Procedural Sedation for Diagnostic Imaging in Children by Pediatric Hospitalists using Propofol: Analysis of the Nature, Frequency, and Predictors of Adverse Events and Interventions

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Objective To evaluate the nature, frequency, and predictors of adverse events during the use of propofol by pediatric hospitalists.

Study design We reviewed 1649 charts of patients sedated with propofol by pediatric hospitalists at St Louis Children's Hospital between January 2005 and September 2009.

Results Hospitalists were able to complete 1633 of the 1649 sedations reviewed (99%). Major complications included 2 patients with aspiration and 1 patient intubated to complete the study. We observed a 74% reduction in the number of patients with respiratory events and airway interventions from 2005 to 2009. Predictors of respiratory events were history of snoring (OR, 2.40; 95% CI, 1.52-3.80), American Society of Anesthesiologists (ASA) physical status classification of ASA 3 (OR, 2.30; 95% CI, 1.22-4.33), age >12 years (OR, 4.01; 95% CI, 2.02-7.98), premedication with midazolam (OR, 1.85; 95% CI, 1.15-2.98), and use of adjuvant glycopyrrolate (OR, 4.70; 95% CI, 2.35-9.40). All except ASA 3 status were also predictors for airway intervention. There was a decline in the prevalence of all of these predictors over the study years ($P < .05$) except for use of glycopyrrolate.

Conclusion Our pediatric hospitalists implemented a successful propofol sedation program that realized a 74% reduction in respiratory events and airway interventions between 2005 and 2009. Decreased prevalence of the predictors of adverse events that we identified likely contributed to this reduction. *(J Pediatr 2012;160:801-6)*.

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There is increasing demand to sedate children for both diagnostic and therapeutic procedures. To meet this demand, non-anesthesiologists are providing sedation using various agents, including propofol. Propofol is a general anesthetic that induces levels of sedation ranging from deep sedation to general anesthesia in a dose-dependent manner. This property has historically limited the use of propofol to anesthesiologists. Today, propofol use by pediatric intensivists and pediatric emergency room physicians is on the rise, and studies show that such use is associated with minimal adverse events.[1-10] However, there are little data on the use of propofol by pediatricians without subspecialty training for the sedation of children for radiologic procedures.

Sedation-trained pediatric hospitalists at St Louis Children's Hospital (SLCH) began using propofol to sedate children for radiologic imaging in 2004, and performed more than 1600 propofol sedations for radiologic procedures between 2005 and 2009. In this article, we describe our propofol sedation program and report the nature and frequency of adverse events and interventions found in a retrospective review of 1649 charts of patients sedated with propofol between 2005 and 2009. We identify predictors of respiratory events and airway interventions and show how a reduction in the prevalence of such predictors correlated with a 74% reduction in the rate of adverse events from 2005 to 2009.

Methods

This retrospective study was approved by the hospital's Institutional Review Board. We used deep sedation Current Procedural Terminology codes 00190, 00300, 00400, 00532, 00635, 00700, 00790, 00860, 01200, 01470, 01922, and 01952 to obtain a list of all patients sedated by hospitalists between January 2005 and September 2009. A total of 1686 patients from the list were sedated with propofol by hospitalists during the study period. Charts were excluded that were incomplete or that noted propofol use in combination with agents other than oral midazolam. A total of 1649 charts were reviewed. Information was obtained from notes made both by nurses and physicians in the sedation records. The majority of

APC	Ambulatory Procedure Center
ASA	American Society of Anesthesiologists
BMV	Bag-mask ventilation
SLCH	St Louis Children's Hospital

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charts (n = 1309) were reviewed by the principal investigator (M.S.); M.S. also audited 10% of the charts reviewed by coauthors M.T. and L.D. to ensure accuracy of data collection.

Sedation Program

Sedation Training. A dedicated team of pediatric hospitalists has provided propofol sedations for radiologic imaging at the SLCH Ambulatory Procedure Center (APC) since 2004, with the oversight of pediatric anesthesiologists. These hospitalists have at least 3-5 years of experience sedating children with such agents as ketamine, nitrous oxide, pentobarbital, and fentanyl/midazolam. Training in propofol administration includes a 4-hour didactic session with anesthesiologists, 10 days of operating room training to demonstrate proficiency in airway management skills, use of simulation scenarios, a written exam, and performance of 25 propofol sedations supervised by pediatric anesthesiologists. Our sedation service procedures and monitoring guidelines were developed by the SLCH Sedation Committee in accordance with the guidelines of the American Academy of Pediatrics, American Society of Anesthesiologists (ASA), Joint Commission, and Center for Medicare and Medicaid Services.[11-14]

Sedation Protocol. When a patient is admitted to the APC, a dedicated sedation unit adjacent to the radiology suite, a presedation assessment is performed by a hospitalist. Nothing by mouth criteria are maintained in accordance with the ASA's fasting guidelines for procedural sedation.[12] At the discretion of the sedating physician, the patient may be premedicated with oral midazolam before placement of a peripheral intravenous line. Patient monitoring is in accordance with American Academy of Pediatrics and ASA guidelines.[12,13] Continuous monitoring of end-tidal CO_2 is instituted after induction of sedation. If tolerated, the patient is preoxygenated before induction. After induction, supplemental oxygen is provided by nasal cannula at a rate of 2 L/min. Depending on individual physician practices, a patient with oral or nasal secretions may be given glycopyrrolate. Isotonic intravenous fluid is administered at the discretion of the sedating physician.

Hospitalists initiate propofol sedation in the APC with a mean bolus dose of 2.1 ± 0.3 mg/kg, with a slight downward adjustment for weight in patients weighing >40 kg. Additional bolus doses of 1 mg/kg are given as needed until the patient is deeply sedated and reaches a University of Michigan Sedation Scale score of 3.[15] Maintenance propofol infusion at a rate of 200 μg/kg/min is initiated immediately after administration of the bolus dose. The patient is then transported to the radiology suite. Once the scan is started, infusion is weaned at an individualized rate. Typically, the rate is initially decreased to 175 μg/kg/min, and if the patient remains deeply sedated, the rate is further decreased to 150 μg/kg/min. A sedation-trained nurse is present throughout induction, transfer to the scanner, and most of the procedure. An anesthesiologist is immediately available for consults or complications.

The sedating physician records vital signs, University of Michigan Sedation Scale score, and adverse events or interventions every 5 minutes during the procedure. The patient is observed directly and on camera during the scan. Standard resuscitation equipment and rescue medications are readily available.

At the conclusion of the procedure, the patient is transported back to the APC, and care is transitioned to a sedation-trained nurse. The hospitalist is available at all times during recovery. The patient is discharged when he or she meets standard discharge criteria, including return of vital signs to baseline ± 20%, Aldrete recovery score ≥9,[16] University of Michigan Sedation Scale score ≤1, and ability to sit/stand with minimal assistance and tolerate fluids without nausea or emesis.

Statistical Analysis

Descriptive analysis was used for demographic characteristics. Mean ± SD and median with IQR are reported for continuous variables, and percentages are reported for categorical variables. The 2-sided Wilcoxon test was used to analyze the differences in procedural and recovery times between groups. The χ^2 test was used to detect the association of patient characteristics and procedural methods that were predictors of either respiratory events or airway interventions. A multiple logistic regression model was then used to estimate the effects of these predictors on outcomes, with ORs and 95% CIs calculated. The χ^2 test was performed to test the differences in percentages of patients with predictors of complications between 2005/2006 and 2008/2009. Data were pooled to provide sufficient numbers for statistical comparisons. All reported P values are 2-sided and are considered significant at $P < .05$. All statistical analyses were performed using SAS 9.1 (SAS Institute, Cary, North Carolina).

Results

The mean patient age was 62 ± 44 months, with a range of 4 months to 28 years (**Table I**; available at www.jpeds.com). The majority of patients were sedated for magnetic resonance imaging (96.6%); the remainder were sedated for computed tomography, nuclear medicine scans or electromyography.

Data on procedure duration, recovery time, and time to discharge are presented in **Table II**. Premedication with midazolam was associated with significantly prolonged median recovery time (by 33%) and time to discharge (by nearly 25%).

Overall, hospitalists were able to successfully complete 99.03% (n = 1633) of all sedations reviewed (**Table III**). Of the remaining sedations, 0.85% (n = 14) were aborted and 0.12% (n = 2) were completed by anesthesiologists. The spectrum and rates of adverse events and interventions in the study population are presented in **Table III**. Note the substantial overlap in the number of adverse events/interventions among patients. A single patient may have had one or more respiratory events requiring either no

Table II. Procedure duration, recovery time, and time to discharge in patients premedicated with and without oral midazolam

	No midazolam		Midazolam		
	Median	IQR	Median	IQR	*P* value
Procedure duration, minutes	65	55-80	65	54-79	.115
Recovery time, minutes	32	20-45	43	29-60	<.001
Time to discharge, minutes	20	15-30	25	15-35	<.001

Procedure duration is defined as the interval from the start of infusion until the patient was transferred to recovery. Recovery time is defined as the interval from the end of the procedure to the end of phase 2 recovery. The end of phase 2 recovery defines the conclusion of sedation care, and the patient meets standard discharge criteria as outlined in the Methods section. Time to discharge is defined as the interval from the end of phase 2 recovery to the time the patient leaves the unit.

intervention, one or more airway interventions, or an urgent anesthesiology consult.

Of the 1649 sedations performed, only 3 major complications were noted (0.18%), each of which led to an unplanned admission for the patient. Two patients experienced possible aspiration. The first patient coughed and desaturated shortly after induction, with increased oxygen requirement. A chest radiograph showed infiltrates suggestive of aspiration. The patient was admitted for observation, but did not require oxygen overnight, and was discharged to home the next day.

The second patient with suspected aspiration coughed and desaturated after completion of magnetic resonance imaging, and had copious amounts of clear fluid suctioned from the mouth and nose. A chest radiograph showed ill-defined opacities in the right upper lobe. She was admitted but did not require oxygen overnight, and was discharged to home the next day.

One patient was electively intubated. She coughed after induction and had a persistent cough despite additional boluses of propofol. Anesthesiology was consulted, and she was electively intubated by the anesthesiologist to allow completion of the study. After extubation, the patient was admitted overnight for observation, and was discharged to home the next day.

The number of patients experiencing respiratory events or airway interventions declined by 74% from 2005 to 2009 (**Figure 1**; available at www.jpeds.com). We hypothesized that the reduced prevalence of specific risk factors for respiratory events or airway interventions during this period made a major contribution to that decline. To identify these risk factors, we identified the patient characteristics and procedural methods that were significant predictors of either respiratory events or airway interventions.

We found that patient sex, diagnostic category for which the patient was sedated, propofol dose, procedure duration, history of prematurity, history of asthma, or history of gastroesophagel reflux disease were not predictors for the occurrence of respiratory events/airway interventions. In contrast, patient age >12 years, history of snoring, upper respiratory infection, ASA physical status classification of ASA 3, premedication with midazolam, and use of adjuvant glycopyrrolate were predictors of respiratory events and airway interventions on univariate analysis ($P < .04$), and were

Table III. Summary of 1649 propofol sedations

	Number of patients	Percentage
Hospitalist completed case	1633	99.03
Study aborted	14	0.85
Urgent anesthesiologist consultation	11	0.67
Anesthesiologist completed case	2	0.12
Unplanned admission	3	0.18
Respiratory event		
Airway obstruction	49	3.0
Cough with desaturation	31	1.9
Desaturation <90%	26	1.6
Apnea	5	0.30
Possible aspiration	2	0.12
Stridor	1	0.06
Cardiovascular event		
Hypotension ≥30 mm Hg with fluid intervention	4	0.24
Transient decrease in heart rate	1	0.06
Airway interventions		
Oral airway	122	7.4
Continuous positive airway pressure	22	1.4
BMV	10	0.61
Oxygen >2 L/min via nasal cannula	5	0.30
Nasal trumpet	4	0.24
Intubation	1	0.06

There was overlap in patients with respiratory events, cardiovascular events, airway interventions, urgent anesthesiologist consultation, study aborted, anesthesiologist-completed case, and unplanned admission.

then used in the multivariate analysis. Our multivariate logistic regression model showed that a history of snoring, age >12 years, premedication with midazolam, and use of adjuvant glycopyrrolate were all independent predictors that increased the likelihood of both respiratory events and airway interventions, and that ASA 3 status was an independent predictor that significantly increased only the likelihood of a respiratory event (**Table IV**). A comparison of the prevalence of these predictors in patients in 2005/2006 and patients in 2008/2009 found significant decreases in all except the use of glycopyrrolate (**Figure 2**).

The increased likelihood of respiratory events and airway interventions in patients aged >12 years was unexpected. Our analysis found similar prevalences of predictors for respiratory events or airway intervention in patients aged >12 years and those aged ≤12 years. Other patient characteristics or primary diagnoses also did not differ between the 2 age groups. We analyzed the propofol doses administered in these groups to determine whether higher doses in the older patients contributed to increased complications. The results showed that in fact the mean total dose of propofol was significantly lower in the patients aged >12 years compared with those aged ≤12 years (12.7 ± 4.0 mg/kg vs 14.4 ± 6.0 mg/kg; $P = .002$).

Discussion

Our hospitalist group had a 99.03% rate of safe completion of procedures in 2004-2009, similar to the 99.12% reported by Cravero et al[1] in the largest study to date of outcomes of propofol sedation (49 836 sedations) performed by the Pediatric Sedation Research Consortium, a prospective study

Table IV. Multivariate logistic regression model of respiratory events and airway interventions

Variable (number of patients)	Respiratory event, OR (95% CI)	Airway intervention, OR (95% CI)
History of snoring (n = 435)	2.40 (1.52-3.80)	2.69 (1.86-3.90)
Premedication with midazolam (n = 481)	1.85 (1.15-2.98)	1.67 (1.14-2.45)
ASA 3 (n = 141)	2.30 (1.22-4.33)	1.10 (0.59-2.05)
Age >12 years (n = 96)	4.01 (2.02-7.98)	5.91 (3.16-9.24)
History of upper respiratory infection (n = 144)	0.90 (0.43-1.90)	1.16 (0.65-2.06)
Use of adjuvant glycopyrrolate (n = 81)	4.70 (2.35-9.40)	5.78 (3.28-10.18)

including anesthesiologists, pediatric emergency physicians, pediatric intensivists, and a small number of other providers, including pediatricians and fellow-level trainees from multiple sites. Our success rate demonstrates the effectiveness of SLCH's sedation program, with a failure rate of <1%, comparable to that of other sedation programs across the nation.[1,5]

Major complications (aspiration, intubations, and unplanned admission) occurred in only 3 of the 1649 patients (0.18%). All of these patients had no sequelae and were discharged to home the next day. Our rate of intubation was 0.06%, compared with 0.1% reported by Cravero et al.[1] Our rates of aspiration and unplanned admissions were 0.12% and 0.18%, respectively, compared with 0.01% and 0.07% in the study by Cravero et al.[1]

Reporting differences make it difficult to compare the rates of other less serious but frequent adverse events, such as apnea, desaturation, and bag-mask ventilation (BMV), between studies. Our retrospective study reports all events and interventions recorded in the charts. The providers in the prospective studies of Cravero et al[1] and Mallory et al[5] reported only unexpected events and unplanned interventions.

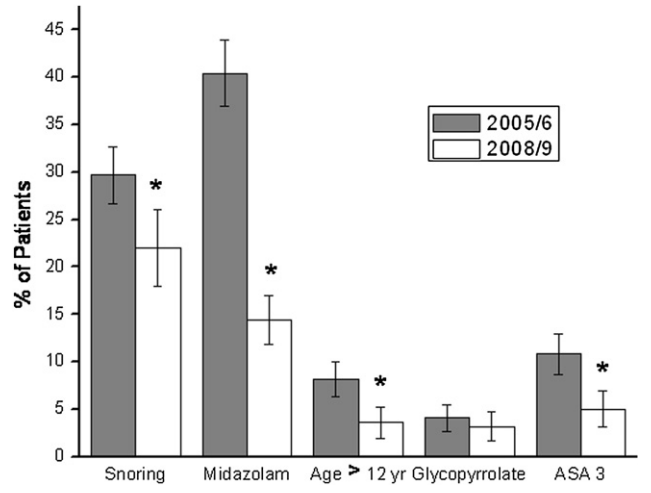

Figure 2. Changes in predictors of respiratory events and airway interventions over time. The percentage of patients with the predictors history of snoring, premedication with midazolam, age >12 years, adjuvant use of glycopyrrolate, and ASA 3 status are shown for 2005/2006 and 2008/2009. Error bars indicate 95% CI. *Indicates a significant difference ($P < .05$) between 2005/2006 and 2008/2009.

Apnea and obstruction are known to occur during propofol administration, and thus such interventions as brief continuous positive airway pressure, BMV, and oral airway placement might not always be considered unplanned.[17,18] Our rates of apnea (0.30%) and desaturation (1.6%) are comparable to the 0.31% and 1.54% reported by Cravero et al.[1] We found a 3.0% rate of obstruction and a 7.4% rate of oral airway placement, compared with 0.93% and 0.65% in Cravero et al.[1] Of those 7.4% of patients requiring an oral airway, 58% had no recorded respiratory event preceding oral airway placement. This was related in part to the placement of an oral airway to relieve obstruction in some patients with significant snoring (unrelieved by airway repositioning), even in the absence of desaturation or respiratory distress. In other cases, oral airways were placed to obtain better end-tidal CO_2 readings. 0.61% of our patients needed BMV, and 0.30% required supplemental oxygen beyond the baseline rate of 2 L delivered via nasal cannula, whereas 1.1% of patients needed BMV and 4.09% required blow-by oxygen in the study of Cravero et al.[1]

A limitation of the present study is its retrospective nature, such that some events might not have been recorded. We recorded data from both nursing and physician notes to capture as many events as possible, regardless of whether they were planned interventions or expected events occurring during propofol sedation. In addition, the study is not large enough to allow for a statistically meaningful determination of the frequency of rare events.

The overall decline in the rate of respiratory events and airway interventions from the initiation of the program in 2005 to the end of the study period in 2009 afforded us the opportunity to identify those predictors that made the greatest contribution to this decline. We found that ASA 3 status, history of snoring, patient age >12 years, and the use of adjuvant midazolam appeared to make the largest contributions to the risk of adverse events our patients. Snoring indicates obstruction, and midazolam has been reported to cause upper airway obstruction.[17,19-21] These 2 risk factors were by far the most prevalent in our study cohort. Nearly 46% of all patients had one or both of these risk factors. Thus, the 26% reduction in the number of patients with snoring and 64% reduction in the number of patients premedicated with midazolam from 2005/2006 to 2008/2009 likely were major factors leading to the decline in the rates of respiratory events and airway interventions over that period (62% and 48%, respectively). Other studies have shown that midazolam increases the likelihood of complications not only when

sedating with propofol, but also with ketamine.[22,23] In this study, both recovery time and time to discharge were significantly prolonged in patients premedicated with midazolam. Moreover, premedication with midazolam was associated with greater agitation during recovery, which contributes to prolonged discharge times. With the increasing use of child life specialists to distract patients for peripheral IV placement and the use of Synera patches (70 mg lidocaine/70 mg tetracaine) to reduce the pain of needlesticks, we have greatly reduced the use of oral midazolam for premedication.

Other studies have identified ASA 3 status as a predictor for adverse events during propofol sedation.[1,23] We found it to be a significant predictor for respiratory events, and the 54% reduction in the number of patients with ASA 3 status from 2005/2006 to 2008/2009 is another factor in the 62% reduction in respiratory events from 2005 to 2009.

We found that patient age >12 years increased the risk for respiratory events by 4-fold and the risk for airway interventions by 5-fold. The proportion of older patients sedated by our hospitalist team declined by 56% from 2005/2006 to 2008/2009, which likely contributed to the decreasing rate of respiratory events/airway interventions over time. The increased risk in this age group was not related to higher doses of propofol administered to these patients. Our results are similar to those reported by Green et al[22] in their analysis of 8282 pediatric ketamine sedations, of an almost 3-fold greater risk for airway and respiratory adverse events in patients aged >13 years, with the increased risk not related to higher doses used in those patients. Further studies are needed to investigate reasons for the increased likelihood of adverse events in our patients aged >12 years.

In this study, the use of adjuvant glycopyrrolate increased the likelihood of respiratory events by 4-fold and that of airway interventions by 5-fold. Interestingly, Green et al's[24] analysis of risk factors for ketamine sedation also found an association between glycopyrrolate use and significantly increased rates of airway and respiratory complications compared with either atropine or no anticholinergic. The increased risk for respiratory events/airway interventions from coadministration of glycopyrrolate with both ketamine and propofol sedation raises the question of whether glycopyrrolate itself is a risk factor for sedation.

It is also likely that the SLCH hospitalist group's experience with propofol improved over time, and that this contributed to the reduced rate of respiratory events/airway interventions over the study period. We do not have objective data to support this hypothesis, because of the turnover of several hospitalists during the period; however, decreases in rate of respiratory events/airway interventions for individual hospitalists who were with the program for the entire study period support this hypothesis.

In conclusion, our study is the first to evaluate a propofol sedation program administered by a pediatric hospitalist group. SLCH has an effective sedation program with a low rate of major complications (0.18%). We have identified predictors of respiratory events and airway interventions for propofol sedation. We found a declining prevalence of all of these predictors except glycopyrrolate use over the study period. Thus, the significant decrease in the rates of respiratory events and airway interventions over the study period is likely related to improved patient selection and decreased use of adjuvant midazolam, as well as increased experience with propofol use by the hospitalist group. ■

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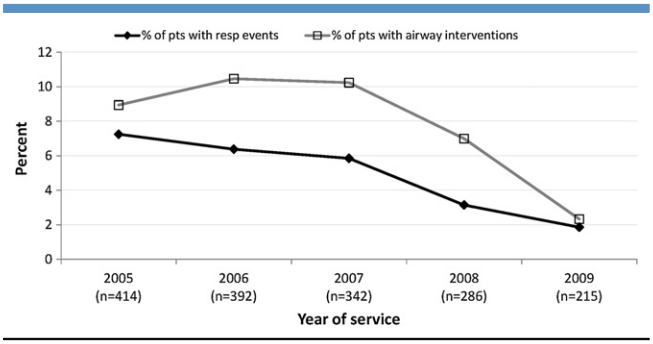

Figure 1. Changes in respiratory events and airway interventions over time. Respiratory events include apnea, obstruction, desaturation <90%, aspiration, and stridor. Airway interventions include use of oral airway, continuous positive airway pressure, BMV, and oxygen >2 L via nasal cannula, nasal trumpet, or intubation. *N*, number of patients sedated each year.

Table I. Patient characteristics

Characteristic	Number	Percentage
Age 0-1 year	92	5.6
Age 1-8 years	1251	75.9
Age 8-12 years	210	12.7
Age >12 years	96	5.8
Male	926	56.2
Female	723	43.8
ASA 1 or 2	1461	88.6
ASA 3	141	8.6
ASA not recorded	47	2.9