NEW TECHNOLOGY

A New Endoluminal Resection Technique and Device: Resector Balloon

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Purpose. **We have developed a new resection technique and designed a special balloon by which resection of endoluminal airway lesions can be safely and successfully done.**

Description. **From April to December 2006, 38 interventions were done in 30 patients; endobronchial tumor or granulation tissues were mechanically removed by a catheter by which the balloon was covered with a polyurethane mesh structure. Acute and long-term complications, results, advantages, and disadvantages of this new technique and device were determined.**

Evaluation. **Resection of endobronchial tumors and also control of bleeding and dilatations were successfully performed in 30 patients.**

Conclusions. **As an alternative to other endobronchial treatments, this new technique and device can be used as a safe method. In addition, the utilization of this new device does not need as much experience as other techniques. On the other hand this method does not need very expensive equipment, such as a laser or cryotherapy equipment.**

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Endoluminal resection techniques have become an increasingly accepted method of palliation for patients with endoluminal tumor lesions in central airways [1]. This management requires palliative procedures in approximately 90% of advanced lung cancer cases [1, 2]. Main bronchi are obstructed in half of these cases. Autopsy studies show that endoluminal tumors cause death in 75% of epidermoid carcinomas and 50% of adenocarcinomas [3]. Therapeutic bronchoscopic procedures (ie, laser, cautery, argon, cryotherapy, stent implantation, and balloon dilatation, and so forth) are used in combination with each other according to the location and type of lesion. This can be done through either a rigid bronchoscope or by flexible bronchoscopy, the latter of which is more widely used [2, 4, 5]. Although 90% of lung cancer patients need palliative treatments, interventional bronchoscopy techniques are not used to their full potential. Dyspnea, postobstructive pneumonia and hemoptysis are the main symptoms of advanced lung cancer. Therapeutic bronchoscopy can provide immediate relief from dyspnea and hemoptysis faster than radiation and chemotherapy. In advanced cases, if we start by using endobronchial techniques initially, time can be gained for other treatment modalities with higher quality of life and less complications [6]. During the endobronchial treatment, balloon application is used mainly to dilate bronchi or control bleeding [4, 7, 8]. However it is also possible to use a modified balloon as a resection tool with dilatation and tamponade capabilities.

Informed consent was obtained from each patient before the procedure and this study was approved by our Institutional Ethics Committee.

Technology

The "resector balloon" is composed of a 120-cm long single lumen polyethylene tube of 2-mm outer diameter. On its distal end a latex balloon is mounted. The length of the balloon is 10 mm, 20 mm, or 40 mm for three different types of application. The maximum inflated diameter of the balloon is 10 mm, 15 mm, and 20 mm, respectively. The balloon is covered with a hexagonal mesh structure made of 0.3-mm thick polyurethane fibers. The minimum deflated balloon diameter with the mesh structure on it is 3 mm for all types.

Technique

When the resector balloon is inflated just at the level of endoluminal tumor, the polyurethane fibers around the balloon cuts and destructs the tumor tissue. At the same time the balloon makes a compression on the tumor to minimize the bleeding. Therefore, when the "resector balloon" is endoluminally inflated it can be used for

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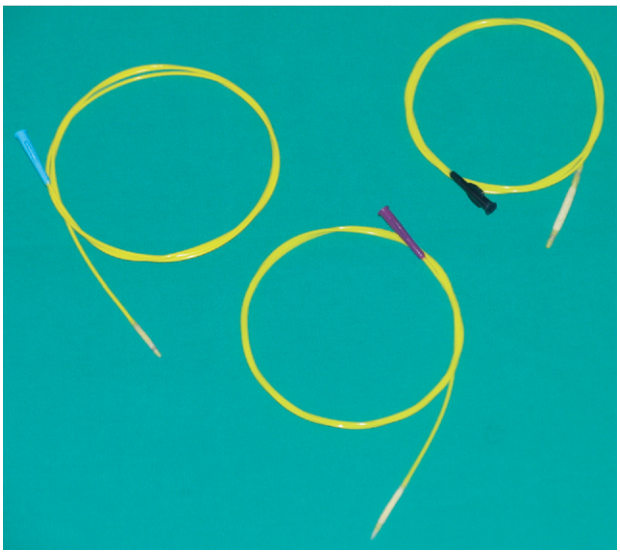

Fig 1. Various sizes of resector balloon.

mechanical destruction and removal of tissues from lesions filling the bronchial lumen (Figs 1, 2).

In this technique the balloon is placed into the bronchial lumen where the tumor overlies the deflated balloon. The balloon is repeatedly inflated until the interior surface of the lumen is in complete contact with the surface of the balloon, which is repeatedly deflated until the tumor tissue is completely flattened out or torn down. This causes destruction in the tumor tissue. If necessary the resector balloon is introduced further into the lumen, inflated, and then moved to and fro to resect pieces from the tumor. The pieces are then aspirated or taken out by using forceps. The same procedure is repeated until lumen patency is established. Any possible bleeding can also be controlled simultaneously by balloon tamponade because the balloon is already in the lumen and the bleeding is prevented.

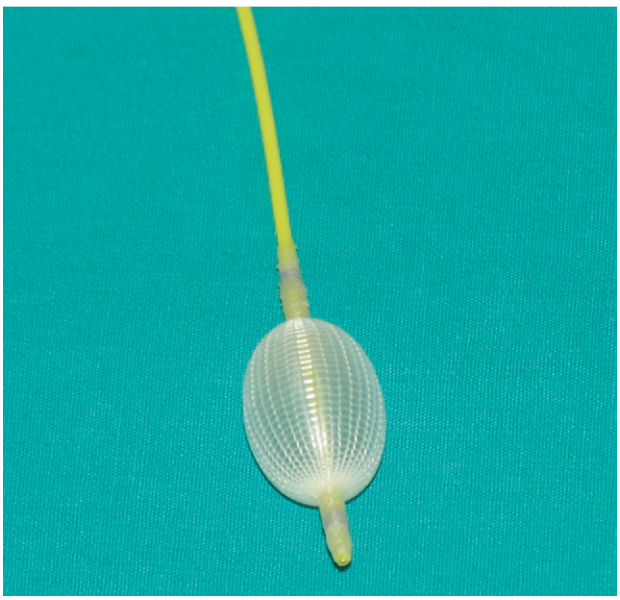

Fig 2. Resector balloon. Special structure is seen when inflated.

Table 1. Patient Demographics

Variable	Value
Patients	30
Age (yr)	19–71
Males/Females	21/9
Symptoms	
Dyspnea	29
Fever	21
Hemoptysis	21
Cough	21
Stridor	9
Respiratory insufficiency (NIMV)	13
Respiratory insufficiency (MV)	2
Diagnosis	
Nonsmall cell lung cancer	20
Small cell lung cancer	6
Metastatic lung cancer	3
Granulation tissue	1

MV = mechanical ventilation; NIMV = noninvasive mechanical ventilation.

Clinical Experience

Between April 2006 and December 2006, 30 patients (21 men and 9 women; age range, 19 to 71 years; mean age, 54 years) with tracheobronchial obstruction due to malignancy (n = 29) and granulation tissue (n = 1) were admitted to our clinic. The symptoms of these patients included dyspnea, stridor, fever, respiratory insufficiency, and hemoptysis. In addition, a rise in white blood cell count and C-reactive protein level due to postobstructive pneumonia is seen in all cases. Diagnosis was established by reviewing the history, computerized tomography (three-dimensional reconstructions), and bronchoscopy of the patient. One male patient with post-intubation tracheal stenosis was the exception. Previously chemoradiotherapy was given in all of the malignant cases. Patient demographics are summarized in Table 1.

Prior to the operation, all patients were evaluated by a cardiologist and anesthesiologist, pre-medicated, and given antibiotics. Interventions were performed under general anesthesia through a rigid and flexible bronchoscope. We used the Dumon-Harrel rigid bronchoscope (Efer, La Ciotat, France) and the Olympus therapeutic bronchoscope BF-XT (Olympus, Tokyo, Japan), which has a 2.8-mm channel diameter. Yttrium aluminum peroxide-laser, cryotherapy, stenting also were performed when required. We used a resector balloon in 38 interventions in 30 cases that had endoluminal and submural lesions at the proximal trachea in 1 patient, the distal trachea in 4, the carina in 3, the left main bronchus in 8,

the left lower bronchus in 5, the left upper bronchus in 5, the left lower segment bronchus in 1, the right main bronchus in 11, the right upper bronchus in 3, the right intermediate bronchus in 3, the right middle lobe bronchus in 1, the right intermediate bronchus in 4, and the right lower bronchus in 4. In 28 of the interventions, endoluminal lesions were completely resected by resector balloon alone. In 10 interventions the resector balloon was used with other endobronchial techniques (ie, laser and cryotherapy). We placed silicone stents in 17 lung cancer patients after their lumen patencies were maintained. The average procedure time was 58 minutes.

Results

A resector balloon was used in 38 interventions. In 28 of these interventions, endoluminal lesions were completely resected by resector balloon alone and no other additional technique was necessary. In the remaining 10 interventions, the resector balloon and other endobronchial techniques were used. The airway patency was maintained in all patients. Complications such as bleeding, perforation, or decreased oxygen saturation were not observed during the procedures. Yttrium aluminum peroxide-laser was used only for vaporization; it was not needed for bleeding control.

Durations of the interventions ranged from 27 to 118 minutes. The mean intervention period was 58 minutes.

All patients were extubated, except for 1, and it was observed that their initial respiratory symptoms were significantly improved. Respiratory distress was relieved in 15 patients who needed mechanical ventilation and noninvasive mechanical ventilation prior to the interventions. In the follow-ups the day after the procedure, complete airway patencies were confirmed by three-dimensional thorax computed tomography.

In spite of initial complete endoluminal resections, a repeated session was necessary in 3 patients because of tumor relapse in a 3-month period. In one case therapeutic bronchoscopic intervention was applied in five different sessions. The patient had a metastatic pancreatic tumor and nearly all of the segment bronchi were obstructed with endoluminal tumor, and the general status of this patient was very poor. She was intubated because of respiratory insufficiency. After maintaining bilateral main bronchial lumen patency by the first therapeutic intervention, it was observed that the left upper and lower lobe segment bronchi and right lower and middle lobe segment bronchi were obstructed by tumor masses. Because of her general status, individual sessions were applied for each different location. For the upper lobar and segmental lobar lesions a resector balloon was used through a flexible bronchoscope. She died 1 month later in the intensive care unit due to *Pseudomonas aeruginosa* sepsis.

Comment

The major limiting factors in endobronchial therapy are the location of the tumor, the type of its invasion, the complication risk of resection methods, and the operation time. It is quite easy to perform laser, cautery, and cryotherapy in large airways such as the trachea and main bronchi. The risk of complication increases when the tumor is located more distally [6, 7, 9]. Prior to resector balloon it was difficult to handle upper lobar bronchi lesions. The resector balloon introduced through a flexible bronchoscope is now easily used to open the upper lobar and distal airways. In these locations it was nearly impossible to achieve complete endoluminal resection due to the high risk of complications of laser, cautery, argon, cryotherapy, and mechanical resection [4, 5]. In such lesions, endoluminal resection, dilatation, and bleeding control can be achieved all together with the resector balloon. Because our resector balloon is technically a balloon catheter covered with a polyurethane mesh, it can be used (other than for resecting purposes) in dilatation and bleeding control, as an advantage of its balloon component.

It was determined that the duration of intervention was much less. The operation time was reduced by at least 50%, giving way to reduction of the anesthesia time and the complication ratio due to anesthesia. Due to resector balloon tamponade, the laser was rarely used; therefore, toxic hot gas inhalation and the other laser risks were reduced. After using this technique, the laser or other hot coagulation and vaporization techniques were not needed as much as before. The tip of the rigid bronchoscope is known to be responsible for complications when used for mechanical resection, which may cause bleeding and destruction of normal bronchial cartilage [9]. The resector balloon is very gentle and only removes the endoluminal lesions. Complications such as heavy bleeding, cartilage destruction, and perforation are not observed.

Exophytic tumor growth is the indication for resection techniques. Neodymium:yttrium-aluminum:garnet laser is the most commonly used method of endobronchial tumor resection [9, 10]. The clinical benefit of a laser tumor resection is high in the trachea, the main bronchus and the lobar bronchus. In our study, there were no bleeding complications observed which continued after tumor resection and dilation of the obstructed bronchus. The resector balloon was used alone and together with laser and cryotherapy. In using the laser, the main determining factor is tissue density. If the tumor tissue is hard (not fragile enough to be destructed by resector balloon), we needed the yttrium aluminum peroxide-laser coagulation and vaporization effect. On the other hand, a cryotherapy catheter was mainly used to extract pieces that could not be grasped by the forceps. It is not possible to apply laser coagulation or vaporization in a 360° circumference position. The resector balloon makes it easily possible to work in a cylindrical anatomical position with a cylindrical resector device.

The significance of therapeutic bronchoscopy increases and is more widely used in the world. New generations of radiotherapy and oncological treatment modalities have a better impact on the prognosis of lung cancer. As the airway obstruction is cleared, better oxygenation may be obtained

and the possibility of resistant lung infections can be avoided. Of course, this will yield to further radiotherapeutic or oncological treatments with higher survival rates and better quality of life [2, 9]. We could not find any publication in the literature in which the balloons were used for resecting purposes. Before we used the resector balloon method, balloons were used for bleeding control and dilation [2, 4, 7, 8, 10]. Using the resector balloon in endoluminal lesions for resection, dilation, and tamponade is considered easy, reliable, and effective.

Disclosures and Freedom of Investigation

No financial support was received for this study. The equipment used was not donated for the purposes of this study. The authors had full control of the study design, methods used, outcome measurements, analysis of data, and production of the written report.

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Disclaimer

The Society of Thoracic Surgeons, the Southern Thoracic Surgical Association, and The Annals of Thoracic Surgery neither endorse nor discourage use of the new technology described in this article.

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INVITED COMMENTARY

Various methods of palliating endotracheal and endobronchial tumors are currently practiced. These include mechanical débridement, balloon dilatation, cautery, neodymium-doped yttrium aluminium garnet (Nd-YAG) laser, photodynamic therapy, and stent insertion, to name a few. In this article, Karakoca and colleagues [1] describe their use of a new "resector balloon" consisting of a balloon covered with polyurethane fibers in a hexagonal mesh pattern and mounted on a single lumen polyethylene tube. The device was used 38 times in 30 patients mostly for malignant endobronchial obstruction (one patient had a granulation tissue obstruction).

Because only 16% of patients with lung cancers present in the earliest stages [2], most lung cancer patients will have locally advanced or metastatic disease. A subset of these patients will have endobronchial tumors at presentation or the tumors will later develop and cause dyspnea, cough, wheezing, or hemoptysis. It is imperative for thoracic surgeons and interventional pulmonologists to aggressively treat malignant endobronchial obstruction to improve the quality of life for patients with advanced disease. The resector balloon described in the article is another tool that can be used to achieve this goal. Although this limited single-institution experience describes a reasonably safe approach—no significant bleeding, cartilage damage, perforation, or deaths were encountered—the main limitation was the balloons inability to destroy hard tumor, thus requiring the use of YAG laser or cryotherapy in 10 of 38 interventions. It cannot be determined from this early experience with limited data whether the resector balloon is superior to the other modalities previously mentioned, and no cost analysis is available for this prototype.

Perhaps future design improvements will allow the resector balloon to destroy firmer tumor, thus obviating the need for additional resources such as laser. Until that time however, thoracic surgeons should continue to use those resources currently available to them to palliate endobronchial tumors.

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