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Areas for quality improvement for airway dilation in children: NSQIP-pediatric 30 day outcomes

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Abstract

Objective: Identify predictors of adverse events and highlight areas for quality improvement for children who underwent laryngeal or tracheal dilation, without prior tracheostomy placement.

Study design: Cross-sectional analysis using a US national database.

Setting: American College of Surgeons (ACS) National Surgical Quality Improvement Program® (ACS NSQIP® - pediatric), years 2012 – 2015.

Subjects and Methods: Patients aged 18 years and less were included. Patients without prior tracheostomy placement were identified using 2017 current procedural terminology (CPT) codes: 31528, 31529, and 31630.

Results: We identified a total of 160 children who met inclusion criteria. 43 (26.9%) patients experienced an adverse event. Mortality was observed postoperatively in one patient (0.6%), one day after the operation. Younger age, increased number of days from hospital admission to operation, and increased number of days from operation to discharge were noted to be associated with adverse events. Lastly, the risk of adverse events appears to be mitigated by concurrent other laryngeal procedures.

Conclusions: There is a high rate of adverse events reported with airway dilation in children. Unplanned reoperations and hospital readmissions are highlighted areas for quality improvement. Airway dilation in children appears to avoid tracheostomy and open laryngotracheoplasty in most cases for at least 30 days postoperatively. Further investigation may be helpful to understand if younger age and delayed operative intervention contributes to increased adverse events.

Keywords

laryngeal dilation; subglottic stenosis; tracheal stenosis; tracheal dilation; NSQIP; pediatric; quality improvement

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Conflicts of interest

The American College of Surgeons National Surgical Quality Improvement Program and the hospitals participating in the ACS NSQIP are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

Introduction

Management of laryngeal and tracheal stenosis in the pediatric population has undergone a significant paradigm shift in the past decade. Balloon dilation/laryngoplasty techniques have crossed over from the treatment of percutaneous interventional cardiovascular disease treatment into the mainstream for use in treatment of airway stenosis in children, particularly in the anatomic region of the glottis and subglottis. One of the first case series to describe the efficacy of balloon laryngoplasty by Durden and Sobol revealed that this technique could be used as a primary intervention for acquired subglottic stenosis in children 2 to 12 months of age and potentially obviate the need for tracheotomy placement or open laryngotracheoplasty (LTP) procedures.¹ Wentzel et al also reported similar findings for laryngeal stenosis in children with balloon dilation and concluded that it was a highly effective alternative compared to other traditional LTP options, with an overall success rate ranging from 64% to 77%.² A systematic review of the literature by Lang and Brietzke also demonstrated low complication rates, as well as Hautefort et al for both primary and secondary laryngeal stenosis.^{3,4} Adverse events related to dilation have not been thoroughly investigated in national databases, and thus, there may be a gap in our understanding.

As dilation has become routinely employed for airway disorders, we sought to provide further information about this technique through the use of a national database. The objective of this work is to identify deficiencies in clinical outcomes to highlight areas for quality improvement and risk factors for adverse events.

Methods

The American College of Surgeons (ACS) has developed a hospital based reporting system called the ACS National Surgical Quality Improvement Program® (ACS NSQIP®). This database was created to enhance identification of surgical morbidity and mortality and potentially preventable complications. Data are collected from the patient's medical chart, not insurance claims; risk-adjusted; case-mix adjusted; and reports 30-day patient outcomes. Starting in 2012, children's hospitals began using this database and reporting results in the ACS NSQIP-pediatric® database. This data repository includes 84,056 observations from 80 sites in 2015; 68,838 observations from 64 sites in 2014; 63,387 observations from 56 sites in 2013; and 51,008 observations from 50 sites in 2012. This database presents a unique opportunity to examine clinical factors that may be associated with adverse events related to airway dilation procedures in children. Duke University Institutional Review Board (IRB) approval exemption was obtained prior to initiating this investigation.

Inclusion criteria included children aged 18 years and younger. Patients without prior tracheostomy placement were identified using 2017 current procedural terminology (CPT) codes. The following CPT codes were included: 31528 (laryngoscopy, direct with dilation, initial), 31529 (laryngoscopy, direct with dilation, subsequent), and 31630 (bronchoscopy, flexible or rigid, with tracheal/bronchial dilation or closed reduction of fracture). The NSQIP-pediatric contains a variable denoting the presence or absence of a tracheostomy. Patients who underwent concurrent tracheostomy were also excluded.

Categorical variables are summarized with frequency counts and percentages, whereas continuous variables are described with means, standard deviations, and relevant quantiles. Comparisons based on grouping patients who experienced adverse events and those who did not, were evaluated through the Fisher Exact test or Wilcoxon sum rank test. Bonferroni correction method was used to account for the family-wise error rate when multiple comparisons were conducted. Adverse events were defined as death, reoperation, readmission, and prolonged hospital stay (> 30 days after surgery). The Chi-squared test was employed to evaluate the association between adverse events and concurrent laryngeal (injection laryngoplasty or excision of lesion) or other procedures (GI, urology, or orthopedic). The threshold for assessing statistical significance was set at α level = 0.05. Statistical analyses were conducted using SAS 9.4 (SAS Institute Inc., Cary, NC).

Results

We identified a total of 160 children who met inclusion criteria (124 from 2015; 24 from 2014; 5 from 2013; and 7 from 2012). At least one unplanned reoperation occurred in 15 (9.4%) patients. Eleven (78.6%) of the unplanned reoperations were related to the primary airway dilation procedure. Included operative codes for the first revision procedure included repeat dilation in five (33.3%) and tracheostomy placement in two (13.3%). Readmission occurred in 22 (13.8%) patients. Mortality was observed in one patient (0.6%) postoperatively and occurred one day after the operation. 16 (10.0%) patients were still in the hospital more than 30 days after the operation.

Patients were divided into two groups, depending on whether or not they had adverse events (reoperation, readmission, death, and prolonged hospitalization) after airway dilation. 43 (26.9%) patients had an adverse event recorded and a summary for adverse events can be found in Table 1. Demographic and clinical risk factors examined for association with adverse events are listed in Table 2. Summary of demographic and clinical risk factor information for the children who had airway dilation can be found in Tables 3 and 4. After adjustment, younger age was noted to be significant, adjusted p-value < 0.003, along with days from admission to operation and days from operation to discharge. The median age of patients without adverse events was 2.1 years, whereas the median age of patients with adverse events was 4.8 months. The median time for patients from hospital admission to operation without adverse effects was 0.0 days, whereas the median time for those with adverse effects was 1.0 days. The median time for patients without adverse events from operation to discharge was 1.0 day, compared to 2.0 for those who had an adverse event. Remaining clinical and demographic factors were not observed to confer any increased risk for adverse events.

62 patients had concurrent laryngeal procedures (injection laryngoplasty or excision of lesion), 9 (14.5%) of whom had adverse events. Decreased adverse events were noted in those children who had concurrent laryngeal procedures ($p = 0.005$). 28 patients had concurrent other procedures (GI, urology, and orthopedic). 7 (25.0%) had adverse events but no association was noted.

Discussion

Endoscopic balloon dilation does not seem to be beneficial for all cases of subglottic stenosis in children and may present some harm. Maresh et al reported that in cases of severe subglottic stenosis endoscopic balloon dilation had limited effectiveness and favored use of LTP in those cases, as they observed an increased risk of unplanned urgent interventions with balloon dilation when compared to LTP.⁵ Increased severity of subglottic stenosis was also noted to be a risk factor for failure in other investigations but not all.^{4,6} Furthermore, serious adverse events have been reported with endoscopic balloon dilation including acute and complete airway obstruction.⁷

Prior investigations of pediatric airway dilation have been retrospective in nature, either in the form of institutional experience with consecutive case series with chart review or systematic literature review. No prospective studies have been reported at this time, but the NSQIP-pediatric is a national, prospective, database gathering information initiative, which may better represent national trends and reduce some of the biases that may be inherent to single-center observational studies. This provides a unique tool and opportunity to further investigate airway dilation in children on a broader scale, so that clinical risk factors that are associated with increased risks for adverse events may be identified as well as areas for quality improvement. Currently, we do not have an established understanding of which pediatric patients are at the greatest risk for complications or treatment failure.

The NSQIP-pediatric database is now a widely recognized quality improvement project but has significant shortcomings when interrogating the database to make interpretations for clinical application and decision making. We feel that the strengths of our findings lie in identification of areas for quality improvement in treating children with airway dilation, such as unplanned reoperations and unplanned readmissions. We observed an unplanned reoperation and readmission rate of 9.4% and 13.8%, respectively; this appears to be quite high with significant room for improvement. It is important to note that this result is from national level data and not applicable to any individual medical center. Unplanned reoperation rates may be artificially inflated, as this may be related to coding discrepancies, as planned surveillance or repeat dilation may be relatively routine. However, if there was a planned follow up dilation or other surveillance procedure, and this was not clearly indicated in the documentation, then this would have been recorded as an unplanned reoperation, which is a fundamental shortcoming of using this database. Another area for potential quality improvement and further investigation is why we observed a significantly high percentage of children who were still hospitalized greater than 30 days postoperatively (10.0%). This raises the question of whether or not there are continued attempts at dilation to avoid tracheostomy or other open airway procedure, and the child may be better managed with another strategy. However, this may also be explained if the patients had other significant medical comorbidities, and the prolonged hospitalization was not necessarily related to their airway problem.

Younger children were noted to be associated with adverse events. These may represent more medically fragile children. Also of note, it does not seem that prematurity conferred any increased risk of association with adverse events. Other potentially clinically interesting

comorbidities and clinical factors that we found to have an association with adverse events also included time from admission to operation and time from operation to discharge. This is likely the result of severity of disease, as those children who were sicker, may have needed more time to medically improve after operative intervention, which may not be a controllable or preventable risk factor. However, one of our other findings was an increased adverse event rate for children who had delay in operation from the time of hospital admission to surgery. This could be explained in two different ways. One, those with more severe clinical disease needed to be medically stabilized prior to operative intervention; thus, they are intrinsically more susceptible to adverse events. However, this may also be explained by delaying operative intervention in the appropriate child, this allowed the child's clinical status to decline and was the primary driver for the increased association with adverse events. As the current NSQIP-pediatric data was insufficient to perform a multivariate analysis, we can not be certain that these were independent risk factors. Our investigation was potentially underpowered to detect a statistically significant difference for other risk factors; however, given the size of included cases, the actual difference between statistically significant thresholds may be small and not clinically relevant. Further investigation is warranted to examine if delay in operative intervention for airway dilation actually contributes to increased adverse events.

Interestingly, performing concurrent laryngeal procedures appeared to be protective against adverse events. It is unclear as to why this was observed, but may be an area for further investigation for quality improvement to assess if concurrent laryngeal intervention may be helpful in improving the clinical outcomes for airway dilation in children. Furthermore, concurrent other procedures did not appear to increase the risk for adverse events.

With an occurrence of less than 1%, mortality was rare. However, it may be of clinical interest to note that this occurred 1 day postoperatively. This perhaps highlights the importance of close monitoring and surveillance in the immediate perioperative time period. It also appears that airway dilation can be effective at delaying tracheostomy placement for at least 30 days. Laryngotracheoplasties may have been performed after this time window and be missed in our investigation. This may be an underestimate, as clinical outcomes are only recorded 30 days postoperatively.

Significant limitations exist in our study. There is an inherent inability to track individual patient outcomes to help develop recommendations for patient selection. Severity of disease and clinical presentation for individual cases could not be ascertained using this database approach, thus, this may have affected which patients were selected for an airway dilation procedure, as opposed to another open airway procedure, such as tracheotomy placement. Our investigation is limited by the definitions and data captured by the NSQIP-pediatric, and in the future, there may be more procedure specific quality outcomes that may be of clinical importance, such as dilation technique and device size used. Included patients in the database may not also accurately describe the general population, as the NSQIP-pediatric only includes participating institutions. As mentioned before, the data are subject to variation based on participating institutions and data that are extracted by codes, which may be subject to inaccuracies based on the documentation available for review. Also, in our current investigation, the dilation CPT codes that we selected to identify patients do not

include the particular technique for laryngeal dilation, and there is no specific procedural code for subglottic stenosis balloon dilation, so we could not make any inferences regarding surgical technique. The primary focus of our findings is to highlight areas of potential quality improvement and not necessarily make recommendations about individual clinical decisions, as these must be made on a case by case basis. However, this is the first of this type of investigation to examine adverse events using the NSQIP-pediatric related to laryngeal and tracheal dilation in children and may serve as a starting point for further discussion and investigation for optimizing clinical outcomes and identifying areas to examine further to identify areas for improvement. We believe that our findings are important, as they confirm prior reports laryngeal and tracheal dilation procedures in children are safe. Our findings may not be generalizable or clinically applicable to management decisions for individual cases, but we have identified potential areas for improvement, especially in reducing unplanned reoperation and readmission rates and further investigation into whether delayed in airway dilation contributes to increased adverse events.

Conclusions

Airway dilation in children appears to avoid tracheostomy and open laryngotracheoplasty in most cases for at least 30 days postoperatively but may be associated with high rates of adverse events. Mortalities were rare. Clinical risk factors and comorbidities associated with adverse events include younger age, days from hospital admission to operation, and days from operation to discharge. It is unclear at this time if these are independent or dependent risk factors. Areas for quality improvement and further study include reducing unplanned reoperations and readmission rates, as well as trying to understand if younger age and delayed operative intervention contributes to increased adverse events.

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Table 1.

Summary of adverse events reported with airway dilation in children.

Adverse event	No. (%)
Unplanned reoperation	15 (9.4)
Readmission	22 (13.8)
Mortality	1 (0.6%)
Prolonged hospitalization (> 30 days)	16 (10.0%)

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Table 2.

Risk factors assessed for associated with adverse events related to pediatric airway dilation.

Demographic and clinical risk factors
Gender
Age
Ethnicity
BMI
Premature birth
Ventilator dependence
Diabetes
Current pneumonia
History of asthma
Bronchopulmonary dysplasia/chronic lung disease
Oxygen support
Cardiac risk factors
Previous cardiac surgery
Stroke or traumatic/acquired brain injury
Developmental delay/impaired cognitive status
Seizure disorder
Cerebral palsy
Neuromuscular disorder
Intraventricular hemorrhage grade
Steroid use
Weight loss or failure to thrive
Nutritional support
Chemotherapy for malignancy within 30 days
Sepsis/septic shock within 48 hours prior to surgery
Congenital malformation
Case status (elective, emergent, urgent)
Days from hospital admission to operation
Days from operation to discharge
Total days of mechanical ventilation

Table 3.

Demographic information for children who underwent airway dilation.

Variable	Adverse effects		Total (N=160)	Unadjusted p-value	Adjusted p-value
	No (N=117)	Yes (N=43)			
Gender				0.1493 ¹	1.0000
Female	46 (39.3%)	23 (53.5%)	69 (43.1%)		
Male	71 (60.7%)	20 (46.5%)	91 (56.9%)		
Race				0.5492 ¹	1.0000
Black or African American	28 (23.9%)	14 (32.6%)	42 (26.3%)		
Others	15 (12.8%)	5 (11.6%)	20 (12.5%)		
White	74 (63.2%)	24 (55.8%)	98 (61.3%)		
Hispanic Ethnicity				0.0213 ¹	0.5964
Missing	5 (.%)	0 (.%)	5		
No	86 (76.8%)	40 (93.0%)	126 (81.3%)		
Yes	26 (23.2%)	3 (7.0%)	29 (18.7%)		
Age in year				<0.0001 ²	<0.0028
N	117	43	160		
Mean (SD)	4.9 (5.2)	2.7 (4.7)	4.4 (5.2)		
Median	2.1	0.4	1.4		
Q1, Q3	0.8, 8.3	0.2, 1.8	0.5, 7.5		
Range	(0.0–17.9)	(0.0–17.3)	(0.0–17.9)		
BMI				0.0293 ²	0.8204
N	110	38	148		
Mean (SD)	18.4 (4.3)	16.6 (4.2)	17.9 (4.3)		
Median	17.7	16.4	17.5		
Q1, Q3	15.4, 20.1	12.9, 18.4	15.2, 19.9		
Range	(11.2–38.1)	(10.6–27.1)	(10.6–38.1)		
Premature Birth				0.2778 ¹	1.0000
Missing	3 (.%)	2 (.%)	5		
No (>=37 weeks)	62 (54.4%)	18 (43.9%)	80 (51.6%)		
Yes (< 37 weeks)	52 (45.6%)	23 (56.1%)	75 (48.4%)		

¹Fisher Exact²Wilcoxon

Table 4.

Clinical risk factors assessed for children who underwent airway dilation.

Variable	Adverse events		Total (N=160)	Unadjusted p-value	Adjusted p-value ^I
	No (N=117)	Yes (N=63)			
Ventilator Dependence				0.0041 ^I	0.1148
No	114 (97.4%)	36 (83.7%)	150 (93.8%)		
Yes	3 (2.6%)	7 (16.3%)	10 (6.3%)		
Diabetes mellitus requiring therapy with non-insulin agents, or insulin				.	.
Missing	53 (.%)	17 (.%)	70		
No	64 (100.0%)	26 (100.0%)	90 (100.0%)		
Current Pneumonia				.	.
Missing	53 (.%)	17 (.%)	70		
No	64 (100.0%)	26 (100.0%)	90 (100.0%)		
History Asthma				0.3196 ^I	1.0000
No	98 (83.8%)	39 (90.7%)	137 (85.6%)		
Yes	19 (16.2%)	4 (9.3%)	23 (14.4%)		
Bronchopulmonary Dysplasia/Chronic Lung disease				0.1345 ^I	1.0000
No	95 (81.2%)	30 (69.8%)	125 (78.1%)		
Yes	22 (18.8%)	13 (30.2%)	35 (21.9%)		
Oxygen support				0.0172 ^I	0.4816
No	106 (90.6%)	32 (74.4%)	138 (86.3%)		
Yes	11 (9.4%)	11 (25.6%)	22 (13.8%)		
Cardiac risk factors				0.0228 ^I	0.6384
No	84 (71.8%)	22 (51.2%)	106 (66.3%)		
Yes	33 (28.2%)	21 (48.8%)	54 (33.8%)		
Previous cardiac surgery				0.3047 ^I	1.0000
No	103 (88.0%)	35 (81.4%)	138 (86.3%)		
Yes	14 (12.0%)	8 (18.6%)	22 (13.8%)		
CVA/stroke or traumatic/acquired brain injury with resulting neurological deficit				0.4966 ^I	1.0000
Missing	53 (.%)	17 (.%)	70		
No	63 (98.4%)	25 (96.2%)	88 (97.8%)		
Yes	1 (1.6%)	1 (3.8%)	2 (2.2%)		
Developmental delay/impaired cognitive status				0.2718 ^I	1.0000
No	90 (76.9%)	37 (86.0%)	127 (79.4%)		
Yes	27 (23.1%)	6 (14.0%)	33 (20.6%)		
Seizure Disorder				0.4463 ^I	1.0000
No	109 (93.2%)	42 (97.7%)	151 (94.4%)		
Yes	8 (6.8%)	1 (2.3%)	9 (5.6%)		

Variable	Adverse events		Total (N=160)	Unadjusted p-value	Adjusted p-value ^I
	No (N=117)	Yes (N=63)			
Cerebral Palsy				0.4665 ^I	1.0000
No	116 (99.1%)	42 (97.7%)	158 (98.8%)		
Yes	1 (0.9%)	1 (2.3%)	2 (1.3%)		
Neuromuscular Disorder				0.0845 ^I	1.0000
No	114 (97.4%)	39 (90.7%)	153 (95.6%)		
Yes	3 (2.6%)	4 (9.3%)	7 (4.4%)		
Intraventricular Hemorrhage (IVH) Grade				0.2349 ^I	1.0000
Grade 1	3 (2.6%)	0 (0.0%)	3 (1.9%)		
Grade 2	1 (0.9%)	0 (0.0%)	1 (0.6%)		
Grade 3	0 (0.0%)	2 (4.7%)	2 (1.3%)		
Grade 4	2 (1.7%)	1 (2.3%)	3 (1.9%)		
IVH reported but no grade assigned	1 (0.9%)	0 (0.0%)	1 (0.6%)		
No IVH reported	110 (94.0%)	40 (93.0%)	150 (93.8%)		
Steroid use (within 30 days)				0.0139 ^I	0.3892
No	100 (85.5%)	29 (67.4%)	129 (80.6%)		
Yes	17 (14.5%)	14 (32.6%)	31 (19.4%)		
Weight loss or failure to thrive				1.0000 ^I	1.0000
Missing	93 (.%)	31 (.%)	124		
No	21 (87.5%)	11 (91.7%)	32 (88.9%)		
Yes	3 (12.5%)	1 (8.3%)	4 (11.1%)		
Nutritional support				0.0058 ^I	0.1624
No	101 (86.3%)	28 (65.1%)	129 (80.6%)		
Yes	16 (13.7%)	15 (34.9%)	31 (19.4%)		
Chemotherapy for malignancy within 30 days				0.2889 ^I	1.0000
Missing	53 (.%)	17 (.%)	70		
No	64 (100.0%)	25 (96.2%)	89 (98.9%)		
Yes	0 (0.0%)	1 (3.8%)	1 (1.1%)		
SIRS/Sepsis/Septic Shock within 48 hours prior to surgery				0.0188 ^I	0.5264
None	116 (99.1%)	39 (90.7%)	155 (96.9%)		
SIRS	1 (0.9%)	4 (9.3%)	5 (3.1%)		
Congenital Malformation				0.4816 ^I	1.0000
No	62 (53.0%)	20 (46.5%)	82 (51.3%)		
Yes, Neonate >=1500 grams at the time of surgery or infant/child/teenager with a history of a congenital defect at the time of surgery	55 (47.0%)	23 (53.5%)	78 (48.8%)		
Case Status				0.0037 ^I	0.1036
Elective	104 (88.9%)	29 (67.4%)	133 (83.1%)		
Emergent	4 (3.4%)	6 (14.0%)	10 (6.3%)		

Variable	Adverse events		Total (N=160)	Unadjusted p-value	Adjusted p-value ¹
	No (N=117)	Yes (N=63)			
Urgent	9 (7.7%)	8 (18.6%)	17 (10.6%)		
Days from Hospital Admission to Operation				<0.0001 ²	<0.0028
N	117	43	160		
Mean (SD)	3.9 (19.6)	13.9 (30.1)	6.6 (23.2)		
Median	0.0	1.0	0.0		
Q1, Q3	0.0, 0.0	0.0, 8.0	0.0, 1.0		
Range	(0.0–192.0)	(0.0–120.0)	(0.0–192.0)		
Days from Operation to Discharge				<0.0001 ²	<0.0028
N	117	37	154		
Mean (SD)	2.5 (4.5)	15.7 (24.4)	5.7 (13.7)		
Median	1.0	2.0	1.0		
Q1, Q3	0.0, 2.0	1.0, 17.0	0.0, 4.0		
Range	(0.0–23.0)	(0.0–81.0)	(0.0–81.0)		
Total Days Mechanical Ventilation				0.2688 ¹	1.0000
<= 30	117 (100.0%)	42 (97.7%)	159 (99.4%)		
> 30	0 (0.0%)	1 (2.3%)	1 (0.6%)		

¹Fisher Exact²Wilcoxon