Sedation and general anaesthesia in children undergoing MRI and CT: adverse events and outcomes†

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Quality assurance data were collected prospectively for children who were sedated ($n=922$) or given general anaesthesia ($n=140$) for magnetic resonance imaging (MRI) or computerized tomography (CT). The data included patient characteristics, concurrent medication, adequacy of sedation, adverse events and requirement for escalated care. The quality of scans was evaluated. Reasons for preselection of general anaesthesia included previously failed sedation (28%), potential for failed sedation (32%) and perceived medical risk (14%). Hypoxaemia occurred in 2.9% of sedated children, and was more common in children classified as ASA III or IV. Sedation was inadequate for 16% of children and failed in 7%. Failed sedation was associated with greater age ($P=0.009$), higher ASA status ($P=0.04$) and use of benzodiazepines as sole sedatives ($P<0.03$). More of the children who underwent general anaesthesia were ASA III or IV than sedated children, yet the procedure was successful in all the children who underwent general anaesthesia, with one incident of laryngospasm. Excessive motion was noted in 12% of scans of sedated children and 0.7% of those completed with general anaesthesia. We conclude that sedation of children for MRI and CT is associated with risks of hypoxaemia and of inadequate or failed sedation. These adverse events were more likely to occur in older children, those with a higher ASA status and those in whom benzodiazepines had been used as sole sedatives. For a preselected high-risk group of children, general anaesthesia may make MRI and CT scans more successful with minimal adverse events.

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The number of diagnostic and therapeutic procedures done outside of the operating room has increased dramatically in recent years. In children, most of these procedures require sedation, analgesia or both to achieve the degree of cooperation or immobilization necessary to complete these procedures successfully. While most of these procedures themselves pose little risk to the child, the administration of sedation or analgesia may add substantial risk.[1–6] This may be particularly relevant for procedures, such as magnetic resonance imaging (MRI), that could frighten the child, and therefore call for deep sedation. In a previous study, we found that 20.1% of children who were sedated for diagnostic procedures experienced an adverse event.[1] Of greatest concern was the 5.5% incidence of respiratory events; these were more likely to occur in children with an ASA status III or IV. The most frequent adverse event in our study, however, was inadequate sedation (13.1%), which resulted in failure of 3.7% of procedures. We also reported that older children were more likely to experience inadequate sedation and that failed procedures were most likely to occur during MRI and computerized tomography (CT) scanning. Of the children who experienced a failed procedure, some were rescanned following general anaesthesia, while in others the procedure was attempted again with sedation. Early identification of children who may be at risk for adverse events, including failed or inadequate sedation, may make it easier to predict patients for whom general anaesthesia would be safe and efficient and lead to a successful procedure.

In some cases, general anaesthesia may be the only available way of making it possible to scan a child successfully. However, the use of general anaesthesia in these settings has been viewed as costly, impractical and inefficient.[7–9] While recent literature has highlighted the risks of sedation, little information is available about outcomes in children who undergo general anaesthesia before scans. The

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aim of this study was to evaluate outcomes related to sedation and general anaesthesia for CT and MRI. Specifically, we sought to determine the incidence of adverse events, including inadequate or failed sedation, in children undergoing CT and MRI, and to identify risk factors for failed sedation in this sample. We also attempted to discover why primary care practitioners chose general anaesthesia to aid scanning, and to define the incidence of adverse events associated with general anaesthesia in these patients.

Materials and methods

This study was conducted in the MRI and CT diagnostic areas at the University of Michigan Health Care Systems, a tertiary care medical centre. With approval from the Institutional Review Board, all children (from birth to 18 yr) who underwent sedation or general anaesthesia for MRI or CT procedures from January 1997 to January 1998 were included in this observational cohort study. Children who were intubated or ventilator-dependent, or both, and those who were hospitalized before the procedure were excluded from the study.

Sedation

Institutional sedation guidelines based on recommendations by the American Academy of Pediatrics (AAP) were in place at the time of this study.[10] In accordance with these guidelines, sedatives were ordered at the discretion of the child's primary physician. Based on the child's underlying medical history and physical examination, the nurse and radiologist reviewed the appropriateness of orders. Trained paediatric nurses in the diagnostic areas administered all sedatives and monitored the children throughout the procedure under the supervision of the radiologist. Monitoring included continuous pulse oximetry in every case. Arterial pressure was measured before and after the procedure, and more frequently at the discretion of the care-giver. Depth of sedation was assessed at least every 15 min by evaluating response to sound, verbal commands or tactile stimulation. Quality assurance tools[1] were prospectively completed by the nurse responsible for care of the child. Quality assurance data included patient characteristics and ASA physical status, significant medical history and physical examination findings. Procedural data recorded on the quality assurance tool included: medication(s) and their route of administration, time from sedative administration to the start of the procedure, duration of the procedure and time to discharge (i.e. recovery). Children were discharged home when their vital signs had returned to baseline, their level of consciousness was close to baseline and they could maintain a patent airway.

All adverse events were documented on the quality assurance tool in a check-box format as well as with narrative comments. Respiratory events included hypoxaemia (decrease in Sp_{O_2} by $\geqslant$10% of baseline for $\geqslant$30 s), upper airway obstruction, pulmonary aspiration and respiratory arrest. Oversedation was defined as prolonged sedation (i.e. continuing for $>$30 min after the procedure had ended) or excessive depth of sedation that resulted in another adverse event or required prolonged monitoring or escalation of care, including admission to the post-anaesthesia care unit, emergency department or inpatient setting. Inadequate sedation was defined as difficulty in completing the procedure because of the child's anxiety or inability to remain still. When the initial dose of sedative was too low to allow completion of the scan, additional doses of the same drug or a second agent were added at the discretion of the nurse and the radiologist after consideration of risk based on the child's underlying medical history. The decision to abort the procedure was made on an individual basis in every case. These sedation failures were documented on the quality assurance tool. Adverse reactions to medications, such as nausea, vomiting or paradoxical reactions, were recorded. For all patients who experienced an adverse event, the following information was recorded: interventions required, patient outcomes related to the adverse event, and escalation of care, i.e. prolonged monitoring or unplanned admission into the hospital.

General anaesthesia

During this study period, quality assurance information was prospectively obtained from all children who underwent general anaesthesia for CT and MRI scans. The decision to use general anaesthesia was made by the primary care physicians, and the reasons for this decision were documented. Decisions were based on guidelines developed by a multidisciplinary committee which recommended an anaesthesiology consultation for children at risk for sedation-related adverse events (such as airway abnormalities and underlying cardiopulmonary disease). Following informed consent, management for children who received general anaesthesia was at the discretion of the attending anaesthesiologist assigned to the care of the child. Care and monitoring were in accordance with mandates from the Joint Commision on Accreditation of Health Care Organizations (JCAHO) and ASA recommendations. Criteria used to determine whether children were ready to be discharged from the post-anaesthesia care unit after general anaesthesia were similar to those for sedation and also included adequate hydration and pain control. Quality assurance data were documented by the anaesthetist and included the same pre-procedure, procedural and recovery information as for sedated children. Adverse event data included airway complications on induction and emergence, hypoxaemia, pulmonary aspiration and respiratory arrest. Cardiovascular events included hypotension, arrhythmia and cardiac arrest. Adverse events and escalation of care as a result of the medication were documented as for sedated children.

The quality of a random sample of MRI and CT scans was evaluated by a radiologist who was blinded to whether general anaesthesia or sedation had been used. These scans were scored using a three-point scale (1, no motion; 2,

Table 1 Reported sedative agents and adverse events. Anxiolytic combination: chloral hydrate and benzodiazepine ($n=111$), or chloral hydrate and benadryl ($n=6$). Analgesic–anxiolytic combination: chloral hydrate and MS ($n=6$), or chloral hydrate and meperidine ($n=1$). The number of adverse events presented in the table is less than the total incidence of adverse events since the medications used were not reported in every case. †$P=0.004$ compared with chloral hydrate as a single agent. *$P = 0.02$ compared with chloral hydrate as a single agent. **Mean (SD) doses of chloral hydrate and midazolam were 63.8 (16.7) + 0.1 (0.05) mg kg^{-1} respectively

Sedative (n)	Oxygen desaturation ($n=27$)	Airway management ($n=9$)	Inadequate sedation ($n=146$)	Oversedation ($n=4$)	Failed procedures ($n=65$)
Single agents					
Chloral hydrate (679)	21 (3%)	7 (1%)	63 (9%)	4 (<1%)	26 (4%)
mean (SD), mg kg^{-1}	69 (9.9)		62 (16.4)	95 (44.1)	60.1 (15.5)
Benzodiazepine (90)	1 (1%)	0	17 (19%)†	0	8 (9%)*
mean (SD), mg kg^{-1}			0.09 (0.05)		0.099 (0.07)
Barbiturate (2)	0	0	0	0	0
Multiple agents					
Anxiolytic combination (117)	2 (2%)	1 (<1%)	59 (50%)	0	28 (24%)**
Analgesic–anxiolytic combination (7)	1 (14%)	0	1 (14%)	0	0

minor movement; 3, major movement making another scan necessary). The anaesthesia and sedation flowsheets in the medical records of a random sample of patients were reviewed to determine the validity of the quality assurance data.

Statistical analysis

Patient characteristics, medication doses and the incidences of adverse events were analysed using descriptive statistics and are presented as percentages or means (SD) where appropriate. The relationships between non-parametric variables such as ASA status and incidence of adverse events were studied using chi-squared analysis or Fisher's exact tests as appropriate. Continuous data, such as age, were compared using unpaired t-tests. For all comparisons, P values of $\leqslant 0.05$ were considered statistically significant. Factors found to be significant by univariate analysis were entered into logistic regression models to determine their contribution to inadequate or failed sedation and to respiratory events.

Results

Nine hundred and twenty-two children (aged 4 (birth–18) yr; 53% male and 47% female) received sedation for CT ($n=392$) and MRI ($n=530$) during the study period. Fifty-three per cent were classified as ASA I, 39% as ASA II and 8% as ASA III or IV. Two-hundred and three children (22%) experienced an adverse event related to sedation, but all events were appropriately managed and the diagnostic procedure was successfully completed in 93% of cases. The description of sedative agents used and adverse events is presented in Table 1.

Twenty-seven children (2.9%) experienced oxygen desaturation. Of these, 21 had been given chloral hydrate as the sole sedative (28–78 mg kg^{-1}), two had received chloral hydrate and midazolam, one midazolam alone, and one chloral hydrate and morphine. In two cases, the medication(s) used were not recorded. In each case, the child returned to baseline saturation with interventions that included: supplemental oxygen ($n=17$), repositioning of the airway ($n=2$) or both ($n=7$). One child returned to baseline saturation without any intervention. The respiratory event necessitated prolonged monitoring/observation at the diagnostic site in two cases, and in the emergency department or the post-anaesthesia care unit in another two cases. One child was admitted overnight because of a continued requirement for supplementary oxygen. Four procedures were aborted as a result of the respiratory event, three of which were rescheduled to be done under general anaesthesia. Interestingly, 7% of children classified as ASA III or IV experienced oxygen desaturation, compared with only 3% of those classified as ASA I or II ($P=0.03$). However, a logistic regression model failed to find any variable that was predictive of respiratory events.

Sedation was deemed inadequate for 146 children (50/392 CT (13%); 96/530 MRI (18%)). One hundred and twenty-three (84%) of these children had received chloral hydrate as the initial sedative. Intravenous midazolam was added in an effort to complete the procedure in 59 (40%) children and morphine was added in one case. Seventeen children who were inadequately sedated had received intravenous midazolam as the sole sedative. In six cases the medication(s) used was not recorded. Children in whom sedation was deemed inadequate were older than those with adequate sedation (4.9 (0.014–17.9) and 3.7 (birth–18.4) yr, respectively; $P=0.001$). Sedation was inadequate more commonly for children classified as ASA III–IV than for those classified as ASA I–II (24% and 15%, respectively; $P=0.04$). Sixty-four procedures were aborted as a result of failed sedation (13/392 CT (3.3%); 51/530 MRI (9.6%)). Of these, 11 (17%) were rescheduled to be done with sedation and 41 (64%) with general anaesthesia. For the remaining 12, it was not reported what course would follow. The interval between failed and rescheduled scans ranged from 2 to 77 days. Children whose sedation failed were older than those with successful procedures (5.1 (0.05–17.9) and 3.8 (birth–18.4) yr, respectively; $P=0.009$). The ASA status of children whose sedation failed was not

significantly different from that of children with successful procedures (10.3% ASA III–IV and 7.8% ASA I–II). Age and ASA physical status were entered into a logistic regression model to determine their value as predictors of inadequate or failed sedation. Of these factors, age was the only variable predictive of inadequate sedation ($P=0.0005$) and of failed sedation ($P=0.004$).

Thirty-four children experienced medication-related adverse events, which included: nausea and vomiting ($n=12$), paradoxical reaction ($n=19$), inadvertent drug overdose ($n=2$) and drug-related rash ($n=1$). Of the children who received the drug overdose (chloral hydrate 160 mg kg^{-1} in both cases), one required prolonged monitoring in the post-anaesthesia care unit and the other in the diagnostic area. Neither of these children experienced respiratory problems.

During the study period, 140 children (aged 4.6 (0.083–15.9) yr; 54% male and 46% female) underwent general anaesthesia for CT ($n=25$; 18%), MRI ($n=112$; 80%) or both procedures ($n=3$; 2%). Of these, 39 (28%) required general anaesthesia as a result of a previously failed sedation. Twenty-six (18%) children were selected to have general anaesthesia because the primary physician thought that the child would be unable to cooperate and 18 (13%) because the procedure was expected to be lengthy. In addition, 19 (14%) children had an underlying medical condition (e.g. sleep apnoea, difficult airway, multiple allergies) that may have made sedation riskier. In 38 (27%) cases, the reason for selecting general anaesthesia was unclear. Given these selection criteria, more children who underwent general anaesthesia were classified as ASA III–IV than those who received sedation during this same period (18% compared with 8%; $P=0.0006$). A significantly greater proportion of children who required general anaesthesia underwent an MRI scan compared with those who were sedated (82% and 57%, respectively; $P<0.0001$).

At the discretion of the responsible anaesthesiologist, general anaesthesia was induced via the inhaled route using halothane or intravenously using propofol or thiopental and maintained with isoflurane with or without nitrous oxide. Patients were allowed to breathe spontaneously via a laryngeal mask airway or endotracheal tube, or were placed on a ventilator depending on their medical history. One child in this sample experienced laryngospasm and oxygen desaturation on the way to the post-anaesthesia care unit. This child was given succinylcholine and required bag and mask ventilation, but subsequently recovered uneventfully. One other child with a history of an underlying seizure disorder had a seizure on emergence that resolved without intervention.

Table 2 shows the time taken to induce sedation or general anaesthesia and the durations of the procedure and the recovery period. The time to onset of procedure was significantly longer in children who were inadequately sedated than in those who had been sedated successfully (52 (26) and 37 (17) min, respectively; $P<0.0001$). Children who experienced failed sedation took longer to recover than those whose procedures were completed successfully (40 (21) and 24 (19) min, respectively; $P<0.0001$). The quality of 165 diagnostic images was reviewed and demonstrated that general anaesthesia resulted in less motion artefact than sedation (Table 3).

A random sample of medical records ($n=65$) was selected to evaluate the reliability of the quality assurance data. Only one (1.5%) of these 65 medical records indicated a respiratory event that was not reported on the quality assurance tool. One sedation record indicated that nausea and vomiting occurred after the child had been given chloral hydrate with his oatmeal. The remaining records were consistent with the quality assurance documentation and reported adverse events in 24 cases.

Discussion

MRI and CT procedures themselves pose little risk to children, but sedation or general anaesthesia–when used to facilitate these procedures–may add substantial risk. Indeed, the present study found a 2.9% incidence of hypoxaemia and a failure rate of 7% in children who received sedation for these procedures. In contrast, the procedure was successful in all of the children who received general anaesthesia during the study period, with one incident (0.7%) of laryngospasm, despite the higher risk characteristics of these children. In all children, adverse events were promptly recognized and managed appropriately, resulting in no long-term sequelae. These findings probably reflect the impact of recent changes in sedation practices based on AAP guidelines[10] and regulatory agency (i.e. JCAHO) mandates.[11]

Previous investigators have highlighted the risk of life-threatening adverse events related to sedation of children for diagnostic and therapeutic procedures.[2–6 12 13] Of greatest concern is the risk of respiratory depression and hypoxaemia that may have potentially long-term consequences. One previous study found an 89% incidence of oxygen desaturation in children who were sedated for gastrointestinal endoscopy.[14] In the present study, we found a relatively low incidence of oxygen desaturation (2.9%). Similar to previous reports, respiratory events were more likely to occur in children with an ASA status III or IV than in those of ASA I or II.[1 15 16] The low incidence of respiratory events in our sample may, in part, be explained by the fact that only 8% of children with ASA III or IV underwent sedation. These findings support the recommendations of the AAP that children with ASA III–IV require additional and individual consideration. While the incidence of these events was low, the majority required intervention (airway management in nine cases) and four procedures had to be aborted as a result of the event; three of these were rescheduled to be done with general anaesthesia. No respiratory event resulted in long-term sequelae, probably because of appropriate monitoring and early intervention in all cases. Despite the low incidence of respiratory events, their life-threatening nature underscores the importance of personnel trained in airway management being present. This recommendation is supported by Sury and colleagues who reported a <1% incidence of oxygen desaturation in 1155 children who were sedated for MRI by nurses trained in sedation and airway management.[17]

Table 2 Duration (in minutes) of procedure and recovery times in the two groups (mean (SD))

Time period	Sedation group		General anaesthesia group	
	MRI	CT	MRI	CT
Procedure onset time	42.4 (19.7)	36 (18.4)	23.1 (11.5)	19.4 (12.6)
Duration of procedure	47 (26.1)	17.4 (11.3)	82.5 (43.3)	54.4 (44.9)
Recovery time	28.8 (18.8)	19.5 (21.2)	70 (34.1)	59.9 (36.9)

Table 3 Quality of MRI and CT scans in the sedation and general anaesthesia groups (*n* (%))

	Sedation group ($n=80$)		General anaesthesia group ($n=85$)	
	MRI ($n=60$)	CT ($n=20$)	MRI ($n=67$)	CT (n=18)
No motion	40 (67)	17 (85)	56 (84)	18 (100)
Little motion	13 (22)	3 (15)	10 (15)	0
Motion requiring repeated scan	7 (12)	0	1 (1)	0

Although not life-threatening, inadequate sedation remains a significant clinical problem. This outcome can be costly in terms of quality of the scan, increased personnel time, variability in onset of sedative action resulting in downtime of the scanner, lost revenue from failed procedures, and inconvenience to patients and families. Indeed, we found that the quality of scans was not optimal in 29% of sedated cases. Furthermore, the time from administration of sedatives to initiation of procedure was significantly longer in children who experienced inadequate sedation. Inadequate sedation led to 63 failed procedures which, if successful, would have been billed at approximately \$1200 h^{-1}. These failures, therefore, resulted in a significant loss of revenue to the institution. Several of these failed procedures were rescheduled with sedation or general anaesthesia, compounding the charges to the institution and third-party payers. Lastly, the costs to patients and families in terms of travel time, repeated trips to the hospital, lost work time and, perhaps most importantly, delayed diagnosis are immeasurable. It is therefore important to identify those at risk for inadequate or failed sedation to permit use of alternative techniques of sedation or even general anaesthesia if necessary.

As we and other investigators have reported previously,[1 18] sedation was more likely to be inadequate or fail in older children. In our sample, the majority of children received a single sedative agent for their scan; this produced adequate sedation in 90% of cases. However, 5% of all cases for which a single drug was used were aborted because of inadequate sedation. Of the children with failed sedation who received chloral hydrate as a sole agent, all had received a dose within the recommended range (50–90 mg kg^{-1}, maximum 2000 mg). Interestingly, a previous study has suggested that the dose of chloral hydrate should be based on age, resulting in larger doses for older children.[19] It is unclear whether such a dosage adjustment would have reduced the incidence of failed sedation in our sample. Compared with chloral hydrate, when a benzodiazepine was used alone, sedation was more likely to be inadequate and to result in a failed procedure. In some cases, a second drug was not added, presumably because of a perceived increased risk. Indeed, previous investigators have reported a greater risk of sedation-related adverse events when multiple sedatives were used.[3 12] We also found that sedation was more often inadequate in children with ASA status III or IV than in those with ASA I or II. This may reflect a reluctance to administer larger doses or multiple sedative drugs to these patients perceived to be at increased risk related to sedation. Variability in response to the initial sedative agent may require titration of a second agent to the desired effect in some instances. Of the children in our sample who received a second sedative agent in an attempt to complete the scan, 77% were scanned successfully. The incidence of respiratory and other adverse events was no different with the use of single or multiple agents. These data suggest that, in selected children, addition of a second drug may aid the completion of scans without increasing risk.

The use of general anaesthesia to aid diagnostic and therapeutic procedures has been viewed as costly, associated with high risk and inefficient.[7–9] Indeed, Squires and colleagues reported that general anaesthesia added \$1200 to the cost of gastrointestinal endoscopic procedures.[9] During our study period, general anaesthesia was used to aid MRI and CT scans in 140 children. In the majority of these cases, the primary physician had chosen general anaesthesia as the initial intervention because of the potential for a failed procedure or a perceived increased risk of adverse events resulting from underlying conditions such as congenital heart defects or airway abnormalities. The children who received general anaesthesia were, therefore, a higher risk group than those who received sedation as evidenced by their higher ASA status. Yet these children experienced few adverse events from general anaesthesia. Of greatest concern was the incident of laryngospasm that occurred on the way to the post-anaesthesia care unit. Prompt recognition and aggressive intervention averted potential long-term consequences of this event which underscores the need for continued monitoring of all children who receive general anaesthesia even during

transport. Furthermore, depending on the location of the procedure, it may be prudent to allow these patients to recover at the diagnostic site before transport.

We were unable to make direct comparisons between children who received sedation and those who received general anaesthesia since it was not possible to randomize children to either group. Children who underwent general anaesthesia were preselected, based upon high risk in some cases and expected duration of the procedure in others, and, as a result, statistical comparisons between groups would have been inappropriate. In general, however, general anaesthesia appeared to be more efficient in terms of time to onset of the procedure, but resulted in a longer duration of recovery in the hospital. The increased costs associated with administration of general anaesthesia may, therefore, include added costs related to recovery. Although general anaesthesia may cost more to administer than sedation, in our patients it helped scans to be completed with negligible movement and a low incidence of adverse events. The costs of general anaesthesia for a selected high-risk group of patients may be offset to some extent by the increased costs related to failed procedures.

One limitation of this study is related to the self-report bias inherent in the method of data collection. To minimize this bias, we reviewed a random sample of medical records in each group. Not surprisingly, we found $<100\%$ compliance with the required documentation and with institutional sedation guidelines. Of the records available for review, only one had a documented respiratory event that was not reported on the quality assurance tool, and one reported non-compliance with institutional nil-by-mouth guidelines for sedated patients. While this review supports the reliability of our data, we emphasize that the incidence of adverse events reported here was probably lower than the true incidence of adverse events from sedation and general anaesthesia.

Our data demonstrate that sedation of children for MRI and CT is associated with risks of hypoxaemia, inadequate sedation and failed sedation, and support the use of stringent guidelines to enhance the safety of sedated children. A higher ASA status was significantly related to the incidence of hypoxaemia and inadequate sedation. Greater age and the use of benzodiazepines as sole sedatives were associated with a higher incidence of failed sedation. These data support the need for careful selection of appropriate candidates for sedation and additional and individual consideration for children with a high ASA status. Furthermore, our data suggest that general anaesthesia is a safe alternative to facilitate MRI and CT scans in children perceived to be at increased risk for sedation-related adverse events or for those with a history of failed sedation.

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