The use of endobronchial valve device to eliminate air leak

James I. Fann\textsuperscript{a,c,*}, Gerald J. Berry\textsuperscript{b}, Thomas A. Burdon\textsuperscript{a,c}

\textsuperscript{a}Department of Cardiothoracic Surgery, Stanford University School of Medicine, Stanford, CA, USA
\textsuperscript{b}Department of Pathology, Stanford University School of Medicine, Stanford, CA, USA
\textsuperscript{c}The Section of Cardiothoracic Surgery, Palo Alto Veterans Affairs HCS, Palo Alto, CA, USA

Received 7 July 2004; accepted 16 November 2005

**KEYWORDS**
Endobronchial valve; Bronchoscopy; Bronchopleural fistula; Post-traumatic pneumothorax

**Summary** We evaluated an endobronchial valve device in the treatment of surgically created air leak or pneumothorax by eliminating antegrade flow. 

**Methods:** Six sheep underwent general anesthesia with positive pressure ventilation and left thoracotomy. After division of the mediastinal pleura, the contralateral cranial lobe was identified and a 2.5 cm × 1.5 cm laceration created with resultant air leak. Using bronchoscopy, we deployed a valve device in the bronchus of the injured segment. Chest drainage tube was placed and the thoracotomy closed. At 1 week (n = 3) and 4 weeks (n = 3), the animals underwent general anesthesia, bronchoscopy and right thoracotomy.

**Results:** All animals survived the procedure. Bronchoscopic valve device placement in the segmental bronchus resolved the air leak immediately. After closure of thoracotomy, the chest tube demonstrated minimal drainage with no air leak. At 1 and 4 weeks, bronchoscopy showed no change in device location, and the treated segments were atelectatic with fibrous scar at the injured site.

**Conclusions:** Collapse of a selected lung segment with resolution of air leak can be achieved using bronchoscopically implanted valve device. The valve device may facilitate treatment of patients with post-surgical or post-traumatic persistent air leak.

© 2005 Elsevier Ltd. All rights reserved.

**Introduction**

Bronchopleural fistula is one of the most serious complications after pulmonary resection, with an incidence of 1% after lobectomy and between 1% and 12% after pneumonectomy.\textsuperscript{1–5} Traditional therapy
may include tube thoracostomy, open drainage, decortication, thoracoplasty, and muscle pedicle closure. Various bronchoscopic approaches to fistula closure have been employed in selected patients, including the use of tissue and fibrin glues and sealants, stents, plugs, balloons, coils, and submucosal injection of ethanol. In patients with larger bronchopleural fistulas, however, bronchoscopic techniques are less efficacious.

Thoracic injuries occur in 30–40% of trauma patients requiring hospitalization.\textsuperscript{15–17} Post-traumatic pneumothorax may result from direct lung puncture, lung lacerations from rapid deceleration, crush injury with alveolar disruption, and alveolar ruptures from increased intrathoracic pressure.\textsuperscript{15–17} In patients with persistent post-traumatic pneumothorax, a less invasive approach using video-assisted thoracoscopic surgery has been shown to be a reliable alternative to an open thoracotomy although general anesthesia with single lung ventilation is required.\textsuperscript{15}

Endobronchial one-way valve devices have been used to alter respiratory dynamics and achieve lung volume reduction in patients with advanced emphysema.\textsuperscript{18–20} In this study, we experimentally evaluated the ability of the endobronchial valve device in treating surgically created air leak or pneumothorax by eliminating antegrade flow.

**Methods**

**Experimental procedure**

Six sheep (mean weight 35 kg) received intravenous atropine, ketamine, and diazepam and underwent endotracheal intubation and general anesthesia using inhalational isofluorane (1–4%) (Hallowell EMC Model 2000, Pittsfield, MA). The animals had electrocardiographic, oxygen saturation, and femoral arterial line monitoring. A left thoracotomy was made at the fourth interspace. The anterior mediastinal pleura was divided and the right cranial lobe identified. A 2.5 cm (long) × 1.5 cm (deep) laceration was made in the cranial lobe with resultant air leak. Bronchoscopy was performed using a Pentax flexible bronchoscope (Pentax FB-19x, Tokyo, Japan). The bronchus to the right cranial lobe was identified. A balloon catheter (Arrow International 6 Fr balloon wedge pressure catheter, Reading, PA) was placed via the working channel into the segmental bronchus, the balloon inflated and the degree of air leak assessed. If the air leak continued, the balloon catheter was placed into another segmental bronchus in the cranial lobe. This was repeated until the bronchus leading to the injured segment was identified as evidenced by air leak resolution. An estimate of the size of the target bronchus was made with the balloon inflated. After deflating and removing the balloon catheter, a 0.035” flexible tip guidewire was passed through the working channel of the bronchoscope and the distal tip of guidewire situated in the target segmental bronchus. The bronchoscope was removed with the guidewire left in place. The valve device within the deployment apparatus (Emphasis Medical, Inc., Redwood City, CA) was loaded onto the guidewire, the bronchoscope was reinserted and the device directed into the target bronchus. The device was deployed followed by removal of the deployment apparatus and guidewire. After assuring the integrity of the valve device, the bronchoscope was removed. The tidal volume was increased so that the peak inspiratory pressure was 40 cmH\textsubscript{2}O to assess the degree of residual air leak. A 14 Fr chest tube was placed at the fifth interspace and the thoracotomy closed. The sheep emerged from anesthesia and extubated. The chest tube was aspirated every 15 min and removed if there was no air leak and drainage. The animals received one intramuscular dose of enrofloxacin (5 mg/kg) (Bayer Pharmaceutical, West Haven, CT) at the time of the initial procedure and maintained on oral enrofloxacin (5 mg/kg/day) during the follow-up period. The animals were sacrificed at 1 week (n = 3) and 1 month (n = 3) after initial thoracotomy and device implant. The animals underwent general anesthesia with induction using intravenous telazol and endotracheal intubation and inhalational isofluorane (1–4%). Bronchoscopy was performed to visualize the valve device. The animals underwent right thoracotomy and the area of lung injury and degree of lung collapse evaluated.

**Device**

The endobronchial valve device, designed to be placed over a guidewire under bronchoscopic guidance, is composed of a one-way valve, a seal, a valve protector, and a retainer (Fig. 1). The silicone one-way valve is mounted onto a nitinol protector and bonded inside the seal, which acts as a barrier between the valve and the wall of the bronchial lumen. The protector prevents compression of the seal by the bronchial wall. The retainer, constructed of a self-expanding nitinol mesh and designed to resist device migration, expands to contact the wall of the bronchial lumen. In order to account for variations in bronchial luminal diameter,
there are three available sizes: 4.0–5.5, 5.0–7.0 and 6.5–8.5mm. Should the device not be optimally situated at or subsequent to the time of implant or if the patient later develops an infectious complication, the valve device may be removed using bronchoscopic graspers.

The use of laboratory animals in this protocol was approved by the animal care committee at the institution. All animals received humane care in compliance with the "Guide for the Care and Use of Laboratory Animals" prepared by the Institute of Laboratory Animal Resources, National Research Council, and published by the National Academy Press (revised 1996).

**Results**

All six animals survived thoracotomy, creation of air leak and valve implant procedure. During bronchoscopy, the segmental bronchus leading to the injured lung is usually identified with one or two separate inflations of the balloon catheter. Placement of the valve device with bronchoscopic guidance was successful in all animals and required no more than 10 min. The chest cavity was filled with water confirming resolution of air leak in the injured region (at peak inspiratory pressure of 40 cmH₂O). The size of the implanted valve devices was 6.5–8.5 mm in all animals. After closure of thoracotomy incision, the chest tube demonstrated minimal drainage (less than 50 cc) and no air leak in all animals. The chest tube was removed within 3 h after operation. No animal developed hypoxemia, bronchospasm, or respiratory distress during or after the procedure. In the follow-up period, none of the animals had clinical evidence of pneumonia, and supplemental oxygen therapy or intubation was not required in any animal.

At 1 and 4 weeks after initial thoracotomy and valve placement, fiberoptic bronchoscopy showed no change in device location; the valves devices were intact and well seated in the bronchial lumen. At thoracotomy, all animals showed atelectasis of the treated segment distal to the device with fibrous reaction in the region of the lung injury (Fig. 2). Because the second operation was performed via a right thoracotomy, no adhesions were appreciated except in the injured region.

**Discussion**

Bronchoscopic techniques aimed at closing a persistent bronchopleural fistula have been employed in the postoperative setting and involve the use of glues and sealants, sclerosing agents, stents, plugs, balloons, coils, submucosal injection of ethanol, or a combination thereof. These less invasive approaches must be individualized since there is no one optimal method. Embolization coils may be associated with gaps between the coils and inadequate sealing. Fibrin and synthetic glues may be difficult to employ and usually are more successful in treating smaller fistulas. Combining coils and glue have been successful in obliterating...
gaps between the coils and stabilizing the coils. In most patients with post-traumatic pneumothorax, early treatment includes tube thoracostomy, adequate volume resuscitation, and serial chest radiographs.  

This technique provides a good healing; however, this technique is not always successful, particularly in larger defects. 

In most patients with post-traumatic pneumothorax, early treatment includes tube thoracostomy, major airway injury should be suspected, diagnosed with bronchoscopy, and treated. If the pneumothorax persists after tube thoracostomy, Carrillo et al. have used video-assisted thoracoscopic surgery to successfully repair the lung injuries. This technique provides a good evaluation of the degree of pulmonary trauma and is a safe alternative to an open thoracotomy; nonetheless, general anesthesia and single lung ventilation are required.

Endobronchial one-way valve devices have been employed as a less invasive means to achieve lung volume reduction in selected patients with advanced emphysema, resulting in improved functional status and quality of life and relief of dyspnea at early follow-up. In this study, we found that placement of the endobronchial valve device reliably treated an iatrogenic air leak by creating collapse of the affected lung segment. Follow-up at 1 week and 1 month demonstrated healing of the injured region and resolution of pneumothorax. In order for this technique to be effectively employed in the clinical setting, it is important to identify the segment or lobe in the region of lung injury. Using temporary balloon inflation, one can identify the involved portion of the lung by noting whether the degree of air leak via the chest tube has diminished or ceased. This bronchoscopic approach holds promise in providing an effective nonsurgical, less invasive alternative to the management of persistent air leak in patients with bronchopleural fistula or post-traumatic lung injury. Although the endobronchial valve devices can be placed in the experimental setting with evidence of healing in the injured region, the long-term outcome using such a technique is unknown and awaits the results of ongoing clinical experience.

This study was directed at evaluating the ability of the valve devices to eliminate air leak created surgically. One limitation of this study is that the animals were not models of emphysema. Thus, in patients with advanced chronic obstructive lung disease, it may be difficult to resolve the air leak by simple placement of an endobronchial valve, since collateral channels in these patients would contribute to the persistence of air leak. Because infection is often associated with chronic bronchopleural fistula, the introduction of a foreign body is of concern and the ability to subsequently remove the device has been demonstrated in the clinical setting. The potential advantage of a one-way valve device is that should there be ongoing infection distal to the device, the valve may provide for drainage.

Acknowledgements

This study was supported by a grant from Emphasys Medical, Inc., Redwood City, CA.

References


