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Intraoperative Reported Adverse Events in Children

Athina Kakavouli, MD,

Department of Anesthesiology, Columbia University, New York, NY

Guohua Li, MD, DrPH,

Department of Anesthesiology, Columbia University, and Department of Epidemiology, Mailman School of Public Health, Columbia University, New York, NY

Margaret P. Carson, CPNP,

Department of Anesthesiology, Columbia University, New York, NY

Julia Sobol, MD,

Department of Anesthesiology, Columbia University, New York, NY

Christine Lin, BA,

College of Physicians and Surgeons, Columbia University, New York, NY

Susumu Ohkawa, MD,

Department of Anesthesiology, Columbia University, New York, NY

Lin Huang, MPhil,

Department of Biostatistics, Mailman School of Public Health, Columbia University, New York, NY

Carolyn Galiza, MD,

Department of Anesthesiology, Columbia University, New York, NY

Alastair Wood, MD, and

Department of Internal Medicine and Department of Pharmacology, Vanderbilt University & Department of Internal Medicine and Department of Pharmacology, Weil Cornell Medical College, New York, NY

Lena S. Sun, MD

Departments of Anesthesiology and Pediatrics, Columbia University, New York

Abstract

Background—Significant intra-procedural adverse events(AE) are reported in children who receive anesthesia for procedures outside the Operating Rooms(NORA). No study, so far, has characterized AE in children who receive anesthesia in the operating rooms(ORA) and NORA when anesthesia care is provided by the same team in a consistent manner.

Objective/Aim—We used the same patient-specific Quality Assurance questionnaires(QAs), to elucidate incidences of intra-operative reported AE for children receiving anesthesia in NORA and ORA locations. Through multivariate logistic regression analysis we assessed the association between patient's AE risk and procedure's location while adjusting for ASA status, age and unscheduled nature of the procedure.

Methods/Materials—After IRB approval, we used returned QAs of patients under 21 years; who received anesthesia from our pediatric anesthesia faculty; from May 1, 2006 through September 30, 2007. We analyzed QA data on: service location, unscheduled/schedule procedure,

age, ASA status, presence and type of AE. We excluded QAs with incomplete information on date, location, age and ASA status.

Results—We included 8,707 cases, with 3.5% incidence of reported AE. We had 1,898 NORA and 6,808 ORA cases with AE incidence of 2.5% and 3.7% respectively. Multivariate regression analysis revealed that patients with higher ASA status or younger age had higher incidence of reported AE, irrespective of location or unscheduled nature of the procedure. The most common AE type, for both sites, was respiratory-related (1.9%).

Conclusions—Pediatric reported AE incidence was comparable for NORA and ORA locations. Younger age or higher ASA status are associated with increased risk of AE.

Keywords

anesthesia; pediatric; adverse events; ORA; NORA

INTRODUCTION

Technological advances in diagnostic/interventional imaging procedures have exponentially increased the demand and complexity of such procedures in children(1–4). Sedation and anesthesia are often needed for these procedures in non-operative settings (non-operating room-anesthesia, NORA)(1,4–11). Reports of serious adverse events (AE) resulting in death and permanent disabilities after sedation for these procedures in NORA locations raised patient safety concerns(5–8,10,12).

Responding to these concerns, the American Society of Anesthesiologists(ASA), the American Academy of Pediatrics(AAP), the American Academy of Pediatric Dentistry(AAPD), and the Joint Commission on Accreditation of Healthcare Organizations(JCAHO) developed guidelines for pre-procedural patient assessment, intra-procedural and post-procedural monitoring, post-procedural discharge criteria, and guidelines for training and credentialing of personnel who provide sedation/anesthesia in NORA locations(2,4–10,13–17).

Concomitant with the implementation of these guidelines, there has been a significant decrease in reported AE incidences in NORA locations in children over the past decade from 20–90% to 0.5–15%(4–7,10,11,17,21,22) along with a decrease in the severity of adverse long term outcomes(4–7,10,11,17,21,22). While there have been numerous anecdotal reports(7,8,12), suggesting that NORA may be associated with a higher incidence of reported AE compared to operating room anesthesia(ORA); there has been no study, so far, presenting incidence of reported AE in pediatric patients for NORA and ORA locations using the same AE monitoring system(18,19). Furthermore there is no study, so far, presenting AE incidence in children for NORA and ORA locations when the provision of anesthesia is consistent across locations with respect to pre-, intra- and post-procedural anesthesia care protocols, monitoring, equipment, personnel and supervision(5–8,10).

In our institution, we use the same intra-anesthetic patient-specific Quality Assurance surveillance questionnaires(QAs), for AE reporting, in NORA and ORA locations(Appendix 1) while our anesthesia personnel receive the same training for the completion of these forms. Our anesthesia practice are consistent for ORA/NORA locations in that we maintain the same pediatric anesthesia personnel, equipment and care protocols for both locations.

In this prospective observational epidemiologic study we elucidated incidences of reported AE for all children receiving anesthesia in our institution and through multivariate logistic regression analysis assessed the association between patient's reported AE risk and

procedure location while adjusting for ASA status, age, and unscheduled/scheduled nature of the procedure.

METHODS

After Institutional Review Board (IRB) approval, for intra-procedural AE reporting, we used all patient-specific Quality Assurance questionnaires(QA) that were completed and returned for any patient who received anesthesia supervised by our pediatric anesthesia faculty. Information, of all returned QAs, was entered into an encrypted Excel database(Office 2007, Microsoft Corporation, Redmond, Washington) for further analysis. For accuracy of information, each QA entry was audited and corrected when necessary. This study encompassed de-identified analysis from entries of all patients under 21 years of age, from May 1, 2006, through September 30, 2007. We analyzed the following data: service location, unscheduled/scheduled nature of procedure, patient ASA status and age, and presence of reported AE. We excluded from analysis; QA entries containing incomplete information on date, location, age and ASA status. If an AE was reported, information on its type was solicited. Each patient was only analyzed once for one or more reported AE. Consequently, if there was more than one reported AE for any patient, the responsible pediatric anesthesia faculty, or two independent pediatric anesthesia providers, would assign a “primary” or “most serious” reported AE based on whether the AE were related. As “primary” AE was defined any reported AE that led to another reported AE. For example, if “laryngospasm” and “oxygen desaturation” were reported in a case, the primary AE would be “laryngospasm”. A “most serious” AE was assigned if multiple unrelated AE were reported. As “most serious” AE was defined, the reported AE which created/or had-the-potential-to-create the most life-threatening condition or detrimental outcome to the patient.

The patient’s observation start-point was upon initiation of pre-anesthetic medication and the observation end-point was when patient’s care was transferred to PACU personnel.

We considered all anesthetizing operating rooms as ORA locations and all “out-of-OR” anesthetizing venues as NORA locations. NORA locations are presented in Appendix 2. We defined as “scheduled” cases all cases that appeared on the printed anesthesia schedule the night before the date of the procedure, and all others as “unscheduled”. Patient’s ASA status was assessed by the supervising pediatric anesthesia faculty and age was calculated in months(20). We included 50 different types of AE, grouped into seven categories: respiratory, cardiovascular, vascular access, trauma, pharmacological, hematological, and other.

Data were analyzed with t-tests for continuous variables and chi-square/Fisher tests for categorical variables. Multivariate logistic regression modeling was performed to assess the association between patient’s AE risk and the location of procedures while adjusting for ASA status, age, and unscheduled nature of the procedure. A $p < 0.05$ was deemed significant.

RESULTS

During the study period, 12,958 pediatric anesthesia cases were performed; 10,120 were ORA cases and 2,838 were NORA.

Initially, we included 8,868 returned QA forms, representing 68.4% of all pediatric anesthetic cases. Of those, we excluded 162 forms; 114 with missing information, 45 with age greater than 21 years, 2 with ASA status VI and 1 of double entry. Final analysis was performed in 8,706 QAs (98.2% of returned QA forms); 6,808 involved ORA and 1,898 involved NORA. There was no difference in the relative proportion of analyzed QA forms

from NORA and ORA locations, which respectively represented 67.3%(6,808/10,120) of all ORA cases and 66.9%(1,898/2,838) of all NORA cases.

All patients

Of all patients, 35.6% had an ASA status of III or higher. NORA patients(NORA-QAs) were of higher ASA status than ORA patients (ORA-QAs) ($ASA \geq III$:NORA-QAs = 56.6% versus ORA-QAs=29.8%, $p < 0.001$)(Table 1).

The age of all patients was 81.6 ± 67.9 months (mean $\pm$ SD), but NORA patients were younger in average age compared to ORA patients(78.5 ± 62 months versus 82.5 ± 69.5 months respectively, $p < 0.05$). However, there were fewer NORA patients who were infants compared to ORA patients ($p < 0.05$)(Table 1).

Unscheduled cases accounted for 14.3%(1,247/8,707) of all patients. The proportion of procedures that were unscheduled was higher in NORA compared to ORA(17.0% versus 13.6% respectively, $p < 0.01$).

AE incidence

The overall incidence of reported AE was 3.5%. NORA patients had a lower incidence of reported AE(2.5%, 47/1,898) than ORA patients(3.7%, 255/6,808, $p < 0.05$). However, after adjusting for patients' age, ASA status and unscheduled/scheduled nature of the procedure through multivariate logistic regression modeling the reported AE incidence was comparable between NORA and ORA(Table 2).

ASA status and age were significant predictors for intra-procedural reported AE. Patients with higher ASA status or younger age had a higher incidence of reported AE, irrespective of location and unscheduled nature of the procedure(Figures 1/2, respectively). In both locations, reported respiratory-related AE were most common, with 1.9%(167/8706) overall incidence rate(Table 3). Reported respiratory-related AEs(1.2%, 22/1,898) was lower for NORA compared to ORA(2.1%, 145/6,808, $p < 0.01$). The most commonly reported respiratory-related AE, irrespective location, were laryngospasm and bronchospasm(Table 4). Sub-analysis using multivariate regression modeling was not possible for specific AE due to small sample sizes.

The incidence of reported cardiac arrest was comparable between sites (ORA=0.07%, 5/6808, NORA=0.05%, 1/1898). There was no fatality from cardiac arrests in NORA patients. Of the reported ORA cardiac arrests 0.6%, 3/5 resulted in intraoperative death. Overall, 4 ORA deaths were reported, all were related to intra-operative events during open heart surgery.

DISCUSSION

Diagnostic/interventional imaging procedures performed outside the operating rooms create a unique environment and are associated with issues related to equipment, supplies and patient access(1–3,7–9,12). There has been no study, so far, that compares the incidences of reported AE between NORA and ORA locations, when all procedures are performed by the same personnel, equipment, monitoring guidelines and according to consistent anesthesia care protocols(10). This is mainly because differences observed in types of procedures, practice protocols, personnel, equipment, and supplies between locations; make a direct comparison extremely challenging.

Children who require sedation/anesthesia while undergoing NORA procedures may have a higher incidence of reported AE compared to ORA procedures(7,8,12), because children

who require NORA procedures are more likely to have co-morbidities(3,6,7). At our institution, patients of higher ASA status had a higher incidence of reported AE. Interestingly, in spite of the larger number of high ASA status patients in NORA, the reported AE incidence was similar to ORA.

“Malviya et al”(6) reported a higher incidence of AE(6.9%) in NORA locations compared to ours(2.5%). Their population consisted of healthier children(ASA status $\geq$ III, 19%) compared to our NORA population(ASA status $\geq$ III, 56.6%) and their population was significantly younger(2.96 ± 3.7 years, mean $\pm$ SD) than ours(6.54 ± 5.16 years of age, mean $\pm$ SD). The majority of their population underwent non-invasive procedures(2% cardiac catheterization patients), whereas the majority of our population had invasive procedures(38.2% cardiac catheterization, 12.01% interventional radiology, 6.7% endoscopies). Given that Malviya’s study occurred over a decade ago, the differences between their study and ours seem to reflect changes in patient populations and procedures performed in NORA locations over time. It is difficult to evaluate the differences in the incidences of reported AE between Malviya’s and our study because these differences might be attributed to differences in definitions of AE and reporting methods, patient characteristics, procedures performed, or changes in anesthesia care protocols over time(1,2,4–10,13–16,19). This highlights the challenges of evaluating contributing factors for reported AE among different studies(4,19).

“Murat et al”(23) reported a similar intraoperative incidence of AE(3.1%) as we did, and similarly found respiratory-related AE to be the most common AE with a similar incidence(1.7%) with ours(1.9%). They also reported a higher incidence of reported AE in patients with higher ASA status or younger age. There were major differences between our study and Murat’s in patients’ ASA status and types of procedures. Our population had more patients with high ASA status(ASA status $\geq$ III:64.4%) compared to theirs(ASA status $\geq$ III: 7%). Our patients had NORA procedures(21.8%,1898/8706) and open heart/neuroanesthesia cases(6.4%,560/6808) that were not included in Murat’s study. Therefore, patient’s ASA status and age seem to be independent contributing risk factors for reported AE irrespective NORA/ORA location and reporting methodology.

Other factors that have been identified to contribute to the high incidence of reported NORA AE include inadequate training of personnel for deep sedation and anesthesia, insufficient or incomplete knowledge/skills to perform pre-procedural assessment, intra-procedural patient monitoring, resuscitation and post-procedural recovery(1,2,5–10).

Our anesthesia practice are consistent for ORA/NORA locations in that we maintain the same pediatric anesthesia personnel, equipment and care protocols for both locations.

In our study, location was not a predictor for AE, and incidence of AE was similar for NORA and ORA locations, after adjustment for age, ASA status and procedure’s scheduled/unscheduled nature. This is consistent with current ORA literature(23), suggesting increasingly safe anesthesia practices in NORA locations over time compared to ORA locations. The similar incidences of intra-procedural reported AE between both locations underscore the importance of following established safety guidelines, regardless of location, as the best approach when it comes to providing care for children who need sedation and anesthesia in NORA locations.

A limitation of this study is that the majority of patients in ORA are undergoing invasive surgery. However, over half of our NORA procedures(56.8%) actually involved invasive procedures performed in the cardiac catheterization, interventional radiology, and endoscopy suites. Nonetheless, it might have been more appropriate to compare incidence of reported AE between procedures performed in NORA locations and minor surgical procedures in

ORA location, which have limited physiological perturbations. Interestingly, 57.4% (27/47) of all intra-operatively NORA AE occurred in the cardiac catheterization suite (CL). The overall reported AE incidence in the CL (3.7%, 27/725) is similar with the overall ORA AE incidence (3.7%, 255/6,808) but higher than the overall incidence of reported AE in all other NORA locations (1.9%, 20/1173, $p=0.006$). Future studies comparing AE incidences between invasive NORA procedures and ORA surgery, or ORA minor surgery and non-invasive NORA procedures; are needed.

Our study used each patient as the denominator and did not use each reported AE as the denominator. This avoided over-representation of those patients with multiple AE which would have created systematic association biases during multivariable logistic regression analysis. However, adopting the patient specific denominator could also create under-representation of their reported AE, since sickest patients undergoing the most invasive procedures might experience multiple reported AE as a result of a primary AE leading to a cascade of physiological compromises.

The majority of AE in our study were due to respiratory causes, irrespective of location. The lower incidence of respiratory AE found in NORA locations (1.2%) compared to ORA locations (2.1%) may be due to the lower number of children who were under one year of age in NORA locations (11.5%) when compared to ORA children (16.5%) (6,23).

Our study had only one case of cardiac arrest in NORA locations (0.0527%, 1/1,898). Although the incidence of cardiac arrest was low in our study, it was higher than the incidence reported by "Cravero et al" (0.003%, 1/30,037 sedation/anesthesia of NORA cases) (5). This may be due to the over-representation of children with cardiac disease undergoing cardiac catheterization procedures in our study (38.1%) compared to theirs (2%) and the sicker population in our study (ASA status $\geq$ III: 56.6%) when compared to theirs (ASA status $\geq$ III: 12.25%).

We did not analyze our data according to gender, airway management protocols, anesthetic agents used, duration and type of procedures performed. Current literature suggests that gender is not a contributing factor for the occurrence of AE (16). The anesthesia care in both locations was provided by the same personnel who used similar techniques and the same equipment according to ASA, SPA and JCAHO standards.

Our self-reporting system for AE was able to capture 68.4% of all pediatric cases. Reported AE incidence could be influenced by the work volume with AE being underreported with higher volumes of cases (6,18). Also, the higher the severity of the AE the more likely is for the AE to be reported (18,19). Furthermore, there has been higher reporting rates of AE among physicians with increased education and continuous feedback (18). Under-reporting could significantly alter the results and the interpretation of the findings. In our QA surveillance system, all anesthesia personnel underwent the identical QA orientation and training. Because the same personnel was assigned to both locations and the fact that the return rates for both locations were almost identical (66.9% for NORA and 67.3% for ORA), it seems unlikely that any systematic reporting biases of AE would create differences in the reported AE incidences between locations. Furthermore, there were no significant differences in ASA status or age (average and age groups) between the total pediatric anesthetized population and the population presented by the QAs suggesting that our study's population is representative of the total pediatric population who had anesthesia. Additionally, we were able to validate the mortality rates of our QA surveillance system with the hospital mortality data. We found no recorded hospital mortality report that was not captured by our QA forms.

Our results indicate that despite the many obstacles related to pediatric NORA anesthesia(1,5,6,10), the incidence of pediatric intra-procedural reported AE in these settings(NORA) can be comparable to that in surgical settings(ORA), when the same personnel utilizes the same equipment and uses anesthesia protocols according to existing safety guidelines. Higher incidence of AE was observed in children with higher ASA status or younger age irrespective location or unscheduled nature of the procedure. This report is limited to report of intra-procedural AE and did not include data from the recovery period. Future studies are planned to examine the epidemiology of AE during the entire perioperative period.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

Figure 2.

Table 1

Patients' ASA status and age distribution by location, 1 May 2006 through 30 September 2007

ASA status distribution	ORA, n=6808 (% all ORA)	NORA, n=1898 (% all NORA)	Total, n=8706 (% all QAs)
ASA I	2558 (37.6)	138 (7.3)	2696 (31)
ASA II	2223 (32.6)	686 (36.1)	2909 (33.4)
ASA III	1669 (24.5)	964 (50.8)	2633 (30.2)
ASA IV	348 (5.1)	106 (5.6)	454 (5.2)
ASA V	10 (0.1)	4 (0.2)	14 (0.2)
Age distribution	ORA, n=6808 (% all ORA)	NORA, n=1898 (% all NORA)	Total, n=8706 (% all QAs)
<1 months	243 (3.6)	15 (0.8)	258 (3)
1–12months	880 (12.9)	203 (10.7)	1083 (12.4)
1–6years	2391 (35.1)	796 (41.9)	3187 (36.6)
6–12years	1548 (22.7)	504 (26.6)	2052 (23.6)
≥12years	1746 (25.6)	380 (20)	2126 (24.4)

Table 2**Multiple regression analysis**

Odd Ratio Estimates. The higher the ASA status and the younger the age, the higher the adverse event incidence

Effect	Point estimate	95% confidence limits
ASA I vs III	0.5	0.4–0.8
ASA II vs III	0.8	0.6–1.1
ASA IV vs III	1.7	1.1–2.7
ASA V vs III	1.6	0.2–13.0
<1 month of age	1.4	0.8–2.4
1–12months of age	1.4	1.0–2.0
6–12 years of age	0.5	0.4–0.8
≥12 years of age	0.6	0.4–0.9
ORA/NORA	1.3	0.6–2.6
Unscheduled	0.9	0.6–1.3

Table 3
Types of Adverse Events (AEs), Site Distribution

The majority of AEs involved respiratory related AEs

Types of Adverse Events	ORA, n=255(% all ORA)	NORA, n=47 n (% all NORA)	Total, n=302 n (% all QAs)
Respiratory	145 (56.9)	22 (46.8)	167 (55.3)
Cardiac	20 (7.8)	6 (12.8)	26 (8.6)
Vascular related	21 (8.2)	3 (6.4)	24 (7.9)
Pharmacological	16 (6.3)	0	16 (5.3)
Trauma	15 (5.9)	6 (12.8)	21 (7.0)
Hematological	9 (3.5)	1 (2.1)	10 (3.3)
Other	21 (8.2)	4 (8.5)	25 (8.3)
Unspecified	8 (3.1)	5 (10.6)	13 (4.3)

Table 4
Respiratory Adverse Events, Site Distribution

The majority of respiratory complications involved laryngospasm and bronchospasm

Adverse Events: Respiratory Types	ORA, n=145(% all ORA)	NORA, n=22 (% all NORA)	Total, n=167 (% all QAs)
Laryngospasm	55(37.9)	5(22.7)	60 (35.9)
Bronchospasm	35(24.1)	5(22.7)	40 (23.9)
Desaturation(SaO ₂ <90%, of any duration)	20(13.8)	3(13.6)	23 (13.8)
Hypercarbia (PCO ₂ =55mmHg)	0	1(4.5)	1(0.6)
Aspiration (any quantity/content)	2(1.4)	1(4.5)	3(1.8)
Pulmonary edema	5(3.4)	0	5 (3)
Difficult intubation (>2 efforts)	13 (9)	3(13.6)	16(9.6)
Accidental extubation	5(3.4)	0	5 (3)
Inadequate ventilation (TV<5ml/kg)	2(1.4)	1(4.5)	3(1.8)
Right main stem intubation	2(1.4)	1(4.5)	3(1.8)
Other respiratory	6(4.1)	2(9.1)	8(4.8)