Risk Factors Leading to Failed Procedural Sedation in Children Outside the Operating Room

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Objectives: Deep sedation enables effective performance of imaging or procedures in children, but failed sedation still occurs. We desired to determine the factors that were associated with failed sedation in children receiving deep sedation by a dedicated nonanesthesia sedation service and hypothesized that the presence of an upper respiratory infection (URI) and/or other risk factors would increase the probability of failing sedation.

Methods: Patient sedation records from January 2007 to December 2011 were reviewed to identify 83 failed sedations. A convenience sample of 523 patients with successful sedation from January 2009 to February 2009 was identified for comparison.

Results: Seven of the 13 predictors were significantly associated with failed sedation; these are as follows: (1) URI ($P = 0.008$); (2) congenital heart disease ($P = 0.021$); (3) obstructive sleep apnea (OSA)/snoring ($P < 0.001$); (4) the American Society of Anesthesiologists (ASA) class of above II ($P < 0.001$); (5) obesity ($P < 0.001$); (6) increased weight ($P < 0.001$); and (7) older age ($P < 0.001$). Sex, prematurity, asthma, gastroesophageal reflux, and cerebral palsy/developmental delay were not associated with failure. Pulmonary hypertension was not able to be assessed because only 1 patient with pulmonary hypertension was sedated. A forward stepwise regression identified 5 variables that could be considered useful predictors of failed sedation, which are as follows: (1) URI (odds ratio [OR], 2.73 [range, 1.58–4.73]); (2) OSA/snoring (OR, 2.06 [range, 1.22–3.48]); (3) ASA class III (OR, 2.31 [range, 1.40–3.84]); (4) obesity (OR, 1.95 [range, 1.01–3.75]); and (5) older age (OR, 1.15 [range, 1.08–1.21).

Conclusions: Presence of a URI, a history of OSA/snoring, ASA class III, obesity, and older age are associated with increased probability of failed sedation. A prospective, multicenter observational study would allow for the robust modeling of comorbidities to guide pediatric sedation management.

Key Words: procedural sedation, upper respiratory tract infection, obstructive sleep apnea, snoring, failed sedation, risk factors, obesity

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The use of procedural sedation and sedation services has become the standard of care to enable effective completion of many pediatric imaging studies and procedures. Through the use of anesthetics such as propofol, the inability to complete a study due to adverse respiratory events or other complications of sedation, defined as a failed sedation, is uncommon.[1] Specifically, a failed sedation results in wasted time for parents, patients, and the sedation service, potential exposure of patients to adverse events, and increased costs. Improved prediction of patients who are likely to fail sedation could potentially increase the safety and efficiency of pediatric procedural sedation provided outside the operating room.

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A paucity of data exists on risk factors associated with failed pediatric procedural sedation, and little in the literature addresses the role of a recent or current upper respiratory infection (URI) that plays in a failed sedation. Most of the studies report on risk factors associated with respiratory complications of children undergoing general anesthesia in an operating room.[2–7] These studies have shown conflicting results with regard to whether a URI is associated with adverse respiratory events such as laryngospasm, bronchospasm, oxygen desaturation, and upper airway obstruction. Most studies, however, conclude that a URI, use of an endotracheal tube, a history of snoring, and passive smoking contribute to respiratory complications during general anesthesia. A single study included pediatric procedural sedation data. However, it is not comparable with the typical outpatient sedation population because of the differences in anesthetic use.[8]

The objective of this study was to identify the risk factors associated with failed procedural sedation in a large pediatric sedation service experience. We hypothesized that the presence of a URI alone or in combination with other risk factors would increase the probability of a failed sedation.

METHODS

Study Population

We conducted a retrospective chart review, approved by the institutional review board, of patients requiring sedation for magnetic resonance imaging (MRI), computed tomographic (CT), nuclear medicine scans, and brief procedures (including auditory brainstem response [ABR] tests, lumbar punctures, peripherally inserted central catheter [PICC] line placements, and renal biopsies) at Children's Healthcare of Atlanta at Egleston and at a free-standing radiology facility managed by Children's at Eggleston. Children's Healthcare of Atlanta at Egleston is a quaternary care, free-standing children's hospital in Atlanta, Ga, that provides inpatient and outpatient procedural sedation to approximately 3500 pediatric patients per year. Sedation services are provided by sedation physicians trained in pediatric intensive care, pediatric emergency medicine, or anesthesiology. Almost all patients in the service receive intravenous propofol by bolus dose for induction and maintenance with propofol infusion for the duration of the imaging study or procedure. Sedation service records were reviewed from January 2007 to December 2011 to identify all patients who received sedation. If the imaging or procedure was not completed because of adverse events or complications, this was defined as a failed sedation. For comparison, a convenience sample of all patients successfully receiving sedation during January to February 2009 was obtained. Successful sedation was defined as completion of imaging or procedure in a sedated patient without requirement for rescheduling or general anesthesia. This large sample was identified to allow statistically relevant comparison with the total failed sedation group. The period during winter months was also selected to increase the likelihood of patients with URIs or respiratory symptoms within the group of successful sedations.

Patients were included in this study from the ages of birth to 21 years. Characteristics of patients compiled included age, sex, weight, American Society of Anesthesiologists (ASA) class, and history of prematurity. Presence of asthma, current URI, gastroesophageal reflux (GER), cerebral palsy/developmental delay (CP/DD), obstructive sleep apnea (OSA)/snoring, congenital heart disease, or pulmonary hypertension (PHTN) were obtained from a standardized presedation history and physical evaluation form. Heights were not obtained on any of the patients and thus did not allow for the calculation of a body mass index as an objective measure of obesity. Obesity was defined as a weight greater than the 95th percentile for sex and age based on the Centers for Disease Control and Prevention growth curves.[9] Procedure start and end times, type of procedure or imaging study, medications administered, complications experienced, and interventions performed during sedation were all obtained from a standard anesthesia record that was scanned into an electronic medical record. Patients who had an ASA class IV status were excluded from review because of the severity of illness.

The complications listed in Table 2 were defined in the following manner: (1) *hypoxemia*, sustained decrease of oxygen saturation below 90% for greater than 1 minute despite oxygen delivery or airway maneuvers; (2) *airway obstruction*, airway obstruction not responsive to airway repositioning; (3) *secretions*, secretions requiring more than just periodic suctioning; (4) *coughing*, coughing episodes that interrupt the procedure; (5) *apnea*, no respiratory effort for greater than or equal to 20 seconds; (6) *wheezing*, unexpected or unexplained wheezing; (7) *agitation*, sustained, out of the ordinary irritability or combativeness; (8) *irregular respirations*, ineffective breaths that do not maintain an oxygen saturation above 90%; and (9) *bradycardia*, heart rate below 60 beats per minute (bpm) and 30% below baseline if below 60 bpm (ie, baseline heart rate of 70 bpm, bradycardia defined for heart rate <49 bpm).

Sample Size and Power

We conservatively estimated that 0.6% of all sedations are unable to be completed. Given approximately 3500 sedations per year, during the period of 4 years, we estimated that approximately 84 failed sedations could be identified from our retrospective chart review. In addition, we estimated that approximately 25% of children undergoing sedation have symptoms of a URI. Power was calculated using a 2-sided z test with pooled variance and significance level of 0.05. In addition, the test assumes that the proportion of cases with URI is 0.25 under the null hypothesis and 0.40 under the alternative hypothesis. Based on the previously mentioned assumptions, group sample sizes of 84 cases and 528 controls achieve 80% power to detect an odds ratio (OR) of 2.0.

Sedation Protocol

The Children's Sedation Service follows protocols and procedures in accordance with the American Academy of Pediatrics Guidelines for Sedation.[10–12] The final choice of sedation medication for each patient is at the discretion of the sedation service physician; however, most physicians used propofol. The sedation protocols and practice patterns of physicians in the Children's Sedation Service at Egleston have been published.[13] Briefly, the standard propofol dosing was 3 mg/kg administered for several minutes by slow intravenous push until the patient fell asleep. The amount of propofol used was titrated to the desired level of sedation, identified by having no patient movement with a loud noise and, for painful procedures, by minimal movement with the initiation of the procedure. Once a level of deep sedation was achieved, a propofol infusion dosage at 5 $mg \cdot kg^{-1} \cdot h^{-1}$ was started to maintain deep sedation. Adjunctive agents (eg, fentanyl for painful procedures or cough suppressant for MRI), additional bolus doses, and/or maintenance dose could be given at the physician's discretion. Patients were positioned supine and continuously monitored with cardiopulmonary monitors, pulse oximetry, and direct caretaker observation. A bag mask and suction setup was immediately available during all phases of sedation.[10] For MRIs, end-tidal carbon dioxide monitoring using a nasal prong apparatus was routinely used, but these values and trends were not tracked in this study. If sedation was inadequate, additional propofol boluses were given to achieve the desired level of sedation and the maintenance infusion dosage was increased at the discretion of the sedation physician. Once the procedure was completed, the infusion was discontinued, and the patients were monitored until complete recovery criteria were met using the Aldrete score.[14]

Statistical Analysis

Patients with an ASA class I and II physical status were grouped together for the purposes of data analysis. The goal of analysis was to determine patient characteristics and comorbidities associated with increased odds of failed sedation. To accomplish this, univariate analysis of each potential risk factor was performed to determine if there was an association between the covariate and the outcome failed sedation. This was accomplished by performing χ^2 tests of association for categorical variables and 2-sample t tests for continuous variables. Based on the results from the univariate analysis, a set of potential predictors was identified that were significantly associated with failed sedation and could be further analyzed for possible interactions with one another using multivariate logistic regression models. A forward-stepwise logistic regression technique was used to determine a subset of variables that were associated with increased odds of failed sedation. A significance level of 0.2 was required to allow the variable to enter the model, and a significance level of 0.1 was required for the variable to stay in the model. Two and three-way interactions were added to the model but were removed if not statistically significant. The Hosmer and Lemeshow goodness-of-fit test was used to assess the fit of the final model.

RESULTS

Summary of Sample

Eighty-three failed procedural sedations were identified between January 2007 and December 2011. Five hundred twenty-three patients with successful sedations were identified in the comparison group. Table 1 summarizes the patient demographics, imaging/procedure performed, sedation medication, and times. The median patient age was 3.77 years (range, 6 days-21.8 y; mean, 5 [SD, 4.3] y). A total of 56.7% of patients were male. The ASA classifications included the following: 23.6% ASA I, 44% ASA II, and 32.4% ASA III. The median patient weight was 15.85 kg (range, 0.7–103 kg; mean, 21.2 [SD, 16.5] kg). A total of 12.5% of patients were considered obese based on a weight greater than the 95th percentile for age and sex as defined by the Centers for Disease Control and Prevention growth parameters. The median sedation time was 45 minutes (range, 5–224 minutes; mean, 50.3 [SD, 30] minutes). A total of 85.6% of patients were sedated with propofol alone, 4.6% with propofol plus fentanyl, and 2.6% with propofol plus midazolam. The remaining sedations were performed with either methohexital (3.8%) or chloral hydrate (2.0%). There were no differences in the total dose of propofol administered to those children who successfully completed or failed sedation. To make a more meaningful comparison, however, the total dose of propofol was normalized to weight and duration of the sedation. Children who failed sedation received on

TABLE 1. Summary of Patient Characteristics and Sedation Profiles

Variable	Level	n (%) (N = 606)
Age, y	Mean (SD) [range]	5.0 (4.3) [0.01–21.82]
Sex	Male	343 (56.7)
	Female	263 (43.3)
ASA class*	I	138 (23.6)
	II	258 (44.0)
	III	190 (32.4)
Weight, kg	Mean (SD) [range]	21.2 (16.5) [0.7–103.0]
Obesity	Yes	76 (12.5)
Sedation time,* min	Mean (SD) [range]	50.3 (30.0) [5.0–224.0]
Sedation medication administered	Propofol	565 (85.6)
	Methohexital	23 (3.8)
	Chloral hydrate	12 (2.0)
	Propofol + midazolam	16 (2.6)
	Propofol + fentanyl	28 (4.6)
	Other	6 (<1)
Scan or procedure	MRI	459 (75.7)
	CT	69 (11.4)
	ABR	43 (7.1)
	Renal biopsy	9 (1.5)
	PET	8 (1.3)
	Bone scan	5 (0.8)
	MIBG	4 (0.7)
	PICC line placement	3 (0.5)
	Other	6 (<1)

*Missing/unknown data.

PET indicates positron emission tomography; MIBG, metaiodobenzylguanidine scan.

average less propofol per weight and time of sedation (13.3 [SD, 13.1] $mg{\cdot}kg^{-1}{\cdot}h^{-1}$) than children who successfully completed their sedation (16.7 [SD, 11.0] $mg{\cdot}kg^{-1}{\cdot}h^{-1}$; $P = 0.011$ [data not shown]). Magnetic resonance imaging studies comprised 75.7% of the patients requiring sedation, followed by CT scans in 11.4%, ABR in 7.1%, and renal biopsies, positron emission tomographic scans, bone scans, metaiodobenzylguanidine scan studies, and PICC line placements in approximately 1% each.

Summary of Failed Sedations

Table 2 describes the complications that occurred and the interventions performed during imaging studies and procedures that failed to be completed because of these adverse events. Children may have experienced multiple complications during sedation; thus, the percentages describing the complications are not expected to sum to 100%. Of the 83 failed sedations, 22 (26.5%) were performed on inpatients, whereas 61 (73.5%) were performed in the outpatient setting. The most common complications leading to a failed sedation were hypoxemia (69.9%), airway obstruction (48.2%), secretions (38.6%), coughing (32.5%), and increased work of breathing (14.5%). Other respiratory complications included apnea, wheezing, stridor, and irregular respirations. Complications that interfered with the procedure and that were related to sedation included vomiting, movement, agitation, and hiccups. The most common interventions performed were providing oxygen (68.7%), suctioning the nasopharynx and/or the oropharynx (51.8%), repositioning the patient to open the airway (37.3%), inserting a nasopharyngeal (25.3%) or oropharyngeal airway (9.6%), and providing bag mask ventilation (24.1%) or continuous positive airway pressure/positive pressure ventilation (PPV; 13.3%). Nebulized albuterol or epinephrine treatments were used in 7.2% and 2.4% of patients and sedations, respectively; however, these patients still failed sedation. Other adjuvant medications to help manage secretions, such as glycopyrrolate and atropine, were used infrequently in this study. Of the 4 patients who received glycopyrrolate, 3 were successfully sedated and 1 failed sedation. None of the patients received atropine. One patient who was an inpatient on the general floor before the imaging study developed bradycardia and poor perfusion that required PPV and chest compressions. This patient was transferred to the pediatric intensive care unit for overnight observation with complete recovery. Only 1 patient had an unplanned admission to the hospital for observation because of complications from sedation. No fatalities or serious morbidity associated with any of the sedations performed was reported. Eight of the failed sedations occurred during the convenience sample period for obtaining successful sedations; during this period, sedation failure rate was thus 1.5% (8/531 total sedates). Although the use of narcotics, such as fentanyl, are associated with hypotension, respiratory depression, and apnea that could lead to failed sedation, none of the patients in our study experienced these complications and the use of fentanyl was not associated with an increased likelihood of failing sedation in our study ($P = 0.627$). Of the children who failed

TABLE 2. Summary of Failed Sedations

Failed Sedation Characteristic	Type	n (%) (n = 83)
Setting	Inpatient	22 (26.5)
	Outpatient	61 (73.5)
Complication	Hypoxemia	58 (69.9)
	Airway obstruction	40 (48.2)
	Secretions	32 (38.6)
	Coughing	27 (32.5)
	Increased work of breathing/retracting	12 (14.5)
	Apnea	5 (6.0)
	Wheezing	4 (4.8)
	Stridor	4 (4.8)
	Vomiting	4 (4.8)
	Movement	4 (4.8)
	Agitation	2 (2.4)
	Hiccups	2 (2.4)
	Irregular respirations	1 (1.2)
	Bradycardia	1 (1.2)
Intervention	Oxygen	57 (68.7)
	Suction	43 (51.8)
	Reposition	31 (37.3)
	Nasopharyngeal airway	21 (25.3)
	Bag mask ventilation	20 (24.1)
	CPAP/PPV	11 (13.3)
	Chin lift/jaw thrust	11 (13.3)
	Oropharyngeal airway	8 (9.6)
	Albuterol NEB	6 (7.2)
	Epinephrine NEB	2 (2.4)
	Chest compressions	1 (1.2)

*Missing/unknown data.

CPAP indicates continuous positive airway pressure; NEB, nebulized.

TABLE 3. Association Between Potential Risk Factors and Sedation Outcome

		Failed Sedation		
Risk Factor	**Level**	**No (n = 523)**	**Yes (n = 83)**	***P***
URI	No	362 (69.2%)	45 (54.2%)	0.008
	Yes	161 (30.8%)	38 (45.8%)	
Prematurity	No	434 (83.0%)	68 (81.9%)	0.813
	Yes	89 (17.0%)	15 (18.1%)	
Asthma	No	410 (78.4%)	63 (75.9%)	0.611
	Yes	113 (21.6%)	20 (24.1%)	
GER*	No	454 (87.0%)	67 (80.7%)	0.126
	Yes	68 (13.0%)	16 (19.3%)	
CP/DD	No	450 (86.0%)	75 (90.4%)	0.283
	Yes	73 (14.0%)	8 (9.6%)	
Congenital heart disease	No	498 (95.2%)	72 (88.9%)	0.021
	Yes	25 (4.8%)	9 (11.1%)	
OSA/snoring	No	412 (78.8%)	49 (59.0%)	<0.001
	Yes	111 (21.2%)	34 (41.0%)	
PHTN*	No	518 (99.8%)	60 (100.0%)	1.000
	Yes	1 (0.2%)	0 (0.0%)	
ASA class*	I	129 (25.6%)	9 (11.0%)	<0.001
	II	229 (45.4%)	29 (35.4%)	
	III	146 (29.0%)	44 (53.6%)	
Sex	Male	298 (57.0%)	45 (54.2%)	0.637
	Female	225 (43.0%)	38 (45.8%)	
Obesity	No	464 (88.7%)	66 (79.5%)	0.019
	Yes	59 (11.3%)	17 (20.5%)	
Weight, mean (SD), kg	—	19.6 (14.2)	30.7 (24.8)	<0.001
Age,* mean (SD), y	—	4.6 (3.9)	7.4 (5.9)	<0.001
Time, mean (SD), min	—	31.5 (25.9)	53.3 (29.5)	<0.001

*Missing/unknown data.

sedation, there was no statistically significant difference (P = 0.13) between those who received propofol (74 failed sedations/565 sedations with propofol only) and those who did not receive propofol (9 failed sedations/42 sedations not receiving propofol).

Analysis of Potential Predictors of Failed Sedation

We assessed 13 patient characteristics and comorbidities for possible associations with failed sedation. After univariate analysis was performed, 7 potential predictors were found to be significantly associated with sedation failure; these are as follows: (1) URI (P = 0.008); (2) a history of congenital heart disease (P = 0.021); (3) OSA/snoring (P < 0.001); (4) ASA class III versus I/II (P < 0.001); (5) obesity (0.019); (6) increased weight (P < 0.001); and (7) older age (P < 0.001). Table 3 lists all the 13 potential risk factors analyzed. In addition to the 13 risk factors analyzed, the median sedation time for failed sedations was 25 minutes (range, 5–107 minutes; mean, 31.5 [SD, 25.9] minutes. The median sedation time for successful sedations was 50 minutes (range, 5–224 minutes; mean, 53.3 [SD, 29.5] minutes). All 9 patients who failed sedation with a history of congenital heart disease were also ASA class III. Because of the high correlation of being classified as an ASA class III physical status with a history of congenital heart disease, we excluded having a history of congenital heart disease because of its high interdependence with ASA class III. In addition, because obesity and weight were highly correlated and weight is highly correlated with age, obesity was selected for inclusion in the model. The forward stepwise regression identified 5 variables that could be considered useful predictors of failed sedation. A summary of the final logistic model coefficients is given in Table 4. Twenty observations were deleted because of missing values for some of the predictor variables. For a given child, the log odds of failed sedation can be evaluated by using the following model: log (Pr(failed sedation)/[1 − Pr(failed sedation)]) = −0.44 + 0.839 *(if ASA class is III) + 1.005 *(if URI is present) + 0.723 *(if OSA/snoring is present)

TABLE 4. Predictors for Logistic Regression (Modeling Probability of Failed Sedation)

Predictor	**Coefficient**	**SE**	**Wald χ^2 Value**	***P***
ASA class				
III	0.839	0.258	10.58	0.001
I and II (reference)	—	—	—	—
OSA/snoring				
Yes	0.723	0.227	7.35	0.007
No (reference)				
URI				
Yes	1.005	0.280	12.84	<0.001
No (reference)				
Obesity				
Yes	0.665	0.336	3.93	0.048
No (reference)				
Age	0.134	0.025	23.03	<0.001
Intercept	0.435	0.434	1.006	0.316

TABLE 5. Odds Ratios and 95% CIs for Significant Predictors of Failed Sedation

Predictor	OR	95% CI	
		95% LCL	95% UCL
ASA class			
III vs (I or II)	2.31	1.40	3.84
OSA/snoring			
Yes vs no	2.06	1.22	3.48
URI			
Yes vs no	2.73	1.58	4.73
Obesity			
Yes vs no	1.95	1.01	3.75
Age	1.15	1.08	1.21

LCL indicates lower confidence limit; UCL, upper confidence limit.

+ 0.665 *(if obese) + 0.134 *(age in years). Table 5 gives the ORs (exponentiated coefficients from Table 4) and associated 95% confidence intervals (CIs) for each risk factor in the model.

Although many children successfully complete sedation in the presence of a URI, there is a subset of children who fail sedation with a URI. The only demographic difference is that children with a URI who fail sedation are, on average, older (mean, 4.6 [SD, 3.6] y; median, 4.0 y; range, 0.3–14.5 y) than children with a URI who successfully complete their procedure with sedation (mean, 3.3 [SD, 2.8] y; median 2.6 y; range 0.2–18.5 y; data not shown). When using the area under the receiver operating characteristic curve as a measure of model's predictive power, using URI with a combination of other risk factors to predict failed sedation provided significantly better predictive power compared with URI alone (receiver operating characteristic curve, 0.753 vs 0.577; $P < 0.001$).

In summary, our model predicts that children with a URI, OSA/snoring, obesity, an ASA class III physical status, and older age are more likely to fail sedation outside the operating room than children with a history of prematurity, asthma, GER, and CP/DD. Thus, a child with a URI, OSA/snoring, obesity, or an ASA class of III is of higher relative importance than other patient characteristics such as a history of prematurity, asthma, GER, and CP/DD when assessing the risk of sedation for radiologic examinations and brief procedures in children.

DISCUSSION

Identification of children at risk for failing sedation would improve the safety and efficiency of children undergoing deep sedation for elective radiology imaging and brief procedures. Identifying the risk factors would allow more directed determination of either postponement or use of general anesthesia. Coté and colleagues[15] have discussed that serious complications are more likely to occur in sedations performed outside the operating room, perhaps because of a longer delay before definitive rescue of severe complications. In our patient review, we found that an ASA class III physical status, presence of a URI, obesity, and a history of OSA/snoring each increased the probability of failing sedation approximately twice as often as not having these risk factors. We did not find an increased risk of failing sedation with a history of asthma, prematurity, CP/DD, or GER. This may be attributable to the fact that the symptoms of the asthma and reflux were well controlled at the time of the sedation. The diagnosis of having a history of congenital heart disease was relatively rare and was confounded by a higher ASA physical status, and the diagnosis of PHTN was extremely rare in our patient population presenting for procedural sedation and thus did not contribute reliably to our model. Our data are consistent with a study by Srinivasan et al[16] who retrospectively learned that the predictors of respiratory events and airway interventions were a history of snoring, ASA class III, age older than 12 years, premedication with midazolam, and use of adjuvant glycopyrrolate. Recently published data from our institution have shown that there is no statistically significant increase in overall need for intervention or rate of failed sedations in sedations lasting longer than 1 hour as compared with shorter sedation duration.[17] Most children who are sedated for prolonged periods required intervention on an average of 18.8 (SD, 17.7) minutes into the procedure consistent with our study results that showed that children who fail sedation are more likely to have respiratory events early on in the procedure leading to sedation times that are statistically shorter than successful sedations. In addition, the overall additional propofol administration rate was similar between prolonged and short sedation groups.[17] The use of less propofol per weight and time of sedation in our study may indicate that children who fail sedation have characteristics, some of which are identified in our model, that make them more sensitive to propofol and more prone to adverse effects of sedation. Although the difference in normalized propofol was statistically different between those children who failed and successfully completed sedation, it is unclear how clinically significant the difference in amounts are. For example, some patients fail quickly and the sedating physician ends the procedure shortly after blousing and starting the propofol drip. Other patients require adjustment of the propofol drip (up and down) and/or require additional boluses of propofol until the sedating physician decides to stop the sedation before completion of the procedure.

The data from this study address the ongoing question of whether a child with a URI who is undergoing procedural sedation outside the operating room should have the procedure postponed and adds to several studies regarding the risks of performing general anesthesia on children with URIs presenting to the operating room for surgical procedures.[2–7,18–21] Children undergoing general anesthesia with a URI have an increased risk of perioperative respiratory complications.[2,3,5,6,19] In a study by Cohen and Cameron,[2] children with a URI were 4 to 7 times more likely to experience respiratory-related adverse events that were not explained by age or ASA physical status score. In this same study, the risk of adverse respiratory events was 11-fold higher if the child has a URI and required endotracheal tube (ETT) intubation for the procedure.[2] Tait and Knight[6] found that asymptomatic children with a history of a recent URI were at a higher risk for intraoperative respiratory complications without any association with the type of anesthetic agent used or whether the patient was managed with ETT intubation. In another prospective study conducted by Tait et al[7] that included more than 1000 children presenting for elective surgery, no difference was found among children with active URIs, children with recent URIs (within 4 weeks), and asymptomatic children with respect to the incidence of laryngospasm and bronchospasm. However, although there were also no long-term sequelae, children with active and recent URIs had significantly more episodes of breath holding, major desaturation (oxygen saturation < 90%) events, and a greater incidence of overall adverse respiratory events than children with no URIs.[7] Inflamed airways are sensitive to airway manipulation, and insertion of a foreign body, such as an ETT, increases the risk of adverse respiratory events perioperatively.[2,3,7]

In trying to devise a clinical tool to provide an objective methodology to guide the anesthetic assessment and management of children with URIs, Parnis et al[3] showed that 8 independent variables were predictors of adverse effects, which are as follows; the use of ETT intubation versus laryngeal mask

airway or face mask, the parent stating that the child has a "cold" on the day of surgery, the child had nasal congestion, the child snores, the child is a passive smoker, the choice of induction agent, the child produces sputum, and the use of a reversal agent. Tait et al[7] showed that 6 variables were independent risk factors for perioperative adverse events for children with active URIs. These risk factors included the following: use of an ETT intubation (<5 y), a history of prematurity, a history of reactive airway disease, a history of paternal smoking, undergoing surgery involving the airway, and the presence of copious secretions. In another study by Tait et al[5] that reviewed the charts of children undergoing general anesthesia for myringostomy and typanostomy tube placement, there was no increase in perioperative complications or morbidity in children with a URI.

Malviya and colleagues[8] prospectively analyzed quality assurance data for children undergoing MRI and CT with both procedural sedation and general anesthesia and found that adverse events, such as hypoxemia, were more likely to occur in older children with an ASA status of III or IV and in those in whom benzodiazepines were used as the sole sedative. The main anesthetic used for procedural sedation in the study of Malviya et al[8] was chloral hydrate. Although the results of increased adverse events in older patients and in those with a higher ASA physical status make clinical sense and are in agreement with our study results, most patients in our study were anesthetized using propofol. This difference in anesthetics used between the study of Malviya et al[8] and our study makes the application of their results to the patients in our sedation service difficult.

There is little available data to assess expected failure rates of patient sedation services. The internal quality data at Children's at Eggleston have demonstrated typical failed sedation rates of less than 1% (Pradip Kamat, personal communication, January 2011). The failed sedation rate during the convenience sample period of our study was 1.5%. Although still low, it is likely higher than the typical rates in our center because of the higher presence of associated URIs in patients undergoing sedation during the winter months chosen, as confirmed by analysis of risk factors. Broader analysis of failure rates at multiple centers would be valuable for future benchmarking.

The limitations of our study include the retrospective nature, the use of a convenience sample as the comparison group of successful sedations that may introduce selection bias, and the single-center experience of the study. Because of the few patients who had multiple risk factors, our study was not powered to detect significant interactions among the risk factors. The period for collection of failed sedations was longer than the period for collection of successful sedations that was used for comparison. This was used both because of the very small number of failed sedations overall and the very large number of patient sedations per month with our service. The chosen convenience sample allowed a manageable number of patients for data collection. The choice of winter months for analysis of successful patients was made because children would be expected to be more likely to present with a URI in the January/February period resulting in more failed sedations because of complications from the URI and is supported by the higher failed sedation rate of 1.5% (8/523) when compared with internal quality control data (<1%, personal communication).

Our single-institution, retrospective study, where most of the procedures are performed with propofol, lends preliminary insight into the most likely risk factors associated with failing sedation. The presence of a URI alone as a test for determining whether a patient will fail sedation was considered poor (area under the curve, < 0.6); however, the presence of a URI along with 4 other characteristics as part of a multiple risk factor model had higher accuracy when classifying patients as failed or successful sedations. Other risk factors to include in the future studies are an objective definition of obesity with the measurement of body mass index, exposure to passive or active smoking, and how well controlled is the patient's asthma. Future prospective studies should address the quality of URI symptoms, such as the presence of clear rhinorrhea versus cough alone versus mucopurulent rhinorrhea with cough, because differences may be detected in those who fail sedation with a URI from those who undergo sedation and complete their scan or procedure successfully with a URI. The ultimate goal is to develop a reliable and robust model to predict the likelihood of failing sedation such that referral to complete the study or procedure under general anesthesia or postponement of the sedation until the URI is resolved can be arranged in advance. A larger prospective study will be needed to develop an algorithm to predict the likelihood of failing sedation with a high degree of accuracy to ultimately increase the safety and efficiency of pediatric sedation services.

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