Original Article

The safety and effectiveness of the treatment of refractory post-intubation subglottic stenosis using short bronchial Dumon stent: a pilot study

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Background: Post-intubation subglottic stenosis (PI-SGS) is a fatal disease which could result in partial or complete narrowing of the airway. Although airway stenting is commonly used as an alternative treatment for PI-SGS patients unsuitable for surgery, complications including stent migration and excessive granulation tissue formation are frequently encountered. Additionally, tracheotomy is necessary in patients undergoing T-tube placement. Therefore, it is necessary to further enhance the effectiveness of airway stenting in refractory PI-SGS. In this study, we aimed to evaluate the safety and effectiveness of utilizing short bronchial Dumon (BD) stents in managing refractory PI-SGS.

Methods: PI-SGS patients who were not suitable for surgery and in whom previous interventional treatments had proven ineffective were enrolled. Short BD stents were inserted via rigid bronchoscopy under general anesthesia. Complications and outcomes were assessed by follow-ups.

Results: Fourteen patients were included and successful stent insertion was achieved in all cases. The median diameter and length of stents was 12 (0.25) and 33.5 (5) mm, respectively. During the 6-month follow-up period, complications were reported in five patients. Granulation tissue formation was the most frequently observed complication (4 in 14 patients, 28.57%), followed by stent migration (2 in 14 patients, 14.29%). Out of the total participants, 11 patients (78.57%) demonstrated good tolerance to the stent, while 3 (21.43%) required stent removal. Among these three patients, two finally underwent subsequent T-tube insertion after the removal. Twelve patients (85.71%) avoided the tracheotomy and T-tube insertion.

Conclusions: The utilization of short BD stents appears to be a safe and effective approach for managing refractory PI-SGS. The complications and tolerability are acceptable.

Keywords: Treatment; refractory post-intubation subglottic stenosis (refractory PI-SGS); bronchial Dumon stent (BD stent); interventional pulmonology

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Introduction

The subglottic space extends from the inferior margin of the vocal cords to the lower border of the cricoid cartilage, which is the narrowest and lowest part of the larynx. Translaryngeal intubation could cause subglottic injury. Though most injuries are not clinically significant (1), post-intubation subglottic stenosis (PI-SGS) is one of the important complications of intubation, which could be potentially life-threatening (2). Currently, the most effective treatment option for subglottic tracheal stenosis, especially for severe cases, is laryngotracheal resection (2-4). However, for patients with long-segmental stenosis, medical contraindications, complicated with underlying diseases, or those who refuse surgical treatment, bronchoscopy intervention offers a better alternative (5-7). Among various minimally invasive interventional treatments for PI-SGS, airway stent implantation plays a crucial role, especially T-tube stenting. However, despite several studies demonstrating successful outcomes in more than 70% patients who underwent T-tube insertion (8,9), complications could be found and this approach requires tracheotomy and exposes one end of the T-tube, resulting in additional nursing care and potential negative psychological and physical effects (10). Other interventional therapies, such as balloon dilatation or electrocauterization, yield uncertain long-term outcomes in the management of complex stenosis, posing a heightened risk of restenosis (11,12). Therefore, alternative methods of stenting therapy for these PI-SGS patients are worth exploring, as there is limited research conducted on this topic.

In this study, we assessed the short- and long-term outcomes of short bronchial Dumon (BD) stent in the treatment of PI-SGS patients. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-24-342/rc).

Highlight box

Key findings

- In our study, short bronchial Dumon (BD) stent insertion demonstrates promising outcomes in the treatment of refractory post-intubation subglottic stenosis (PI-SGS), serving as a promising alternative therapy for patients who are unsuitable for surgery and circumvent the need for T-tube insertion.

What is known and what is new?

- In PI-SGS patients who are either unsuitable for or refuse surgery, T-tube placement is frequently adopted as an alternative treatment strategy. Notably, T-tube insertion necessitates tracheotomy, which carries an increased risk of infection. Moreover, T-tube management imposes considerable demands on nursing care.
- Our study reveals that patients with refractory PI-SGS exhibited favorable tolerance to short BD stent, with complications remaining controllable. More than 80% patients successfully avoided surgical procedures and T-tube insertion.

What is the implication, and what should change now?

- Short BD stents could present a promising alternative therapy for patients with refractory PI-SGS, and there is an urgent need for large-scale cohort studies to further prove its safety and efficacy.

Methods

Patients and procedures

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study protocol was approved by the Ethics Committee of The First Affiliated Hospital of Guangzhou Medical University (ethics review number: 2018-16). Written informed consent was obtained from all patients involved in this study. This prospective, interventional, single-arm cohort study was designed to assess the safety and effectiveness of short BD stents in managing refractory PI-SGS. Patients presented with a history of tracheal intubation and had an unsatisfactory therapeutic response to at least two bronchoscopic therapies, such as balloon dilatation or electrocauterization, were diagnosed with refractory PI-SGS. We recruited refractory PI-SGS patients aged 18 to 80 years old who were either unsuitable for or declined surgery at The First Affiliated Hospital of Guangzhou Medical University. Medical records and radiological files were reviewed.

Chest computed tomography and balloon dilatation were performed in order to measure and assess the location and dimension of stenotic area. The selection of the type and size of the airway stent was determined by the operator based on evaluation results. The stents we used

were BD stent (Novatech, France), and according to the specific characteristics of the stenotic lesion, adjustments to the stent were made, including cutting and trimming. All procedures were performed under general anesthesia and mechanical ventilation. Pre-dilatation procedures, such as balloon dilatation or electrocauterization, were performed by bronchoscopy prior to stenting. The stent was introduced using a rigid bronchoscope (Karl-Storz, Germany) and a flexible bronchoscope (Olympus, Japan). The follow-up period was established with a minimum of 6 months, and for patients who tolerated the stent for more than 6 months, the endpoint of the follow-up was set at the time of stent removal. Time points were set up at the 3rd day, 1st month, 3rd month, 6th month, 1st year and once a year after stent placement. Bronchoscopy examination was performed in every follow-up. Patients were advised to revisit for consultation as needed during follow-up intervals and instructed to adhere to a long-term, regular aerosol therapy regimen, consisting of three sessions per day, each involving the use of 5 mL saline.

Statistical analysis

Categorical variables were presented as frequency (percentage), while continuous variables were expressed as mean ± standard deviation (SD) or median (interquartile range, IQR). Statistical analysis was performed by using SPSS version 22.0 (SPSS Inc., Chicago, USA).

Results

Patients

From June 2019 to March 2023, a total of 14 refractory PI-SGS patients were included, with the majority being male (10, 71.43%). The average age was 38.29±16.79 years. The most common cause of intubation was car accident (5, 35.71%). A comorbidity of diabetes was present in 3 patients (21.43%), while 11 patients (78.57%) had undergone previous surgeries due to primary illness or PI-SGS. The average number of bronchoscopic therapies was 6.79±4.25, including balloon dilatation, electrocauterization, laser ablation, cryoablation and stenting therapy (*Table 1*). Ten patients had undergone at least two sessions of electrocauterization and balloon dilatation. Eight patients had undergone stent placement, metallic or silicone. However, complications, mainly stent migration and excessive granulation tissue formation or restenosis, led to treatment failure. According to the Myer-Cotton classification (MCC), 4 (28.57%) patients had Grade II stenosis, while 10 (71.43%) patients presented with Grade III stenosis.

Bronchoscopic interventions

Bronchoscopic findings and interventions are summarized in *Table 1*. The median distance from the stenosis to the glottis was 15 (6.25) mm, and the median length of the stenosis was 21 (5) mm, as measured by bronchoscopy and chest computed tomography. The luminal diameter before the procedure was 3.5 (1.25) mm. For BD stent implantation, the median length of the stent was 33.5 (5) mm, while the median diameter was 12 (0.25) mm. The median distance from the upper end of the stent to glottic area was 12 (5) mm. All patients underwent pre-dilatation before stent placement, and all stents were successfully inserted.

Follow-up

The follow-up durations for all patients were no less than 6 months, with the longest lasting more than 24 months and the shortest lasting 6 months. The average stent duration was 15.71±8.98 months. During the 6-month follow-up period, complications were observed in five patients. The most common complication was granulation tissue, which occurred in 4 out of 14 patients (28.57%), 3 out of these 4 patients had granulation removed via forceps excision because of cough (2, 14.29%) or mucus retention (1, 7.14%). Additionally, stent migration was observed in 2 patients (14.29%). Among all patients, 11 (78.57%) were able to tolerate the stent and lead a normal life, while 3 (21.43%) required stent removal. After the stent removal, two of these three patients underwent T-tube insertion. Another patient had the stent removed due to stent migration in the 9th month after placement. Twelve out of 14 patients (85.71%) avoided the tracheotomy and T-tube placement. A total of ten patients were able to tolerate the stent for more than 12 months, with the longest durability recorded at over 27 months, and their conditions remained stable (*Figure 1*).

Discussion

The subglottic space, located at the cricoid level, is the lowest and narrowest part of the trachea, extending from the inferior margin of the vocal cords to the lower border of the cricoid cartilage. Subglottic stenosis can manifest as

Table 1 Bronchoscopic findings and interventions of patients

Patient No.	Gender	Age (years)	Underlying disease	Cause of intubation	Treatments before placement	Diameter and length of stenosis (mm)	Distance from stenosis to glottis (mm)	Myer-Cotton classification	Size of stent (mm)	Distance from stent to glottis (mm)	Stent duration (month)	Outcome
1	M	41	Diabetes	Alcoholism	16 times, Balloon dilatation, electrocauterization, cryoablation, stenting therapy (TD 13, 35)	4, 22	15	Grade III	BD 12, 32	10	3	Stent removed and T-tube inserted
2	M	29	–	Car accident	6 times, Balloon dilatation, electrocauterization, cryoablation	4, 25	15	Grade III	BD 12, 32	12	9	Stent removed
3	M	24	–	Car accident	3 times, Balloon dilatation, electrocauterization, stenting therapy (TD 13, 50)	4, 22	15	Grade III	BD 12, 35	12	>21	Stent sustained
4	M	21	–	Falling injury	3 times, Balloon dilatation, electrocauterization	3, 20	15	Grade III	BD 11, 32	10	>22	Stent sustained
5	M	38	–	Cerebral aneurysm rupture	7 times, Balloon dilatation, stenting therapy (Metallic 16, 60)	4, 25	15	Grade II	BD 11, 30	12	>24	Stent sustained
6	F	54	–	Gastrointestinal hemorrhage	4 times, Balloon dilatation, electrocauterization, stenting therapy (Metallic 14, 35)	5, 20	25	Grade II	BD 12, 30	20	>27	Stent sustained
7	M	58	Diabetes, cardiac disease	Cardiac disease	5 times, Balloon dilatation, electrocauterization	3, 25	12	Grade III	BD 12, 35	10	3	Stent removed and T-tube inserted
8	M	19	–	Falling injury	5 times, Balloon dilatation, electrocauterization, stenting therapy (Metallic 14, 35)	3, 20	15	Grade III	BD 12, 35	13	>19	Stent sustained
9	M	34	–	Acute pancreatitis	16 times, Balloon dilatation, electrocauterization, stenting therapy (TD 15, 50)	2, 20	15	Grade III	BD 12, 30	10	>26	Stent sustained
10	F	24	–	Car accident	9 times, Balloon dilatation, electrocauterization, stenting therapy (ST 14-12-14, 15-20-15)	5, 20	25	Grade II	BD 12, 30	20	>27	Stent sustained
11	M	38	–	Septic shock	6 times, Balloon dilatation, laser ablation, cryoablation	5, 25	20	Grade II	BD 12, 40	15	>12	Stent sustained

Table 1 (*continued*)

Table 1 (*continued*)

Patient No.	Gender	Age (years)	Underlying disease	Cause of intubation	Treatments before placement	Diameter and length of stenosis (mm)	Distance from stenosis to glottis (mm)	Myer-Cotton classification	Size of stent (mm)	Distance from stent to glottis (mm)	Stent duration (month)	Outcome
12	F	75	Colon tumor	Car accident	3 times, Balloon dilatation, electrocauterization, stenting therapy (Metallic 14, 60)	3, 35	20	Grade III	BD 12, 50	10	>11	Stent sustained
13	M	25	Diabetes	Intestinal rupture	6 times, Balloon dilatation, electrocauterization	3, 20	15	Grade III	BD 12, 35	12	>11	Stent sustained
14	F	56	–	Car accident	6 times, Balloon dilatation, electrocauterization	2, 20	25	Grade III	BD 11, 35	15	5	Stent removed

TD a, b: tracheal Dumon stent with the diameter of a millimeters and the length of b millimeters; Metallic a, b: metallic stent with the diameter of a millimeters and the length of b millimeters; ST a-b-a, c-d-c: tracheo-bronchial Dumon stent with the diameter of a-b-a millimeters and the length of c-d-c millimeters; BD a, b: bronchial Dumon stent with the diameter of a millimeters and the length of b millimeters. M, male; F, female.

congenital, idiopathic, or acquired conditions (13). Acquired subglottic stenosis, predominantly caused by tracheal intubation, has now emerged as the most prevalent form of laryngotracheal stenosis (13). Subglottic stenosis caused by intubation, which called post-intubation subglottic stenosis (PI-SGS) is a fibrotic condition that arises as a serious complication of intubation. It shares a similar pathogenesis with keloid scarring or hypertrophic scarring, as prolonged intubation creates an environment conducive to fibrosis (14). Individuals with PI-SGS frequently encounter symptoms indicative of airway obstruction, such as dyspnea and cough.

For the management of PI-SGS, treatment options can be broadly categorized into two main methods: surgery and bronchoscopic interventional therapies. Tracheal resection and reconstruction (TRR) as well as laryngotracheal resection and reconstruction (LTRR) are frequently undertaken procedures for managing post-intubation tracheal stenosis, and they are widely regarded as the preferred therapeutic options with low associated mortality rates (2,3,6,15). However, it is important to note that complications can occur in approximately one-fifth of patients undergoing surgery, with anastomotic complications being particularly significant. Granulations and subcutaneous air may also arise (6). Risk factors for surgical complications include reoperation, diabetes, lengthy resections, laryngotracheal resections, young age, and the need for preoperative tracheostomy (5,6). Therefore, for selected patients who have severe diabetes, extensive lesions, previous unsuccessful surgeries, advanced age, or poor overall health, interventional therapy by bronchoscopy becomes a critical option. Various forms of interventional therapies, such as cryoablation, balloon dilatation, and transglottic corticosteroid injection, have shown efficacy in treating post-intubation stenosis (16,17). However, their long-term effectiveness may be unsatisfactory. In those scenarios, stent placement emerges as a promising alternative. T-tube insertion is a method that can be considered, which has satisfying outcomes in more than 70% treated patients (9,18). However, studies have revealed that nearly half of the patients who undergo T-tube insertion experience crusting within the tube, with approximately one-third exhibiting granulation tissue growth, and over 30% necessitating T-tube placement for a second time due to restenosis (8,19,20). In addition, it is worth noting that patients may demonstrate reluctance towards T-tube placement due to the need of tracheotomy and the exposure of the tube, which also necessitates higher requirements for daily nursing care and could cause

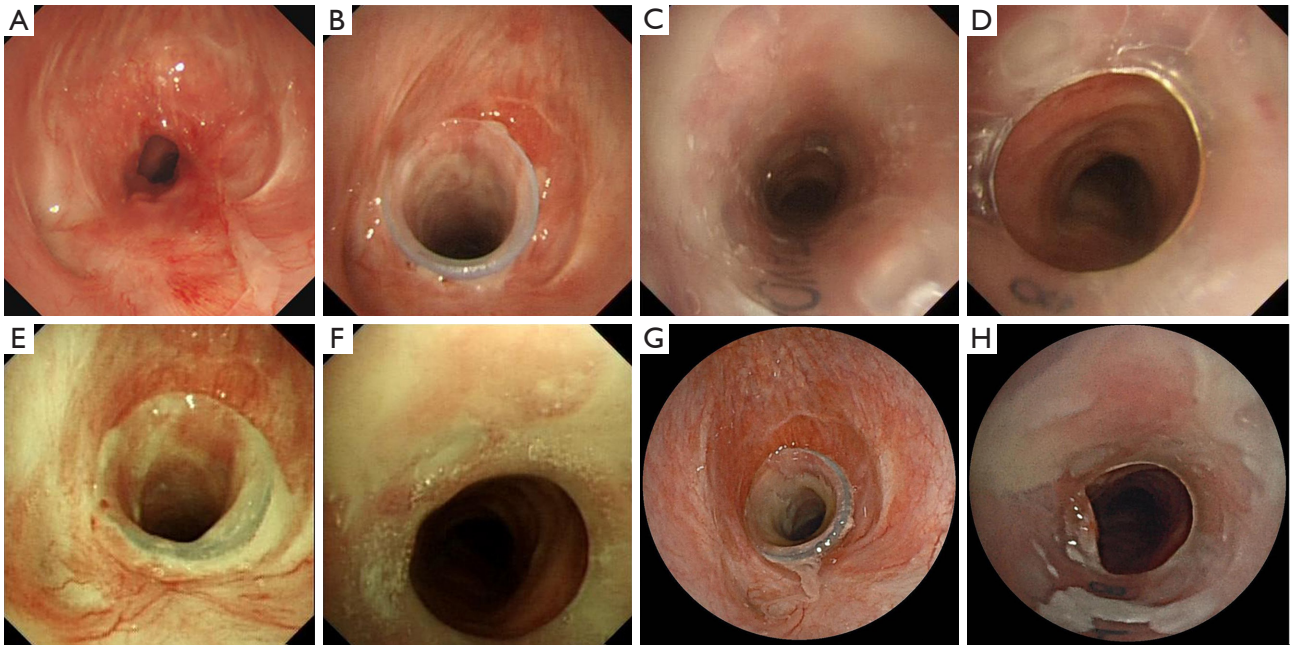

Figure 1 The conditions of stenosis before and after stent placement of a 38-year-old patient. Image (A) is stenosis area before implantation. Images (B-D) are the upper end, middle and the lower end of the stent at 1st month after implantation, respectively. Images (E,F) are the upper and lower end of the stent at 1st year after implantation. Images (G,H) are the upper and lower end of the stent at 2nd year after implantation.

potential negative psychological and physical effects (10). The present study enrolled selected PI-SGS patients who had severe diabetes or were in poor overall condition, rendering them ineligible for surgery, or had no willingness for surgical treatment, but had demonstrated limited improvement after previous interventional therapies. Due to the impracticability of surgery and the lack of positive response to prior interventional treatments, a novel stent implantation strategy was elected as the therapeutic approach.

Subglottic stenosis frequently results in more severe lesions and symptoms compared to tracheal stenosis, attributed to the inherent narrowness of this region. Furthermore, the choice is limited and difficult due to unsatisfied results caused by previous treatment with dilatation, electrotome, stent or other therapies. This scenario presents a significant obstacle in identifying suitable stent therapies. Among the enrolled patients, a subset had previously undergone treatment with metallic stents or tracheal Dumon stents (TD stent), but the outcomes were unsatisfactory. Based on the unique anatomical location and assessment through bronchoscopy and radiology images, we made the decision to apply the short BD stent. To the best of our knowledge, there have been no previous reports on the use of BD stents in treating PI-SGS. Compared to the TD stent, the BD stent demonstrates superior compliance, which contributes to reduced airway wall stimulation and provides improved support without inducing undue compression. Moreover, in cases of severe subglottic stenosis, TD stent may be excessively large, rendering the smaller-sized BD stent a more suitable option for these patients. To minimize friction between the upper and lower ends of the stent and the trachea, the stent was made longer than the lesion but not exceeding 2 cm. We placed the stent using a rigid bronchoscope, ensuring that it covered the lesion while keeping both ends dissociated from the airway wall. We believe that the short and small size of the BD stent improve patient's tolerability and reduce irritation, resulting in less granulation tissue formation and fewer clinical symptoms. This approach also enhances stent stability. Compared to other types of airway stents, such as T-tube, short BD stent implantation is more acceptable to patients in this study. It eliminates the need for tracheotomy and T-tube, which can cause nursing challenges and self-esteem issues. Furthermore, in the present study, the incidences of granulation tissue formation and mucus

retention or crusting within the stent were lower than the reported complication rates associated with T-tube (8,20). In the subsequent follow-up, complications were observed in five patients, with three requiring stent removal within 6 months and one at the 9th month. Only two patients had to accept the T-tube insertion after removal. Eleven patients tolerated the stent well. Twelve patients successfully avoided the tracheotomy and T-tube insertion. We believe that this method holds promise in the treatment of patients with refractory PI-SGS, and could be a promising alternative of T-tube treatment.

There are several limitations in our study. Firstly, it is a single-center study. Furthermore, the patient population in our study was limited, preventing us from conducting comparative analysis, and the likelihood of complications may have been underestimated. However, our research has demonstrated the safety and effectiveness of this treatment in a preliminary manner. In addition, when the multi-center, large-scale cohort study is promoted, the safety and effectiveness of the application of short BD stent in refractory PI-SGS can further be proven.

Conclusions

In conclusion, our study has preliminarily explored the feasibility and tolerability of using short BD stents in patients with refractory PI-SGS. The results are highly encouraging and indicate that the short BD stent can be safely employed in PI-SGS patients. The observed complications and tolerability were acceptable. Therefore, for PI-SGS patients who are unsuitable for surgery, short BD stent implantation could be a promising alternative treatment.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-24-342/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-24-342/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-24-342/coif). N.Z. serves as Editor-in-Chief of *Journal of Thoracic Disease*. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study protocol was approved by the Ethics Committee of The First Affiliated Hospital of Guangzhou Medical University (ethics review number: 2018-16). Written informed consent was obtained from all patients involved in this study.

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