Balloon Dilatation in Laryngo Tracheal Stenosis: An Update

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Laryngotracheal stenosis (LTS) describes narrowing of the airway that can be found from the true vocal cords to the distal trachea. LTS is usually acquired but can be congenital and frequently associated to other anomalies. The most common cause of acquired LTS is trauma by prolonged endotracheal intubation. The incidence of acquired LTS has greatly decreased over the past 40 years. In the late 1960s, when endotracheal intubation and long-term ventilation for premature infants began, the incidence of acquired LTS was high, 24% in patients requiring such care. In the 1970s and 1980s, estimates of the incidence of LTS were 1-8%[1]. Nowadays, despite the awareness of the potential damage related to intubation and the continuous advancements in using minimally invasive instruments for the intubation tools, the incidence of acquired post-intubation stenosis in neonates remains at 1-2%[1,2] and it still represents the first indication to tracheotomy in the first year of life. Although it has a low incidence, congenital LTS is the third most common laryngeal congenital anomaly after laryngomalacia and vocal cord paralysis. Its true prevalence is difficult to determine, as many cases are aggravated by an emergency ET intubation leading to the so-called acquired on congenital or mixed LTS. Severe airway stenosis remains the most common laryngeal anomaly requiring tracheotomy in children under 1 year of age[2]. Historically, LTS was managed with endoscopic antegrade bouginageas as early as the 1970s [10.] This method has gradually fallen out of favor since the shearing forces of the bougie predispose to further scar tissue formation of restenosis. Open surgery with laryngo-tracheal reconstruction has become the standard treatment for LTS. In order to avoid as much as possible open and invasive techniques, such as tracheotomy, cricoid split, laryngotracheoplasty, laryngotracheal reconstruction and cricotracheal resection, balloon laryngoplasty has gained much interest in the last decade. As a matter of fact, various techniques and devices have been employed moving through metal dilators, endotracheal tubes and angioplasty balloons. Recently, high-pressure, noncompliant airway balloons acquired US Food and Drug Administration approval for the management of pediatric airway stenosis.

This treatment is performed in the operating room under general anesthesia, maintaining spontaneous ventilation. The patient is positioned in cervical hyperextension. After that is performed, direct laryngoscopy using a 3-4 mm and 0 degree rigid endoscopy is used to establish the level and the severity of stenosis attending to the Myer-Cotton scale (**Table 1**):

Table 1. LTS classification and surgical indication

Cotton's Classification		Surgical Indication
1°	No obstruction -> 50%	Wait and see/endoscopical
2°	51% -> 70%	Endoscopical/open surgery
3°	71% -> 99%	(endoscopical)open surgery
4°	No lumen	open surgery

In order to avoid erroneous valuations of the level and diameter of the stenosis, it is necessary to known the regular laringo-tracheal lumen and length for age (**Tables 2**, **3** and **4**):

Age y	Median mm	Minimal mm
0-1	4,6	3,7
1-2	5,5	4,9
2-3	6,7	6,2
3-4	6,8	5,8
4-5	7	6,2

Table 2. Sub Glottic Lumen

Age y	Median mm	Minimal mm
0-1	4,6	4,1
1-2	5,3	4,1
2-3	6,7	6,4
3-4	7,4	5,8
4-5	7,8	7,5

Table 3. Tracheal Lumen

Age y	Length cm
0-2	5,4
2-4	6,4
4-6	7,2
6-8	8,2
8-10	8,8

Table 4. Tracheal length

The mechanism of the Balloon dilation is that the fibroblast bridges are interrupted in the scar tissue by high balloon pressure. Because balloon dilation applies the entire force of dilation in a radial direction, longitudinal shearing forces and subglottic trauma are decreased, as compared to dilation with rigid instruments and serial bouginage [11].

The use of balloon dilation in both congenital and acquired stenosis without cartilage involvement is limited to a 2nd or 3th degree of the stenosis, also 1st degree with a symptomatic patient.

Balloon dilation is not indicated in tracheal complete ring. The best use of the balloon is indicated in post intubation tracheal stenosis. There are different treatment for acquired tracheal stenosis: open resection surgery, endoscopic laser treatment, temporary implantation of a stent. If it is possible we can avoid open surgery for the major complications of this procedure, the considerable failure rate (5-15%)[4,5,9], and the limited application to select candidates. Also the use of tracheal stent has a high incidence of complications: migration and fracture of the stent, granulation tissue formation or mucous retention. Endoscopic treatment with balloon is less dangerous, although there is the risk of a tracheal laceration, because during the treatment we can see only the proximal airway to the stricture[13]. We use fluoroscopically guided balloon dilation to reduce negative outcomes. (**Figure 3**).

The scar "thin and young" (M.J. Rutter) gives better outcomes in balloon dilation.

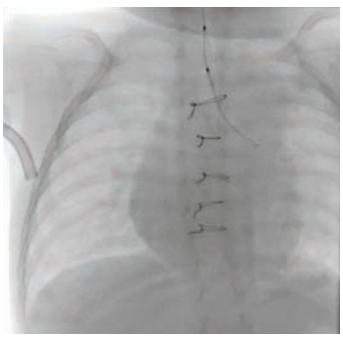

Figure 3. Radiograph taken during tracheal balloon dilation

A very gentle dilation tool is the Inspira AIR Balloon Dilation System (Acclarent Inc,Johnson & Johnson Medical; California). It is designed to safely dilate airway strictures with minimal mucosal trauma achieved through controlled radial pressure with precise inflation and pressure regulation.

Balloon dilation is controindicated in the presence of:

- Significant active bleeding from the site of the proposed dilation
- Presence of a known perforation at the site of the proposed dilation
- Presence of a known fistula between the tracheobronchial tree and esophagus, mediastinum or pleural space

Precaution during use of balloon dilation:

- Never advance, retract, or hold the balloon catheter with stylet against resistance as this could cause tissue trauma or device damage
- Check for proper position of the balloon catheter using fluoroscopic or endoscopic visualization. Balloon inflation in an improper location may lead to patient injury.
- Carefully monitor patient oxygen levels during balloon dilation. Occlusion of the airway for an extended period of time may result in hypoxia.
- Use of a balloon catheter that is too large for the targeted anatomy may cause damage to the surrounding anatomy.
- Use of an undersized balloon catheter may result in failure to properly treat the target anatomy.

Select the appropriate balloon size such that the diameter does not exceed the expected diameter of a healthy airway (**Figure 1**).

Inspira Air™ Balloon Dilation System				
Balloon Size	Saline Required	Nominal Pressure	Maximum Pressure	Actual Diameter*
5 x 24 mm (15 fr)	6 - 8cc	5atm	16atm	
7 x 24 mm (21 fr)	6 - 8cc	5atm	16atm	
10 x 40 mm (30 fr)	12cc	5atm	12atm	
14 x 40 mm (42 fr)	12cc	5atm	10atm	

*At nominal pressure

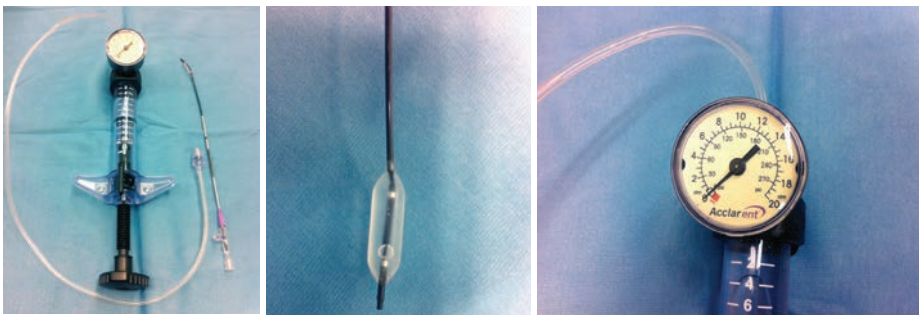

Figure 1. Inspira AIR Balloon Dilation System

BAMBINO GESU CHILDREN'S HOSPITAL'S EXPERIENCE

At our Institution, these types of balloons have been introduced over the past five years.

Since they were introduced in 2009, we have been examining the clinical outcomes of patients treated for either congenital or acquired LTS.

We retrospectively reviewed the records of 31 patients who underwent balloon dilation for LTS from September 2009 to September 2013. Information obtained from our medical electronic archive included patients, grade and nature of stenosis, demographics, comorbidities, history of airway surgery, coexisting bronchopulmonary disease, presence of other airway lesions, and outcome.

Assessment of the grade of the stenosis was made according to the Myer-Cotton Grading System. All the procedures were conducted under general anesthesia with the patient ventilating spontaneously.

Direct laryngoscopy and tracheoscopy were performed before using a flexible 3.5 or 2.2. Then, by direct visualization with a Benjamin-Parsons blade, with a 2.7 or 4.0-mm 0° rigid telescope (Karl Storz, Rod Hopkins Germany), fixed on a thoracic suspension support (mod. Göttingen) and the balloon catheter (Inspira AIR Balloon Dilation System; Acclarent Inc, Johnson & Johnson; California) was introduced into the laringeal lumen through the stenosis (**Figure 2**). It was then inflated using an inflation/deflation handle mounted with a syringe and gauge assembly (Acclarent Inflation Device) designed to monitor and maintain the balloon pressure for 30-55 seconds, or until the patient's oxygen saturation level dropped below 90%. The size and diameter of the balloon was selected according to degree of stenosis, age and weight of the patient.

The procedures were performed twice for each session. Final airway size after each procedure was made with cuffless endotracheal tubes (Mallinckrodt) or laringeal dilators (Rusch dilators), very gently inserted, in order to avoid tissue trauma infliction.

Balloon size was chosen accordingly to laringeal (1 mm more) and tracheal (2 mm more) diameters expected for the age[3]. Patients were all followed-up every 8 days for the first month, after three months and then accordingly to clinical symptoms.

Proton pump inhibitor was administered to all patients in the 3 months postoperatively, depending on the clinical evolution. None of the patients received postoperative antibiotic treatment. Follow-up endoscopy was performed using a laryngotracheal videoendoscope (Karl Storz), under general anestesia. A patient was considered totally healed if asymptomatic after one year from the last dilation.

There were 31 patients treated by balloon dilations for the treatment of SGS from September 2009 to September 2013. There were 20 males and 11 females with a mean age of 42.6 months (range, from 1 to 167) at the time of the first procedure. Time of follow-up was calculated from the last dilation procedure. Almost all patients (28 out of 31) had comorbidities (diabetes, Down syndrome, Noonan syndrome, Fallot tetralogy, aortic coartation, interatrial defect, neuropathy, prematurity, GERD, esophageal atresia). Twelve patients had concomitant airway lesions, including tracheomalacia, bronchomalacia, vocal cord paralysis, granulomas and

pouches. None of the patients experienced immediate complications, such as tracheal rupture, pneumothorax, pneumomediastinum, or bleeding.

In our institution we had results according to international literature, 80,9% of patients completely healed, and rate of restenosis was of 57%. 72,7% of patients with SGS 3th degree had a successful treatment, avoiding the need for open airway surgery.

In our series there were 11 patients who suffered with clinical conditions which could theoretically represent a negative predictive factor for their outcome (2 diabetes, 1 Noonan syndrome, 1 with mycoplasma encephalopathy, 3 Down syndrome, 1 oesophageal atresia type III, 3 severe prematurity). We could not demonstrate the impact of coexistence of airway lesions in treatment failure or rate of recurrence, due to lack of control group.

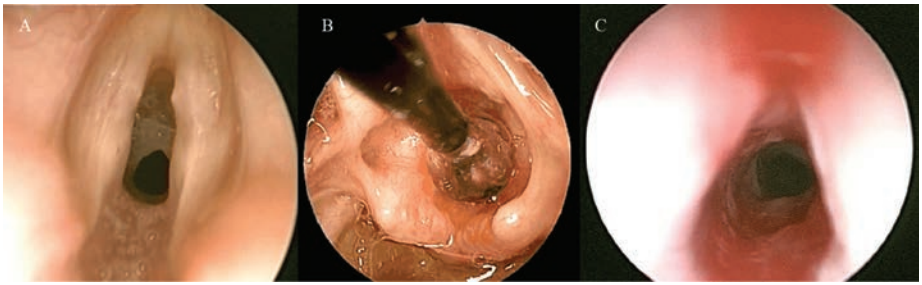

Figure 2A. Subglottic stenosis, **Figure 2B**. Balloon dilation treatment, **Figure 2C**. Result after the treatment

Conclusions

Balloon dilation laryngoplasty is an efficient technique and is a safe tool for management of post-operative care in laryngo-tracheal reconstruction as well as in primitive congenital and acquired stenosis.

Balloon dilation procedure for the treatment of subglottic stenosis and other airway benign strictures remains a challenge for the otolaryngologist. Primary, feasibility, non-invasivity, immediate feedback and rare severe complications are the main advantages of this technique, secondary, a patient could need more than one procedure to remain symptom-free and maintain an adequate airway, given the relatively high rate of recurrence of stenosis (40-80%)[5,8].

Compared to open LTR, endoscopic treatment of acquired SGS reduces operative time and morbidity but often requires multiple procedures. Although this has been cited as a disvantage, serial treatment may allow time for the patient and airway diameter to grow and can be considered a viable alternative to open LTR as long as serial endoscopy demonstrated improvement[12].

Furthermore, balloon dilation could necessitate adjuvant treatments (intralesional steroid injection, mitomycin application)[6,12], to provide more benefits to the airway and to reduce the incidence of restenosis. Studies demonstrate the growing evidence that balloon dilations are safe and efficient in the treatment of subglottic stenosis in children and reduce the need for open laringeal surgery by 70 to

80%[4,5,10,11,12]. There was no statistical association between treatment and rate of recurrency by age, sex, etiology and grade of stenosis, coexisting airway disease, comorbidities, and treatment modality.

Unfortunately, we could not compare the outcome resulting from the use of the latest Inspira Airway balloon system and the old angioplasty catheters or metal dilators. However, as it was described by Bent et al, in contrast to the older rigid dilation, balloon dilation offers a different mechanism where the balloon is inflated under direct visualization without necessarily needing tracheotomy or endotracheal intubation. The forces are radial, avoiding the shearing forces of rigid dilators[6,11].

We didn't register any complications. Gungor et al reported one case of massive edema obstructing the airway lumen, by means of these airway balloons[7].

Further studies are needed to focus on the predictive impact of concomitant airway disease and comorbidities in balloon dilation outcomes.

References

1. Choi SS, Zalzal GH. Changing trends in neonatal subglottic stenosis. Otolaryngol Head Neck Surg 2000;122:61-3.
2. Philippe Monnier. Pediatric airway surgery. Management of laryngotracheal stenosis in infants and children. Pag. 119. Edited by Springer. ISBN 978-3-642-13534-7. © Springer-Verlag Berlin Heidelberg 2011
3. Rutter, MJ. ASPO 2010-2011. Lecture n° 5.
4. Schweiger C, Smith MM, Kuhl G, Manica D, Marostica PJ. Balloon laryngoplasty in children with acute subglottic stenosis: experience of a tertiary-care hospital. Braz J Otorhinolaryngol. 2011 Nov-Dec;77(6):711-5. English, Portuguese.
5. Hautefort C, Teissier N, Viala P, Van Den Abbeele T. Balloon dilation laryngoplasty for subglottic stenosis in children: eight years' experience. Arch Otolaryngol Head Neck Surg. 2012 Mar;138(3):235-40. Epub 2012 Feb 20.
6. Edmondson NE, Bent J 3rd. Int J Pediatr Otorhinolaryngol. Serial intralesional steroid injection combined with balloon dilation as an alternative to open repair of subglottic stenosis. 2010 Sep;74(9):1078-81. Epub 2010 Jun 17.
7. Gungor A. Balloon dilation of the pediatric airway: potential for disaster. Am J Otolaryngol. 2012 Jan-Feb;33(1):147-9. Epub 2011 Jul 23.
8. Bent JP, Shah MB, Nord R, Parikh SR. Balloon dilation for recurrent stenosis after pediatric laryngotracheoplasty**.** Ann Otol Rhinol Laryngol. 2010 Sep;119(9):619-27
9. Whigham AS, Howell R, Choi S, Peña M, Zalzal G, Preciado D. Outcomes of balloon dilation in pediatric subglottic stenosis. Ann Otol Rhinol Laryngol. 2012 Jul;121(7):442-8.
10. Kristelle Chueng, Neil K. Chadha. Primary dilatation as a treatment for pediatric laryngotracheal stenosis: a systematic review. Int.J.Pediatr. Otorhinolaryngol. 2013 Jan; 77:623-628
11. J.Lindhe Guarisco, Christina J. Yang. Balloon dilation in the management of severe air way stenosis in children and adolescents. J of Pediatric Surgery. 2013 Aug, 48: 1676-1681
12. R. Ortiz, E.Dominguez, C. De La Torre, F. Hernandez et al. Early endoscopic dilation and mitomycin application in the treatment of acquired tracheal stenosis. Eur J Pediatr Surg. 2014; 24: 39-45
13. W.H. Lee, J.H. Kim, J.H. Park. Fluoroscopically guided balloon dilation for post intubation tracheal stenosis. Cardiovasc Intervent Radiol. 2013; 36: 1350-1354