

ONLINE FIRST

Balloon Dilation Laryngoplasty for Subglottic Stenosis in Children

Eight Years' Experience

Charlotte Hautefort, MD; Natacha Teissier, MD; Paul Viala, MD; Thierry Van Den Abbeele, MD, PhD

Objective: To evaluate outcomes of balloon dilation laryngoplasty for laryngeal stenosis in children.

Design: Retrospective study.

Setting: Academic tertiary care department of pediatric otolaryngology.

Patients: All children treated with laryngeal balloon dilation (primarily or secondarily following laryngeal surgery) from 2002 to 2010.

Main Outcome Measures: Stenosis severity, measured using the Cotton and Myer classification.

Results: A total of 44 children ranging in age from 1 month to 10 years (14 [32%] with grade II stenosis, 25 [59%] with grade III stenosis, and 4 [9%] with grade IV stenosis) were included. Twelve children [27%] had congenital laryn-

geal stenoses, and the in other 32 [73%], stenosis was acquired. A total of 52 balloon dilation laryngoplasties were performed, and 37 (71%) were deemed successful. Twenty of the 31 patients undergoing primary dilation (65%) had successful outcomes, and in the other 11 [35%], outcomes were unsuccessful (4 had grade II stenosis and 7 had grade III stenosis) and required either laryngotracheal reconstruction or tracheotomy. Twenty-one balloon dilations were performed as a secondary procedure after recent open surgery; 17 of the procedures (81%) were successful, and thus surgical revision was avoided.

Conclusion: Balloon dilation laryngoplasty is an efficient and safe technique for the treatment of both primary and secondary pediatric laryngotracheal stenosis.

Arch Otolaryngol Head Neck Surg. 2012;138(3):235-240.
Published online February 20, 2012.
doi:10.1001/archoto.2011.1439

ALTHOUGH MANY ADVANCES have improved the treatment of congenital and acquired laryngotracheal stenosis in children over the past decade, therapeutic decision making remains challenging for otolaryngologists. Different treatment options include tracheotomy, open surgical procedures, and mini-invasive surgery. Initially, balloon dilation was reported by Hebra et al¹ for treating laryngeal or tracheal stenosis in children using classic spherical angioplasty balloons. Durden and Sobol² recently revisited balloon dilation techniques for acquired pediatric subglottic stenosis using new types of balloons. This minimally invasive approach seems attractive both as primary treatment and as secondary treatment after open surgical procedures. Secondary postsurgical dilation after laryngotracheal reconstructions (LTRs) aims to reduce recurrence and open surgical revision. Since then, several authors^{3,4} have reported varying results and associated en-

doscopic techniques, including the use of laser dissection, microinstruments, balloon dilations, stenting, and steroid injections and/or mitomycin application.

Our main objectives were to investigate some of the controversies concerning this new technique in order to define the best indications and limitations: (1) appropriate patient selection for primary balloon dilation treatment; (2) identification of predictive factors for success or failure of primary balloon dilations; (3) definition of a suggested standard program for dilation sequences: number of sessions, periodicity, and delay; and (4) evaluation of the efficacy and the indications of secondary dilation treatment after open laryngeal surgery.

METHODS

We performed a retrospective patient file analysis including all patients who underwent balloon dilation for subglottic stenosis from Janu-

Author Affiliations:
Department of
Otolaryngology–Head and Neck
Surgery, Robert Debré Hospital,
APHP, University Paris VII
Denis-Diderot, Paris, France.

Table 1. Age and Increasing Theoretical Airway Diameter, Tube Size, Grade II Stenosis, and Balloon Diameter

Age	Normal Larynx Tube Size, ID (OD), mm	Normal Larynx Imaging/Anatomic Measurement, mm	Grade II Stenosis, Myer-Cotton Classification ^a (Size, mm)	Balloon Diameter, mm
Premature infant	2.0-2.5 (3.4)	<4.0 ^b	<2.0 (2.9)	6
0-3 mo	3.0-3.5 (4.8)	4.0 ^a -4.6 ^c	<2.5 (3.4)	6
>3-9 mo	4.0 (5.5)	4.6 ^c	<3.0 (4.2)	8
>9-12 mo	4.5 (6.2)	4.6 ^c	<3.5 (4.8)	8-10
2 y	5.0 (6.8)	6.3 ^d	<3.5 (4.8)	10
4 y	5.5 (7.6)	7.7 ^d	<4.0 (5.5)	12
>6 y	6.0 (8.2)	8.2 ^d	<4.5 (6.2)	12

Abbreviations: ID, inner diameter; OD, outer diameter.

^aSee Myer et al.⁵

^bFrom Fayoux et al.⁶

^cFrom Eckel et al.⁷; anatomical measurements of the cricoid.

^dFrom Al-Mazrou et al.⁸; magnetic resonance imaging measurements of the cricoid.

ary 2002 to September 2010. Demographic and clinical data, including age, sex, comorbidities, and stenosis etiology, were collected for all children. Stenoses were endoscopically graded prior to all dilations using the classification by Myer et al⁵ (hereinafter, Myer-Cotton classification). Two types of clinical situations were distinguished: a primary treatment group, including all children treated primarily by balloon dilations or with a history of open laryngeal surgery more than 1 year previously, and a secondary treatment group, including all children undergoing dilations less than a year after LTR. The minimum delay between open procedures and balloon dilations was 10 days for LTR and 3 weeks for tracheal anastomosis so as to avoid airway ruptures or leakage. A successful program of dilation was defined by the absence of significant recurrent stenosis (endoscopic grade 0 or I) at least 1 year later.

SURGICAL TECHNIQUE

A balloon dilation treatment program was defined as a series of 1 to 4 consecutive dilation procedures over a maximum period of 6 months. Dilation technique involved an endoscopic high-pressure balloon catheter under general anesthesia with spontaneous ventilation following a standardized protocol. Direct laryngoscopy was performed using a 2.7 or a 4 mm 0° telescope (model 10324 AA; Karl Storz) and the balloon catheter (MaxForce esophageal balloon; Boston Scientific) introduced into the laryngeal lumen through the stenosis. It was then inflated using an inflation/deflation handle mounted with a syringe and gauge assembly (Boston Scientific) designed to monitor and maintain the balloon pressure for 30 seconds or until the patient's oxygen saturation level dropped below 92%. The size and diameter of the balloon were selected according to the theoretical ideal diameter of the cricoid ring (**Table 1**). The minimum balloon diameter was 6 mm. This procedure was performed 2 or 3 times during each session under general anesthesia and was followed by 1 to 2 minutes of topical application of cottonoid pledgets soaked with mitomycin, 1 mg/mL, if available. In most cases, children were not intubated after dilation, were monitored in the pediatric intensive care unit for 24 to 48 hours, and had follow-up endoscopy 5 to 7 days later depending on clinical progress. Follow-up endoscopy included a second balloon dilation when necessary. All patients received 3 to 10 days of systemic steroids (prednisolone, 1-2 mg/kg/d), proton pump inhibitors (esomeprazole, 2 mg/kg/d), and epinephrine nebulizers. Follow-up endoscopy was performed weekly for 3 weeks, every 3 weeks until complete healing, and then every 6 months. Follow-up endoscopy was performed using a nasofibroscope (FNL 10 RP3; Pentax) con-

nected on a camera (Karl Storz) under local anesthesia with oxygen and nitrous oxide delivered by mask ventilation. General anesthesia was required in a minority of follow-up endoscopies.

STATISTICAL ANALYSIS

Descriptive statistics were generated, and 2 groups of children were compared (primary vs secondary dilations, and successful vs failed cases) using χ^2 or Mann-Whitney rank sum tests where appropriate. Logistic regression multivariate analyses were performed to assess potential predictors of failure. All statistical analyses were performed using Sigmasat 3.0 software (Sysstat Software). $P < .05$ was considered statistically significant.

RESULTS

Forty-four patients were included in the study: 15 girls and 29 boys with a mean (SD) initial age of 26 (34) months (range, 1 day to 140 months) and a mean initial weight of 11.0 (7.0) kg (range, 2.0-35.0 kg). All patients were admitted for subglottic stenosis that was endoscopically confirmed and graded according to the Myer-Cotton classification under general anesthesia.⁵ Stenoses were distributed as follows: 14 (32%) had grade II stenosis, 26 (59%) had grade III stenosis, and 4 (9%) had grade IV stenosis. Thirty-two children (72%) had acquired stenoses. They were related to endotracheal intubation in 24 cases, 18 of them being premature infants, or secondary to other diseases in 8 cases (eg, laryngeal papillomatosis, varicella, subglottic hemangioma, pseudoinflammatory tumor). Twelve children (27%) had a congenital stenoses, of whom 5 (42%) had associated 22q11 microdeletions (DiGeorge syndrome). Five children (42%) had a tracheotomy before laryngeal stenosis assessment. **Table 2** shows patient demographics and outcome and whether treatment is primary or secondary.

Forty-four patients were included in 52 balloon treatment programs and underwent a total of 98 balloon dilation procedures. Thirty-seven dilation programs were deemed successful according to the criteria described herein, yielding an overall success rate of 71%. Sixty-six endoscopic procedures were necessary to obtain a stable airway (ie, 1.8 ± 1 procedure per successful case). A single

Table 2. Demographic Data

Characteristic	Patients (n = 44)	Dilations		P Value	Total (n = 52)
		Primary (n = 31)	Secondary (n = 21)		
Age, mo, mean (SD)	26 (34)	26 (31)	27 (38)	.07 ^a	26 (34)
Sex				.47	34 of 18
Male	29	22	12		
Female	15	9	9		
Weight, kg (SD)	11 (7)	11.5 (8.0)	11.3 (9.0)	.31 ^a	11 (8)
Initial Myer-Cotton stenosis grade ^b				.47 ^a	
II	14	11	5		16
III	26	20	12		32
IV	4	0	4		4
Patients with acquired vs congenital stenosis	32 vs 12	23 vs 8	12 vs 9		35 of 17
Dilations, No.	98	57	41	.35 ^a	98
Mean (SD)		1.8 (1.0)	2.0 (1.1)		1.9 (1.0)
Treatment success vs failure, No. (%) of success in total cases		20 vs 11 (65)	17 vs 4 (81)	.23 ^c	37 vs 15 (71)

^aRank test.

^bSee Myer et al.⁵

^cFisher test.

dilation procedure was enough in 19 of 37 cases (51%). **Figure 1** illustrates the distribution of these endoscopic procedures. There were no clinically significant observed complications with balloon dilation (notably, no hemorrhage, cervical emphysema, or pneumothorax). The narrow diameter of the deflated balloons made endoscopic dilations feasible in all cases, even in pinpoint stenosis, without forcing maneuvers. The distribution of the stenosis grades was not different in successful cases (13 cases of grade II stenosis, 21 of grade III, and 3 of grade IV) when compared with failed cases (3 of grade II, 11 of grade III, and 1 of grade IV) (rank sum test $P = .48$). Mitomycin was used in 40 of 52 balloon treatment programs, without a significant difference in success rate (28 of 40 [70%] vs 9 of 12 [75%]). Five children died during the follow-up: all deaths were related to severe comorbidities, and none directly were due to stenotic airways.

SECONDARY VS PRIMARY DILATIONS

Thirty-one patients received endoscopic balloon dilations as primary treatment (9 girls and 22 boys). Their mean (SD) age was 26 (31) months (range, 2 weeks to 118 months), and their mean weight at the beginning of the treatment was 11.5 (8.0) kg (range, 3.3-35.0 kg). Twenty-three children (74%) presented with acquired laryngeal stenoses, 8 of whom (35%) had congenital laryngeal stenoses, including 2 children with 22q11 microdeletion. Five of these children (22%) had a history of LTR more than 1 year previously. Twenty children (65%) were successfully treated with balloon dilations. There was no statistical difference between successful and failed cases in terms of weight (11.9 [7.0] kg vs 10.9 [10.0] kg), age (28 [21] months vs 22 [35] months) and grade (grade II compared with grade III: 8 of 12 cases vs 3 of 8 cases). Successful cases included 3 children weighing less than 3.0 kg. The success rate was higher in acquired stenoses than in congenital stenoses (16 of 23 [ie, 70%] vs

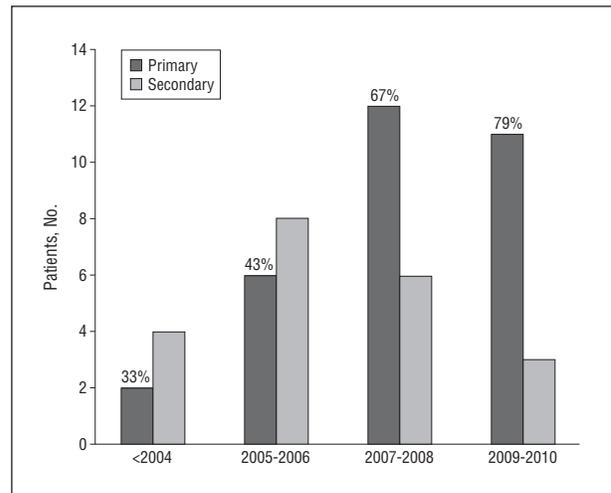


Figure 1. Evolution of the primary and secondary dilation procedure from 2002 to 2010. The histograms indicate the number of patients receiving balloon dilation during the study. The percentages of primary cases are shown above the dark gray bars.

4 of 8 [50%]), but this difference was not significant ($P = .41$).

Twenty-one children (9 girls and 12 boys) received balloon dilations as secondary treatment in the year following LTR (range, 5 days to 11 months). Their mean (SD) age was 27.0 (35.0) months (range, 1-145 months), and their mean weight was 11.3 (9.0) kg (range, 1.7-35.0 kg). Eight of these children requiring secondary balloon dilation treatment had failed primary dilation treatment before surgery. Seventeen children (81%) were successfully treated. There was no difference between acquired and congenital stenosis (10 of 12 [83%] vs 7 of 9 [78%]). Only 4 children failed to respond to secondary endoscopic dilations. Two of them were premature infants younger than 1 month who could not be extubated after dilations owing to severe pulmonary disease and associated comorbidities and finally died.

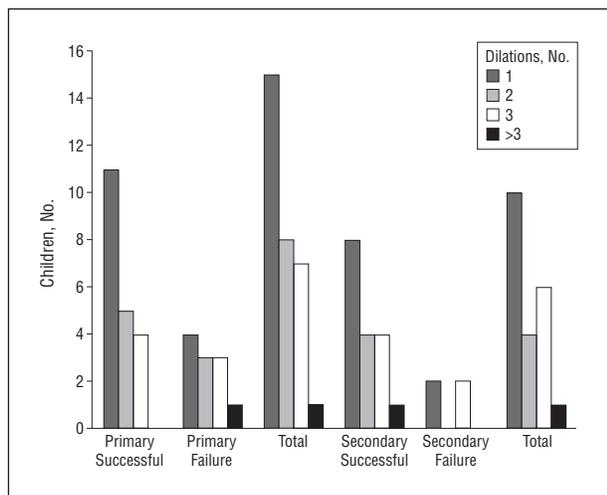


Figure 2. Distribution of the number of dilations procedure per program. Nineteen of 37 children with successful either primary or secondary dilation programs (51%) underwent only 1 procedure.

Although secondary dilations seem more successful than primary dilations, no significant difference was found between both groups ($P = .15$ and $P = .23$, respectively) (χ^2 with Yates correction and Fisher exact test). **Figure 2** illustrates the evolution of our practice, showing the predominance of primary dilations in the second period of the study. **Figure 3** and **Figure 4** show endoscopic views before and after dilation treatment in samples of successful and failed cases.

ROLE OF POTENTIAL PREDICTING FACTORS

Multivariate analysis for predictors of dilation failure (**Table 3**) showed no significant association with sex, prematurity, stenosis etiology, Myer-Cotton grade, or mitomycin application. However, there was a significant association with gastroesophageal reflux (GER) ($P < .02$) and a nonsignificant association with secondary vs primary dilations ($P = .07$), where 3 or more dilations were required ($P < .10$) and to a lesser extent when weight was below 5 kg ($P < .15$). The 5 children who died during follow-up did so as a result of severe cardiac and/or pulmonary comorbidities.

COMMENT

Several surgical approaches have been proposed for the treatment of subglottic stenosis in children. Since the early 1980s, the gold standard technique has been open laryngeal surgery combining laryngeal expansion with cricoid sections and/or cartilage grafts and various types of stenting.⁹⁻¹¹ Single-stage laryngotracheoplasty was introduced in the 1990s and replaced tracheostomy with endotracheal intubation during the first days of postoperative healing. The overall success of these procedures is about 80% and is influenced by several factors, such as stenosis grade, patient age and weight, and the association of GER and other comorbidities.¹²⁻¹⁴ Monnier et al¹⁵ first introduced the concept of complete resection of the

stenosis and reported an excellent outcome of about 90% with partial cricotracheal resection.

Before these advances, therapeutic options included prolonged tracheostomy and/or “bougienage,” an often inefficient and sometimes dangerous dilation technique that was subsequently abandoned. Despite the well-demonstrated efficacy of balloon dilations in vascular diseases and esophageal stenosis, many otolaryngologists are still reluctant to use these new techniques in the airway.⁴ However, there are several theoretical advantages of balloon dilation when compared with rigid techniques: reduced shearing forces, radial balloon inflation, limited dilation trauma even in pinpoint stenoses, and lower complications rates.¹

Despite continuing improvements in open surgical techniques, in comorbidity treatments (GER), and the advances in pediatric intensive care, some patients still require several open procedures to obtain a patent and stable airway.⁹ Balloon dilations were progressively introduced into our practice starting in 1990 and have proved very useful in the treatment of anastomotic stenoses after esophageal atresia repair and in some cases of tracheal or bronchial stenosis.^{1,15,16} Recently, new types of balloons have been introduced that are characterized by higher resistance and stability owing to their oblong shape. These balloons seem to particularly well suited for use in the laryngotracheal lumen. Since 2002, we have progressively extended balloon dilation use to include laryngeal stenoses, and it has become an important adjunct in the postoperative care of open laryngeal surgery. The rationale was that while the normal cricoid is a nonexpandable cartilaginous structure and therefore ineligible for dilation, the anterior and/or posterior divisions and sometimes lateral sections of the cricoid performed during LTR procedures restore some capacity for expansion.^{11,17} In our series, secondary dilations succeeded in about 80% of cases, with a mean number of 2 dilation sessions, and avoided revision surgery. Similar results were recently reported in 10 children by Bent et al,⁴ whereas Quesnel et al³ obtained a success rate of only 60% in 20 children after secondary balloon dilations. Since 2005, we have used balloon dilations as a primary technique in children presenting with laryngotracheal stenosis. Most of the children had acquired stenosis, and the results obtained were comparable with those in children with secondary stenoses. Although the number of patients is limited, we observe that congenital stenosis responds well to secondary dilations. Primary dilations in congenital disease seem less efficacious, probably owing to the abnormal thickness of the cricoid cartilage and the considerable forces required to disrupt the cartilaginous ring in these cases.

Recently, Mirabile et al¹⁸ reported a success rate of 83% in a series of 18 children who underwent endoscopic cricoid splits combined with balloon dilations. This success rate is comparable with that of patients in our series who underwent primary dilations for acquired stenoses. Their study included 8 children with congenital stenosis with a 75% success rate, although patients received up to 7 postoperative dilations. These results suggest that endoscopic cricoid split may be not necessary for acquired stenoses but may increase success rates in

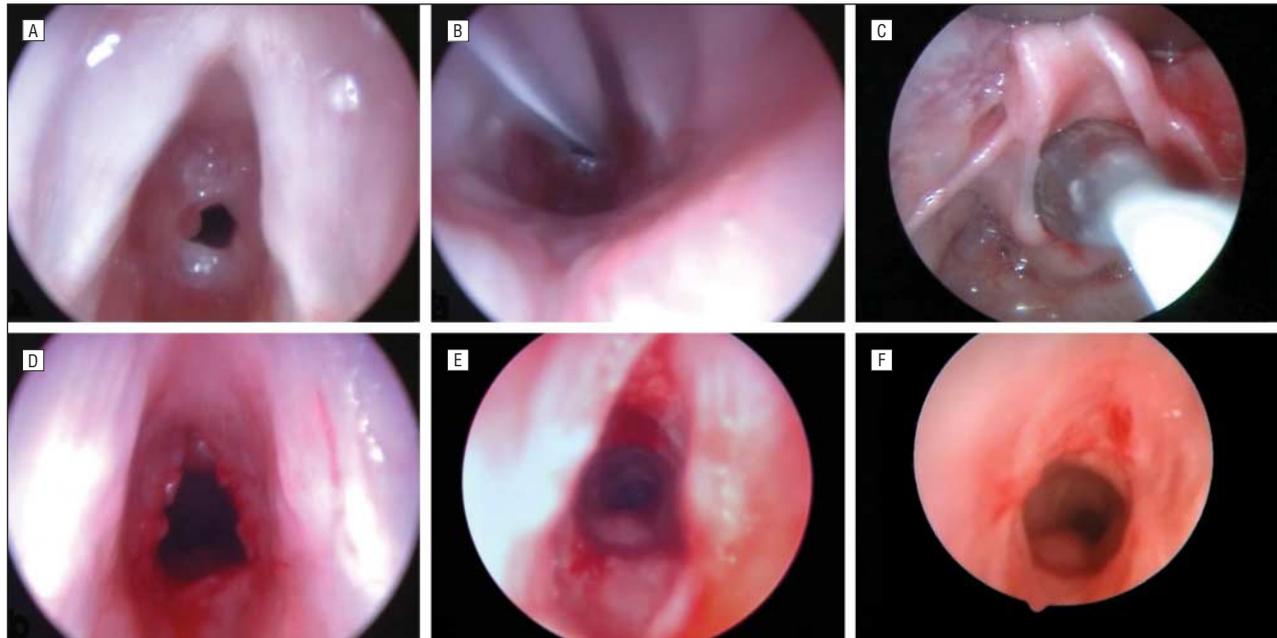


Figure 3. Endoscopic images of a 20-month-old girl presenting with an acquired postintubation subglottic stenosis (grade III). A-E, Endoscopic images using rigid 0° 4-mm telescope (Karl Storz) under general anesthesia with spontaneous ventilation. A, Subglottic stenosis before endoscopic dilation. B, Introduction of a 10-mm diameter deflated balloon through the stenosis. C, Endoscopic view of the balloon inflated through the larynx. D, Endoscopic appearance immediately after the first balloon procedure. E, Endoscopic appearance after the second balloon procedure. F, Flexible revision endoscopy under local anesthesia after 3 months.

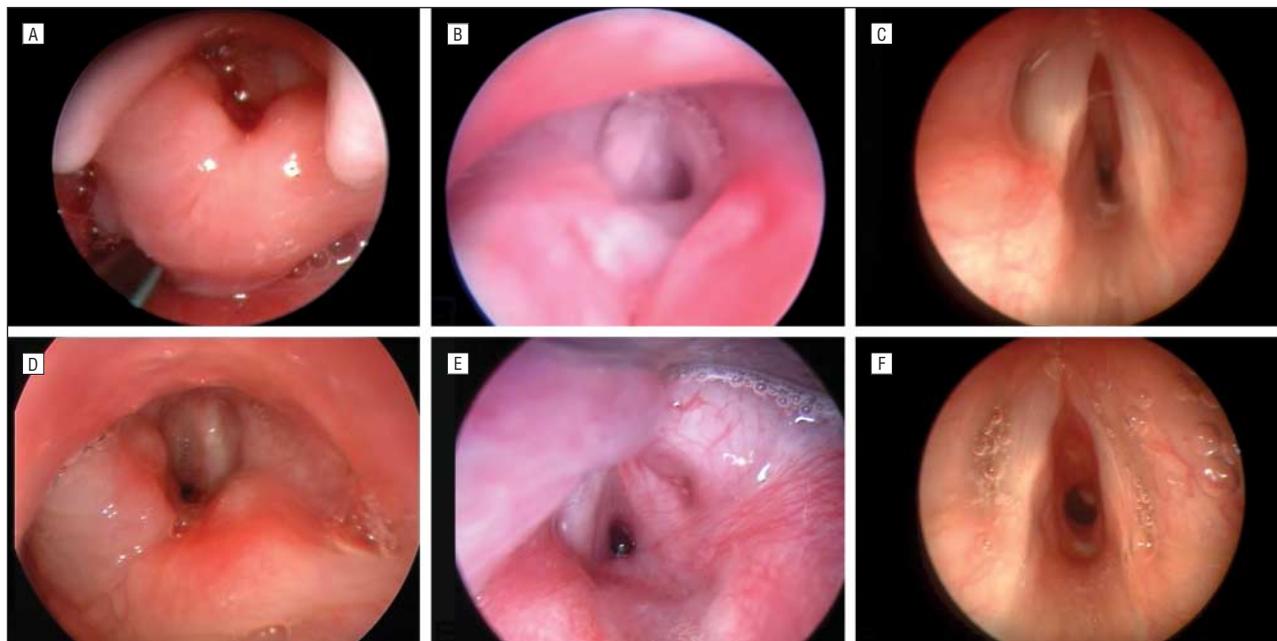


Figure 4. Endoscopic images of 3 failed cases. Case 1, a child with a severe congenital stenosis, preoperative (A) and postoperative (D) images; case 2, a premature infant with prolonged intubation and glottosubglottic stenosis, preoperative (B) and postoperative (E) images; and case 3, a 10-year-old child with acquired fibrous posttraumatic stenosis, preoperative (C) and postoperative (F) images.

congenital disease. Recent experimental data in rabbits showed that balloon dilations of the normal larynx produce cricoid fractures on the thinner part of the cricoid ring mimicking a cricoid split.¹⁹ These findings are in accordance with our results and could explain the good results obtained in acquired stenoses and the failures in congenital cases involving thickened cricoids.

As emphasized in the most recent reports,³ no consensus exists with regard to the specific indications for

laryngeal dilations vs open surgery for subglottic stenosis in children. However, our experience with balloon dilations over the past 10 years has led to this technique becoming our first choice in acquired or low-grade congenital subglottic stenosis. Open surgery is proposed for cases in which dilation fails or in the contexts of bilateral vocal fold immobility or severe pinpoint congenital stenosis. In our series, the stenosis etiology (acquired vs congenital) was not a significant factor of failure, but pa-

Table 3. Multivariate Analysis

Parameter	Estimate (SE)	P Value	OR
Age >3 mo	0.95 (1.37)	.49	2.57
Sex	-0.78 (0.95)	.41	0.46
Weight > 5 kg	1.97 (1.37)	.15	7.15
Prematurity	0.17 (0.90)	.85	1.19
Etiology	1 (0.93)	.28	2.72
Primary/secondary	1.91 (1.05)	.07	6.75
Stage, Myer-Cotton classification ^a	0.03 (0.78)	.97	1.03
Dilations, No. <3	1.65 (0.98)	.09	5.20
GER, absence	2.73 (1.16)	.02	15.35
Mitomycin	-0.52 (1.10)	.63	0.59

Abbreviations: GER, gastroesophageal reflux; OR, odds ratio.

^aSee Myer et al.⁵

tients with very severe congenital stenosis were excluded. The interval between 2 dilations was about 7 days in our series. This interval was dependent on inflammatory and healing processes and regular endoscopic evaluations. Dilation failure may be anticipated in cases in which no obvious improvement of the subglottic diameter is obtained after 2 or 3 procedures. Some authors reported children who underwent more than 7 dilation procedures before a successful outcome.^{1,3,18} Our belief is that these particular cases require cartilage grafting or resection and that an earlier decision to perform an open procedure is preferable to avoid prolonged hospitalization and a high rate of general anesthesia. In our series, GER and primary vs secondary dilations are the 2 most significant predicting factors of failure.

In conclusion, our study illustrates the growing evidence that balloon dilations are safe and efficient in the treatment of subglottic stenosis in children and reduce the need for open laryngeal surgery by 70% to 80%. Good indications include primary or secondary treatment of acquired stenosis of all grades, secondary treatment of congenital stenosis, and primary treatment of some selected congenital cases. Open surgery remains the best choice in case of severe congenital stenosis, glottis immobility, or after 2 to 3 dilation procedures without significant improvement.

Submitted for Publication: August 22, 2011; final revision received October 26, 2011; accepted December 6, 2011.

Published Online: February 20, 2012. doi:10.1001/archoto.2011.1439

Correspondence: Thierry Van Den Abbeele, MD, PhD, Otolaryngology Service, Robert Debré Hospital, 48 Boulevard Serurier, 75019 Paris, France (thierry.van-den-abbeele@rdb.aphp.fr).

Author Contributions: All authors had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Van Den Abbeele. *Acquisition of data:* Hautefort, Teissier, and Viala. *Analysis and interpretation of data:* Hautefort, Teissier, and Van Den Abbeele. *Drafting of the manuscript:* Hautefort, Viala, and Van

Den Abbeele. *Critical revision of the manuscript for important intellectual content:* Teissier. *Study supervision:* Van Den Abbeele.

Financial Disclosure: None reported.

Previous Presentation: Part of this study was accepted for podium presentation and was presented at the 24th Annual Meeting of the American Society of Pediatric Otolaryngology; May 23, 2009; Seattle, Washington.

Additional Contributions: Christopher Brasher, MD, provided helpful criticisms and corrections to the manuscript.

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