Site-Level Variance for Adverse Tracheal Intubation–Associated Events Across 15 North American PICUs: A Report From the National Emergency Airway Registry for Children*

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**Objective:** Tracheal intubation in PICUs is associated with adverse tracheal intubation–associated events. Patient, provider, and practice factors have been associated with tracheal intubation–associated events; however, site-level variance and the association of site-level characteristics on tracheal intubation–associated event outcomes are unknown. We hypothesize that site-level variance exists in the prevalence of tracheal intubation–associated events and that site characteristics may affect outcomes.

**Design:** Prospective observational cohort study.

**Setting:** Fifteen PICUs in North America.

**Subjects:** Critically ill pediatric patients requiring tracheal intubation.

**Interventions:** None.

**Measurement and Main Results:** Tracheal intubation quality improvement data were collected in 15 PICUs from July 2010 to December 2011 using a National Emergency Airway Registry for Children.* None of the PICUs had implemented formal interventions to reduce tracheal intubation–associated event prevalence and severity. The prevalence of tracheal intubation–associated events (25% vs 15%; p = 0.006) was observed to be higher in larger PICUs (> 26 beds), but patient and provider characteristics, both PICU size and fellowship presence were not associated with tracheal intubation–associated events (p = 0.44 and p = 0.18, respectively). Presence of mixed ICU with cardiac surgery was independently associated with a higher prevalence of tracheal intubation–associated events (25% vs 15%; p < 0.001; adjusted odds ratio, 1.81; 95% CI, 1.29–2.53; p = 0.01). Substantial site-level variance was observed in medication use, which was not explained by patient characteristic differences.

**Conclusions:** Substantial site-level variance exists in tracheal intubation practice, tracheal intubation–associated events, and severe tracheal intubation–associated events. Neither PICU size nor fellowship training program explained site-level variance. Interventions to reduce tracheal intubation–associated event prevalence and severity will likely need to be contextualized to variability in individual ICUs patients, providers, and practice. (Pediatr Crit Care Med 2014; 15:306–313)

**Key Words:** pediatric; quality improvement; respiratory failure; tracheal intubation

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*See also p. 369.

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Pediatric tracheal intubation (TI) is hazardous and commonly associated with recognized potential adverse outcomes in high-risk patients (1–12). Prospective communication, facilitated teamwork, and planning affect patient care flow, rapid detection, and response to changes in patient condition. Poor laryngoscope handling causes dental and laryngeal trauma (6), and poor intubation technique necessitates multiple attempts or prolonged intubation duration, which are associated with airway trauma, desaturation, and/or bradycardia (7). Tracheal tube misplacement or displacement may produce morbidity or mortality. Despite these known risks, TI in the PICU is practiced routinely in already complex, hazard-prone microsystems (11, 13). Although the risks of these procedures are well known in this critically ill population, accurately measured, multicenter performance and outcome data are lacking. Our National Emergency Airway Registry for Children (NEAR4KIDS) clinical research collaborators, supported by the Pediatric Acute Lung Injury and Sepsis Investigators (PALISI) network, have recently reported the landscape of safety and process of care for this procedure in diverse PICUs (1). We reported that adverse tracheal intubation–associated events (TIAEs) are common, occurring in approximately 20% of TI attempts. We identified several patient and provider factors associated with occurrence of TIAEs and severe TIAEs, such as pediatric resident laryngoscopists (2), patient histories of a difficult airway, acute oxygenation and ventilation failure, or unstable hemodynamic conditions as the indication for TI.

However, it is unclear how much variance in TI patient safety outcomes are due to patient and provider variability versus site-level characteristics and practice variance.

In this article, we attempt to describe the variance in TIAE and severe TIAE outcomes across 15 PICUs and assess the impact of site-level factors while controlling for provider and provider characteristics previously demonstrated to affect these outcomes. We hypothesize that there is substantial variance in the prevalence of TIAEs and that site-level factors, such as unit size, presence of pediatric critical care fellowship, and presence of mixed cardiac patient populations, are associated with the prevalence of TIAEs even after adjusting for patient- and provider-level factors.

MATERIALS AND METHODS

Settings

This study was conducted across 15 academic PICUs in North America. Sites were recruited through the PALISI network (Appendix 1) with bimonthly teleconferences to review quality improvement data, site compliance, and data accuracy.

Design

The NEAR4KIDS registry tool was developed by members of the PALISI network in conjunction with the National Emergency Airway Registry investigators (13–18). A data collection form was developed and piloted in a single tertiary care PICU and refined for the NEAR4KIDS investigators for the multicenter project. Institutional review board approval was obtained at each participating site. Each site project leader developed a site-specific compliance plan to ensure more than 95% TI encounter capture rate and the highest accuracy of the data. Two centralized compliance officers reviewed and approved each compliance plan for each site. Data collection was then initiated for each TI that occurred in the PICU at each center.

Separately from individual TI data collected on the patient, provider, and practice characteristics, each participating center submitted information pertaining to the individual site characteristics: size (number of PICU beds), number of PICU admissions per year, presence of a residency program, fellowship training program, case mix, and presence of in-hospital 24-hour critical care attending physicians.

Outcome Measures

Adverse events were defined as TIAEs with two categories: nonsevere TIAEs and severe TIAEs (1–3, 8, 9). Briefly, nonsevere TIAEs include mainstem bronchial intubation, esophageal intubation with immediate recognition, emesis without aspiration, hypertension requiring therapy, epistaxis, dental or lip trauma, medication error, arrhythmia, and pain and/or agitation requiring additional medication and causing delay in intubation. Mainstem bronchial intubation was considered only when it was confirmed on chest radiograph or recognized after the clinical team secured the tracheal tube.

Severe TIAEs include cardiac arrest, esophageal intubation with delayed recognition, emesis with witnessed aspiration, hypotension requiring intervention (fluid and/or vasopressors), laryngospasm, malignant hyperthermia, pneumothorax/pneumomediastinum, or direct airway injury. Note that hypoxemia itself is not included as a TIAE as it is often observed simultaneously with other adverse TIAEs, and the clinical impact of isolated hypoxemia is unclear.

Three airway management events, encounter, course, and attempt, were explicitly defined a priori and periodically reinforced on bimonthly conference calls, as described previously (1, 2). Briefly, “encounter” is defined as one episode of completed advanced airway management intervention, including TI. “Course” is defined as one method or approach to secure an airway (e.g., oral vs nasal, awake vs sedated vs rapid sequence) and one set of medications including premedication and induction. “Attempt” is defined as a single advanced airway maneuver (e.g., beginning with the insertion of the device such as laryngoscope/laryngeal mask into patient’s mouth or nose and ending when the device is removed).

Statistical Methods

Statistical analysis was performed using STATA 10.0 (Stata Corp, College Station, TX). Summary statistics were described with mean and SD for parametric variables and median with interquartile range (IQR) for nonparametric variables. For categorical variables with a dichotomous outcome, a contingency table method was used with chi-square or Fisher exact test analysis, as appropriate. Site-level variables, such annual admission (above or below median), unit size (above or below median), presence of a pediatric critical care fellowship, and presence of cardiac surgical patients, were also evaluated for an association with...
occurrence of TIAEs with chi-square analysis. Correlation statistics were evaluated using t test for significance. For site-level analysis, we adjusted for patient- and provider-level variables using a random effects model. Previously identified covariates (patient age, history of difficult airway, unstable hemodynamics, and pediatric resident as a primary airway provider) were adjusted for site-level analysis (1–3). A p value of less than 0.05 was considered significant for all hypotheses.

RESULTS

Site Characteristics

A total of 15 academic PICUs participated during the study period (July 2010 to December 2011). The median number of PICU beds was 26 (IQR, 16–30; range, 10–55) with median admissions 1,300/yr (IQR, 980–1,550; range, 640–3,500). Eleven of the 15 ICUs (73%) had a PICU fellowship and those ICUs had more ICU beds compared with ICUs without fellowship (median, 26; IQR, 16–30 vs median, 17; IQR, 13–26; p = 0.33). Nine ICUs admitted cardiac surgical patients during the study period. Seven ICUs (47%) had 24-hour in-hospital PICU attending presence (Table 1). All PICUs had a pediatric residency program.

Patient Characteristics

Table 2 describes the patient, provider, and practice characteristics previously associated with TIAE outcomes (1–3). Cardiac cases consisted of 13% of all patients (encounters). In approximately one third of the intubation events, the indication for advanced airway management was acute respiratory failure. Unstable hemodynamics (shock state) was identified as an indication in 13%. Fourteen percent of the patients were reported to have a history of difficult airway. Pediatric residents were the primary airway providers in 23%, pediatric critical care fellows in 41%, and critical care attending physicians in 12%. The majority of the encounters (96%) used direct laryngoscope, whereas indirect laryngoscopy such as video laryngoscope was rarely used as a primary device (1.7%).

Primary Outcomes

A total of 1,720 primary intubations were reported from 15 sites during the study period. Nine to 410 TIs per site were reported during the study period. This corresponded to a frequency of one TI every 1.3–26.8 days. The overall prevalence of TIAEs and severe TIAEs were 20.3% and 6.5%, respectively. The prevalence of TIAEs varied significantly across the sites: from 0% to 44.1% (p < 0.001). The prevalence of severe TIAEs was also significantly variable: 0–20.4% (p < 0.001) (Fig. 1).

Table 3 describes the univariate and multivariate analyses for the association between site-level characteristics and prevalence of TIAEs. The larger size of the ICUs (> 26 beds: more than median value) was associated with fewer TIAEs (TIAE, 17.8% vs 23.3%; p = 0.006). Presence of PICU fellowship,
however, was not associated with prevalence of TIAEs (20.4% vs 18.0%, p = 0.58). With multivariate analysis adjusting for patient and provider characteristics, both the size of the ICUs and presence of fellowship were not associated with TIAEs (odds ratio [OR], 0.83; 95% CI, 0.52–1.33; p = 0.44 and OR, 1.62; 95% CI, 0.80–3.31; p = 0.18). Mixed ICU with cardiac surgical patients was associated with a higher prevalence of TIAEs in both univariate and multivariate analyses (TIAE: 25.2% vs 14.9%, p < 0.001, multivariate OR, 1.81; 95% CI, 1.29–2.53, p = 0.001). This analysis result remained significant when we further adjusted for patient diagnostic category for cardiac condition (OR, 1.80; 95% CI, 1.28–2.54; p = 0.001).

**Practice Variance**

Substantial site-level variance was observed in the types of medication used for sedation and paralysis during TI (Fig. 2). The proportion of elective TI for procedural sedation substantially varied across the sites. Although the fentanyl/midazolam combination was widely used across the sites, the use of atropine, propofol, and ketamine was highly variable. Of note, the use of atropine and the proportion of infants per site had no significant correlation (r = 0.103, p = 0.72). Similarly, the use of ketamine and shock state, the use of propofol, and elective indication were not significantly correlated at the site level (r = 0.48, p = 0.07; r = –0.001, p = 1.00, respectively). The rate of resident involvement as a first provider also varied significantly among the centers (0–78%) (Fig. 3). The frequency of cuffed tracheal tube use was also diverse (mean, 91%; range, 59–100% per site). The PICUs with large number of admissions (> 1,300/yr) were associated with more frequent cuffed tracheal tube use (OR, 2.8; 95% CI, 1.4–5.7; p = 0.003). In contrast, a laryngoscope was commonly used in all PICUs (overall, 96%; 92–100% per site; p > 0.05).

**DISCUSSION**

Our study revealed a significant variability in the occurrence of TI and safety outcomes, as well as practice variables, across 15 PICUs. After adjusting for patient and provider characteristics, neither PICU size nor presence of fellowship training program explained site-level variance. Mixed PICUs with cardiac surgical patients were associated with a higher prevalence of TIAEs in both univariate and multivariate analyses. Successful interventions to impact TIAE prevalence and severity will likely need to be contextualized to variability in individual PICU patients, providers, and practice.

In our previous analysis of the NEAR4KIDS database, we identified patient, provider, and practice factors associated with occurrence of TIAEs. Specifically, patients with respiratory failure, with history of difficult airway, with hemodynamic instability such as shock or ongoing cardiopulmonary resuscitation, and having a pediatric resident as a primary airway provider were associated with occurrence of TIAEs. Use of atropine was also associated with higher prevalence of TIAEs. This was postulated to be due to selective use of atropine for high-risk patients with bradycardia and hemodynamic instability (1, 19, 20).

In this analysis, we have further identified site-level variability and the association of site characteristics with TIAE outcomes. As was expected, we described for the first time a large variance in practice and TIAE outcomes across diverse PICU sites. Despite the finding that pediatric critical care fellow airway provider was significantly associated with fewer TIAEs,
after adjusting for provider-level factors, the presence of fellowship itself was not associated with prevalence of TIAEs.

After controlling for patient and provider characteristics, the only site-level factor associated with increased TIAE rates was cardiac mixed unit status. The identification of the cardiac mixed unit status as an independent risk factor for higher TIAEs was unexpected and has not been previously reported. Cardiac arrest or hypotension requiring intervention occurred in 5% of patients (cardiac arrest, 1.8%; hypotension, 3.5%). Of note, cardiac mixed unit status was not significantly associated with the occurrence of these hemodynamic adverse events (OR, 1.6; 95% CI, 0.63–4.1; \( p = 0.32 \)). However, this is a post hoc analysis and likely underpowered, requiring future investigation with a larger dataset with more participating sites. The design of this study does not allow for identification of causality of this association, but several explanations can be speculated. This increased risk may reflect a particular severity of patients in those centers. The association remained significant when adjusted for several patient variables including diagnostic category and hemodynamic instability; however, it is possible that other patient characteristics not controlled for may play a role. Another potential contributing characteristic of cardiac mixed units is that physicians and fellows have been trained in more diverse specialty programs (cardiology, anesthesiology, surgery, and critical care) than in other PICUs. One could speculate that this difference may result in different intubation practices and level of training. However, no specific practice has been shown to be associated with TIAEs with the exception of resident involvement as first provider. In addition, we did not identify any specific patterns of TIAEs in those cardiac mixed units when compared with other PICUs. Future studies are necessary to evaluate the structure and process of care for critically ill children who require TIs in these different kinds of PICUs.

Figure 1. Prevalence of tracheal intubation–associated events (TIAEs) and severe TIAEs. Note that sites are sorted in the order of TIAE prevalence.

Table 3. Site-Level Characters Associated With Occurrence of Tracheal Intubation–Associated Events

<table>
<thead>
<tr>
<th>Site Character*</th>
<th>Univariate Analysis (OR, 95% CI)</th>
<th>Multivariate Analysis (OR, 95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual admission (&gt; 1,300 vs ( \leq ) 1,300)</td>
<td>0.95 (95% CI, 0.74–1.23; ( p = 0.74 ))</td>
<td>1.01 (95% CI, 0.62–1.65; ( p = 0.97 ))</td>
</tr>
<tr>
<td>ICU beds (&gt; 26 vs ( \leq ) 26)</td>
<td>0.71 (95% CI, 0.56–0.90; ( p = 0.006 ))</td>
<td>0.83 (95% CI, 0.52–1.33; ( p = 0.44 ))</td>
</tr>
<tr>
<td>Fellowship (present vs absent)</td>
<td>1.13 (95% CI, 0.73–1.78; ( p = 0.66 ))</td>
<td>1.62 (95% CI, 0.80–3.31; ( p = 0.18 ))</td>
</tr>
<tr>
<td>Cardiac surgery (present vs absent)</td>
<td>1.92 (95% CI, 1.51–2.46; ( p &lt; 0.001 ))</td>
<td>1.81* (95% CI, 1.29–2.53; ( p = 0.001 ))</td>
</tr>
</tbody>
</table>

OR = odds ratio.

*All sites had pediatric residency program.

The OR was 1.80 (95% CI, 1.28–2.54) when the multivariate model included cardiac diagnostic category as a patient-level factor.
Procedural training should be an important concern particularly in the PICUs in which a high percentage of intubations are performed by residents. From the hospital-wide patient safety perspective, it would be helpful to know how often those adverse TIAEs and severe TIAEs occur on other nonoperating room settings, such as emergency departments, neonatal ICUs, and regular inpatient units. Limited data from a single center suggest that adverse TIAEs are more often observed in emergency departments (9). We hope the comparative data with the standardized operational definitions among multicenter PICUs, emergency departments, and neonatal ICUs will become available in next a few years.

Limitations
Data are self-reported. Although each participating

Figure 2. Practice variance. A, Midazolam and fentanyl combination. B, Infants versus atropine use. C, Elective versus propofol use. D, Shock versus ketamine use. "r" denotes correlation coefficient. Each site number indicates a specific site in Figures 1-3. This is different from the alphabets shown in Table 1.

Figure 3. Proportion of the course with pediatric resident participation as laryngoscopists. Note that "course" is defined as one method or approach to secure an airway (e.g., oral vs nasal, awake vs sedated vs rapid sequence) and one set of medications including premedication and induction. Please refer to Materials and Methods section for details.
center followed an individual compliance plan to assure complete capture and an accurate data reporting, we cannot rule out the possibility of reporting and recall bias. We attempted to minimize these biases by bimonthly teleconferences and the education to site leaders and staff. Several site providers also participated in American Board of Pediatrics Maintenance of Certification quality improvement activity, which provided a mandatory education regarding the importance of the compliance plan and minimization of the reporting bias.

Our dataset does not contain detailed clinical descriptions of each case with severe TIAEs. Therefore, judging the preventability of those TIAEs is difficult. Rather, this information should be further discussed as a quality improvement activity at each PICU using their local NEAR4KIDS data. Furthermore, several site factors were not evaluated, as good quality information was not consistently available; this includes the presence of local management protocols, the attitude regarding non-invasive ventilation use prior to intubation, average Pediatric Index of Mortality 2 score at each site, and the nurse/patient ratios. In addition, patient-level factors such as history of a difficult airway and difficult airway features were reported by bedside providers. Although the data verification process with operational definitions was in place, those data points might have reflected providers’ perception rather than actual facts, especially as “difficult airway” is not specifically defined.

CONCLUSIONS
Substantial site-level variance exists in TI practice, adverse TIAEs, and severe TIAEs. After adjusting for patient and provider characteristics, neither PICU size nor presence of fellowship training program explained site-level variance. Mixed PICUs with cardiac surgical patients were associated with a higher prevalence of TIAEs. The reason for this association requires further investigation. Successful interventions to reduce TIAE prevalence and severity will likely need to be contextualized to variability in individual PICUs patients, providers, and practice.

REFERENCES
**APPENDIX 1. NEAR4KIDS and PALISI Network Investigators List**

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