This value is comparable to the 57% (N=12 of 21) of patients that had a reduction in air leak with EWS as reported by Kaneda *et al.* in the largest study to date of that modality (8). Chemical pleurodesis with sclerosants or autologous blood patch pleurodesis may be necessary as complementary therapy in these cases, although neither modality is used commonly due to the lack of safety and efficacy data from large studies.

Seventy percent of patients in the study by Gilbert *et al.* had valves placed for a non-FDA approved indication (7). As Mahajan *et al.* astutely note, valves are commonly being inserted prior to postoperative day 5 in an effort to minimize morbidity associated with PAL (5). We agree with Mahajan *et al.* that this should be a consideration in patients with chronic obstructive pulmonary disease (COPD) who develop a pneumothorax, since these patients have a higher complication and mortality rate than their non-COPD counterparts (5,9). While valves may not completely eliminate a vigorous air leak, they can often sufficiently reduce it so that wall suction is no longer required. In this scenario, patients may be discharged with a chest tube attached to a Heimlich valve that can be removed on an outpatient basis after the fistula tract has healed. Widespread off-label use reflects an unacceptable paucity of high quality data and the consequential lack of supporting guidelines.

Revised management guidelines, with an emphasis on nonsurgical interventions, are critical. Such guidelines will permit a more standardized approach to a serious medical dilemma with worldwide relevance. With the advent of improved endobronchial devices, minimally invasive treatment for PAL has become a viable option. Many leading centers have shifted to a first-line bronchoscopic approach despite the lack of supporting guidelines. Well designed, randomized, multicenter trials, such as the ongoing Valves against Standard Therapy (VAST) trial, can provide the requisite safety and effectiveness data to support guideline revision. These high-quality data are necessary to develop contemporary, evidence-based guidelines to support the paradigm shift that has already begun in the management PAL.

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