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Methodological Aspects of Bronchoscopic Lung Volume Reduction with a Proprietary System

Tudor P. Toma Michael I. Polkey Peter G. Goldstraw Clifford Morgan
Duncan M. Geddes

Department of Respiratory Medicine, Royal Brompton Hospital, London, UK

Key Words
Interventional bronchoscopy · Bronchoscopic volume reduction · Lung volume reduction · Emphysema · Bronchial valve implants

Abstract
Bronchoscopic lung volume reduction (BLVR) is emerging as a new technique to palliate symptoms in patients with severe emphysema. Several devices and techniques are being developed to occlude airways resulting in collapse and reduced lung volume. Here we present in detail the methodological aspects of one such interventional bronchoscopic approach.

Introduction

Bronchoscopic lung volume reduction (BLVR) is being explored as a new way to palliate dyspnea in patients with severe emphysema. The technology is still under development and currently there are several BLVR systems under various stages of testing. Ingenito et al. [1, 2] suggested collapsing target regions of the lungs using a procedure similar to bronchoalveolar lavage. The lavage involves controlled removal of bronchial epithelial lining cells with a washout solution and the deployment of a fibrin hydrogel. In a sheep model of emphysema this procedure achieved scar tissue formation, which replaced hyperinflated lung, reduced overall lung volume, and improved respiratory function safely and consistently. Spiration Inc. suggests another approach, and proposes an intrabronchial removable valve system that can be delivered through the working channel of the flexible bronchoscope [3]. This mechanical blocker should collapse the target lung and reduce lung volume. In a preliminary study on healthy swine, the intra-bronchial valves produced lung collapse and volume reduction. The valves were easily implanted, repositioned, removed and replaced using standard flexible bronchoscopy with no short-term complications. Broncus Technologies developed the Exhale™ Emphysema Treatment System, which achieve extra-anatomic transbronchial decompression through the creation of passages through the bronchial walls maintained with stents. In an ex vivo lung model, placement of 5 stents improved FEV_1 with about 350–400 ml [4]. Companies such as Pulmonix and Closure have patents and preliminary work in this area and other companies may follow.

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Dr. Duncan M. Geddes, MD, FRCP
Department of Respiratory Medicine
Royal Brompton Hospital, Sydney Street
London, SW3 6NP (UK)
Tel. +44 2073518182, Fax +44 2073518999, E-Mail D.Geddes@rbh.nthames.nhs.uk

We present here our experience with the introduction of the Emphasys BLVR system (Emphasys Inc., Redwood City, Calif., USA), which is a mechanical endobronchial valve. This article details the methodology; the results of safety and efficacy pilot studies, and the characteristics of the selected patients were published elsewhere [5].

General Guidelines

In order to ensure safety we think that certain precautions should be observed. First, BLVR should be initiated under trial conditions in a center with adequate experience. Second, prior to working in humans significant training is useful. Third, a minimum of two operators are required in addition to the anesthetic team.

Training

For training, we used a plastic model of the human bronchial tree and upper airways (Nakhosteen Bronchoscopy Model 'Scopin', supplied by KeyMed, UK). The endotracheal tube adds to technical difficulties of the procedure and therefore the model should be 'intubated' for training. One of us (T.P.T.) received additional training on an anaesthetized live animal (sheep) and found that this gave useful insight into what to expect in patients.

The Team

A team of two bronchoscopists and an assistant in charge only of loading implants into the delivery catheter ('the loader') is needed. We have not found it helpful to designate a primary and secondary operator because the main role changes frequently from one operator to another. This may be a matter of preference rather than necessity.

We enlisted the help of an anesthetic team experienced in interventional bronchoscopy support, to be in control of airways and of monitoring vital signs. However, more recently, we have performed valve insertion under local anesthetic and sedation.

Accessories for BLVR

See tables 1 and 2 and figures 1–3. We prepared all the equipment sterile before the procedure.

Table 1. Accessories for bronchoscopic volume reduction

General accessories
A preparation table covered with sterile drapes where the loading of the implants will be done
KY lubricant or a silicon based lubricant
Sterile normal saline, 500 ml × 2
About five 5 ml syringes and two 20 ml
Sterile scissors
2 three-way sterile taps
2 kidney basins
Sterile towels to remove sterile KY jelly from the hands when handling the scopes
Suction system and tubing
2 × 1 ml adrenaline; 1:1,000 ratio
A documentation system (video tapes/CDs)
Specific accessories
A flexible bronchoscope with the external diameter smaller than 6 mm
Single lumen ET tube with an internal diameter of 9 mm minimum together with a backup similar tube
Balloon catheters and measuring ruler
Specific (Olympus) endoscopic measuring device
1.8 and 2.3 mm rat tooth grasping forceps
Basket forceps and balloon catheters

Table 2. Bronchoscopic volume reduction kit provided by the manufacturer

Bronchial valves of different sizes (small, medium, large)
The loading system for each valve size
The delivery system for each valve size
J-tipped and straight guidewires
Anesthesia adaptors with an operating channel diameter large enough to accommodate at the same time the flexible bronchoscope and the delivery catheter

Airway Control and Anesthesia

BLVR can be performed under local anesthesia, but we preferred general anesthesia for our first eight cases. This was because a general anesthesia secured the airway and the concomitant mechanical ventilation optimized alveolar ventilation during the procedure. All procedures were done under an intravenous anaesthetic regimen based on propofol and remifentanil. Management of ventilation was strictly pressure limited to a maximum peak airway pressure of 20 cm H_2O, irrespective of the potential for hypercapnoea, to avoid cumulative air trapping. All our patients received pre-op 1–1.5 g IV Cefuroxime which was continued with 7 days of Co-amoxiclav 625 mg t.i.d.

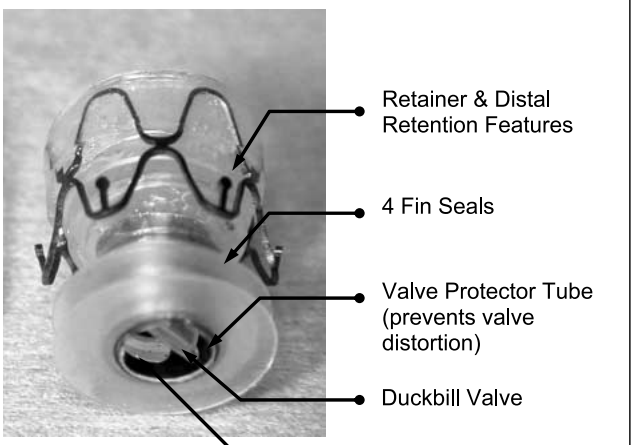


Fig. 1. Emphasys endobronchial valve (EBV; referred in the text as 'the implant') is a stent-supported one-way valve with retention features. EBV is designed to allow air to be vented from the isolated lung segment under normal exhalation pressure, and prevents air from refilling the isolated lung area during inhalation. In addition, it allows secretions and mucus to be eliminated from the target lobes.

Preoperative Identification of the Target Area and Sizing

We targeted in one session all the airways leading to the one lobe which was most affected by emphysematous destruction, on one side only (one session – one lobe – one side). This strategy was considered the safest but not necessarily the one with the maximum chance of achieving collapse. We did not implant bilaterally or more than one lobe at a time (except left upper and lingula) because of the risk of post-remodelling lung tear and pneumothorax. However, different targeting protocols may emerge in the future.

The severity and distribution of emphysema was determined from the high-resolution computed tomographic scans of the chest obtained during full inspiration. In addition, we used a ventilation perfusion scan to confirm that the target area received little ventilation.

Once a target area had been identified, we used computer multiplane reconstructions of the CTs and 3D rendering to try to understand the anatomy of the airways leading to the target areas. It has been suggested that if obtained with proper software and multidetector CT scanning, airway imaging can be superior to endoscopy [6], but in our case, this additional analysis has not aided sizing decisions more than simple intraoperative observation. A pre-op flexible bronchoscopy to assess airways was not considered necessary.

Table 3. Endobronchial valve sizes

Small: 4.0–5.5 mm external diameter
Medium: 5.0–7.0 mm external diameter
Large: 6.5–8.5 mm external diameter
Extra large: 8.0–10.0 mm external diameter

Procedure

Step 1: Exploration

A quick visual exploration of the entire bronchial tree confirmed the target area and that no other associated bronchial pathology was present.

Step 2: Decisions

Three decisions were taken at this step:

(1) Choice of segmental airways of the target lobe for valve insertion. The site of the implants was decided on the visual anatomy of the airways. We aimed to use the minimum number of implants for blocking the maximum number of segmental bronchi. Most of the implants were delivered in the first segmental bronchi (rarely subsegmental and rarely lobar).

(2) What size of valve to use for each location? We found that the quickest way to do the sizing is to assess the location diameter using the tip of the flexible bronchoscope as a reference. In addition, if the housing of the delivery catheter nearly fits the airway where the implant is intended to be deployed, then the size of the implant inside is likely to be appropriate. We did not find helpful any additional sizing instruments (table 3).

(3) In which order to perform the delivery? For us it worked best if the easiest site was implanted first. In terms of difficulty, the upper lobes were the most difficult to implant, with the right upper lobe more difficult than the left. Within the upper lobes, the apical segment was the most difficult to implant and the anterior was the easiest.

Step 3: Guidewire Deployment

The flexible bronchoscope was directed in the first target segment and the guidewire was placed through the working channel.

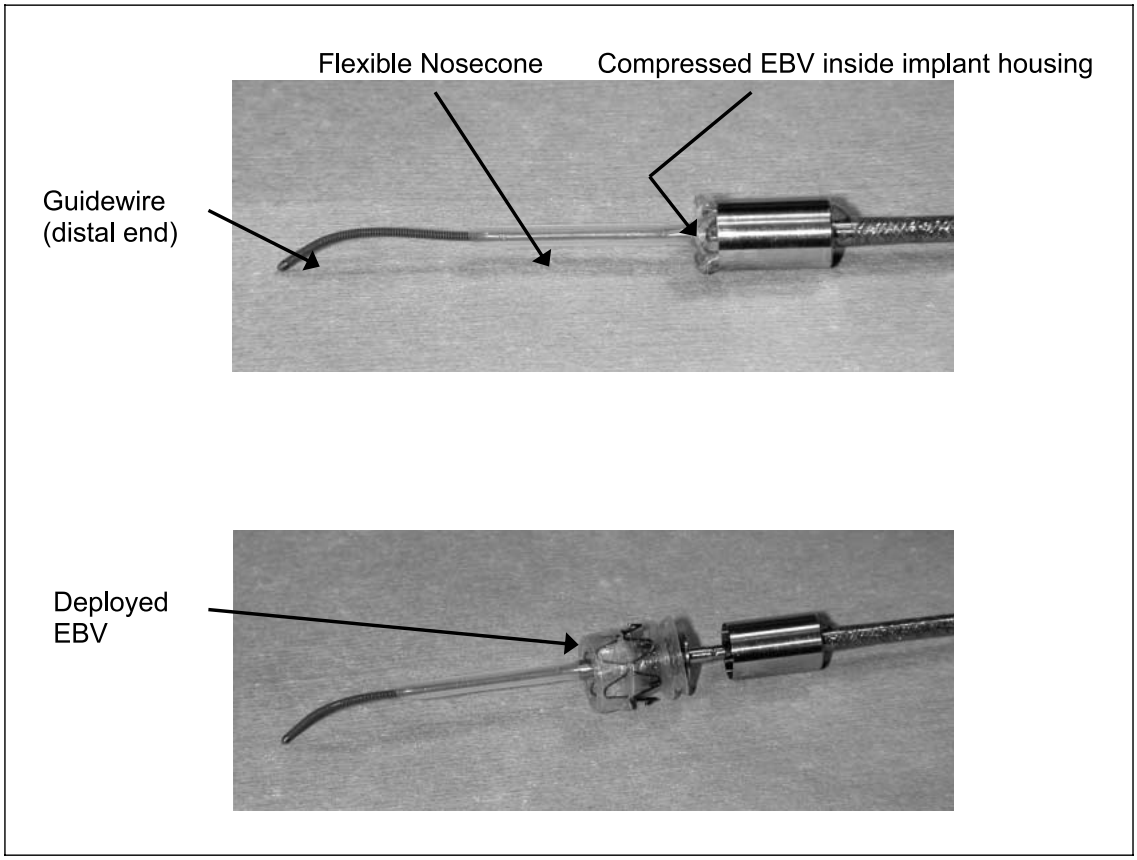


Fig. 2. Delivery system. The delivery catheter is designed to track over a standard guide wire. Actuating the deployment handle, which retracts the distal housing and releases the implant, deploys the EBV.

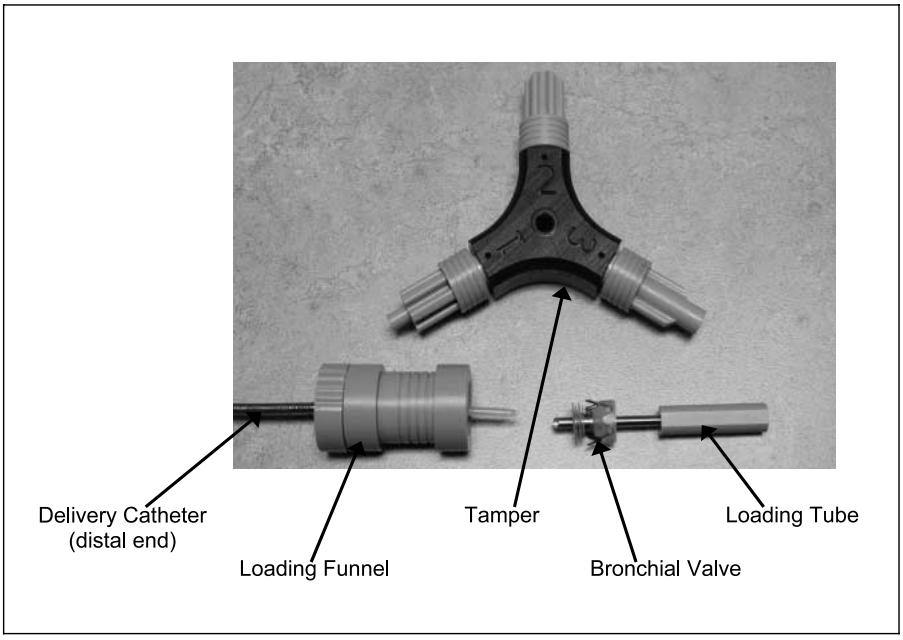


Fig. 3. The loading tool is a three-piece device designed to compress and load the implant into the distal housing of the delivery catheter. Water-based sterile lubricant such as KY jelly, which sometimes needs to be diluted, is required to facilitate loading.

Table 4. Endobronchial valve loading on delivery catheter procedure

Loading funnel is clipped onto catheter
EBV and funnel are lubricated
EBV are dilated with loading tube and loaded over nosecone
Valve is compressed into catheter with three presses of tamper

Step 4: Wire Exchange

The flexible bronchoscope was removed while the guidewire was maintained in the same place. This is similar to any routine airway wire placement manoeuvres.

Step 5: Loading the Implant on the Delivery Catheter

While operators performed step 4, the assistant loaded the first valve of chosen size in its corresponding delivery catheter (table 4).

Step 6: Visual Control of Guide Wire's Position

The flexible bronchoscope was inserted alongside the guidewire to check for the wire position in the target segment.

Step 7: Tracking the Delivery Catheter to the Target

The bronchoscope was withdrawn and one of operators back loaded the guidewire into the delivery catheter while the other operator was keeping the guidewire fixed. The delivery catheter was advanced until it met a resistance; if no resistance was met, the delivery catheter was not advanced blindly in the endotracheal tube for more than 15 cm. The flexible bronchoscope was introduced in the endotracheal tube alongside the delivery catheter to visualise the position of the implant housing. The bronchoscope was not advanced in front of the implant housing because this can displace the guidewire and can damage the bronchoscope.

The delivery catheter was further advanced under visual control. To move the implant housing forward, one may need to rotate the delivery catheter on the guidewire. If the delivery catheter does not advance with direct forward pressure, it is better to continue with a spiral rotation on the delivery catheter and pressure forward. These small manoeuvres will usually advance the implant housing to the desired place, providing that the guidewire remains in the right position.

Step 8: Deployment

The device is deployed by unlocking and pulling back the distal end of the handle on the delivery catheter. New versions of the delivery catheter may have a simpler deployment system. Deployment happens very quickly, and only a backward movement of the implant housing is visible on the monitor; in particular, the implant itself may not become immediately visible. The operator, however, feels at the handle a release, indicating a successful deployment.

Step 9: Withdrawal and Visual Control

Once fully deployed, the flexible bronchoscope was withdrawn together with the delivery catheter under visual control. The delivery catheter may snag on the distal margin of the endotracheal tube. If this happens, small forward movements and a combination of rotations followed by repeated backward movements will help the release of the delivery catheter.

Sometimes after delivering the implant in the apical segment of the right upper lobe, the delivery catheter tip is flexed almost at 180 and its withdrawal needs to start with a pushing forward (and not pulling) to release it from the valve. If this is not done, the delivery catheter may not come out from the valve and may not be easily pulled out.

When the delivery catheter was completely outside the ET, the flexible bronchoscope was reinserted and checked the position of the implant.

This concludes one insertion sequence (fig. 4, 5). For the subsequent implants the same steps were repeated.

Post-Procedure

The patients recovered from the anaesthesia under medical supervision in a monitored surgical recovery room. The first few hours after recovery can be most difficult for the patients who frequently demonstrate a transiently increased oxygen requirement due to shunting and possible other adaptation mechanisms. We performed an immediate chest X-ray to exclude pneumothorax (beware of the skin folds which can mimic a lung margin). Chest X-ray also serves to confirm satisfactory placement and retention of the implants which are radio opaque (fig. 6). In the recovery room and post procedure we gave codeine 10 mg p.o. q4–6 h to inhibit cough. All patients received a prophylactic 7 days course of oral antibiotics; the patients received their regular inhaled bronchodilator medication. At the time of discharge, we gave patients 24 h contact information for the BLVR physician. Patients should be advised to avoid overexertion during the first month as the lungs may be remodelling during this time with the risk of pneumothorax.

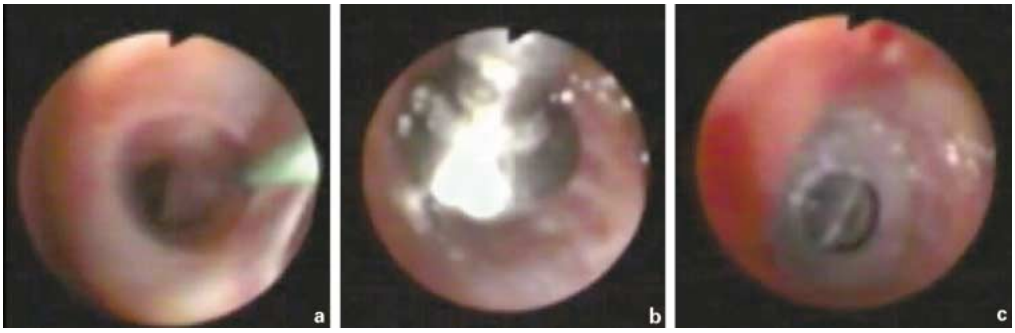
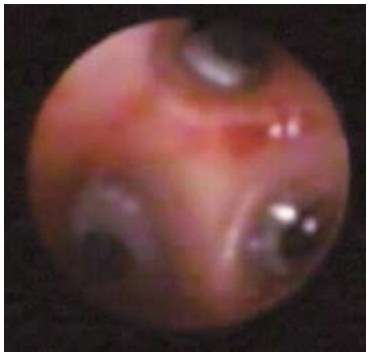


Fig. 4. Sequence for valve insertion: guide wire deployment (**a**), delivery catheter in situ (**b**), deployed valve (**c**).



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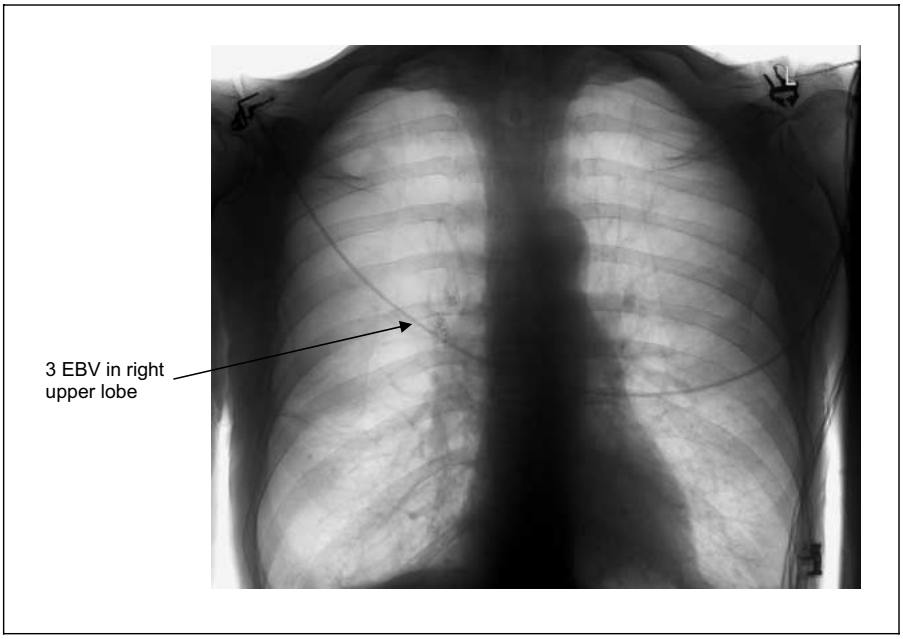

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Fig. 5. Visual control of the deployed valve: three valves in the right upper lobe.
Fig. 6. Chest X-ray post procedure, which confirms the satisfactory placement and retention of the implants.

Final Comments

We have been able to achieve successful implantation in all fourteen procedures so far attempted. We found that with good training and a coordinated team, BLVR with the described system was easy and safe to perform. The foreseeable introduction of new devices such as bronchial valves that can be deployed through the working channel of the bronchoscope will certainly simplify the procedure. However, even with the current system we could easily work through the endotracheal tube and did not need to use rigid bronchoscopy, which was available on standby – but this may be a matter of preference. Our preliminary results with the method described here showed that BLVR can work, it does not always work and seems to be safe [5]. Controlled studies are warranted to evaluate the clinical value of this therapeutic approach.

Acknowledgement

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