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Endobronchial valves for bronchopleural fistula: pitfalls and principles

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Abstract

Background: Placement of endobronchial valves for bronchopleural fistula (BPF) is not always straightforward. A simple guide to the steps for an uncomplicated procedure does not encompass pitfalls that need to be understood and overcome to maximize the efficacy of this modality.

Objectives: The objective of this study was to discuss examples of difficult cases for which the placement of endobronchial valves was not straightforward and required alterations in the usual basic steps. Subsequently, we aimed to provide guiding principles for a successful procedure.

Methods: Six illustrative cases were selected to demonstrate issues that can arise during endobronchial valve placement.

Results: In each case, a real or apparent lack of decrease in airflow through a BPF was diagnosed and addressed. We have used the selected problem cases to illustrate principles, with the goal of helping to increase the success rate for endobronchial valve placement in the treatment of BPF.

Conclusions: This series demonstrates issues that complicate effective placement of endobronchial valves for BPF. These issues form the basis for troubleshooting steps that complement the basic procedural steps.

Keywords: bronchopleural fistula, endobronchial valves, prolonged air leak

Introduction

Endobronchial one-way valves (EBVs) have been available since 2003. Their use for treatment of persistent bronchopleural fistula (BPF) was first described in 2005 [Snell *et al.* 2005], and in 2006 they gained approval for humanitarian use in the treatment of persistent BPF. There is still limited experience with their use. There is a standard protocol for insertion, but a simplified, uniform approach cannot address all of the potential barriers to effective EBV placement. Our institutions have been placing EBVs since 2012, with over 60 cases over that interval. In this report, we have selected from this caseload several complicated cases as a basis for a discussion of problems that can occur during placement, and suggest principles with respect to how to approach difficult cases. It is our hope that these troubleshooting steps will help increase the success rate for this important intervention.

Case 1

A 52-year-old with severe chronic obstructive pulmonary disease (COPD) admitted for pancreatitis subsequently suffered recurrent hospital-acquired pneumonia, ventilator-dependent respiratory failure, and bilateral pneumothoraces. Pigtail catheters had been placed, one on the right and two on the left. The left anterior pigtail had a persistent leak, and it was felt, based upon imaging, that this pigtail was in the pulmonary parenchyma, not the pleural space. Because of this, the entry site was widened, and a 28-French chest tube was inserted. When the location of this tube also was in doubt, digital palpation was performed through the incision, adhesions holding the lung against the chest wall were broken down by blunt digital dissection, and a 16-French pigtail catheter was placed into the left pleural space through this same access. Still, 7 days later, an air leak and pneumothorax persisted despite intrapleural

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location of the anterior tube. Thoracic surgery felt that the patient was too ill for a surgical approach. Interventional pulmonary (IP) was consulted for bronchoscopy and EBV placement. [The EBVs used for this and all subsequent cases in this article were those manufactured by Spiration (Redmond, Washington)]. The patient was taken to the operating room (OR) for EBV placement. As per standard protocol, the procedure began with testing for site of leak starting with mainstem occlusion using a balloon-tipped catheter passed through the working channel of a bronchoscope. Amount of air leak was quantified visually by observation of the bubbling rate through the water chamber of the water seal chest drain (Atrium USA, Hudson, New Hampshire) before and during balloon occlusion. When occlusion of the left main bronchus did not stop the air leak, the pigtail dressing was taken down. The skin at the entry of the anterior chest tube was visibly vibrating from entry of air into the pleural space *via* the insertion tract. Pressure on the skin at the pigtail entry site led to complete cessation of the leak. Subsequent lobar occlusion was diagnostic; occlusion of the left upper lobe (LUL) led to a decrease in air leak, and three valves were required to effectively block all segments of the LUL, with complete resolution of the leak. The patient was eventually moved to comfort care status by her family because of her severe lung disease with lack of improvement and ventilator dependence, and she died 21 days after EBV placement, but pneumothorax was not a complicating factor.

Case 2

A 44-year-old woman admitted for a necrotizing right upper lobe (RUL) pneumonia developed a right-sided pneumothorax after she was put on positive pressure mechanical ventilation. A 16-French pigtail catheter was placed. She had an air leak that was persistent 9 days after chest tube placement, and she was taken to the OR for EBV placement.

In the OR, there was a slow leak, making it difficult to assess for a decrease in the leak with occlusion. Suction was increased to −40 cm H_2O, and ventilator tidal volume was increased; the leak increased. The right main bronchus was occluded, and the leak stopped. Sequential lobar occlusion was begun. There was no change in leak with lobar occlusion. The right main bronchus was reoccluded, and this time there was no decrease in the air leak. The chest tube was undressed. There was no visible evidence of an air leak or of an external chest tube fenestration. The patient started to decompensate, with visible hyperinflation of the right hemithorax and with a decrease in blood pressure. The chest tube was flushed. This led to a marked increase in rate of airflow through the water seal chest drain. The RUL was reoccluded, and the air leak stopped after 20 respiratory cycles. Seven 5 mm valves were placed in the RUL at subsegmental levels due to large diameter segmental airways, with complete cessation of the leak. The chest tube was removed 5 days after EBV placement, and the valves were removed after 6 weeks.

Case 3

A 55-year-old assault victim developed an empyema and underwent right anterolateral thoracotomy with fifth rib resection and decortication after failure of conservative treatment. There were continuous air leaks in all three of his surgical chest tubes postoperatively. On postoperative day 8, he was assessed by the IP team. He underwent bronchoscopy with placement of three endobronchial valves, one each in the posterior, anterior, and apical segments of the RUL. The air leak decreased significantly with placement of the final valve, and it resolved completely 3 days after EBV placement.

The patient was brought in a few weeks later for removal of the endobronchial valves. Given the significant lung injury caused by the complicated empyema and decortication surgery, a repeat CT of the chest was ordered prior to bronchoscopy. It showed persistent communication of one of the RUL airways with the pleural space. Given this finding, the EBVs were not removed.

Case 4

A 57-year-old man with a past medical history of pulmonary tuberculosis and severe COPD was admitted for a spontaneous pneumothorax. Chest CT demonstrated significant RUL bullous disease. The patient underwent video-assisted thoracoscopic surgery, with resection of apical and posterior segments of the RUL. It was felt that the anterior segment was less diseased, and given the severity of baseline compromise and the need for tissue sparing, it was decided that the anterior segment was better not resected. A postoperative leak was present, and on postoperative day 5, IP was consulted; a completion lobectomy was not considered, again due to severity of underlying disease. Bronchoscopy with balloon occlusion was performed in the ICU. Sequential balloon occlusions from the proximal to the distal airways failed to impact the rate of air bubbling through the fluid chamber of the water seal chest drain. Whereas the BPF most likely emanated from the area of resection, the RUL, EBVs were empirically placed in two adjacent segments, the remaining anterior segment of the RUL and the superior segment of the right lower lobe (RLL), with a marked decrease in air leak. The next day, however, there was a marked increase in leak. Bronchoscopy with balloon occlusion was again performed, this time under general anesthesia in the OR. Only minimal reduction of the leak was seen, even with occlusion of the right main bronchus. The chest tube was clamped at its exit from the chest wall, with complete cessation of bubbles in the water chamber. This maneuver demonstrated that there was no defect in the chest tube apparatus external to the thorax. Given the lack of benefit from the previously placed EBVs, they were removed. A CT of the chest was ordered to look for an anatomic explanation for the EBV failure. This showed that the chest tube had migrated into an apical bleb present in the unresected anterior segment of the RUL. Based on these findings, the chest tube was clamped despite the air leak. The postclamp chest X-ray was stable without any evidence of a pneumothorax, and the chest tube was removed 2 days later, with repeat chest roentgenogram showing no pneumothorax. The patient was subsequently discharged in stable condition.

Case 5

A 46-year-old man with newly diagnosed acute myeloid leukemia underwent wedge resection of a portion of the right middle lobe (RML) for consolidation and hydropneumothorax secondary to angioinvasive aspergillus. An air leak was present postoperatively. When the leak persisted unabated on postoperative day 5, IP was consulted for EBV closure of the BPF. The patient was taken to the OR. Neither occlusion of the right main bronchus nor sequential balloon occlusion of the lobes of the right lung effected cessation of the leak. Because of the high clinical suspicion that the BPF came from the RML, 2 EBV valves were used to occlude both the medial and lateral segments. The leak improved but did not resolve. Balloon occlusion of the RUL was then performed, and the leak stopped completely. Two EBVs were then deployed in the RUL, with complete resolution of the leak. Finally, two days later, the leak remained resolved, and the chest tube was removed. The patient was subsequently discharged home in stable condition.

Case 6

A 66-year-old woman was transferred for a prolonged air leak. She had undergone right lower lobectomy for a lung mass a month prior to transfer. Pathology had shown an adenocarcinoma with clear surgical borders and no evidence of metastatic disease. She had developed an air leak after the surgery. At another institution, a Heimlich valve had been placed and she had been discharged, but the leak persisted. She had been readmitted twice for episodes of dyspnea associated with increased pneumothorax, and was transferred from the other institution after the second such decompensation.

At our facility, the patient underwent bronchoscopy with balloon occlusion. Occlusions of the right mainstem bronchus, RLL surgical stump, and all remaining subsegments were performed. Occlusion of the right mainstem bronchus and of the RUL bronchus both caused moderate decrease in air leak. No occlusion caused complete cessation of leak.

Based upon the moderate decrease apparent with RUL occlusion, two EBVs were placed, one in the anterior and one in the posterior segment of the RUL, leading to a diminution of the air leak similar to that caused by balloon occlusion. The next day, however, the patient had a large air leak that increased markedly with cough. A CT of the chest was obtained, and a small communication about 1–2 mm in diameter between the surgical stump and the pleural space was identified by documentation of air just distal to the surgical staples.

A second bronchoscopic procedure was performed. A Jagwire (Boston Scientific, Natick, Massachusetts) could be passed through the communication identified on CT scan, but its small diameter did not allow intraluminal valve placement, so a 5 mm EBV was used to occlude the stump. The anchors and shaft of the valve were placed in the distal stump with the umbrella covering the proximal end. There was an immediate decrease in air leak, although it did not resolve. A Heimlich valve was attached to the patient's chest tube. She was discharged 2 days after the second EBV placement with a stable apical pneumothorax and with the Heimlich valve in place. She had no subsequent decompensations, and over time, her pneumothorax resolved. Her surgeon was able to remove the chest tube without complication. Her EBVs were removed 7 weeks after insertion.

Discussion

EBVs allow air to exit, but not to enter, their subtended segments. They were originally designed for nonsurgical lung volume reduction. To date, the lung volume reduction data have not been strong enough to lead to US Food and Drug Administration approval for this application [Mahajan *et al.* 2013], although there is growing evidence that they can be clinically effective if interlobar fissures are intact [Davey *et al.* 2015]. Although it is difficult to perform a prospective study of BPF, several reports have described the efficacy of EBVs in the closure of BPFs [Travaline *et al.* 2009; Sterman *et al.* 2010; Gillespie *et al.* 2011; Firlinger *et al.* 2013; Reed *et al.* 2015; Gilbert *et al.* 2016]. EBVs were approved as a humanitarian-use device for the treatment of BPF in 2006.

A standard approach to EBV in the management of BPF has been described: EBV placement should be considered for patients with BPF lasting 5 days despite appropriate management. It is recommended that the lung/lobe/segment through which the leak occurs be localized with bronchoscopy and balloon occlusion. An endobronchial balloon is first inflated in the ipsilateral main bronchus while observing for a decrease in rate of air leak through the water chamber of a water seal chest drain, allowing for five breathing cycles. This sequence is then repeated while advancing the balloon distally, isolating lobar and then segmental airways. The results of balloon occlusion guide serial EBV placements until there is cessation of air leakage through the BPF. An average of three to four valves is required per patient [Gillespie *et al.* 2011]. Following EBV placement, the patient is first observed with a chest tube in place. When the patient is persistently stable, either the chest tube is removed or a Heimlich valve is attached to the chest tube. Patients with lasting resolution have their EBVs removed bronchoscopically approximately 6 weeks after insertion.

These cases demonstrate some of the pitfalls of EBV insertion not addressed in the steps delineated above. EBV placement for BPF is a flow-directed process with a goal of terminating flow through a nonphysiologic channel. All of the pitfalls relate to an inability or apparent inability to decrease or terminate flow through a BPF before or after EBV placement. With that in mind, and the above cases as illustrative, we have the following comments:

The critical role of chest tube function in the process of EBV insertion and evaluation cannot be overemphasized. The diagnostic accuracy of balloon occlusion depends upon a chest tube that is effectively and selectively draining the pleural space. Any chest tube(s) should be undressed and inspected prior to beginning balloon occlusion. A port external to the pleural space (in the soft tissues of the chest wall or overtly visible external to the thorax) or an incision that allows air to enter the pleural space when chest tube suction is applied will render all occlusions nondiagnostic. In case 1, a BPF was present, but air was also entering the pleural space *via* a large chest tube incision, confounding diagnostic testing. We would note that any time a chest tube is downsized, the provider should be alert to the possibility that this may occur. In case 2, the patient developed tension pneumothorax physiology while the chest tube appeared to be functioning; due to partial occlusion of the chest tube, the rate of pneumothorax formation was exceeding the rate of chest tube drainage prior to flushing of the tube. (We note that pigtail catheters have smaller lumens than large-bore chest tubes and in our experience, are more likely to clog.) If during balloon occlusion all attempts to decrease air flow through the chest tube fail, the chest tube(s) should be checked again prior to the additional considerations described below:

Sessions for balloon occlusion do not have to occur at the same time as EBV placement. Patients with clinically relevant BPFs are often in the ICU and frequently intubated. EBV placement is most often performed in the OR. A balloon occlusion study the day before anticipated EBV placement can be relatively easy if the patient is indeed in the ICU, can be informative, and can

Table 1. Principles to improve success rates with endobronchial one-way valve placement for bronchopleural fistula.

Recommendation	Commentary
Undress and inspect chest tube(s) prior to balloon occlusion bronchoscopy.	Not all chest-tube issues will be visible, but an external chest tube hole or an incision large enough to allow air entry into the chest tube from external air may be.
When feasible, consider performing the balloon occlusion procedure the day before EBV placement.	Lack of efficacy can lead to re-evaluation of the chest tube system and possibly to CT scanning.
If the air leak at the outset of the procedure is small, consider an increase in tidal volume and/or in negative pressure.	This is the one instance in which one would intentionally increase flow through a BPF. If the leak is too small, changes related to balloon occlusion might be missed.
If after five breaths there is no decrease in air leak following the main bronchus occlusion, wait longer.	Often, five breath cycles are not enough. Occasionally, the balloon may not effectively occlude.
If there is no decrease in air leak with main bronchus occlusion, first recheck the chest tube and clamp it at its site of entry into the thorax.	If, after chest tube clamping, there is still air bubbling through the water seal chest drain water chamber, there is a leak in the chest tube system external to the patient.
Consider CT scanning of the chest if systems appear intact but there is no apparent success.	CT can at times detect problems, such as a new (or newly apparent) BPF or a chest tube within the parenchyma.
At times, it is reasonable to place EBVs based upon anatomic logic, even when classic flow cessation does not occur.	EBV placement occludes airways more effectively than balloon inflation.
Complete cessation of air leak through a BPF is desirable, but it is not always a requisite for a successful outcome.	At low flow rates, many BPFs will heal.
An increase in air leak after an initially successful procedure does not always mean that the initial attempt had failed.	There may be a chest tube problem, or there may be a newly developed or increased additional BPF.

CT, computed tomographic scan; EBV, endobronchial one-way valve; BPF, bronchopleural fistula.

lead to further evaluation such as CT scanning prior to EBV placement.

CT scanning can play an important role and add to the efficacy of the procedure. In case 3, CT findings led to a decision not to remove the EBVs at the standard postinsertion interval. In case 4, CT scanning documented that the tip of the chest tube had migrated into an apical bulla. In case 6, CT scanning led to detection and subsequent occlusion of a leaking bronchial stump.

Lack of decrease in flow with balloon occlusion does not predict failure *per se*; it appears that the balloon used for occlusion, though conformal, does not in every case match the anatomy of the airway enough to cause occlusion. Cases 4 and 5 illustrate this point: in both cases, initial valve placement was based upon anatomic logic after flow had not been affected by balloon occlusion. In case 5, lobar balloon occlusion was effective in guiding final EBV placement after initial deployment based upon anatomic logic.

One must at times wait longer than the five respiratory cycles described as standard. Even if balloon occlusion is complete, five breaths are not always enough to observe a marked change in air leak. A large pneumothorax or a chest tube in lung parenchyma can provide a reservoir of air that does not follow the five-cycle rule. While in theory mainstem balloon occlusion should eventually lead to lung collapse and cessation of flow, the reservoir of air can be such that flow continues for an extended period of time (even if one assumes that all flow past the balloon has ceased); balloon occlusion loses its accuracy.

While the goal of EBV placement is to completely eliminate flow of air through a BPF, immediate elimination does not always occur and is not always necessary for ultimate success. A decrease in flow (coupled perhaps with pleural juxtaposition) may bring the rate of flow below that critical rate of flow required to maintain BPF patency and thus allow healing. In case 6, a marked decrease in air leak after EBV insertion was followed by complete resolution over a period of days.

Finally, one must consider the dynamics of pressure gradients. If flow through a path of least resistance is hindered, other pathways may become more physiologically relevant or may develop *de novo*. An increase in air leak after apparent success should lead to a search for a second BPF (as well as for chest tube malfunction). In case 6, effective EBV placement in the RUL led to an increase in air leak through a bronchial stump.

Conclusion

EBVs can be extremely effective in the treatment of persistent BPF. EBV placement is relatively noninvasive, often with high-risk surgery as its only alternative. Given the cost of extended ICU stays and the morbidity of unresolved BPF, EBV placement may be cost effective [Podgaetz *et al.* 2016; Mahajan *et al.* 2013] Effective deployment, however, is not always straightforward. This case series illustrates some of the pitfalls that can be associated with EBV placement. Table 1 summarizes steps that can be taken to improve success with this important modality.

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