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Pediatric Procedural Sedation in the Emergency Setting

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Background: Pediatric emergency department (ED) visits are common. Many are due to injury, which require procedural treatments with sedation. There are many well researched independent predictors of adverse events for pediatric procedural sedation. The duration of sedation as a predictor of adverse events has not been well studied. This study aims to determine the complication rate and severity of procedural sedation as well as determine if the duration of sedation is correlated with an increased risk of complications.

Methods: After Institutional Review Board approval, a retrospective study was performed on all patients seen at Helen Devos Children's ED who received sedation from August 1, 2011, to August 15, 2016. Study variables included age, weight, type of procedure, American Society of Anesthesiologist (ASA) physical status class, Mallampati score, comorbidities, sedation medication, sedation time, and complication. A logistic regression was performed assessing risk factors for complications. Statistical significance was assessed at $P < 0.05$.

Results: There were 1,814 patients included in the study. Median sedation time was 20 minutes. There were 70 (3.9%) total complications. Controlling for age, weight, comorbidities, ASA class, Mallampati score, and total sedation medication, sedation time was a significant predictor of a complication (odds ratio: 1.021; 95% CI, 1.004–1.039).

Conclusions: Pediatric patients can safely undergo procedural sedation in the ED. This study demonstrates a high safety profile for long procedural sedations with slight increases in risk as sedation time increases. There is no identifiable time where the duration of sedation significantly increases the risk of complication.
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INTRODUCTION

Pediatric emergency department (ED) visits are common, with 30 million visits in 2015.[1] Although over 96% of these visits are "treat and release," nine million visits are related to an injury that require a procedure. Procedural sedation in the ED is an alternative that can be time- and cost-effective and has a similar safety profile compared to general anesthesia in the operating room for managing pediatric injuries. Procedural sedation is used to allow the patient to tolerate procedures while maintaining protective reflexes via the use of sedative or dissociative agents. Sedation has been safely performed in ED settings by ER physicians trained in ACLS/PALS care.[2,3] Similar complication rates have been shown between ER physicians and anesthesiologists, intensivists, and pediatricians.[4]

Patient safety and the minimization of adverse outcomes related to the use of procedural sedation are primary concerns of all health care providers. Specifically studying pediatric patients is important because of the potential for variation in pharmacokinetics and pharmacodynamics between children and adults. There are a number of independent predictors of the incidence of adverse events in pediatric patients undergoing procedural sedation, including age of the patient, total dose administered, American Society of Anesthesiologists (ASA) physical

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status classification, and the co-administration of either anticholinergic or benzodiazepine agents. Prior studies have focused on techniques to provide safe sedation[5,6] predictors of adverse events[7,8] as well as looking at various drug regimens[9–11] but none to our knowledge have determined safe sedation time. This study begins to address the question of safety of procedural sedation—particularly with respect to its duration—when administered to pediatric patients. The specific aims of this study included determining the complication rate associated with sedation for procedures at our institution's pediatric ED, as well as the risk factors, including duration of sedation, for complications associated with procedural sedation.

METHODS

After Institutional Review Board approval, a retrospective review was performed on pediatric patients at Helen DeVos Children's Hospital, a level 1 trauma center in Grand Rapids, Michigan. This is an academic teaching hospital with residents working under the guidance of attendings. Data were collected from August 1, 2011, to August 15, 2016. Inclusion criteria for patients were patients less than 18 years of age who underwent sedation while in the ED. Data collection included review of the electronic medical record, as well as the ED, nursing, sedation, and procedural team's notes. Specific data collected included age, weight, ASA classification, and Mallampati score. The Mallampati score is used to evaluate the accessibility of a patient's airway before sedation to prepare for any major respiratory complication. With the patient's mouth open, the oropharynx is evaluated to determine which structures are visible with or without phonation in which 1 indicates all structures visible and 4 indicates that only the hard palate is visible.

The duration of sedation, pre- and postprocedure diagnosis, procedure performed, specialty performing procedure, sedation medication used, route of sedation medication administration (intravenous, intramuscular, inhalational, intranasal, or oral), and dose was also recorded. Adverse events were recorded and grouped into minor events (agitation, apnea, desaturation below 90%, change in blood pressure or heart rate, emesis, rash, secretions, aborted procedures) and major events (laryngospasm).

Summary statistics were calculated for the data. Sedation time and medication dose were log-transformed before analysis due to the non-normality of the data. Nominal data are reported as percentages. Risk factors for complications were assessed using logistic regression. Independent variables included age, weight, comorbidities, ASA class, Mallampati score, total sedation medication, and sedation time. Comparisons between complication groups (none, minor, and major) for age and weight were performed using the Kruskal-Wallis analysis of variance test. Post-hoc pairwise comparisons were performed using Dunn's test, using the Holm-Sidak adjustment. Comparisons between the complication groups for nominal variables were performed using the Fisher's Exact test. Significance was assessed at $P < 0.05$. Data were analyzed using IBM SPSS Statistics v. 23 (IBM Corp, Armonk, NY) and Stata v.15.1 (StataCorp, College Station, TX).

RESULTS

There were 1,814 patients included in the study. Demographic and clinical characteristics of the sample are shown in Table 1. The median age of patients was significantly higher at 9 years of age compared to those without complications ($P = 0.017$). The median weight was also statistically significantly higher in patients with minor complications compared to those with no complications, at 40 and 26.4 kg, respectively ($P = 0.024$). The majority of all the patients had an ASA class of 1 (84%) and a Mallampati score of 1 (78.1%). The most frequent specialties performing the procedures were Orthopedics (56.4%), the ED (34.5%), and plastic surgery (3.4%) (Table 2). There were 21 different procedures performed by 13 different specialties. The most frequent procedure was reduction (60.9%) followed by laceration repair (20.4%) (Table 3).

Type of medication used was recorded for 1,811 patients. A total of 1,251 (69.1%) patients received IV Ketamine and 404 (22.3%) patients received IV Propofol as the first-line medication to achieve sedation. A single medication was used for 1,760 (97.2%) patients, 48 (2.7%) patients underwent sedation with 2 medications, and 3 (0.2%) patients underwent sedation with 3 medications. The average dose of sedation medications was 3.49 mg/kg ketamine IM, 1.82 mg/kg Ketamine IV, 3.56 mg/kg Propofol IV, 9 μg/kg Fentanyl, 0.72 mg/kg Brevital IV. Sedation time was available for 1,725 patients, median time was 20 minutes. One thousand five hundred eighty-six (91.9%) patients were under sedation for 45 minutes or less, while 139 (8.1%) patients were under sedation for more than 45 minutes. Plastic surgery had the longest mean time of sedation at 46 minutes.

The complication summary data are shown in Table 4. If patients experienced both a major and minor complication, the most severe complication experienced was recorded. If a patient experienced more than one minor complication for statistical analysis it was just included as one complication. The overall complication rate was 3.9% (5 major and 65 minor). There were no patient deaths and no patients required intubation. The sedation times of the 5 major complications time ranged from 17 to 81 minutes. Due to incomplete charting, a total of 1,445 patients were included in the regression analysis to assess predictors of complications. When controlling for age, weight, comorbidities, ASA class (1, 2, ≥3), Mallampati score (1, 2, ≥3), and total sedation medication, sedation time was a significant predictor of a complication (odds ratio: 1.021; 95% CI, 1.004–1.039) (Table 5). A logistic regression was performed with any complication as the outcome variable. Controlling for age, weight, comorbidities, ASA class, Mallampati score, and total sedation medication, the only significant predictor of a complication was sedation time. For every 10% increase in sedation time, the complication rate increased by 7.8%. In other words, for every 10-minute increase in sedation time, the chances of a complication occurring increase by 23%. However, these are mostly minor complications as defined above. Most often, the complication experienced was desaturation below 90% which resolved with supplemental oxygen. Within our data, there was no identifiable cut off point where the complications significantly increased.

Table 1. Demographic and Clinical Characteristics

Variable	Patients without Complications (n = 1744)	Minor Complication (n = 65)	Major Complication (n = 5)	*P*
Median age at sedation (y) (range)	7 (0–17)	9 (0–17)	2 (2–11)	0.021*
Median weight (kg) (range)	26.4 (4.5–152)	40 (9.1–13)	14.4 (10.5–52)	0.028†
Comorbidities (% yes)	299	26.2	0	0.080
ASA class				
1	1,292 (84.1%)	48 (78.7%)	5 (100%)	0.060
2	202 (13.1%)	8 (13.1%)	0 (0%)	
3	40 (2.6%)	4 (6.6%)	0 (0%)	
4	2 (0.1%)	1 (1.6%)	0 (0%)	
5	1 (0%)	0 (0%)	0 (0%)	
Mallampati score				
1	1,136 (78.3%)	40 (67.8%)	3 (60%)	0.105
2	252 (17.4%)	14 (23.7%)	1 (20%)	
3	57 (3.9%)	5 (8.5%)	1 (20%)	
4	5 (0.3%)	0 (0%)	0 (0%)	

*Patients without complications vs. minor complications, $P = 0.017$; all other pairwise comparisons, $P > 0.05$.
†Patients without complications vs. minor complications, $P = 0.024$; all other pairwise comparisons, $P > 0.05$.

Table 2. Procedures Performed by Consulting Service

Consulting Service	n (%)
Orthopedics	1023 (56.4)
Emergency Department	625 (34.5)
Plastic and Reconstructive Surgery	62 (3.4)
Radiology	42 (2.3)
Pediatric Surgery	31 (1.7)
Gastroenterology	8 (0.4)
Obstetrics/Gynecology	7 (0.3)
Oral and Maxillofacial Surgery	5 (0.3)
ENT	4 (0.2)
Neurosurgery	2 (0.1)
Ophthalmology	2 (0.1)
Urology	2 (0.1)
Cardiology	1 (0)

Table 3. Procedures Performed

Procedure Type	Frequency	Percent
Arthrocentesis	35	1.9
Cast/splint	7	0.4
Central line	4	0.2
Chest tube	9	0.5
CT	18	1.0
Debridement	1	0.1
Disimpaction	4	0.2
Dressing change	2	0.1
Endoscopy	8	0.4
Enteral Access	2	0.1
EUA	4	0.2
Foreign Body	44	2.4
I&D	126	6.9
Imaging	1	0.1
Lac	370	20.4
LP	50	2.8
MRI	8	0.4
Other	10	0.6
Reduction	1,104	60.9
Tooth Extraction	5	0.3
Ultrasound	2	0.1
Total	1,814	100.0

Table 4. Complication Data

Complication	
Minor (%)	64 (3.5%)
Complication type	
Agitation	10 (0.5%)
Apnea	6 (0.3%)
Desaturation	35 (1.9%)
Change in BP or HR	3 (0.2%)
Emesis	9 (0.5%)
Rash	4 (0.2%)
Secretions	2 (0.1%)
Aborted procedure	1 (0.01%)
Major (%)	5 (0.3%)
Complication type	
Laryngospasm	5 (0.3%)

CONCLUSIONS

In this study, we retrospectively reviewed pediatric ED sedations to assess complications and to determine if duration of sedation is related to complications. Our study found a complication rate of 3.9%, which is consistent with the literature of the range 0.4%–9.1%.[4] Most often, the complication experienced in our study was desaturation below 90% which resolved with supplemental oxygen.

There was no identifiable cut off point where the risk of sedation increased. However, for every 10-minute increase in sedation time, the chances of any complication occurring increase by 23%. The plastic surgery department had a major complication rate of 0% and the longest sedation times of any service at 47 minutes. Seeing as the majority of plastic surgery consults are for laceration repairs of the head and neck, one would reasonably expect the plastic surgery department to have the most complications given the long sedation time and location of repair needed. However, this was not seen in our data. This could be explained by the ability to use nerve blocks to reduce painful stimuli and therefore decrease the amount of sedation medication needed.

The increase risk of complications for increased time could be explained a number of ways. More medication is required to keep a child under sedation longer. Further, the amount of stimulation during a long procedure can change which can alter the sedation depth. The procedure can be very stimulating at first with manipulation or injection of local, but that may lessen as the procedure duration continues. The lack of stimulation can deepen the sedation which increases the risk of cardiorespiratory depression. However, the number of complications can be skewed by what is defined as a complication. In this study, we included agitation, desaturation requiring oxygen, and aborted procedures as complications. Agitation can almost be expected from children in an uncomfortable environment surrounded by strangers. A desaturation that resolves with oxygen could be avoided by automatically

Table 5. Logistic Regression Analysis

Variables in the Equation		B	S.E.	Wald	df	Sig.	Exp(B)	95% CI for EXP(B) Lower	Upper
Step 1*	Age (at sedation)	0.029	0.045	0.409	1	0.522	1.029	0.942	1.124
	ASA class I			4.801	2	.091			
	ASA class II (1)	−0.859	0.557	2.376	1	0.123	0.424	0.142	1.263
	ASA class III (2)	0.511	0.620	0.679	1	0.410	1.667	0.495	5.614
	Mallampati 1			1.969	2	0.374			
	Mallampati 2 (1)	0.334	0.318	1.106	1	0.293	1.397	0.749	2.602
	Mallampati 3&4 (2)	0.553	0.507	1.190	1	0.275	1.738	0.644	4.695
	Comorbidities(1)	0.500	0.438	1.304	1	0.253	1.649	0.699	3.891
	Hospital Admission (1)	0.304	0.345	0.777	1	0.378	1.355	0.690	2.661
	Sedation time trans	0.712	0.271	6.890	1	0.009	2.039	1.198	3.470
	Total medication trans	0.162	0.232	0.486	1	0.486	1.175	0.746	1.852
	Constant	−6.358	0.943	45.503	1	0.000	0.002		

*P value significant <0.05.

giving everyone supplemental oxygen before the start of sedation, and this was our most common complication.

The risk of complications for sedation is similar to that of general anesthesia.[12] The complication rate for sedations is also equivalent amongst all provider groups, including anesthesiologists, emergency room physicians, pediatricians, and intensivists.[4] Unique to ED visits is that the visit and the injury itself are unexpected. Most patients that come into the ED have not been fasting. Nil per os (NPO) status is not an independent predictor of aspiration or other major complications.[13,14] The ability to provide sedation and allow for a more rapid procedural repair of the injury is important. The injuries and associated procedures are unexpected and can be frustrating for patients and parents as well as distressing. Having to wait for an available operating room or for the appropriate NPO time can add undue stress to the family.

Limitations of the study include the retrospective design and low power given the low rate of complications. These results are also based on practice patterns of the physicians at Helen DeVos, other areas of the nation may use different sedation medications or techniques when performing sedation.

Future studies should look at cost savings of sedation versus general anesthesia. Studies should also examine postgraduate year performing sedation and rate of complications.

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REFERENCES

1. McDermott K, Stocks C, Freeman W. Overview of Pediatric Emergency Department Visits, 2015. 2015. HCUP Statistical Brief #242. Rockville, MD: Agency for Healthcare Research and Quality; 2018. Available at: www.hcup-us.ahrq.gov/reports/statbriefs/sb242-Pediatric-ED-Visits2015.pdf. Accessed December 18, 2019.
2. Harvey M, Cave G, Betham C. Contemporary sedation practice in a large New Zealand emergency department. *NZ Med J.* 2011;124:36–45.
3. Cudny ME, Wang NE, Bardas SL, et al. Adverse events associated with procedural sedation in pediatric patients in the emergency department. *Hosp Pharm.* 2013;48:134–142.
4. Couloures KG, Beach M, Cravero JP, et al. Impact of provider specialty on pediatric procedural sedation complication rates. *Pediatrics.* 2011;127:e1154–e1160.
5. Coté C, Wilson S. Guidelines for monitoring and management of pediatric patients before, during, and after sedation for diagnostic and therapeutic procedures: update 2016. *Pediatrics.* 2016;138:1–31.
6. Grunwell JR, Marupudi NK, Gupta RV, et al. Outcomes following implementation of a pediatric procedural sedation guide for referral to general anesthesia for magnetic resonance imaging studies. *Paediatr Anaesth.* 2016;26:628–636.
7. Green SM, Roback MG, Krauss B, et al; Emergency Department Ketamine Meta-Analysis Study Group. Predictors of emesis and recovery agitation with emergency department ketamine sedation: an individual-patient data meta-analysis of 8,282 children. *Ann Emerg Med.* 2009;54:171–80.e1.
8. Mallory MD, Baxter AL, Yanosky DJ, et al; Pediatric Sedation Research Consortium. Emergency physician-administered propofol sedation: a report on 25,433 sedations from the pediatric sedation research consortium. *Ann Emerg Med.* 2011;57:462–8.e1.
9. Cravero JP, Beach ML, Blike GT, et al; Pediatric Sedation Research Consortium. The incidence and nature of adverse events during pediatric sedation/anesthesia with propofol for procedures outside the operating room: a report from the pediatric sedation research consortium. *Anesth Analg.* 2009;108:795–804.
10. Shah A, Mosdossy G, McLeod S, et al. A blinded, randomized controlled trial to evaluate ketamine/propofol versus ketamine alone for procedural sedation in children. *Ann Emerg Med.* 2011;57:425–33.e2.
11. Kannikeswaran N, Mahajan PV, Sethuraman U, et al. Sedation medication received and adverse events related to sedation for brain MRI in children with and without developmental disabilities. *Paediatr Anaesth.* 2009;19:250–256.
12. Bhananker SM, Posner KL, Cheney FW, et al. Injury and liability associated with monitored anesthesia care: a closed claims analysis. *Anesthesiology.* 2006;104:228–234.
13. Beach ML, Cohen DM, Gallagher SM, et al. Major adverse events and relationship to nil per os status in pediatric sedation/anesthesia outside the operating room: a report of the pediatric sedation research consortium. *Anesthesiology.* 2016;124:80–88.
14. Mace SE, Brown LA, Francis L, et al; EMSC Panel (Writing Committee) on Critical Issues in the Sedation of Pediatric Patients in the Emergency. Clinical policy: critical issues in the sedation of pediatric patients in the emergency department. *Ann Emerg Med.* 2008;51:378–99, 399.e1.