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RESEARCH

Balloon tracheoplasty for tracheal stenosis after prolonged intubation: a simple procedure, but is it effective?

Abdallah Nosair^{1*}, Mahmoud Singer¹, Mohamed Elkahely², Rezk Abu-Gamila² and Waleed Adel¹

Abstract

Background: Tracheal stenosis following prolonged intubation is a relatively rare but serious problem. This condition is usually managed by surgical or endoscopic interventions. Bronchoscopic balloon dilatation for tracheal stenosis is considered a valuable tool used for the management of tracheal stenosis. In this article, we try to evaluate the role of balloon tracheoplasty in the management of tracheal stenosis and to assess the number of dilatation sessions usually needed as well as the short to midterm outcome.

Results: This study involved 40 patients with tracheal stenosis diagnosed by computed tomography (neck and chest) and bronchoscopy at the Security Force Hospital in Riyadh, KSA, between January 2013 and August 2018. Patients' data were retrospectively reviewed and analyzed. Patients' age ranged between 18 and 60 years. Thirty patients were males (75%); those patients underwent balloon tracheoplasty via dilatation of areas of narrowing using catheter balloon insufflation guided by fiber-optic bronchoscope. Ninety-five percent of the patients had initial success with acceptable dilatation of the stenotic area and improvement of the symptoms. There were no technical or major problems which resulted from the procedure, and no patient complained of severe pain or severe discomfort after the procedure. From the total of 81 BBD sessions, no in-hospital mortality is related to the procedure itself, and ICU stay ranged between 1 and 5 days post-procedure. Among those 40 patients, 16 patients (40%) needed one session, 10 patients (25%) needed two sessions, 8 patients (20%) needed three sessions, and 6 patients (15%) needed more than three sessions of balloon dilatation.

Conclusion: Balloon tracheoplasty is a simple, safe method and could be a promising and effective approach that offers immediate symptomatic relief for tracheal stenosis in cases with a history of prolonged intubation. It is worth mentioning that BBD is considered as a temporary measure, and most of the cases will need definitive or additional treatment either resection or stent placement.

Keywords: Balloon tracheoplasty, Tracheal stenosis, Prolonged intubation, Bronchoscopy

Background

Tracheal stenosis (TS) is the narrowing of the trachea, which interferes normal breathing. Symptoms of tracheal stenosis vary from very mild to severe; this stenosis can cause dyspnea, wheeze, cough, stridor, or recurrent

* Correspondence: abdallah_nosair@live.com

Full list of author information is available at the end of the article

respiratory tract infections; however, the condition could be well treated [1, 2].

Different pathologies cause tracheal stenosis after prolonged intubation like mucosal and cartilage ulceration and inflammatory reactions which causes granulation tissue and fibrous tissue formation as well as fibrous scar tissue contraction. Capillary perfusion pressure has critical consideration in mucosal injury as well as ischemia from direct contact with an endotracheal tube segment

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¹Cardiothoracic Surgery Department, Faculty of Medicine, Cairo University, Cairo, Egypt

or by an increase in the pressure in the cuff of the endotracheal tube [3, 4].

Airway dilation has become a very effective and important step for the management of patients with laryngotracheal stenosis in the last decades. Dilatation is traditionally achieved through the passing of different devices through the stenotic area such as rigid bronchoscopes and endotracheal tubes. All of these instruments produce shearing forces which cause damage in the lining mucosa in the healthy and stenotic parts of the airway.

It was suggested by many authors that balloon dilatation offers many advantages over alternative dilatation instruments; the most important one is that if we put the balloon in right place, it exerts a radial expansile force on the stenotic part, and this method distributes forces over the whole circumference of the stenosis; this force distribution minimizes the risk of airway rupture at any point. Also, balloons can be tuned by the surgeon to apply the desired force to the stenosis. The length, shape, and flexibility of balloons also give more control for the surgeon to manage it and to pass easily through long and tight lesions [5].

Bronchoscopic balloon dilatation (BBD) by the angioplasty balloon catheter was successfully used for the management of tracheobronchial stenosis (TBS) especially in children and in selected cases in adults. The response to balloon dilatation usually depends on the characteristics of the stenotic lesion, so improvement and good response found likely in thin or web-like lesions being soft and consist of immature friable scar tissue. But the response to BBD is poor in firm or mature scar tissue and cartilaginous airway narrowing [6].

Balloon catheters used for managing airway stenosis have two ports. The first one is the inflation port, which allows the fluid injection to inflate the balloon and is suitable for attachment to the inflation device. The second port could be used to introduce a stylet and for fluid lung lavage. There are two types of balloons compliant and semi-compliant, which offer different options in adjustment, shape, and distribution of the pressure resulting from balloon inflation with fluid.

The aim of this study was to present our experience in the management of tracheal stenosis via balloon tracheoplasty and to assess the number of dilatations needed.

Methods

This study was retrospectively done at Security Force Hospital in Riyadh-KSA on 40 patients who were admitted to the intensive care unit (ICU) for different etiologies from January 2013 to August 2018.

All patients needed to stay on mechanical ventilation with endotracheal intubation. The diagnosis was confirmed by computed tomography (CT) neck and chest with the reconstruction of the airways to have virtual bronchoscopy.

We excluded from the study other causes of TBS like patients with a malignant or benign tumor in the respiratory system and esophagus, granulomatosis, congenital TS, and other local causes rather than prolonged intubation.

Twenty-five (62.5%) of our patients intubated postroad traffic accident (RTA) due to brain insult, disturbed conscious level, lung contusions, or other abdominal injuries, or any other cause of hemodynamic instability. Other causes of prolonged intubation in our series were: pulmonary disease, malignant disease other than lung cancers, and post cardiovascular surgery.

Indications for BBD in our study were symptomatic TS such as stridor or dyspnea (70%), retention of secretions (12.5%) of cases, retention pneumonia (10%), and atelectasis (7.5%).

Full medical records were reviewed; demographic and clinical data were obtained for each patient, including patients' age, sex, and comorbidities. Each patient had been through a detailed medical assessment, including a full history of any existing medical disorder, cause of previous intubation, and clinical examination at admission as well as laboratory tests, chest radiography, and computed tomography.

The procedure was done after obtaining informed consent from the patients or the relatives, and bronchoscopies were performed with standard monitoring in a fully equipped operation room.

The follow-up period lasts for 12 months; during this, regular follow-up was accomplished via clinical assessment in the outpatient clinic. Symptomatic cases were followed by CT (chest and neck) and/or bronchoscopy. Further therapy was done according to the severity of symptoms and recurrence rate and was individually selected.

Procedure

The procedures were carried out using flexible fiber optic bronchoscopy and balloon dilation catheter (CRE, Pulmonary Balloon Dilation Catheter, Boston Scientific Co). The size which reaches a diameter of 15 mm at 4.5 ATM pressure and 18 mm at 7 ATM pressure and length of 5.5 cm as it has low shoulder effect and near-uniform distribution of the pressure to avoid the hourglass effect where most of the pressure may be distributed above and below the level of stricture causing less effect on the stenotic site and more mucosal damage above and below the stenosis.

The setup of the inflation system before introduction was checked as follows: we inspected the integrated inflation handle for damage and pumped the handle lever to ensure the device's ability to move in the direction as labeled by arrows.

We turned the lever of the inflation system handle upwards to the neutral position, put the syringe into the slots in the handle, moved the plunger forward till the end, immersed the tip of the syringe in a basin with normal saline then turn the lever to the deflate position, and pumped the handle to fill the syringe with 35 ccs of normal saline. After that, we turned the angle of the tip of the syringe upward, turned the lever to the inflate position, and pumped the handle to purge the air out of the syringe.

The balloon catheter was then connected to the syringe. We turned the lever back to the deflate position and pumped the handle until it stops removing the air from the catheter creating a negative vacuum, and then the protective sleeve from the balloon can be removed.

All procedures have been performed in the operating room and under general anesthesia; there must be good communication between the surgeon the and anesthesiologist. The surgeon should inform the anesthesiologist before inflating the balloon before the airway full occlusion. On the other side, the anesthesiologist should be always alert and rapidly inform the surgeon if critical desaturation occurred so that the surgeon would deflate the balloon to avoid excessive desaturation and hypoxia [7].

After visualization of the stenotic segment by the bronchoscopy, the catheter is introduced via the working channel and placed under vision in the site of the stenosis. We turned the lever to the inflate position and then pumped the handle to the predetermined pressure corresponding to the desired diameter.

After the balloon is inflated to target pressure, the pressure will slowly go down as collagen fibers within the scar are destructed. We adopted the three-stage technique for the sessions where inflation would be done over three times each of them 40–60 s according to the patient's oxygen reserve and oxygen saturation during each inflation.

After each inflation, we turned the lever to the deflation position and pumped the handle till the 35 ccs of saline were returned back to the syringe. At the end of the session and full deflation of the balloon, we removed the catheter from the working channel and inspected the stenotic area for proper dilation and then passed the bronchoscopy downwards below the level of the stenosis to check if there are double stenotic segments or thick mucus plugs which needed lavage.

The number of dilation sessions was different among patients, and the timing of repeating dilation also varies widely. However, dilatation is commonly done at 1- to 2-week intervals. If a patient does not get benefit from repeated dilation, other plans are considered, including other alternative ways of tracheal dilatation or surgical reconstruction [8].

Statistical analysis

Statistical analysis was done using the IBM SPSS Version 24.0. Continuous data have been analyzed and depicted in the form of means and standard deviations; however, categorical data had to be reported as frequencies and percentages.

Results

Our study included 40 patients with symptomatic tracheal stenosis indicated for BBD. The patients' age ranged from 18 to 60 years with a mean age of $34.5 \pm$ 12 years. Thirty out of them were males. Specific symptoms as stridor or dyspnea (70%), retention of secretions (12.5%), retention pneumonia (10%), and atelectasis (7.5%) of cases.

Our patient's symptoms appeared after 2 weeks up to 8 weeks with a mean value of 4 ± 1 week following or during the ICU admission and prolonged intubation.

There were different causes for ICU admission and prolonged intubation. Although tracheal stenosis traumatically occurred in all patients, 25 (62.5%) of the patients intubated post-RTA due to brain insult, disturbed conscious level, lung contusions, or other abdominal injuries, or any other cause of hemodynamic instability. Causes are shown in Table 1.

The mean time for intubation in our series was 12 days \pm 4 days ranging from 7 to 19. All stenosis was located in the trachea.

We classified our patients according to the degree of stenosis (Table 2). Twenty-six (65%) of them had 3rd to 4th degree of TS. The need for BBD sessions was two in 28 (70%) of the cases. BBD sessions were repeated according to the severity of lesion at first bronchoscopic assessment and recurrence on the regular follow-up visits; from these 40 patients, one session was enough for dilatation in 14 (35%), two sessions in 15 (37.5%), three-session in 7 (17.5%), and more than three in 4 (10%) of patients (Table 3).

After 1 month, follow-up showed that 95% of the patients had initial success with the increased diameter of the stenotic area and improvement of symptoms (Fig. 1). There were no technical or major problems related to the procedure itself, and no patient complained of severe pain or severe discomfort after the procedure. Only two patients needed to continue on tracheostomy tube due to respiratory failure after dilatation. Two patients

 Table 1
 Patient's characteristics according to the cause of intubation

History of other diseases	No (%)
Pulmonary disease	6 (15%)
Malignant disease (other than airway and lung cancer)	5 (12.5%)
Post cardiovascular surgery + intubation	4 (10%)
Post road traffic accident	25 (62.5%)

 Table 2 Degree of tracheal stenosis in the studied patients according to Freitag classification [9]

Number of patients	% Degree of tracheal stenosis
5 (12.5%)	Grade 1: < 25%
9 (22.5%)	Grade 2: 26–50%
14 (35%)	Grade 3: 51–75%
12 (30%)	Grade 4: 76–90%
0	Grade 5: 90–100%

developed surgical emphysema during the procedure but no intraoperative pneumothorax or bleeding.

Nine patients suffered post-procedure from different degrees of self-limited laryngeal edema for the maximum of 3 days in the form of changes in voice, productive cough, and throat pain as summarized in Table 4.

After 1 year, follow-up of our patients done by monitoring of symptoms, clinical assessment, and investigation by bronchoscopy or CT if needed.

From our 40 patients, seven patients (17.5%) died from the original disease, 2 patients died from end-stage malignancy, 2 patients with pneumonia and respiratory failure, one patient from complications post-cardiac surgery, and two patients after RTA with brain insult.

Nineteen patients (47.5%) who already had a severe form of stenosis needed surgical intervention and tracheal resection and anastomosis; the 1st one was done after 3 months, and the last one needed resection after 11 months. The mean vertical extension in this subgroup was 12 mm \pm 7 mm. Among these patients, 11 (57.89%) patients had grade 4 tracheal stenosis, 6 patients (31.57%) had grade 3 tracheal stenosis, and 2 patients (10.52%) had grade 2 tracheal stenosis.

From the rest of the patients, stents were placed in six patients (15%) within the 1st year as these patients needed repeated sessions of dilatation and were unfit for tracheal resection due to the presence of one or more of these factors as recurrent convulsions, end-stage malignancy, and advanced recurrent respiratory failure with the high possibility of recurrent intubation with mechanical ventilation and uncontrolled diabetes mellitus. The mean vertical extension in this subgroup was 11 mm ± 4 mm. Among these patients, 4 patients (66.67%) had grade 3 tracheal stenosis and 2 patients (33.33%) had grade 2 tracheal stenosis.

 Table 3 Number of attempts of bronchoscopic balloon

 dilatation

Number of bronchoscopic session	No (%)
One session	8 (35%)
Two sessions	15 (37.5%)
Three sessions	13 (17.5%)
Need more than 3 sessions	4 (10%)

The other eight patients (20%) passed the 1st year (our follow-up period) without the need for any intervention. The mean vertical extension in this subgroup was 9 mm \pm 4 mm. Among these patients, 2 (25%) had grade 3 tracheal stenosis, 2 patients (25%) had grade 2 tracheal stenosis, and the other 4 patients (50%) had grade 1 tracheal stenosis.

The level of obstruction was closely related to the main etiology which was the endotracheal cuff, so we found the level of stenosis in 26 patients (70%) in the upper 1/3 of the trachea, 5 patients (12.5%) had tracheal stenosis between the upper and middle third of the trachea, and 5 patients (12.5%) had middle third tracheal stenosis (three of them needed tracheal stenting), while the other two patients (5%) had lower third tracheal stenosis and were managed successfully using balloon dilation alone.

Discussion

BBD has become an important tool in the management of TBS. Our study assessed the effectiveness of BBD procedures performed in 40 patients with tracheal stenosis due to a single etiology namely prolonged intubation [10, 11].

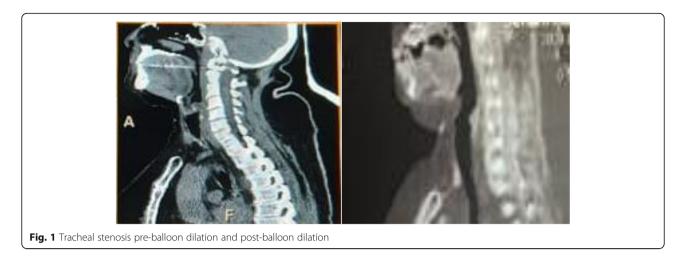
Tracheal dilatation is initiated to enlarge the diameter of the airway in cases of subglottic stenosis and tracheal stenosis. Patients with these conditions complain of shortness of breath and dilation is a minimally invasive way of enlarging the airway [3].

Our patients were critically ill, and 95% showed immediate significant success following BBD, and this effect persisted for at least 1 month. This may be attributed to the good selection of patients in which patients with malignant disease or granulomatosis were excluded; also, patients with long thick fibrotic segments especially if there are calcifications were referred for other means of interventions; similar results were reported by Mayse et al., and in other authors, the use of high-volume and low-pressure cuff endotracheal tubes is advised [12, 13].

The common symptoms of tracheal stenosis in our patients and also in other studies were dyspnea and stridor in severe cases [14, 15].

Bronchoscopic tracheal dilatation using the balloon or using other alternative surgical instruments helps in the temporary improvement of the symptoms and provides more data about the level and extent of stenosis in the trachea. During the dilatation procedure, we can also diagnose the cause of the stenosis if it is not already known [16, 17].

Proper chest physiotherapy is important for such cases to help clearance of secretions and avoid further retention with subsequent atelectasis and collapse which may be the cause of failure of extubation in our study documented in 2 cases [18].



Surgical resection with end-to-end anastomosis for the management of post-intubation tracheal stenosis may be inappropriate for some cases due to the risk of recurrence at the site of anastomosis especially if these patients are high-risk surgical candidates [11].

In our patient group as well as in the case series presented by Lee et al., most of those who had a severe degree of stenosis and underwent more than one BBD session required additional therapy; in our group, nineteen patients needed tracheal resection surgery during the 1st year and another six patients had tracheal stent inserted due to unfitness for surgery [19].

Therefore, at the time of any repeated dilation, especially in case of the severe and tight form of stenotic lesions, one should consider another advanced way of management.

Other alternative therapies like laser resection are expensive and need more experience and available only at highly equipped centers. Balloon tracheoplasty is a relatively simple procedure that can be done at multiple centers without major complications [20, 21].

Even with the use of low-pressure high-volume cuffed tubes being reported in some studies to cause postintubation stenosis, 11% of critically ill patients were intubated using these endotracheal tubes and had also suffered from tracheal stenosis at the cuff site [22].

Multiple factors are responsible for stenosis after prolonged intubation: cuff pressure, size of the tube in relation to the diameter of the trachea, duration of intubation, vascularity and perfusion status during intubation, manipulation, and movement of the tube during the whole period of intubation, sex, and age of the patient. Also, the

Table 4 Post-procedure complications

Post-procedure complication	No (%)
Post-procedure laryngeal edema	9 (22.5%)
Continuation on the tracheostomy tube	2 (5%)
Surgical emphysema and ICU admission for 1 day	2 (5%)

material cuff itself and the possible side effects of long use and high doses of steroids may have a role. Although previously it was believed that tracheal stenosis needs 15 days at least of intubation to occur, in our study, cases had tracheal stenosis after intubation of 7–19 days; other studies similarly reported that tracheal stenosis may also occur after short intubation time, even if it was as short as 24 h only. It is also similar to what Emam et al. found in their study as 60% of their cases were intubated for less than 15 days [23, 24].

The major advantage of balloon dilatation is lower morbidity and mortality than open surgical procedures especially with our comorbid and multi-traumatic patients. Balloon dilatation has been reported in some literature to cause tracheal lacerations. Although tracheobronchial lacerations were found in 51% of procedures, most of these lacerations were superficial, and there were no incidents of transmural laceration [25].

We had two cases of surgical emphysema, but they were mild with no associated pneumothorax or pneumomediastinum. So, precautions should be taken during this procedure to prevent unneeded complications.

Excessive careless dilatation can lead to major problems such as airway rupture, pneumothorax, pneumomediastinum, and mediastinitis which did not happen to any of our patients. Bronchoscopy laser-assisted procedures in managing tracheal stenosis are an added advantage in well-trained and experienced hands and wellequipped centers [1, 8].

Balloon dilatation alone showed a success rate in 8 patients (30%) during follow-up as the only line of management similar to what Mayes et al. found during evaluation of the efficiency and safety of balloon tracheoplasty in 26 patients. Balloon dilation was the only needed intervention in 26% of their cases with no significant adverse events being detected [8].

Fifty-six percent of our patients had success during the follow-up of 1 year using only bronchoscopic

interventions in the form of balloon dilation (either single or multiple sessions) or tracheal stenting; we found our results similar to the interesting study of Sun et al., where he had a success rate of 63% during a 1-year follow-up [26].

Tracheal resection of the stenotic segment with endto-end anastomosis for indicated cases is the definitive surgical treatment. The stenotic segments are resected, and end-to-end anastomosis is done with many release procedures that may be needed. Otherwise, various synthetic materials can be used to bridge the gap.

In our study, during the 1st year, nineteen patients (47.5%) who already had a severe form of stenosis and did not improve despite repeated sessions of balloon dilatation needed surgical intervention and tracheal resection and anastomosis. They get the benefits of balloon dilatation in delaying the definitive surgical repair when it becomes fit for the procedure.

However, patients need to have good cardiovascular, neurological, and respiratory conditions to be candidates for tracheal resection. Contraindications for surgery include the expected need for prolonged ventilation in the postoperative period, medical contraindications, and a long length of stenosis which is difficult and not feasible for resection and anastomosis

Similar results were found in Freitas et al., a study in which 82.6% of the patients had upper third tracheal stenosis, 12.2% of the patients had mid-tracheal stenosis, and 5.2% of the patients had lower tracheal stenosis. We found 95% of patients located in the upper two thirds of the trachea. Lower third stenosis was found to be completely managed by dilatation alone with no further intervention needed during the 1st year of the follow-up. Lower and middle third tracheal stenosis seemed to be more responsive to bronchoscopic approaches in either dilation or stent, but further studies including multicentric data are needed to get sufficient numbers to get statistically significant values [27].

The success rate of balloon tracheoplasty is much higher when used for benign non-inflammatory stenosis, especially annular stenosis. Also, the 32 monthly followups to assess the long-term efficacy regarding the balloon tracheoplasty especially in benign stenosis were reported to be 43%. The failure rate of surgery is reported to be less than 15% as reported by Bonette et al. after following 340 patients who underwent tracheal resection with end-to-end anastomosis [28].

A definitive cure was obtained at the first attempt in 265 patients, while six patients needed a second surgical intervention. Also, trials for resection anastomosis for long segments of more than 4 cm were achieved with good results in Mohsen et al.'s series of tracheal resection and anastomosis using different release maneuvers [29]. Different options for the primary management of tracheal stenosis include dilatation using different sizes of rigid bronchoscopy, laser resection, and stenting. Rigid bronchoscopy with neodymium ±yttrium aluminum garnet (ND-YAG) laser resection or stent implantation (removable stent) was chosen as the first line of treatment. The success of web-like stenosis after using laser resection was reported to be 66%. However, tracheal stents were needed in patients with complex stenotic lesions or failed laser treatment [23].

During follow-up, if the patient became fit for surgery, a trial to remove the stent would be carried out and the patient would have definitive tracheal resection surgery. Hazardous complications of laser therapy are pneumothorax, injury of major intrathoracic blood vessels, or pneumomediastinum secondary to perforation of the airway wall and endobronchial ignition.

The mechanism of balloon tracheoplasty is to create some cracks at the stenotic site to expand the tracheal wall. Balloon tracheoplasty is an easy and effective way to relieve tracheal stenosis and can also be repeated safely several times.

Additional therapies in the form of laser, stent placement, or surgical resection may be needed for those patients who had to do more than one session of balloon dilatation. The overall complication rates are less than 5%. Superficial and sometimes deep ulceration of the tracheal mucosa may occur during balloon tracheoplasty, but it usually heals smoothly without excessive granulation tissue or fibrosis. If the tracheal cartilages are not damaged, a good outcome can be achieved by a single dilation session. Excessive balloon inflation may cause rupture of the airway leading to hemorrhage, pneumothorax, pneumomediastinum, or mediastinitis [8].

Study limitations

Our study has several limitations. The retrospective nature of the study and the sample size was relatively small. Longer follow-up period also is needed to be investigated.

Conclusion

Balloon tracheoplasty is a simple, safe procedure that could be a promising and effective approach for tracheal stenosis in selected patients after prolonged intubation.

Abbreviations

BBD: Bronchoscopic balloon dilatation; CT: Computed tomography; ICU: Intensive care unit; ND-YAG: Neodymium ±yttrium aluminum garnet; RTA: Road traffic accident; TBS: Tracheobronchial stenosis; TS: Tracheal stenosis

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Authors' contributions

All authors participated in getting the conception, data collection, analysis, and manuscript writing. AN was a major contributor in the analysis and interpreted the patient data regarding the comparative parameters. WA was a major contributor in writing the manuscript. MS was a major contributor in revising and editing the manuscript. ME was a contributor in revising and editing the manuscript. RA was a contributor in revising and editing the manuscript. All authors read and approved the final manuscript

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Competing interests

The authors declare that they have no competing interests.

Author details

¹Cardiothoracic Surgery Department, Faculty of Medicine, Cairo University, Cairo, Egypt. ²Cardiothoracic Surgery Department, Faculty of Medicine for Girls, Al-Azhar University, Cairo, Egypt.

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