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Comparison between traditional and small-diameter tube-assisted bronchoscopic balloon dilatation in the treatment of benign tracheal stenosis

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Abstract

Objective: To compare the safety and efficacy between using a small-diameter tube-assisted bronchoscopic balloon dilatation (BBD) and the traditional BBD in the treatment of benign tracheal stenosis.

Methods: A retrospective study included 58 patients with benign tracheal stenosis from August 2009 to December 2014 was made. The patients who underwent traditional BBD were divided into group A, and who underwent a small-diameter tube-assisted BBD were divided into group B. The tracheal diameter, dyspnea index and blood gas analysis results were detected before and after BBD. Efficacy and complications were evaluated after BBD.

Results: There were significant differences in oxygen saturation (PaO_2) during the operations comparing with before and after operations in group A ($P = .005$), while there was no significant difference in group B ($P = .079$). The tracheal diameter obviously increased (in group A, from 4.16 ± 1.43 mm to 12.47 ± 1.41 mm, $P = .000$; in group B: from 4.94 ± 1.59 mm to 12.61 ± 1.41 mm, $P = .000$). Dyspnea index obviously decreased (group A: from 3.21 ± 0.93 to 0.50 ± 0.59, $P = .000$; group B: from 3.24 ± 0.89 to 0.65 ± 0.69, $P = .000$). The immediately cure rate in both groups was 100%. Long-term effect was significantly better in group B than that in group A (85.3% vs 59.1%, $P = .021$), at the end of the follow-up period.

Conclusions: Small-diameter tube-assisted BBD obtains better safety and long-term efficacy than the traditional BBD in the treatment of benign tracheal stenosis. However, close attention should be given to the risk of the adverse effects caused by carbon dioxide retention.

KEYWORDS
benign tracheal stenosis, bronchoscopic balloon dilatation, tube

1 | INTRODUCTION

In recent years, physicians have been confronted with great difficulties in the therapy of benign tracheal stenosis with different causes. Interventional pulmonology developed rapidly in recent years,[1] and it has become the first choice in the treatment of benign tracheal stenosis.[2] Bronchoscopic balloon dilatation (BBD) is regarded as a safe and effective strategy in the treatment of benign tracheal stenosis,[3] which can be combined with other techniques, such as neodymium—doped yttrium aluminum garnet (Nd: YAG) laser resection, cryotherapy, argon plasma coagulation, stent implantation, and electrocautery.[4]

*These authors contributed equally to this study.

TABLE 1 Clinical features

Feature	Group A	Group B	Statistic	*P* value
Cases	24	34		
Male	8	22		
Female	16	12		
Average age (years)	34.75 ± 13.24	33.12 ± 11.79		
Causes of tracheal stenosis				
Tracheotomy or endotracheal intubation	22	31		
Tracheal trauma	0	1		
Tracheal tuberculosis	2	2		
Positions of stenosis				
Upper trachea	11	12		
Upper and middle trachea	8	10		
Middle trachea	5	11		
Whole trachea	0	1		
The lengths of the tracheal stenosis(cm)	3.38 ± 0.76	3.06 ± 0.73	$t = 0.164$	.107

The procedures of tracheal stenosis treatment always require general anesthesia and patients usually cannot hold their breath for a long time, which has become a limitation of BBD. Under such conditions, physicians need to find a more secure, effective and easily accepted approach. We reviewed the files of 58 patients with benign tracheal stenosis underwent traditional BBD and small-diameter tube-assisted BBD respectively at the Department of Respiratory Medicine, First Affiliated Hospital of Guangxi Medical University from August 2009 to December 2014. Then, we compared the safety and efficacy between these strategies.

2 | METHODS

2.1 | Study population

Patient characteristics were summarized in Table 1 We retrospectively reviewed the clinical information of 58 patients (30 male and 28 female) with an average age of 34.31 ± 11.62 years (range, 16-70 years). The causes of tracheal stenosis were tracheotomy or endotracheal intubation in 53 cases, tracheal trauma in 1 case and tracheal tuberculosis in 4 cases. The positions of stenosis were the upper trachea in 23 cases, the upper and middle trachea in 18 cases, the middle trachea in 16 cases, and the whole trachea and right main bronchus in 1 case. All patients were divided into two groups according to method of the BBD procedures. The patients who underwent traditional BBD were divided into group A in 24 cases, and who underwent a small-diameter tube-assisted BBD were divided into group B in 34 cases. This study was approved by the First Affiliated Hospital of Guangxi Medical University Medical Ethics Committee. All patients were informed of the facts and then signed informed consents.

2.2 | Instruments

The fiberobronchoscopy (model BF-260) made by Olympus was adopted during BBD procedures. Besides, a fiberobronchoscopy (model BF-1T260) made by Olympus was prepared for emergency. We chose a guide wire with a diameter of 0.85 mm, a length of 180 mm and balloon catheter (the balloon with a diameter of 14-16 mm, a length of 40-60 mm, the catheter with a length of 110 cm) (Jiuhong Medical Equipment Co., Ltd., Changzhou, China). The inflation device was made by Shenzhen Ant Hi-Tech Industrial Co., Ltd., Shenzhen, China. The tube, used for assisted ventilation, was made of a special medical polycarbonate plastic and taken from a metal stent push device (Micro-Tech [Nanjing] Co., Ltd., Nanjing, China), with a length of 30-40cm, inner diameter of 2.5-3.5 mm (Figure 1A).

2.3 | Methods of BBD

The full preoperative preparation covered coagulation function, blood platelets count, blood gas analysis, blood pressure and electrocardiogram. All patients completed the examinations, such as computerized axial tomography of neck and chest, trachea three-dimensional imaging, bronchoscopy, to determine the location, extent and length of stenosis and

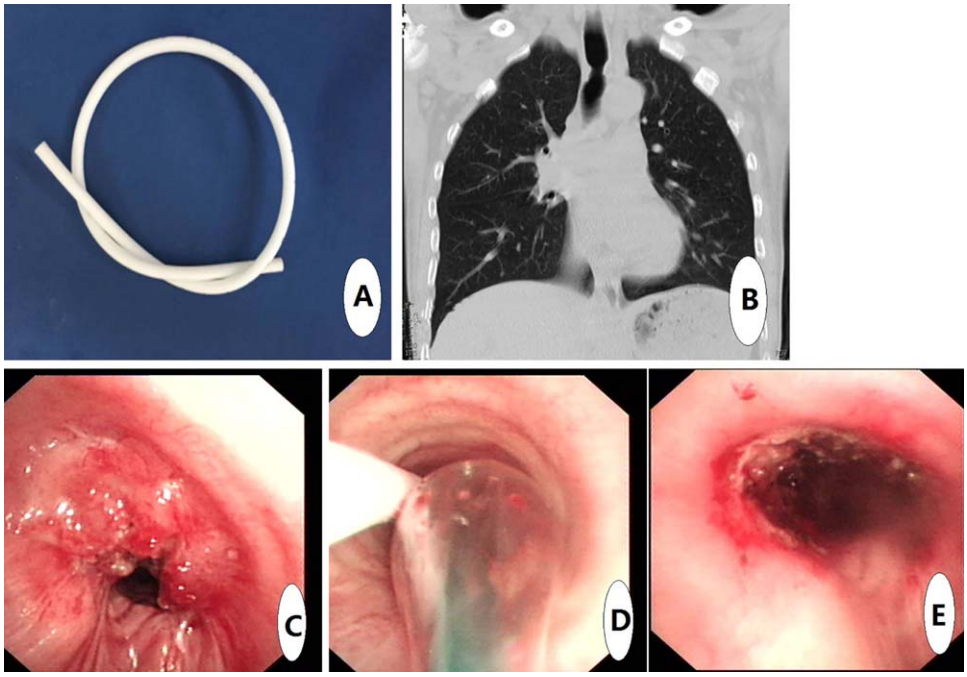

FIGURE 1 (A) Tube was used in procedures. (B) Subglottic stenosis in a 51-year-old woman was shown in CT image. (C) Severe stricture with 2 mm under bronchoscopic visualization. (D) A balloon catheter was inserted to the tracheal stenosis after a assisted tube (The right was the dilatation of balloon, and the left was a assisted tube). (E) The tracheal diameter was larger after BBD procedure

select the appropriate size of balloon catheter. The same was done with traditional bronchoscopy, and 2% lidocaine aerosol inhalation was taken for localized anesthesia. Every patient signed a consent form including common complications after bronchoscopy procedure and alternative treatment options.

With oxygen flow of 3-5 L/min, electrocardiographic and pulse oxygen saturation (SpO_2%) were monitored by a multifunction electrocardiographic monitor during all procedures. Traditional bronchoscopy was performed as previously described Sheski and Mathur[4] The tube-assisted BBD procedures included the following steps: after adequate anesthesia, the fiberobronchoscopy (model BF−260; Olympus) was inserted into trachea by a nostril, sometimes by mouth rather than narrow nostrils. A high frequency electrotome took radial incisions from the fibrotic narrowing ring, inserted through the working channel of the bronchoscopy. Then necrotic material was produced after cauterization and cleared immediately for expanding tracheal lumen, to insert a tube and a balloon catheter. A guide wire was inserted through the working channel of the bronchoscopy and reached the tracheal stenosis. Then the bronchoscopy was pulled out. At the same time, a tube was inserted along the guide wire to distal tracheal stenosis of 2-3cm.To avoid similar unilateral pulmonic ventilation, insertion of the tube should avoid the main bronchus. After pulling out the guide wire and mobilization of the tube, an oxygen tube was attached to the tube for oxygen. Bronchoscopy was inserted from the other side of nostrils, and a guide wire was inserted to distal trachea. The bronchoscopy was withdrawn, and reinserted through the same nostril. Under the guidance of bronchoscopy, a prepared balloon catheter was inserted to the tracheal stenosis along the guide wire, and the balloon catheter must be inserted to middle of tracheal stenosis. If the tracheal stenosis was too long to expanded at a time, sectionalized expansion should be taken. Water was poured into a balloon inflation by a pressure pump device with 1-5 k*P*a of pressure gradually. Actual duration of balloon inflation was recorded in group A. Duration of balloon inflation was recorded by a multiple of 5 s in group B, and it ranged from 30 to 180 s. If the SpO_2% was lower than 90% or declined higher than 5% baseline of preoperation or the patient could not tolerate hypoxia, the BBD procedure was immediately stopped. After each balloon was inflated, operators must observe whether there was tracheal laceration, bleeding and tracheal expansion. Then a secondary balloon inflation was undertaken. Postoperative management was taken after procedures.

2.4 | Postoperative management

The next bronchoscopy was taken and necrotic tissues were carefully removed in the trachea, on the 3th and 7th day postoperative. All patients were given 2mg of inhalation of budesonide by nebulization twice a day.

2.5 | Clinical indicators

Several indicators were valued, included blood gas analysis (1 h before the BBD procedure, during the procedure, and

TABLE 2 Comparison with PaO2, PaCO2 before, during and after procedures between groups A and B

	A		B	
	PaO_2 (mm Hg)	$PaCO_2$ (mm Hg)	PaO_2 (mm Hg)	$PaCO_2$ (mm Hg)
Before	95.84 ± 18.22	42.61 ± 3.29	87.11 ± 15.22	44.87 ± 7.14
During	87.38 ± 7.50	49.14 ± 7.10	94.03 ± 11.73	48.38 ± 8.10
After	99.42 ± 8.02	39.18 ± 2.85	92.73 ± 10.51	43.15 ± 5.34
Statistic	$F = 5.88$	$F = 24.87$	$F = 2.64$	$F = 5.44$
P value	0.005	0.000	0.079	0.007

2 h after the procedure), tracheal diameter (before and after the BBD procedure), dyspnea index (before and after the BBD procedure, using the American Thoracic Society dyspnea rating criteria[5]: Level 0: normal; Level 1: anhelation while fast walking; Level 2: anhelation while walking at a normal speed; Level 3: stopping a normal-speed walking for anhelation; Level 4: anhelation after mild exercises), initial and long-term efficacy and complications.

2.6 | Follow-up and long-term effect definition

All patients were followed 6 months after each BBD procedure. Long-term effect was defined as improvement of symptoms after the initial or repeat (no more than four sessions) BBD procedures. If the improvement of symptoms lasted less than 1 week and the patient needed additional treatment, such as stent implantation and surgery, or improvement of symptoms lasted less than one follow-up period (6 months) after 4 BBD procedures, we considered it without long-term effect.

2.7 | Statistical analysis

All analyses were performed using SPSS version 17.0. Quantitative data were expressed as mean ± standard deviation (SD). The tracheal diameter and dyspnea index were analyzed using the paired-sample t test. Comparison of duration for balloon inflation was analyzed using the two-sample t test. Arterial partial pressure of oxygen (PaO_2, before procedure, during, and after) and arterial carbon dioxide pressure ($PaCO_2$,procedure, during, and after) were analyzed using the randomized block design ANOVA. Differences of two group rates were analyzed using the Chi-square test. A value of $P < .05$ was considered statistically significant.

3 | RESULTS

Changes of the blood gas analysis results (before, after), tracheal diameter and dyspnea index: A total of 124 BBD procedures were undertaken on 58 patients. 68 traditional BBD were undertaken on 24 patients in group A. And 56 tube-assisted BBD were undertaken on 34 patients in group B. All tubes were successfully inserted to trachea by one time in each procedure. The lengths of the tracheal stenosis in groups A and B were 3.38 ± 0.76 cm and 3.06 ±0.73 cm, retrospectively, ($P = .107$), (Table 1). The blood gas analysis results were as follows: changes of PaO_2 had statistical significance ($P = .005$) in group A. PaO_2 during procedures significantly decreased and there was no statistical significance in pre-operation and post-operation comparison. $PaCO_2$ showed statistical significance ($P = .000$). $PaCO_2$ after procedures significantly decreased, and there was no statistical significance in pre-operation and intra-operation comparison. Nevertheless, there was no statistical significance in PaO_2 in group B ($P = .079$). $PaCO_2$ showed statistical significance ($P = .007$). $PaCO_2$ significantly increased during procedures and decreased after procedures. All of the patients, dyspnea were relieved immediately after procedures. Tracheal diameters increased and dyspnea index decreased after procedures (Tables 2 and 3).

3.1 | Complications, efficacy and follow-up results

124 BBD procedures were undertaken on 58 patients. The complications related to the BBD procedures included mild chest pain, bleeding, tracheal laceration, respiratory tract infection and convulsion, and the incidence of these complications was 83.3%, 62.5%, 16.7%, 16.7%, 2.1% in group A and 79.4%, 72.1%, 41.2%, 29.4%, 5.6% in group B. Only tracheal laceration was directly related to BBD. All patients with chest pain recovered in 1-2 days without any treatment. In all the bleeding procedures, the volume of bleeding was no more than 50 mL, and tracheal bleeding was effectively stopped after the treatment of intratracheal instillation of epinephrine at a concentration of 1:10,000. The tracheal lacerations were superficial, without massive bleeding and dyspnea. Mild Pneumomediastinum only occurred in 2 patients in group B. All patients with tracheal laceration and the pneumomediastinum could recover 7 days after BBD

TABLE 3 Comparison with tracheal diameters and dyspnea index before, during and after procedures between groups A and B

	A		B	
	Tracheal diameters (mm)	**Dyspnea index**	**Tracheal diameters (mm)**	**Dyspnea index**
Before	4.16 ± 1.43	3.21 ± 0.93	4.94 ± 1.59	3.24 ± 0.89
After	12.47 ± 1.41	0.50 ± 0.59	12.61 ± 1.41	0.65 ± 0.69
Statistic	$t = -21.309$	$t = 13.899$	$t = -23.362$	$t = 16.926$
P value	0.000	0.000	0.000	0.000

procedure without specific treatment. When patients experienced convulsion, bronchoscopy, tube and balloon catheters were withdrawn immediately. Then convulsion could stop in 5-10 s later without calmative and antiepileptic drugs. There was a 100% initial cure rate in both groups. After 1 to 4 BBD procedures, 59.1% of patients in group A and 85.3% of patients in group B could maintain symptom remission in a follow-up period ($P = .021$). The failure patients were total 3 cases (2 cases in group A and 1 case in group B), alternative treatment including short-term stent placement in 2 cases and surgery in 1 cases (Table 4). Typical computed tomography and BBD images are shown in Figure 1B–E.

4 | DISCUSSION

With the rapid development of intensive care medicine, tracheal intubation and tracheotomy has been widely used in medical rescue. Then, tracheal stenosis, the complication of tracheal intubation and tracheotomy, has been clinical common disease. The most common cause of benign tracheal stenosis is tracheal intubation and tracheotomy.[6–8] In the series of 58 patients in our study, the causes of benign tracheal stenosis were as follows: tracheal intubation or tracheotomy in 53 cases (91.4%), tracheobronchial tuberculosis in 4 cases (6.9%) and tracheal trauma in 1 case (1.7%).

It is reported that the incidence of benign tracheal stenosis after tracheal intubation or tracheotomy is 10%-20%[9,10] and 1%-2% of patients have clinical symptom or serious tracheal stenosis.[9,11] However, the estimated incidence of severe tracheal stenosis after tracheal intubation or tracheotomy in the general population is 4.9 per million per year.[9,12] Patients with tracheal stenosis always experience chest distress, anhelation and dyspnea after physical activities, as well as recurrent pulmonary infection due to tracheal stenosis. All of these symptoms seriously affect

TABLE 4 Comparison with duration of inflation, cure rate and incidence of complication between groups A and B

	Group A	Group B	Statistic	*P*
Duration of inflation	42.71 ± 8.97 s	98.76 ± 40.13 s	$t = -7.87$	.000
BBD sessions	2.83 ± 0.87	1.65 ± 0.60	$t = 6.17$	.000
Cure rate (%)				
Initial cure rate	100%	100%		
Long-term cure rate	59.1%	85.3%	$\chi^2 = 5.33$	.021
Incidence of complication				
Chest pain	83.3%	79.4%	$\chi^2 = 0.00$	.97
Bleeding	62.5%	72.1%	$\chi^2 = 0.80$	.371
Tracheal laceration	16.7%	41.2%	$\chi^2 = 3.95$	.047
Infection on the lower airway	16.7%	29.4%	$\chi^2 = 1.25$	.264
Convulsion	2.1%	5.6%	$\chi^2 = 0.81$	.367
Failure patients	2	1		
Alternative treatment				
Stent placement	1	1		
Surgery	1	0		

their quality of life, and even lead to suffocation, which often need emergency treatment.

Balloon dilatation for the treatment of tracheobronchial stenosis was first used and reported by Cohen et al. in 1984.[13] Nowadays, BBD is regarded as a safe, efficient and relatively mature technique in treatment of tracheobronchial stenosis. BBD can be combined with many other technologies, such as Nd: YAG laser treatment, stent placement, cryotherapy, and electrosurgical cautery.[4] A weakness of BBD in treatment of tracheal stenosis is that airway must be totally blocked. But, patients usually cannot endure serious hypoxia for enough long time, affecting the efficacy of the procedure. In previous reports, most interventional therapy of tracheal stenosis use rigid bronchoscopy under laryngeal mask ventilation and anesthesia machines or general anesthesia to ensure ventilation for completing bronchoscopy.[3] There are a few studies just focused on BBD for the treatment of benign tracheal stenosis under local anesthesia. A study reported by Lee et al.[7] described that the duration of balloon inflation was just 10-20 s in their BBD procedures, and symptoms recurred in fifty-seven percent of patients within 6 months. However, the recommended duration of balloon inflation in the treatment of tracheobronchial stenosis was 60-180 s.

In our clinical experience, we discovered that patients with tracheal stenosis in a tracheal diameter of 3 mm can keep PaO_2 at a safe level at an oxygen inhalation rate of 3 L/min. According to the clinical observations, we introduced a tube to the distal trachea while operating BBD procedures, as a channel for airflow during balloon inflation. In this study, 56 tube-assisted BBD procedures were undertaken on 34 patients in group B. The duration of balloon inflation in group B (rang 30-180 s, mean 98.76 ± 40.13 s) was longer than that in group A (rang 30-60 s, mean 42.71 ± 8.97 s), $P = .000$. Also, it was significantly longer than the balloon inflation time reported by Lee et al. and Low et al.[7,14] Patients in group B had no sense of suffocation. Just 1 patient experienced sensation of asphyxia with oxygen saturation below 90% and then the BBD procedure was immediately stopped. Other patients could keep oxygen saturation higher than 90% or less than 5% decrease. There was no statistical significance in preoperative, intraoperative and postoperative blood gas analysis results in PaO_2 ($P = .079$), which was dramatically different from the respiratory endoscopic interventional therapy with decline of PaO_2 (rang 8-20 mm Hg),[15] Therefore, we reasonably considered that this is the most direct demonstration to ensure safety during tube-assisted BBD. The tube is regarded as a channel for airflow during BBD procedures. Airway is not completely blocked ensuring continuous oxygen. And a oxygen tube can be held on to the tube to maintain oxygen saturation and PaO_2 at a safe level, which are benefited from the introduction of a tube. Postoperative PaO_2 in both groups was lower than preoperative, because some patients refused to keep oxygen, while symptoms disappeared. Long-term effect was significantly higher in group B than that in group A (85.3% vs 59.1%, $P = .021$) at the end of the follow-up period (6 months), after 1-4 BBD sessions of BBD (mean 2.83 ± 0.87 sessions in group A and 1.65 ± 0.60 sessions in group B, $P = .000$). Also, the long-term effect of the patients in group B in our study was longer than the effect within 6 months reported by Lee et al.,[7] and was similar with the effect in the treatment of tuberculous tracheobronchial strictures (TTBSs) reported by Cho et al.[16] We reasonably believe that tube-assisted BBD for benign tracheal stenosis is superior to conventional BBD in long-term effect belonging to the longer period of balloon inflation. However, we still need a longer follow-up period to evaluate the long-term therapeutic effects by this technique. Thus, the greatest advantage of tube-assisted BBD is that dyspnea can be resolved successfully during BBD procedures and good long-term effects are obtained. Moreover, it does not increase the cost of treatment. It is another advantage of this new technique. This technique may form a novel approach to the treatment of benign tracheal stenosis.

124 BBD procedures were undertaken in groups A and B, and the complications including chest pain, bleeding, infection on the lower airway and convulsion had no statistical significances between groups A and B. These complications were observed during procedures and have nothing to do with balloon inflation. Only tracheal laceration was directly related to balloon inflation. The incidence of tracheal laceration in groups A and B had statistical significance (16.7% vs 41.2%, $P = .047$). Kim et al.[17] reported that tracheal laceration occurred at a rate of 56.1% (60 were superficial and 4 were deep) during 124 BBD. Patients with tracheobronchial laceration were at a higher rate than those without laceration, which suggested a better therapeutic effect. In our study, the incidence of tracheal laceration (in group B) was almost consistent with the study performed by Kim et al., but no deep laceration and major bleeding. Only 2 patients in group B experienced mild pneumomediastinum, without obvious dyspnea. Pneumomediastinum was absorbed without any special treatment. We believed that the reasonable explanation for this phenomenon was the balloon inflated under a lower pressure (1-5 k*P*a) but longer time. In this context, the narrow ring of fibrous tissue would be fully broken to ensure efficacy and avoid severe side effects, which is regarded as the third advantages of tube-assisted BBD. However, an unexpected finding was that blood gas analysis results in group B showed significant increase in $PaCO_2$ ($P = .000$). We suggest two possible explanations for such phenomena. First, the over-long tube might lead to the increase in dead space. Second, as patients with tension, respiratory rate and oxygen consumption were increased so

that carbon dioxide increased during operations. Intraoperative blood gas analysis results showed that only 3 patients (8.8%) underwent $PaCO_2$ higher than 60 mm Hg (mean 48.38 ± 8.10 mm Hg). $PaCO_2$ increased to 73 mm Hg in 1 case. The $PaCO_2$ of these patients decreased (mean, 43.15 ± 5.34 mm Hg) after 2 h of the BBD procedures. It was proved that the increase in $PaCO_2$ was mild and temporary. In our later study, we prolonged the period between twice balloon inflation to increase the ventilation volume. Then, blood gas analysis results showed that the $PaCO_2$ just increased slightly during the subsequent procedures. Excitingly, the situation of $PaCO_2 \geq 60$ mm Hg did not recur any more. Therefore, it was a simple and practical way to reduce carbon dioxide retention during procedures. Balloon was generally deflated for 3-5 min during the subsequent procedures. Not only was carbon dioxide retention reduced appropriately, but also operation time was not prolonged too much to increase the probabilities of pain and complications.

Further work involving diameter expansion, models of ventilation, preoperative sedation should be performed to decrease carbon dioxide retention. Although complications directly related to carbon dioxide retention were not observed (during and after BBD procedure), strengthening monitoring was necessary while carrying up the tube-assisted BBD, especially applied to patients with chronic obstructive pulmonary disease, cardio-cerebrovascular disease with organic lesion and elderly patients. If necessary, to promote emissions of carbon dioxide, and reduce the potential risk of carbon dioxide retention, a short-term mechanical ventilation should be taken. Moreover, to avoid life-threatening complications, such as deep laceration and severe pneumomediastinum, it is worth paying attention to select catheters with different balloon diameters, because the tube occupy a certain space of the tracheal and is not susceptible to compression.

In short, compared with the traditional BBD, tube-assisted BBD is a better safety and long-term efficacy selection for the treatment of benign tracheal stenosis. However, close attention should be given to the risk of adverse effects caused by carbon dioxide retention during BBD procedures.

CONFLICT OF INTERESTS

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

AUTHOR CONTRIBUTIONS

Analyzed data and wrote the paper: Li-Hua Li
Designed study: Yi-Lin Liang
Collected data: Yu Li
Analyzed data: Ming-Peng Xu
Collected data: Wen-Tao Li
Designed the study and reviewed the manuscript: Guang-Nan Liu

ETHICS

This study was approved by the First Affiliated Hospital of Guangxi Medical University Medical Ethics Committee. All patients were informed of the facts and then signed informed consents.

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