Trends in Outpatient Procedural Sedation: 2007–2018
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abstract

BACKGROUND: Pediatric subspecialists routinely provide procedural sedation outside the operating room. No large study has reported trends in outpatient pediatric procedural sedation. Our purpose in this study was to identify significant trends in outpatient procedural sedation using the Pediatric Sedation Research Consortium.

METHODS: Prospectively collected data from 2007 to 2018 were used for trending procedural sedation. Patient characteristics, medications, type of providers, serious adverse events, and interventions were reported. The Cochran–Armitage test for trend was used to explore the association between the year and a given characteristic.

RESULTS: A total of 432,842 sedation encounters were identified and divided into 3 4-year epochs (2007–2011, 2011–2014, and 2014–2018). There was a significant decrease in infants <3 months of age receiving procedural sedation (odds ratio = 0.97; 95% confidence interval, 0.96–0.98). A large increase was noticed in pediatric hospitalists providing procedural sedation (0.6%–9.5%; P < .001); there was a decreasing trend in sedation by other providers who were not in emergency medicine, critical care, or anesthesiology (13.9%–3.9%; P < .001). There was an increasing trend in the use of dexmedetomidine (6.3%–9.3%; P < .001) and a decreasing trend in the use of chloral hydrate (6.3%–0.01%; P < .001) and pentobarbital (7.3%–0.5%; P < .001). Serious adverse events showed a nonsignificant increase overall (1.35%–1.75%).

CONCLUSIONS: We report an increase in pediatric hospitalists providing sedation and a significant decrease in the use of chloral hydrate and pentobarbital by providers. Further studies are required to see if sedation services decrease costs and optimize resource use.

WHAT’S KNOWN ON THIS SUBJECT: Pediatricians and various pediatric subspecialists provide procedural sedation outside the operating room. There has been an explosive growth in this field in the last decade. Trends in outpatient procedural sedation in terms of medications used, providers, and adverse events remain understudied.

WHAT THIS STUDY ADDS: This study provides the latest trends and progress in outpatient pediatric procedural sedation. We report an increase in pediatric hospitalists providing sedation and a significant decrease in the use of chloral hydrate and pentobarbital by providers between 2008 and 2018.


Drs Kamat, Mallory, Stormorken, and Cravero conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript; Drs Simon and Chumpitazi conceptualized and designed the study and critically reviewed the manuscript for important intellectual content; Dr McCracken designed the data collection instruments, collected data, conducted the initial analyses, and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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In the last 2 decades, there has been tremendous growth in pediatric procedural sedation outside the operating room provided by various pediatric subspecialists. Pediatricians and various pediatric subspecialists now routinely provide sedation for a variety of invasive and noninvasive procedures at various locations outside the operating room. Because of the disparate practitioners involved in provision of procedural sedation and the wide variation in practice across institutions, the evaluation and description of global sedation practice are difficult. Furthermore, prospective randomized blinded trials in outpatient sedation are difficult to perform and are limited by cost and resource shortages. Since 2004, the Pediatric Sedation Research Consortium (PSRC), the research arm of the Society for Pediatric Sedation, has collected prospective observational data on sedation and anesthesia encounters from sedation programs in the United States. Multiple peer-reviewed publications from the PSRC have shed light on sedation outcomes data, such as association of adverse events with comorbidities and medications used.

The purpose of this study was to identify trends in outpatient procedural sedation from 2007 to 2018. Evaluating trends in sedation practice provides an opportunity for the clinicians, researchers, and other stakeholders, including patients and their families, to understand how sedation practice may have evolved in the last 2 decades. The sedation community will be informed about changes in providers of sedation, types of procedures for which sedation is provided, type of medications, adverse events, and success rates. Furthermore, studying trends can be used to provide insight into institutions that are contemplating starting a sedation program. This kind of reporting can allow institutions to understand how their practice aligns with that of a group of high-performing organizations across the country.

**METHODS**

**Study Population and Data Collection**

The PSRC is a collaborative group of sedation providers from multiple sedation programs in the United States dedicated to furthering sedation research and optimizing sedation practices in children outside the operating room by collecting prospective observational data from sedation and anesthesia encounters. The Supplemental Information lists programs participating in the PSRC.

The PSRC methods have been well described. A standardized Web-based data collection tool is used to capture deidentified data. Data are stored in a secure-site data system maintained by the Dartmouth Bioinformatics Group. Data collected include patient demographics, diagnoses, reasons for procedural sedation, locations and type of procedures performed, medications and adjuncts used, adverse events, and interventions required for adverse events. The PSRC uses a standardized definition of sedation-related adverse events (Supplemental Information). Painful procedures are listed in the Supplemental Information.

In this study, we used data from the PSRC database from January 1, 2007, to December 31, 2018. All pediatric patients <21 years of age who received procedural sedation outside the operating room during that time frame were included in the study. The main outcome measures were procedural success rates, type of providers, patient age, sex, American Society of Anesthesiologists physical status classification, primary diagnosis, reasons for sedation, medications, type of procedures, fasting times, adverse events, and interventions. Among adverse events, only serious adverse events (SAEs) were included (Supplemental Information) and were defined as sedation-related events with the potential to cause irreversible neurologic harm. The SAEs are readily identifiable by sedation providers, which allows for standardized data reporting across the PSRC sites.

Although multiple adverse events could occur in a single sedation, the adverse event rate was reported as the number of sedations in which at least one adverse event occurred out of the total number of sedations. Additionally, patients could have undergone more than one procedural sedation and therefore appear multiple times in the data set. For analysis, multiple sedations were considered independently. Because of the nature of data collection of the PSRC, long-term follow-up or subsequent care related to an adverse event could not be obtained.

**Statistical Analysis**

Descriptive statistics were calculated for all variables of interest and included counts with percentages or medians with interquartile ranges when appropriate. For trend analysis, data were split into 3 4-year epochs (2007–2010, 2011–2014, and 2015–2018) because some of our outcomes, including SAEs, are rare, and this allowed us to have an adequate number of events during modeling. Second, we did not want to burden the audience with too many time points. Time was examined both continuously (when possible), as a year-to-year change, and during epochs that were created on the basis of dividing the cohort into equal time intervals. To explore how patient demographics or sedation characteristics changed over time, the year was treated as an ordinal variable, and the Cochran–Armitage test for trend was used to explore the association between the year and a given characteristic. Given the large
number of observations in this data set, small differences were statistically significant without clear clinical correlation. In an effort to overcome this, logistic regression was used to obtain effect sizes, namely odds ratios (ORs), to aid in the interpretation in trend over time. To estimate the impact of a continuous characteristic, we used linear regression in place of logistic regression, and the effect size is presented as a slope. Multivariable logistic regression was used to examine the effect of multiple risk factors on the outcome of SAE occurrence, and trends for study epochs were examined. Results are presented as ORs with 95% confidence intervals (CIs). Analysis was conducted by using software (SAS version 9.4; SAS Institute, Cary, NC).

Sensitivity Analysis
Not all PSRC centers contributed data for the entire study period. To evaluate the impact of centers entering or leaving the PSRC, we conducted sensitivity analyses. We included data from institutions that were consistent with data entry for the last decade within the PSRC. Trends in demographic and sedation characteristics were reexamined and compared with results when all PSRC institutions’ data contributions were analyzed.

RESULTS
Trends in Patient Demographics
During the study period, a total of 437,842 sedation encounters were analyzed. The demographic distribution of patients for the overall study period and for individual 4-year epochs is shown in Table 1.

From 2007 to 2018, sedation encounters involving patients <1 year showed an overall decrease, which was primarily in children <3 months of age, from 10.6% in the 2007–2010 epoch to 8.0% in the 2015–2018 epoch (OR = 0.97; 95% CI, 0.96–0.98).

Trends in Procedures and Sedation Providers
Trends in sedation providers over the study period are shown in Fig 1. There was an increasing trend seen in pediatric hospitalists providing sedation. In the earliest period (2007–2010), hospitalists accounted for <1% of sedations, but they jumped to 9.5% in the latest period (2015–2018; OR = 1.28; 95% CI, 1.28–1.29; P < .0001). A decreasing trend was noted in other sedation providers (radiologists, nurse anesthetists, other advanced practice nurses or physician’s assistants, physician trainees, nurses, surgeons, and general pediatricians), with rates decreasing from 13.9% in the earliest epoch to 3.1% in the latest epoch (OR = 0.78; 95% CI, 0.77–0.78; P < .0001).

A decreasing trend was noted in procedural sedation for radiologic imaging from 61% to 48% (2007–2011 vs 2014–2018; P < .0001), an increase in procedural sedation for hematologic procedures from 13.6% to 21.4% (2007–2011 vs 2014–2018; P < .0001) was noted, and a small increase in gastrointestinal procedural sedation from 8.7% to 9.3% (2007–2011 vs 2014–2018; P < .0001) was noted. This is shown in Supplemental Table 3. There was no change in the overall procedural success rate through the study epochs (99.7% for all).

Trends in Medications Administered
There was an overall significant, decreasing trend in use of pentobarbital and chloral hydrate, with rates in the earliest epoch of 7.3% (decreased to 0.5%; P < .0001) and 6.5% (decreased to <0.1%; P < .0001), respectively. Dexmedetomidine showed a bimodal pattern with increasing use from 2007 to 2009, followed by a decrease and plateau from 2010 to 2014. Since 2014, the use of dexmedetomidine has continued to increase. This pattern is shown in Fig 2. Medications stratified by type of sedation provider are shown in Supplemental Fig 4.

Trends in Adverse Events and Interventions
Trends in rates and type of SAE during the study period are shown in Table 2. The overall SAE rate was 1.78%. Airway obstruction was the most common SAE, occurring in 1.55% of all sedation encounters. There was a small, nonsignificant increase in the SAE rate, from 1.35% to 1.75% (2007–2011 vs 2014–2018). Excluding airway obstruction, the SAE rate was 0.31%, or 3.1 serious events per 1000, with an increase from 0.23% to 0.37% (2007–2011 vs 2014–2018; P < .0001). There were no deaths.

Interventions performed in response to adverse events are shown in Supplemental Table 4.

Risk Factors Associated With Adverse Events by Using Multivariable Analysis
A multivariable logistic regression analysis was performed for odds of an SAE by using variables including age; weight; American Society of Anesthesiologists physical status classification; primary diagnosis; comorbidities such as developmental delay, upper respiratory tract infection, asthma, prematurity, and obstructive sleep apnea; and medications and adjuncts administered. Results are shown in Fig 3. There were increased odds of having an SAE in the latest epoch compared with the middle epoch (OR = 1.18; 95% CI, 1.09–1.27; P < .001). No difference was noted between the
Over time, similar trends and effect sizes for most outcomes of interest. Over time, these centers showed decreases in the use of ketamine (4.4% to 2.7%) and dexmedetomidine (6.5% to 4%) compared with increased use in the overall cohort (data not shown). The overall SAE rate when airway obstruction was included was slightly higher (2.1% vs 1.8%); however, after exclusion of airway obstruction, rates were similar (0.32% vs 0.31%). Risk factors for an SAE were also similar with the exception of risk associated with dental procedures, which demonstrated significantly higher odds of an SAE (OR = 4.15; 95% CI, 3.41–5.04).

**DISCUSSION**

Using this multicenter prospective observational cohort study, we provide data on the trends in outpatient procedural sedation in the last decade. Understanding trends in outpatient sedation may help institutions better allocate resources.
for sedation programs provided by pediatric subspecialists outside the operating room.

Although most patients sedated in our consortium continue to be in the age group of 1 to 13 years, we noted a decrease in sedation provided for infants in the 1- to 3-month age group, which may reflect an increasing effort to complete some procedures in this population, especially radiologic procedures, without using sedation. It is possible that awareness of the Food and Drug Administration’s warning about potential neurotoxicity from sedation and/or anesthesia may have resulted in elective procedures being delayed until patients are older. It is also possible that some institutions routinely refer patients <3 months of age to anesthesiologists, who provide general anesthesia in these cases and are thus not included in this database.

Pediatric intensivists and pediatric emergency medicine physicians remained the major providers of procedural sedation throughout the study period. This is likely because sedation and airway management are part of the core competencies of these specialties. Interestingly, our data reveal a significant, increasing trend in sedation provided by pediatric hospitalists throughout the study period as this subspecialty has grown. Training and supporting pediatric hospitalists to provide procedural sedation has the potential to avoid unnecessary referrals to anesthesia professionals and to decrease painful procedures done without sedation, as reported by Srinivasan et al. The increasing trend in sedation provided by the hospitalists in this study should concern pediatric hospital medicine program directors because Librizzii et al. reported that the majority of the hospitalists (fellowship as well as nonfellowship trained) surveyed perceived they had not achieved competency in sedation. Given that the American Board of Medical Specialties has recognized pediatric hospital medicine as a subspecialty of pediatrics, it is imperative that pediatric hospital medicine program directors inculcate robust sedation training in their curricula.

We also found a significantly decreasing trend in the other providers providing sedation. This category includes radiologists, nurse anesthetists, other advanced practice nurses or physician’s assistants, physician trainees, nurses, surgeons, and general pediatricians. This decrease is likely explained by the fact that many pediatric hospitals are moving toward a sedation team–based model to provide sedation services and are becoming less dependent on the single-operator

![Image](https://via.placeholder.com/150)

**FIGURE 1**
Distribution of sedation providers by epochs. Data were divided into 3 4-year epochs. There was an increase in sedation provided by hospitalists and a decreasing trend in the percentage of sedations provided by other sedation providers (who were not from pediatric critical care, pediatric emergency medicine, or pediatric anesthesiology). EM, emergency medicine.

**FIGURE 2**
Percentage of sedations with drug category by year. Although propofol was the most commonly used sedative, there were notable decreases in the use of chloral hydrate and pentobarbital over the study period.
The American Academy of Pediatrics has expressed concerns about increased adverse events associated with the single-operator model for providing procedural sedation.26 Our data support the concept that pediatric sedation is becoming a specialty aspect of pediatric practice and should be considered as such for training and credentialing. The 2019 American Academy of Pediatrics guidelines for procedural sedation recommend the involvement of an independent observer (independent of performing or assisting with the procedure) who is trained in airway rescue and whose only responsibility is to monitor the patient undergoing deep procedural sedation.27 Additionally, the American Society of Anesthesiologists and the US Food and Drug Administration specify that propofol used for sedation and anesthesia should be administered by sedation and anesthesia providers who are trained in their administration and are not involved in the conduct of the surgical or diagnostic procedure.28

Consistent with previous publications, our study found that sedation providers often provide sedation for pediatric patients requiring radiologic, hematologic-oncologic, and gastrointestinal procedures.4,5,14 With the shift from use of computed tomography to magnetic resonance imaging in infants and children due to concerns about ionizing radiation, there is an increasing need for sedation because of the longer duration of magnetic resonance imaging as well as the increased need for patient immobility and cooperativeness.29–32

Propofol, because of its quick onset and emergence properties, remains the most favored agent in procedural sedation, especially for radiologic imaging. It is used in combination with fentanyl or ketamine for painful procedures.12,33 We observed a decreasing trend in the use of chloral hydrate and pentobarbital. A decrease in chloral hydrate use is almost certainly due to nonavailability of the oral formulation of chloral hydrate in the United States after the discontinuation of its manufacture. A minority of institutions compound chloral hydrate using the raw ingredients.34 The trend toward less use is appropriate because chloral hydrate has a narrow therapeutic index and

### TABLE 2 SAE Rates by Epoch

<table>
<thead>
<tr>
<th>SAE</th>
<th>Overall (N = 437 842), n (%)</th>
<th>95% CI</th>
<th>2007–2010 (N = 131 859), n (%)</th>
<th>2011–2014 (N = 162 954), n (%)</th>
<th>2014–2018 (N = 142 929), n (%)</th>
<th>P for Trend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>7.802 (1.78)</td>
<td>1.74–1.82</td>
<td>1777 (1.35)</td>
<td>3529 (2.17)</td>
<td>2496 (1.75)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Overall without airway obstruction</td>
<td>1343 (0.31)</td>
<td>0.29–0.32</td>
<td>303 (0.23)</td>
<td>515 (0.32)</td>
<td>525 (0.37)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SAE type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Airway obstruction</td>
<td>6805 (1.55)</td>
<td>1.52–1.59</td>
<td>1529 (1.16)</td>
<td>3198 (1.96)</td>
<td>2090 (1.46)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Laryngospasm</td>
<td>1112 (0.25)</td>
<td>0.24–0.27</td>
<td>228 (0.17)</td>
<td>441 (0.27)</td>
<td>443 (0.31)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Unplanned admission and/or increased level of care</td>
<td>210 (0.05)</td>
<td>&lt;0.01–0.05</td>
<td>78 (0.06)</td>
<td>56 (0.03)</td>
<td>76 (0.05)</td>
<td>.527</td>
</tr>
<tr>
<td>Emergency anesthesia consult</td>
<td>52 (0.01)</td>
<td>0–0.02</td>
<td>4 (0)</td>
<td>24 (0.01)</td>
<td>24 (0.02)</td>
<td>.001</td>
</tr>
<tr>
<td>Aspiration</td>
<td>47 (0.01)</td>
<td>0–0.02</td>
<td>8 (0.01)</td>
<td>20 (0.01)</td>
<td>19 (0.01)</td>
<td>.070</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>13 (&lt;0.01)</td>
<td>0–&lt;0.01</td>
<td>3 (&lt;0.01)</td>
<td>4 (&lt;0.01)</td>
<td>6 (&lt;0.01)</td>
<td>.349</td>
</tr>
<tr>
<td>Death</td>
<td>0 (0)</td>
<td>—</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>—</td>
</tr>
</tbody>
</table>

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**FIGURE 3**
Results from the multivariable logistic regression model of SAEs. Risk factors were examined for their association with an SAE. Results are presented as model-adjusted ORs (green diamonds) with bars spanning the 95% CIs. The dashed line crossing 1 shows the line of no association. ASA, American Society of Anesthesiologists; NPO, nil per os.
no antidote for toxicity. Its use has been associated with prolonged sedation or clinical resedation and has been linked to multiple deaths during procedural sedation. Unlike chloral hydrate, pentobarbital is most often delivered intravenously and has a rapid onset of action; however, the duration of sedation can be prolonged, making it a less viable option for high-volume outpatient radiologic services, which rely on a quick patient turnover. Miller et al have also reported a similar trend in sedative use (decreasing use of chloral hydrate and pentobarbital) across children’s hospital emergency departments.

Contrary to the situation with chloral hydrate and pentobarbital, there was an increasing trend in the use of dexmedetomidine, especially via the intranasal route. Dexmedetomidine, a central α2 agonist, has anxiolytic and mild analgesic properties while preserving airway tone and respiratory drive in patients. Compared with chloral hydrate, dexmedetomidine does not induce neuroapoptosis and may in fact be neuroprotective, especially when used with sedatives like propofol and especially in infants and young children. Additionally, dexmedetomidine has a quicker onset of sedation, faster recovery, and higher success rate compared with chloral hydrate, especially when used for short radiologic procedures or auditory brainstem-response testing.

Previous studies from the PSRC have reported high success rates with intravenous and intranasal administration of dexmedetomidine as well as a low association with adverse events. Sedation providers should consider the use of dexmedetomidine, especially in infants and young children, for short, nonpainful procedures given its distinct advantages over chloral hydrate.

Our data indicate a small increase in the SAE rate in the most recent epoch compared with previous ones, but overall, the adverse event rate is low and consistent with what has been previously reported from the PSRC. Furthermore, we found, consistently through all epochs, that conditions such as prematurity, upper respiratory tract infection, asthma, developmental delay, and obstructive sleep apnea, as well as procedures such as gastrointestinal or dental procedures, can have a higher propensity for an adverse event, especially airway events. Similar to what Coté et al found in their report, we found that the combination of medications is also associated with a higher incidence of adverse airway events through all epochs. We are unable to discern if the adverse events from a combination of medications in our study were related to the drugs themselves, drug dosing errors, drug interactions, or differences in monitoring standards. Although Coté et al reported death or neurologic injury in 72% of their patients (36 of 50) who received a combination of 2 or more drugs (mostly long-acting drugs with long half-lives, such as chloral hydrate and pentobarbital), our study had no deaths or severe neurologic injury. The lack of mortality in our study despite drug combinations is probably because shorter-acting agents, such as propofol, were used in combination with opioids or benzodiazeptines (both with reversal agents, namely naloxone and flumazenil).

Furthermore, when propofol is combined with ketamine, ketamine maintains airway reflexes and is less likely to be associated with respiratory depression.

Authors of previous studies have reported limitations of the PSRC database. The PSRC institutions enter data voluntarily and are therefore highly motivated and organized sedation systems that would outperform other less-controlled systems that are not a part of the PSRC. Another limitation is that the PSRC database does not capture continuous intraprocedure hemodynamic monitoring data but reports a change of 30% or more from baseline. Although most centers use the American Academy of Pediatrics–recommended monitoring and discharge criteria, the PSRC does not mandate these monitoring criteria. The PSRC database also does not capture the depth of sedation nor medication dosing, and it is possible that the depth of sedation could have a bearing on adverse events reported. Determination of the depth of sedation requires patient stimulation and is contrary to the goal of procedure completion with adequate anxiolysis, hypnosis, analgesia, and immobility if required.

CONCLUSIONS

In this article, we report the latest trends in outpatient pediatric procedural sedation in the PSRC database. We report an increase in pediatric hospitalists providing sedation and a significant decrease in the use of chloral hydrate and pentobarbital by providers.

ACKNOWLEDGMENTS

We thank the Emory University and Children’s Healthcare of Atlanta Biostatistics Core for their help with statistical analysis and Kathleen Louden, ELS, who provided editorial assistance. We also thank all the participating members of the PSRC.

ABBREVIATIONS

CI: confidence interval
OR: odds ratio
PSRC: Pediatric Sedation Research Consortium
SAE: serious adverse event
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