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Risk factors for inadequate sedation after endotracheal intubation in the pediatric emergency department

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1. Introduction

Rapid sequence intubation (RSI) is performed for the majority of children undergoing emergency endotracheal intubation in pediatric emergency departments (PED) or pediatric intensive care units (PICU) [1,2]. RSI is defined as administration of a sedative and paralytic in rapid succession to facilitate efficient tracheal intubation [1,3]. After RSI, additional sedation is typically necessary to avoid patient harm and discomfort [4-6].

Inadequate post-intubation sedation has been reported in as many as one-third of adult patients in critical care settings [5]. Further, awareness of paralysis has been recently been reported in 2.6% of intubated adult ED patients [6]. Patients with awareness from inadequate sedation after paralysis and intubation describe feelings of fear, violation, loss of control, or even imminent death [4]. Inadequate sedation also potentially increases the risk of unplanned extubation and hypoxemia with its downstream adverse effects [7]. In addition, assessing the depth of sedation for a paralyzed patient after RSI is difficult. Without visible breathing and other movements, the available indicators of patient distress are indirect and limited, including tachycardia and hypertension.

There are two published studies of post-intubation sedation in pediatric patients, both reporting inadequate post-intubation sedation in more than three-quarters of patients [8,9]. Kendrick et al. focused on RSI with etomidate and a long-acting paralytic, and did not explore risk factors for inadequate sedation [8]. Berg et al. reported three risk factors for inadequate sedation: the use of a long-acting paralytic, lower systolic blood pressure, and admission to the pediatric intensive care unit [9]. There are no studies of post-intubation sedation performed in the setting of a standardized RSI process. Standardization, in particular with a procedural checklist, has been reported to improve the safety of RSI [10-13].

Since 2012, our academic PED utilized a standardized, checklist-based protocol for RSI and modified RSI performed in the department. We reported our RSI protocol resulted in improved performance, safety, and timing of medication administration [11,14]. The objective of this current work is to determine the proportion of pediatric patients who experience inadequate sedation after RSI, despite use of our standardized RSI protocol which prompts providers to remember post intubation sedation. We also sought to identify risk factors for inadequate sedation in those patients who experienced a delay.

2. Materials and methods

2.1. Study design and setting

We performed a retrospective cohort study of pediatric patients undergoing RSI in an academic PED from January 2014 through December 2018. The PED is an urban, regional referral center with 60,000 annual combined patient visits. All critical procedures, including RSI, are performed in a dedicated four room resuscitation area. Board certified/eligible Pediatric Emergency Medicine physicians lead care teams made up of pediatric nurses, respiratory therapists, residents, paramedics, and other staff. ED pharmacists were involved in bedside care, though not available 24 h a day. The study protocol was reviewed by our Institutional Review Board prior to commencement and was determined exempt. The current report was written to be consistent with published guidelines for observational studies [15].

The RSI procedural checklist and other key RSI processes are performed for more than 90% of patients since 2012 [11]. The checklist includes medication options for the sedative and neuromuscular blocker (Fig. 1) [14]. Checklist choices for sedative included etomidate and ketamine, and for neuromuscular blockade succinylcholine or rocuronium. Throughout the study period, other options included fentanyl or midazolam for sedation and vecuronium for neuromuscular blockade. For post-intubation sedation, there are no recommendations for specific medications or timing of administration.

Each of the four resuscitation rooms are equipped with an audio-visual recording system. Recording is automatic and continuous, occurring 24-h a day. Recordings are available for review using a

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proprietary software program (LiveCapture, B-Line Medical, Washington, D·C).

2.2. Subjects and sampling

Patients were eligible for inclusion if they underwent RSI from January 2014 through December 2018 and were younger than 18 years-of-age. RSI was defined as rapid and successive administration of a sedative and a neuromuscular blocking agent prior to an attempt at endotracheal intubation [1,3]. Patients who did not receive both a sedative and neuromuscular blocking agent were excluded.

Eligible patients were identified using an existing internal database of all patients undergoing RSI. This database is maintained as a part of regular quality assurance and peer review activities. Daily reports of all resuscitation area patients are generated from our institution's electronic medical record (EMR). Manual EMR and video review are then performed to confirm performance of RSI and collect relevant process and outcome data.

2.3. RSI protocol

We defined the post-intubation sedation period from the initial sedative administered for RSI to the next administration of any sedative medication (benzodiazepine, opioid, ketamine). We defined post-intubation sedation as *inadequate* if the patient did not receive a second dose of sedative within a specific time frame (Table 1). We selected cutoffs for these time frames a priori, based on guidance from our ED pharmD (MB) and each medication's reported duration of action [16]. For etomidate and ketamine, the time cutoff for inadequate sedation was a second dose of sedative given greater than 10 min after the initial dose. For fentanyl and midazolam, the time cut-off was more than 30 min after the initial sedative. Succinylcholine was categorized as a short-acting paralytic and rocuronium and vecuronium as long-acting paralytics [16].

2.4. Data collection

We performed structured data collection from the EMR as well as our internal RSI database. An application specialist and research coordinator aided the primary investigator with the collection of data. Patient demographics, diagnosis, vital signs, length of stay, medication timing and administration were collected from the EMR. During prior studies of our RSI process, the timing of medication administration recorded in the patient chart was observed to be similar to the time the patient actually received medication [14,17]. The timing of intubation was determined by video review, collected by a research coordinator.

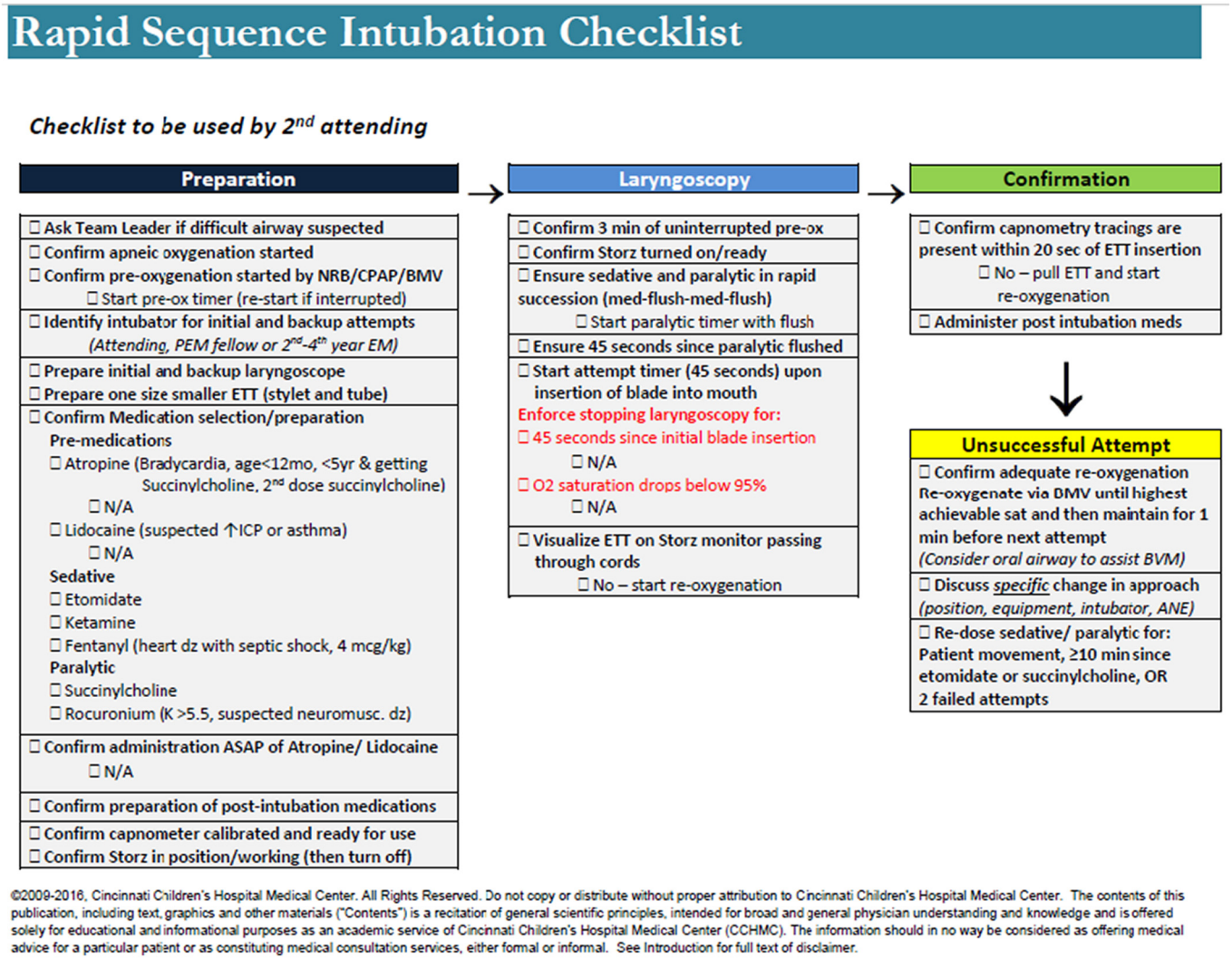

Fig. 1. Legend: checklist for rapid sequence intubation.
NRB = nonrebreather mask, CPAP = continuous positive airway pressure, BMV = bag–mask ventilation, PEM = pediatric emergency medicine, EM = emergency medicine, sux = succinylcholine, N/A = not applicable, ICP = intracranial pressure, K = serum potassium concentration, $ETCO_2$ = end tidal carbon dioxide concentration, Storz = Storz video laryngoscope (Karl Storz GmbH & Co. KG, Tuttingen, Germany), ETT = endotracheal tube.

Table 1
RSI checklist: medications, dosage and duration of action[18].

Sedative	Neuromuscular Blockade
Etomidate 0.3 mg/kg Max Dose: 20 mg Duration of action: 10 min	Succinylcholine 1.5 mg/kg Max Dose: 100 mg
Fentanyl 2μg/kg Max Dose: 100 μg Duration of action: 30 min	Rocuronium 1.2 mg/kg Max Dose: 100 mg
Midazolam 0.1 mg/kg Max Dose: 5 mg Duration of action: 30 min	Vecuronium 0.1 mg/kg Max Dose: 10 mg
Ketamine 2 mg/kg Duration of action: 10 min	

2.5. Outcomes

The primary outcome was the proportion of patients with inadequate sedation post-endotracheal intubation. Additional outcomes included possible risk factors associated with inadequate sedation, specifically the use of rocuronium or vecuronium, a second dose of a neuromuscular blocker, hypotension prior to intubation, trauma, lorazepam use prior to intubation or prolonged length of stay in the ED.

2.6. Analysis

We first tabulated data and generated descriptive statistics. We then used multivariable logistic regression to determine factors independently associated with inadequate sedation. We started with bivariable logistic regression to generate unadjusted odds ratios for each independent variable, including all independent variables with a p-value <0.2 in an initial multivariable model. We then used a backwards selection strategy to determine final variable inclusion. We removed the variable with the highest p-value, and if the odds ratio changed by more than 10%, the variable was left in the model. We repeated this approach until all variables were either significant with a P-value of <0.05 or identified as a potential covariate [18]. Correlation matrices were run to assess for multicollinearity. SAS (Version 9.4) was used to conduct the analysis.

3. Results

3.1. Enrollment and study subjects

During the 5-year study period, we identified 385 eligible patient encounters. We excluded 27 patient encounters: 9 who did not have RSI performed and 18 who had no intubation times recorded due to issues with video capture. The final study sample consisted of 358 patient encounters (93%). Thirteen patients were included twice, and 2 patients were included 3 times; each encounter was counted separately for analyses. Other than intubation times, missing data were rare.

The most common indication for intubation was neurologic and was present in almost one-third of study subjects (Table 2). Etomidate was the RSI sedative for more than 80% of patients, and rocuronium or vecuronium (long-acting paralytics) were used for more than 60% of patients (Table 3). Thirty-three patients (9.2%) received only the sedative administered for RSI, with no follow up sedation. For the 4 sedatives used for RSI, the median time to administer post-intubation sedation was: 9 min for etomidate (IQR 6,12) 11 min for ketamine (IQR 9,16) 26 min for midazolam (IQR 19,38) and 18 min for fentanyl (IQR 10,22).

3.2. Main outcome

Based on the time cut-offs selected a priori, inadequate sedation occurred in 149 study patients (42%, 95% confidence interval (CI) 37%, 47%). Eighty-two percent of patients with inadequate sedation received etomidate as the RSI sedative (123 patients); inadequate sedation occurred in 40% of the 306 patients who received etomidate as the RSI sedative. For the remaining 26 patients with inadequate sedation, the RSI sedative was ketamine in 17 (71% of patients receiving ketamine for RSI) and fentanyl in 8 (33% of patients receiving fentanyl) (Fig. 2). Only one patient with inadequate post-intubation sedation received midazolam (25% of patients receiving midazolam).

Table 2
Characteristics of 358 pediatric patients undergoing rapid sequence intubation in a pediatric emergency department over a 5-year period.

	$N = 358$
Age, y	2 [1,9]
Male	227 (63)
Race	
Caucasian	222 (62)
African American	100 (28)
Multiple Races	17 (5)
Other	11 (3)
Unknown	8 (2)
Ethnicity	
Hispanic	12 (3)
Non-Hispanic	345 (96)
Unknown	1 (1)
Indication for Intubation	
Neurologic	103 (29)
Respiratory	92 (25)
Trauma	89 (25)
Infection (not respiratory)	42 (12)
Ingestion	23 (6)
Other	9 (3)
ED Length of Stay Post-Intubation	
>30 min	309 (86)
Insurance Type	
Governmental	231 (64)
Commercial	117 (33)
Other	2 (1)
Self-Pay	8 (2)

Median (interquartile range) or (%) shown.

3.3. Risk factors for delayed sedation

Inadequate sedation occurred in approximately twice as many patients who received succinylcholine (72 of 114, 63%) compared with those who received rocuronium or vecuronium (78 of 244, 32%; Fig. 3). In the adjusted analyses, inadequate sedation was more common with succinylcholine use (aOR 3.6, 95% CI 2.2, 5.8) and when a second dose of a paralytic was given post successful intubation but prior to any further sedation (aOR 4.9, 95% CI 1.7, 14.7; Table 4). There was no evidence of collinearity between these variables based on correlation matrices. In the multivariable analysis, inadequate sedation was not statistically associated with short (etomidate/ketamine) versus longer-acting (fentanyl/midazolam) RSI sedative, hypotension prior to

Table 3
RSI Medication used for 358 pediatric patients undergoing rapid sequence intubation in a pediatric emergency department over a 5-year period.

	N = 358
Sedatives	
Etomidate	306 (85)
Ketamine	24 (7)
Midazolam	4 (1)
Fentanyl	24 (7)
Neuromuscular Blockade	
Succinylcholine	114 (32)
Rocuronium or Vecuronium	244 (68)

N and (%) shown.

intubation, trauma, lorazepam before intubation, or prolonged length of stay in the ED.

4. Discussion

In our retrospective, video-based study, we found that 4 of 10 patients in a PED experienced inadequate sedation after endotracheal intubation. Our main results are generally similar to both the adult and pediatric literature, all of which have found inadequate post-intubation sedation to be common. In a study of 84 pediatric patients undergoing RSI in a PED, more than three-quarters of patients received post-intubation sedation more than 15 min after the etomidate was given for RSI sedative, with the average time to post-intubation sedation 46 min after etomidate [8].

Quality improvement work in our PED has improved the process of intubation in the past few years, including the use of a checklist for intubation [19]. Checklist use is known to improve the efficiency and safety of RSI medication administration [14,20,21]. The RSI checklist used in our PED includes options for sedative and paralytic selection, a prompt to administer both medications in rapid succession, and a prompt to prepare a medication for post-intubation sedation. We may have found a lower frequency of inadequate sedation after ED intubation due to the impact of a standardized RSI process. The frequency of inadequate sedation, however, remains high.

The results of our multivariable analysis to identify risk factors for inadequate post-intubation sedation are more conflicting with the available literature. First, the use of a short-acting sedative was not statistically associated with inadequate sedation. As more than 90% of patients in our sample received a short-acting sedative for RSI, we believe this finding was largely due to a combination of unmeasured confounders increasing the frequency of inadequate sedation in the group receiving longer-acting sedatives and the low number of patients receiving these sedatives. There may also be unique RSI medication practices in our PED, especially given our long-standing efforts to standardize the process. As 94% of patients with inadequate sedation received a short-acting sedative for RSI, the results of our multivariable analysis should not be interpreted as indicating that short-acting sedatives are without risk for inadequate post-intubation sedation.

Second, the use of a long-acting, non-depolarizing neuromuscular blocker is an established risk factor for inadequate sedation in adult ED patients [22-25]. In a study by Berg et al., long-acting paralytics (rocuronium and vecuronium) were associated with delayed post

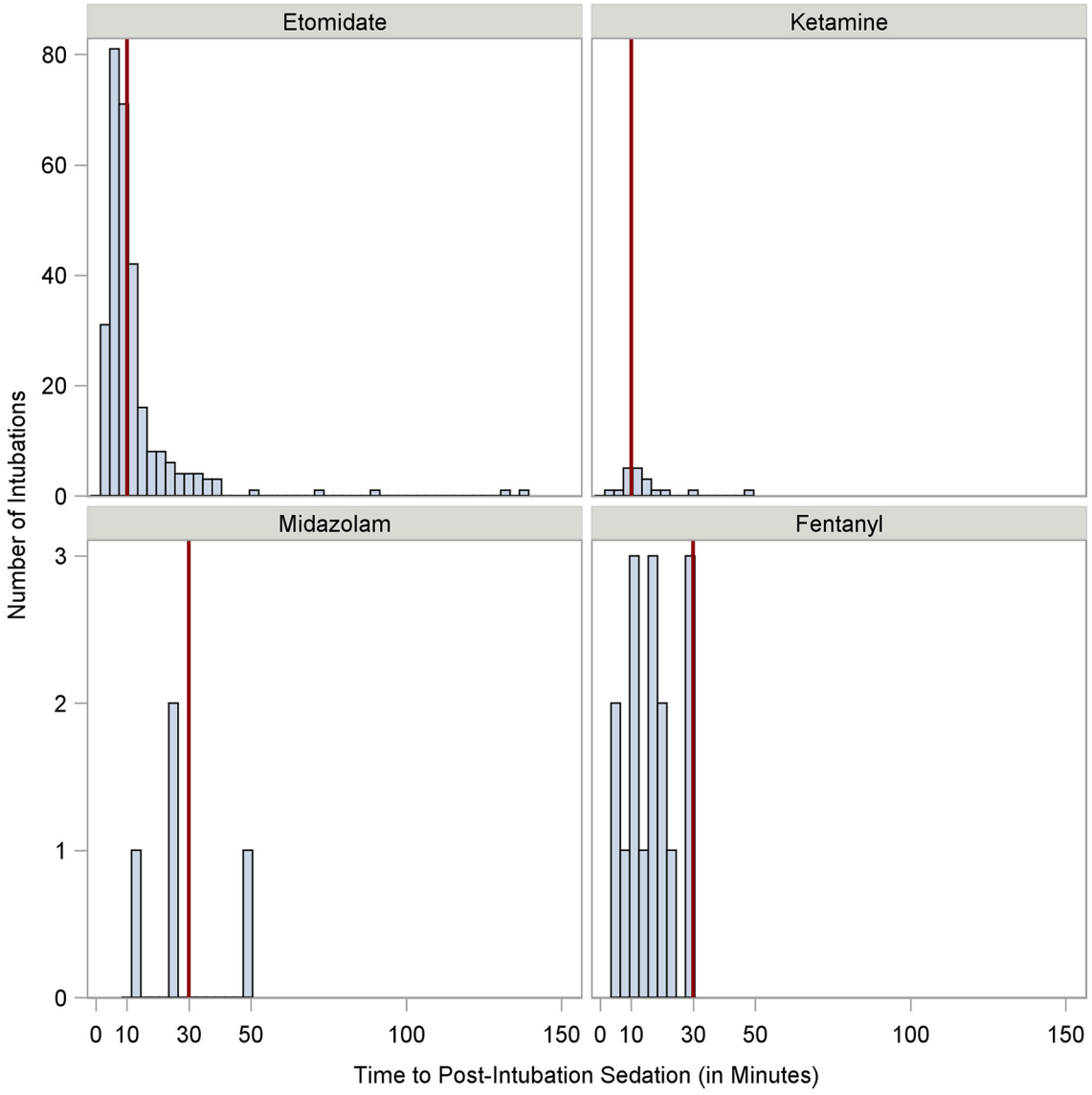

Fig. 2. Distribution of Time to Next Sedative after Intubation.

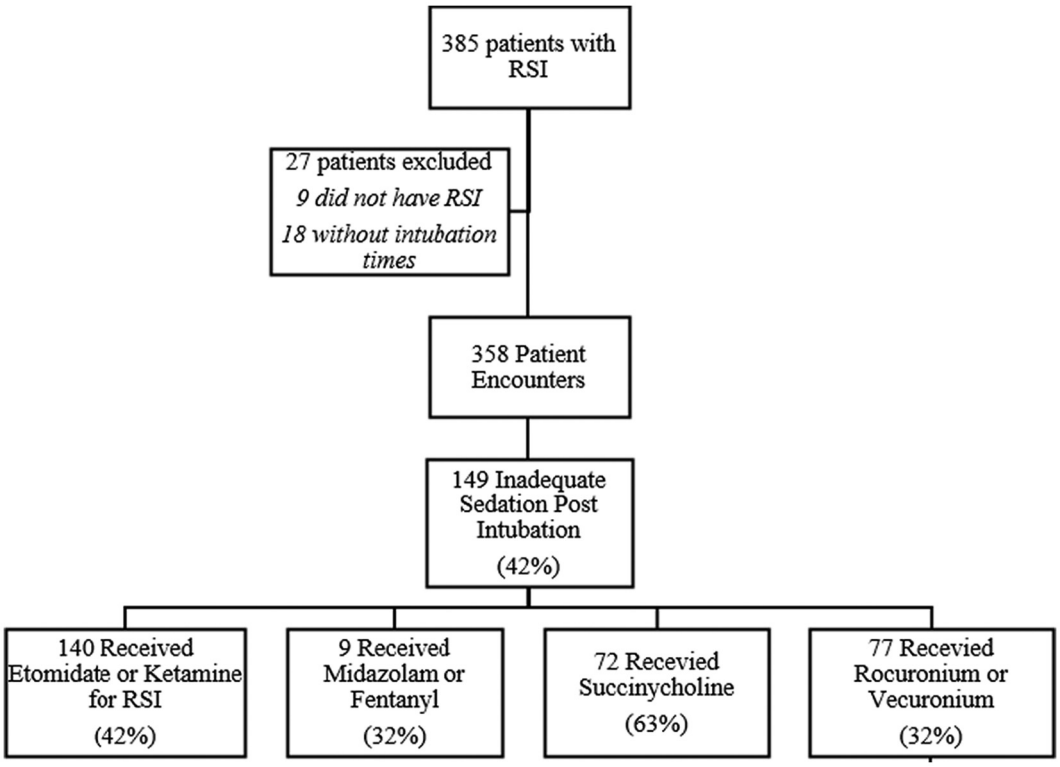

Fig. 3. Patients undergoing rapid sequence intubation in a pediatric emergency department over a 5-year period.

intubation sedation [9]. In contrast to the published literature, we found that patients who received succinylcholine were more likely to experience inadequate sedation. Similar to our failure to find an association between short-acting sedatives and inadequate post-intubation sedation, this result may be specific to the RSI process in our PED. Another explanation is that clinicians may be more aware of the risk of inadequate post intubation sedation after a short-acting neuromuscular blocker and therefore more likely to give appropriately timed sedatives.

Finally, we found that a second paralytic given after a successful intubation was associated with inadequate post-intubation sedation. We believe this result is due to a combination of factors, including prolongation of patient paralysis limiting clinician awareness of the need for additional sedation in these intubated patients.

With these risk factors identified, future work includes improvements to our RSI checklist. This work includes modifying the checklist to prompt the preparation of sedatives prior to intubation, including post intubation sedatives in order sets, reminders of the duration of action of sedatives, use of a standardized sedation scale and providing staff education to increase awareness of the risk factors for inadequate sedation. Current RSI protocol adjustments can be made to improve our post-intubation care, including increasing the recommended dose of fentanyl and standardizing the RSI medication selection. During this study, our PED did not have an ED pharmacist available at all hours to participate in patient care. This has recently changed, which may have an impact on post intubation sedation. We hope this work will improve the proportion of patients who receive adequate sedation after endotracheal intubation.

4.1. Limitations

There are several important limitations to our study. First, this was a retrospective cohort study, with inherent limits to validity. We attempted to mitigate these limitations by using video review data. Our estimates of inadequate sedation after intubation should not be limited by the usual issues with chart or electronic record review.

Second, our definition of *inadequate* sedation is somewhat subjective, in that it relies on the pharmacology of each medication rather than directly measuring the patient's sedation. Our team included an ED pharmD to mitigate this limitation. Other studies have used weight-based dosing or time estimates of duration of action– all of

Table 4
Risk Factors for inadequate post-intubation sedation in 358 pediatric patients undergoing rapid sequence intubation in a pediatric emergency department over a 5-year period.

	Bivariable OR	*p*-value	Multivariable OR	*p*-value
Short-acting paralytic ($N = 72$)	3.7 (2.3, 5.9)	<0.0001	3.6 (2.2, 5.8)	<0.0001
Second paralytic ($N = 145$)	6.1 (2.1, 17.6)	0.0009	4.9 (1.7, 14.7)	0.004
Etomidate or ketamine for RSI ($N = 140$)	1.5 (0.6, 3.5)	0.2	1.9 (0.8, 4.8)	0.14
Hypotension before intubation ($N = 12$)	1.8 (0.8, 4.6)	0.16	n/a	n/a
Lorazepam before intubation ($N = 46$)	1.1 (0.7, 1.7)	0.73	n/a	n/a
LOS >30 min post-intubation ($N = 124$)	0.6 (0.4, 1.2)	0.15	n/a	n/a
Trauma Patient ($N = 37$)	1.3 (0.8, 2.1)	0.27	n/a	n/a

OR = odds ratio.
LOS = Length of Stay.
Point estimate and 95% confidence interval shown.

these approaches are also indirect measures. Ideally, we would directly measure the patient's level of sedation. However, there are no standard approaches to determine the level of sedation in the ED. An alternative is patient self-report [4,6], but this approach also has limitations, especially in critically ill or injured children.

Finally, our study took place in a single academic PED with a highly refined and standardized process for RSI intubation. Applicability to either other PEDs or EDs caring for children may be limited. For example, our RSI protocol calls for 2μg/kg dosing of fentanyl, which for some patients may be inadequate to provide sedation. However, underdosing fentanyl would further contribute to the potential for delayed sedation.

5. Conclusion

Despite the use of an RSI checklist, 42% of children experienced inadequate post-intubation sedation. Though this is an improved proportion from the limited pediatric literature on this topic, there is certainly still improvement to be made. This study found that risk factors associated with inadequate sedation included succinylcholine use and a second paralytic given after successful intubation. We concluded that providers choosing to use medications for RSI should be mindful of these risk factors and the need for timely post intubation sedation when intubating pediatric patients.

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Credit authorship contribution statement

Katherine J. Edmunds: Methodology, Investigation, Formal analysis, Data curation, Conceptualization, Supervision, Writing – review & editing, Writing – original draft. **Terri Byczkowski:** Writing – review & editing, Methodology, Formal analysis, Data curation, Conceptualization. **Mary Frey:** Conceptualization, Data curation, Writing – review & editing. **Stephanie Boyd:** Writing – review & editing, Data curation, Conceptualization. **Michelle Caruso:** Conceptualization, Methodology, Writing – review & editing. **Yin Zhang:** Writing – review & editing, Formal analysis. **Benjamin T. Kerrey**: Conceptualization, Methodology, Writing - review & editing. **Nathan Timm:** Writing – review & editing, Supervision, Methodology, Data curation, Conceptualization.

Declaration of Competing Interest

The authors of this study do not have any conflicts of interest or financial agreements.

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