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# Balloon dilatation for paediatric airway stenosis: Evidence from the UK Airway Intervention Registry

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## Abstract

**Objectives:** To assess the safety and efficacy in routine clinical practice of balloon dilatation procedures in the treatment of paediatric airway stenosis.

**Design:** Observational data collection in prospective online research database.

**Setting:** Acute NHS Trusts with ENT department undertaking complex paediatric airway work.

**Participants:** Children (<18) undergoing balloon dilatation treatment for airway stenosis.

**Main outcome measures:** Airway diameter, complications, hospital resource usage.

**Results:** Fifty-nine patients had 133 balloon procedures during 128 visits to 10 hospitals. Sixty-nine (52%) of balloon procedures were conducted with a tracheostomy. Intra-operative Cotton-Myer grade decreased in 43 (57%). The mean pre-balloon subglottic diameter was 4.2 [95% CI: 3.8 to 4.5] mm, and its rate of increase was 0.8 [0.5 to 1.2] mm per year modelled on 30 patients' long-term data. As the primary treatment of stenosis, the procedural success rate of balloon dilatation (n = 52) was 65% (22% with tracheostomy, 88% without tracheostomy), and 71% as an adjunct to open reconstructive surgery (n = 7). In the 64 hospital visits where a balloon procedure was conducted with a tracheostomy in place, only one in-hospital complication (lower respiratory tract infection) occurred. For those without a tracheostomy in place, in-hospital complications occurred in seven of 64 balloon hospital visits, all related to ongoing or worsening stenosis. Six out-of-hospital complications were deemed related to ongoing or worsening stenosis following the procedure, and two complications were a combination of lower respiratory infection and ongoing or worsening stenosis.

**Conclusions:** Balloon dilation increases the size of the airway intraoperatively and is associated with long-term increase in airway diameter. Safety outcomes mostly relate to ongoing or worsening stenosis and are more common in patients without a tracheostomy.

## 1 | INTRODUCTION

Stenosis (narrowing) of the airway encompasses a range of potentially life-threatening conditions that may be congenital or caused by prolonged or repeated airway intubation. Children with airway stenosis often experience difficulties with breathing, speaking or eating.[1] Such symptoms may require further intubation, leading to a cyclical problem. Surgical interventions for airway stenosis include cricoid split procedures, reconstructive laryngotracheal procedures and more commonly, tracheostomy. Endoscopic balloons offer a potential alternative or adjunct to open surgery.[2] In 2012, the National Institute for Health and Care Excellence (NICE) published Interventional Procedures Guidance which identified that safety and efficacy evidence for endoscopic balloon dilatation for subglottic or tracheal stenosis was lacking in quantity and quality.[3] The guidance recommended that clinicians wishing to conduct the procedure should do so under special arrangements for clinical governance, audit and consent, including national data collection.

In response to this NICE guidance, the Airway Intervention Registry (AIR) was developed, enabling UK data collection for ENT/respiratory procedures conducted on children.[4] This study reports results from the AIR, to determine whether balloon dilatation procedures in the treatment of paediatric airway stenosis are effective and safe, in a National Health Service (NHS) setting.

**Keypoints**

- A total of 133 balloon procedures conducted during 128 hospital visits in 59 paediatric patients with airway stenosis were recorded in the Airway Intervention Registry.
- 88% of visits were for the sole and primary treatment for stenosis, 50% with a tracheostomy in place.
- Balloon dilatation was associated with increase in airway diameter over time, but this was not compared with increases due to natural growth.
- Procedural success (defined as not requiring tracheostomy and avoiding open airway surgery) was achieved in 88% of patients without tracheostomy undergoing primary treatment of stenosis.
- In-hospital complications occurred in 8/133 balloon dilatation procedures (6%). However, there is no long-term adverse safety signal.

## 2 | MATERIALS AND METHODS

### 2.1 | Ethical considerations

Favourable opinion was received from the Newcastle & North Tyneside 1 Research Ethics Committee on 29 December 2014 (REC reference: 14/NEC/1200).

### 2.2 | Data source

The AIR is hosted by The Newcastle upon Tyne Hospitals NHS Foundation Trust in collaboration with the British Association for Paediatric Otorhinolaryngology and NICE. Data submission commenced on 27 March 2015. This study was adopted onto the NIHR Clinical Research Network portfolio on 18 November 2016 (CPMS 32800).

The AIR records the following: clinical history, patient questionnaires, medical assessments, procedural details, post-procedure, discharge and hospital resource usage information (Supplementary Material 1). Data were extracted from the AIR for analysis on 3 October 2019.

### 2.3 | Study population

#### 2.3.1 | Inclusion criteria

Patients <18 years old with airway stenosis treated by balloon dilatation within an acute NHS hospital.

#### 2.3.2 | Exclusion criteria

Procedures conducted for indications other than airway stenosis and records with no balloon dilatation procedure data.

### 2.4 | Data cleaning

Balloon procedures were numbered consecutively for each patient based on the hospital procedure date. Interim analyses and data quality checks were conducted bi-monthly.

### 2.5 | Data coverage

Registry coverage was estimated by comparing the number of in-patient/day-case balloon procedures reported by NHS hospitals in England with the total number of airway balloon procedures recorded in the Hospital Episode Statistics (HES) Admitted Patient Care (APC) data set for the data collection period.[5] HES data (between 1 April 2015 and 31 March 2019 provisional data set) were interrogated using the clinical codes described in Supplementary Material 2. Pseudonymised data from the HES and the Office of National Statistics (ONS) mortality data set were supplied under DARS agreement DAR-NIC-17011-Z1B4J.

### 2.6 | In-hospital outcome measures

Efficacy outcome measures were as follows: intra-operative change in airway diameter (millimetres) and Cotton-Myer grade directly before and after the balloon dilatation intervention. Cotton-Myer grade was calculated using the measured airway

diameter compared with an age-related healthy cricoid anteroposterior diameter.[6] In the absence of a measured airway diameter, Cotton-Myer grade was estimated by the treating clinician. Safety outcome measures included in-hospital complications and in-hospital death. All reported complications were clinically reviewed and aggregated into an in-hospital complication rate. Secondary outcome measures were hospital resource usage, discharge to planned location and length of stay.

### 2.7 | Longer-term outcome measures

The AIR and HES were pseudonymously linked on treating hospital, patient gender, age, procedure, admission and discharge dates to create longitudinal records for registry patients. Each patient was followed from the date of their earliest balloon dilatation procedure until either the 31 March 2019 (if matched to HES), the latest date in the registry for the patient (if unmatched to HES), or date of death, if sooner.

Outcomes from the AIR were changed in airway diameter over time, and all reported post-procedural complications. Secondary outcome measures included hospital resource usage and subsequent airway intervention. Outcomes from HES were subsequent hospital admissions, further respiratory surgical intervention (Supplementary Material 3) and in-hospital deaths. For those patients successfully matched to HES, all-cause mortality was extracted from ONS.

Overall procedural success at the end of the study was defined as avoidance of surgical intervention (*eg* laryngotracheal reconstruction or tracheostomy insertion) for those with no tracheostomy present at the time of the index balloon procedure and maintained decannulation for those with tracheostomy in place.[7,8] Subgroup analysis of overall procedural success was conducted for patients undergoing primary treatment of stenosis and those undergoing adjunctive treatment post-reconstructive surgery.

### 2.8 | Statistical analysis

All scripts for applying eligibility criteria, data cleaning, processing and statistical analysis were written in the statistical programming language R.[9]

Patient characteristics, clinical history and complications were summarised using descriptive statistics. Repeated-measures models (taking into account the random effect of some patients having multiple balloon procedures over time) were used to test for intra-operative changes in airway diameter with confidence intervals and significance-level derived using a parametric bootstrap hypothesis test with a generalised likelihood ratio test statistic.[10] Cotton-Myer grades before and after the balloon dilatation procedure (in-hospital) were compared using Fisher's exact tests.[11]

## 3 | RESULTS

### 3.1 | Cohort for analysis

A total of 65 patients were entered into the AIR database; five patients did not have any recorded information regarding the balloon dilatation intervention, and one procedure was conducted for indications other than airway stenosis (Supplementary Material 4). The remaining 59 patients had a total of 133 balloon procedures during 128 separate hospital visits, at 10 treating centres.

### 3.2 | Data coverage

A total of 247 hospital admissions (212 balloon dilatations of subglottic stenosis, 35 balloon dilatations of tracheal stenosis) in 170 paediatric patients were identified in the HES APC data set using the recommended clinical coding advised in NICE IPG425. This would give an estimated registry coverage of 51% (125/247). More generally, 2370 hospital admissions from 1164 paediatric patients were identified using generic respiratory procedure codes ("E" chapter in OPCS) supplemented by a dilatation of organ "Y40" OPCS code (Supplementary Material 4), and we cannot exclude the possibility that some of these were eligible procedures not coded using NICE recommendations.

### 3.3 | Patient characteristics

Characteristics of the 59 eligible patients are summarised in Table 1. Fifty patients (85%) had a history of prolonged intubation (admitted to intensive care unit [ICU] > 24 hour), and 16 (27%) had a history of difficult/traumatic intubation. No Voice Handicap Index[12] and nine general quality of life questionnaires were entered into the AIR.

### 3.4 | Procedures

Characteristics of the 133 registry procedures are summarised in Table 2; 31 patients had a single balloon dilatation procedure, 13 had two, five had three, five had four, and five patients had five or more (maximum of nine balloon dilatation procedures in one patient). A total of 69 (52%) balloon procedures were conducted with a tracheostomy in place, 50 (38%) alongside cold steel or laser incisions, 79 (59%) in combination with steroid treatment, 35 (26%) alongside concomitant procedures (such as cyst, granulation or scar tissue removal, web division, stent insertion, endoscopic cricoid split, endoscopic posterior cartilage graft, laryngotracheal reconstruction with cartilage, recurrent respiratory papillomatosis debridement, suture lateralisation of vocal cord, triamcinolone injection) and 15 (11%) as adjunctive/secondary treatment after open reconstruction surgery.

**TABLE 1** Patient characteristics for all eligible patients

| | All eligible patients (n = 59) |
|---|---|
| Male | 36 (61%) |
| Age, y | |
| Neonates (<1 y) | 21 (36%) |
| Toddlers (1-2 y) | 7 (12%) |
| Children (3-11 y) | 28 (47%) |
| Adolescents (12-18 y) | 3 (5%) |
| Ethnicity | |
| Caucasian | 45 (76%) |
| Asian | 7 (12%) |
| Black | 5 (9%) |
| Other | 2 (3%) |
| Gestation at birth (wk) | |
| <25 | 12 (20%) |
| 25-29 | 16 (27%) |
| 30-36 | 8 (14%) |
| 37+ | 23 (39%) |
| No. of previous intubations | |
| 0 | 1 (2%) |
| 1-2 | 16 (27%) |
| 3-5 | 15 (25%) |
| 5+ | 15 (25%) |
| Comorbidities[a] | |
| Chronic lung disease | 29 (49%) |
| Reflux | 17 (29%) |
| Recurrent lower respiratory infection | 5 (9%) |
| Other | 26 (45%) |
| None | 10 (17%) |
| Weight, kg[b,c] median (Q1,Q3) [range] | 11.2 (7.5,15.5) [3.0-57.0] |
| Medications at time of assessment[a,b] | |
| Anti-reflux | 43 (34%) |
| Antibiotics (prophylactic) | 26 (20%) |
| Other | 28 (22%) |
| None | 49 (38%) |

[a]Multiple choices permitted.
[b]Recorded per hospital visit (n = 128).
[c]Influence on balloon size.

**TABLE 2** Characteristics of balloon dilatation procedures

| | All balloon procedures (n = 133) |
|---|---|
| Stenosis location | |
| Glottis | 27 (20%) |
| Subglottis | 105 (79%) |
| Trachea | 1 (1%) |
| Stenosis type | |
| Oedema and granulations only | 17 (13%) |
| Soft or immature scar tissue | 66 (50%) |
| Hard, firm or mature scar tissue | 49 (37%) |
| Laryngeal web | 1 (1%) |
| Cause of stenosis[a] | |
| Intubation or ICU care | 100 (75%) |
| Prematurity | 54 (41%) |
| Congenital | 20 (15%) |
| Infection | 5 (4%) |
| Secondary to tracheostomy | 1 (1%) |
| Other | 19 (14%) |
| Airway diameter, mm median (Q1,Q3) [range] | |
| Glottis (n = 9) | 4.2 (4.0,4.8) [2.0-4.8] |
| Subglottis (n = 81) | 4.2 (3.5,5.4) [1.0-8.0] |
| Upper trachea (n = 1) | 6.0 (6.0,6.0) [6.0-6.0] |
| Cotton-Myer grade | |
| 1 | 39 (40%) |
| 2 | 32 (33%) |
| 3 | 26 (27%) |
| 4 | 0 (0.0%) |
| Balloon catheter diameter (n = 126), mm median (Q1,Q3) [range] | 7 (7,8) [4-10] |
| Balloon catheter length (n = 72), mm Median (Q1,Q3) [range] | 40 (24,40) [10-55] |
| Balloon pressure (n = 101), median (Q1,Q3) [range] | 10 (7,12) [3-16] |
| No. of inflations (n = 112), median (Q1,Q3) [range] | 2 (2,2) [1-5] |
| Average duration of individual dilatations (n = 100), s median (Q1,Q3) [range] | 60 (60,60) [2-120] |
| Topical Mitomycin C | 2 (1%) |
| Length of stay, days (n = 90)[b] median (Q1,Q3) [range] | 0.5 (0,1) [0-19] |

[a]Multiple choices permitted.
[b]Calculated per hospital visit (n = 128).

### 3.5 | In-hospital outcomes

Seventy paired measurements of airway diameter (*ie* before and after a balloon procedure) were recorded from 39 patients (Figure 1). The starting airway diameter, stenosis type (oedema, soft and hard), Cotton-Myer grade (pre-balloon) and procedure number were not associated with intra-operative change in subglottic airway diameter (Supplementary Material 5-8). Of the 76 procedures with Cotton-Myer grade reported both before and after the procedure, a decrease in Cotton-Myer grade (*ie* immediate reduction in airway stenosis) was documented in 43 (57%), and the Cotton-Myer grade was unchanged in 33 (43%).

The anticipated and actual discharge location was recorded in 127 balloon visits, with 94% going to their expected discharge location; 4 procedures with no tracheostomy resulted in an unplanned ICU visit with intubation, three procedures with no tracheostomy

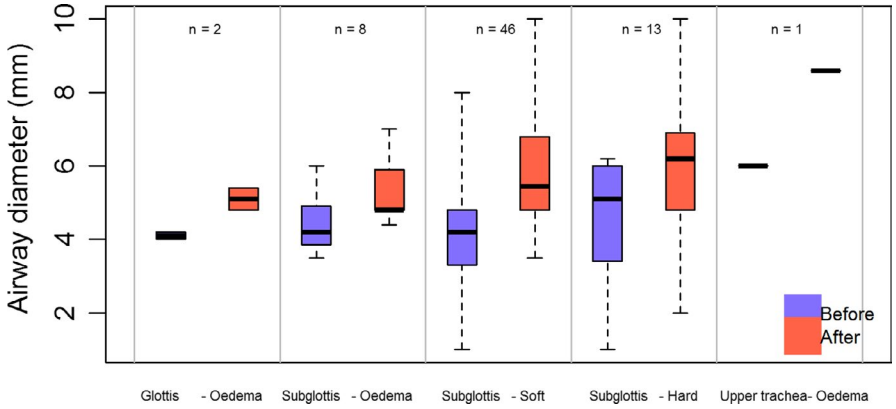


**FIGURE 1** Airway diameters before and after balloon dilatation procedure (in-hospital) by stenosis location and type

required an unplanned high-dependency unit (HDU) visit without intubation and one patient with a tracheostomy was admitted to ward (rather than anticipated HDU).

In-hospital complications were reported in 11 hospital visits where a balloon dilatation procedure was conducted, three of which were excluded following clinical review as they were not considered to be a complication of the procedure (Supplementary Material 9). Of the 64 balloon dilatation visits with a tracheostomy in place, one reported an in-hospital complication (lower respiratory tract infection). Of the 64 balloon dilatation visits without a tracheostomy, seven reported complications (five airway obstruction, one emergency tracheostomy and one staged tracheostomy with prolonged intubation). The increased odds of experiencing a complication without a tracheostomy (versus with) were not significant, odds ratio 7.7 [95% CI 0.9 to 64.8] and $P = .06$.

### 3.6 | Long-term outcomes

Follow-up information from the registry (after the first recorded balloon admission) was available in 40 (68%) patients making 119 subsequent hospital visits (including 69 balloon and 50 non-balloon visits). A total of 45 (76%) patients from the AIR were linked to HES APC. Of these, 43 patients were readmitted a total of 500 times (median eight readmissions per patient). The total patient follow-up (across the two data sources) was 45,495 days, with a median follow-up duration of 869 days per patient (Q1:Q3 232:1152) [range 0 to 1511], during which 33 patients (56%) had additional balloon dilatations. No deaths were reported for matched patients in ONS.

A total of 91 measurements of subglottic diameter were entered into the AIR for 30 patients during follow-up (20 male, median age 1.4 years, 53% with tracheostomy present, 77% with soft/oedema stenosis, 80% with stenosis following intubation). The mean pre-balloon subglottic diameter was 4.2 [95% CI: 3.8 to 4.5] mm, and its rate of increase was 0.8 [0.5 to 1.2] mm per year ($P < .001$) (Figure 2).

Of the 59 patients having balloon dilatation procedures, 19 out-of-hospital complications occurring in 12 patients were recorded in AIR. This included one death which was deemed unrelated to the balloon dilatation procedure by the treating clinician. Following clinical review, six were deemed related to the efficacy of the balloon dilatation procedure, one related to safety (airway obstruction and lower respiratory tract infection 4 days post-balloon), one related to safety and efficacy (prolonged intubation due to LRTI, additional balloon and endoscopic anterior cricoid split 9 days post-balloon) and the remaining 11 reported outcomes deemed unrelated to the balloon procedure (and likely due to natural history of stenosis), Supplementary Material 10.

From HES, approximately half the cohort (29/59 patients) were readmitted to hospital a total of 83 times within 30 days of a balloon dilation procedure (Supplementary Material 11). Thirty-two of these readmissions within 30 days (39%) were related to airway stenosis.

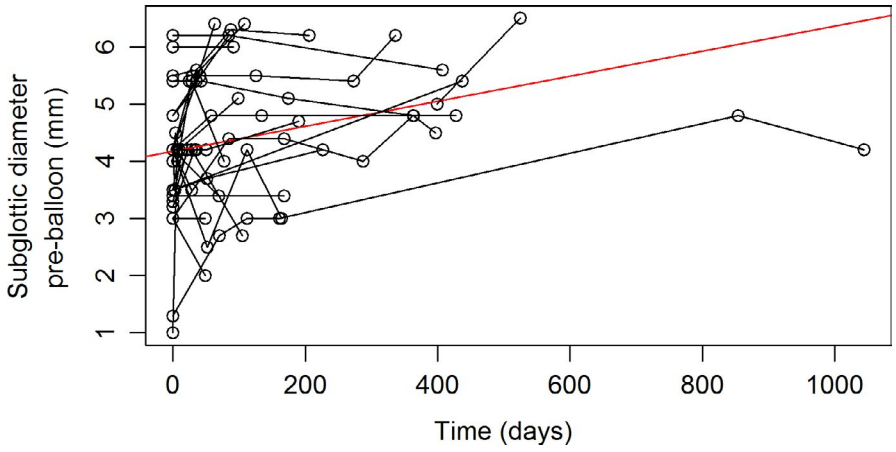


**FIGURE 2** Subglottic airway diameter over time for 30 patients. [Key: circles indicate individual pre-balloon airway diameter measurements, circles connected with a solid line indicate measurements from an individual patient, and the solid red line indicates the overall population increase in subglottic airway diameter over time generated from the linear mixed model fit taking into account multiple measurements in each patient]

### 3.7 | Overall success

Overall procedural success rate in patients undergoing balloon dilatation as the primary treatment of stenosis (n = 52) was 65% (22% in the presence of tracheostomy, 88% in those with no tracheostomy), and 71% in those patients undergoing balloon dilatation as an adjunctive treatment subsequent to open reconstructive surgery (n = 7; Figure 3).

## 4 | DISCUSSION

### 4.1 | Synopsis of key findings

The children having balloon dilatation captured in the AIR were a high-risk population: 61% were born prematurely; 51% had three or more intubations, 49% had chronic lung disease, and 12% had adjunctive treatment post-laryngotracheal reconstruction.

In terms of safety, clinically verified in-hospital complications occurred in 8/133 balloon dilatation procedures (6%). Our study suggests that the rate of complication in those without a tracheostomy exceeded the rate in those with, but our study was too small to show this conclusively. Pending further evidence, a precautionary approach would be to conduct balloon dilatation in large acute hospitals with paediatric intensive care facilities.

In terms of efficacy, our study of 59 patients demonstrates a significant immediate reduction in Cotton-Myer grading of stenosis in approximately half of patients and a longer-term increase in mean subglottic diameter of 0.8 mm/y. The majority of patients underwent multiple balloon dilatations and other endoscopic procedures to maintain their airway, throughout the duration of this study (one patient having up to nine dilatations).

When considering overall procedural success, for patients undergoing balloon dilatation as the primary treatment of stenosis the success rate was 86% in the subgroup of patients who did not have a tracheostomy in place at the time of the balloon. This is likely due to this population having softer and lower Cotton-Myer grade stenoses. Success rates were lower in the tracheostomy group, but balloon dilatation did enable 22% to be successfully decannulated by the end of the study. However, procedural success is a crude outcome measure determined at the end of the study and may not reflect the final outcome for each child, whose pathway may extend beyond this time.

### 4.2 | Strengths of the study

Our study represents the largest multi-centre prospective study of balloon dilatation in treatment of laryngotracheal stenosis in the UK. Good clinician engagement with the AIR was achieved, with a high volume of registered users and centres thus enabling collection of rich data (not routinely available from administrative data).

### 4.3 | Comparisons with other studies

Previously published evidence on the efficacy of balloon dilatation in the treatment of laryngotracheal stenosis in children is limited to retrospective case reviews and case reports. One systematic review, including seven case series and 150 patients, estimated the overall treatment success (avoidance of tracheostomy or laryngotracheal reconstruction) as 65% (95% CI 60 to 71%) over short-term follow-up of 7 months and mean number of 1.9 dilatation procedures per patients during that time.[8] Another systematic review determined procedural success in achieving a functional airway without open surgery or tracheostomy for balloon and rigid dilatation separately.[7] This reported an overall success rate of 50% in studies using balloon dilatation alone (six case studies, n = 10 patients) and between 50% and 78% in studies using balloon dilatation with an adjuvant therapy including $CO_2$ or KTP laser, topical or intra-lesional steroid (six studies, n = 24 patients). Lastly, this systematic review calculated morbidity and mortality rates associated with dilatation of 14% and 1%, respectively; however, this combines results from both balloon and rigid dilatation.

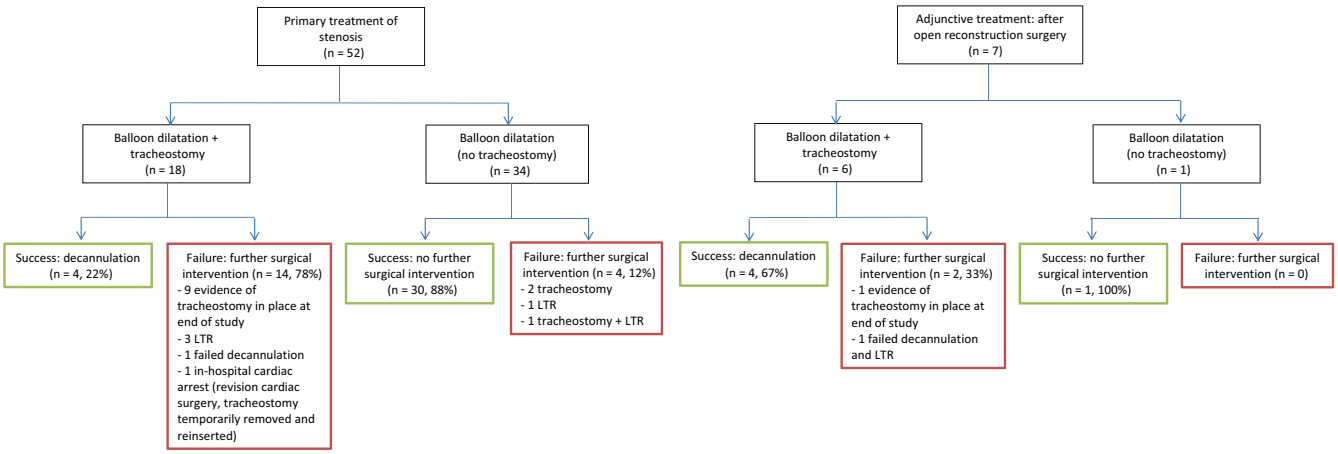


**FIGURE 3** Overall procedural success and clinical outcomes for all balloon dilatation patients (n = 59) using follow-up from the Airway Intervention Registry and administrative data from Hospital Episodes Statistics

Retrospective reviews have reported up to 33 balloon procedures in a single patient,[13] and a ten-year retrospective review in the UK found that 148/166 patients (89%) required multiple balloon procedures.[14] In our study, 56% of patients (33/59) had multiple balloon procedures to maintain the airway. Therefore, balloon dilation is one modality which should be considered as part of a series of interventions and form part of a management plan.

### 4.4 | Clinical applicability of the study

Short-term efficacy evidence demonstrates a significant increase in subglottic airway diameter, which is independent of pre-balloon Cotton-Myer grade, airway diameter, stenotic type and balloon procedure number. Some patients show a clear benefit in increased airway following balloon dilatation which is sustained over time; however due to heterogeneity in patients (ie tracheostomy status, prematurity, stenotic type soft/hard and congenital cause), we did not identify particular patient characteristics that predicted benefit. Additionally, our study did not have enough information to determine change in patient quality of life.

The long-term increases in airway diameter found in this study were not compared with the increases expected due to natural growth;[6] however, the natural history of progression of airway stenosis is not well understood. It cannot be assumed that stenosis will progressively widen with the general growth of the child. In many cases, soft stenosis will worsen over time and result in a firmer and narrower stenotic segment. Therefore, demonstration of a significant and sustained increase in airway diameter in this complex population over time does add to the evidence base for the procedures. However, one needs to consider the high likelihood of multiple balloon procedures and the requirement for adjunctive treatments to maintain the airway.

The prospective AIR database was set up to capture safety and efficacy evidence for balloon dilatation procedures, and by conducting pseudonymised linkage to administrative data, we have been able to demonstrate both short- and long-term safety and efficacy to support the use of balloon dilatation in the treatment of subglottic stenosis.

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## CONFLICT OF INTEREST

None to declare.

## AUTHOR CONTRIBUTIONS

All authors contributed to the concept and design of the study. Kim Keltie managed the registry, analysed its data and conducted the Hospital Episode Statistics analysis. All authors contributed to the interpretation of data. All authors contributed to the writing of the manuscript. Final approval of the manuscript was provided by all authors.

## DATA AVAILABILITY STATEMENT

Any external researchers requesting data from the Airway Intervention Registry will be required to submit a formal application form. Only formal applications with appropriate ethical approvals in place (reviewed by an independent Ethics Committee) will be reviewed by the established AIR Steering Group committee. If approval is given, only anonymised data will be shared for the purposes of external research studies.

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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