RESEARCH ARTICLE

Pediatric Procedural Sedation Using Dexmedetomidine: A Report From the Pediatric Sedation Research Consortium

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ABSTRACT

OBJECTIVES: Dexmedetomidine (DEX) is widely used in pediatric procedural sedation (PPS) by a variety of pediatric subspecialists. The objective of our study was to describe the overall rates of adverse events and serious adverse events (SAEs) when DEX is used by various pediatric subspecialists.

METHODS: Patients from the Pediatric Sedation Research Consortium (PSRC) database were retrospectively reviewed and children that received DEX as their primary sedation agent for elective PPS were identified. Demographic and clinical data, provider subspecialty, and sedation-related complications were abstracted. SAEs were defined as death, cardiac arrest, upper airway obstruction, laryngospasm, emergent airway intervention, unplanned hospital admission/increased level of care, aspiration, or emergency anesthesia consult. Event rates and 95% confidence intervals (CIs) were calculated.

RESULTS: During the study period, 13 072 children were sedated using DEX, accounting for 5.3% of all sedation cases entered into the PSRC. Of the sedated patients, 73% were American Society of Anesthesiologists Physical Status class 1 or 2. The pediatric providers responsible for patients sedated with DEX were anesthesiologists (35%), intensivists (34%), emergency medicine physicians (12.7%), hospitalists (1.1%), and others (17%). The overall AE rate was 466/13 072 (3.6%, 95% CI 3.3% to 3.9%). The overall SAE rate was 45/13 072 (0.34%, 95% CI 0.19% to 0.037%). Airway obstruction was the most common SAE: 35/13 072 (0.27%, 95% CI 0.19% to 0.37%). Sedations were successful in 99.7% of cases.

CONCLUSIONS: We report the largest series of PPS using DEX outside the operating room. Within the PSRC, PPS performed using DEX has a very high success rate and is unlikely to yield a high rate of SAEs.

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Procedural sedation and analgesia outside of the operating room have become common and widespread.[1,2] A diverse group of pediatric subspecialists such as pediatric anesthesiologists, pediatric intensivists, pediatric emergency medicine physicians, and pediatric hospitalists provide pediatric procedural sedation (PPS).[3,4] Dexmedetomidine (DEX) (Precedex; Hospira, Lake Forest, Illinois), a highly selective α-2 receptor agonist, has gained popularity in pediatrics as an adjunct to traditional sedation or as a sole agent for imaging studies.[5–7] DEX offers the advantage of having both sedative and anxiolytic effects, as well as relatively mild analgesic properties with minimal respiratory effects and a relatively short elimination half-life of 2 h.[8] Because of its safety profile and success; DEX has now become widely used as a sedation agent in pediatric procedural sedation by a variety of providers.[5,9–11]

Furthermore, because of the restriction of propofol use to anesthesiologists in some institutions, DEX is an attractive option for PPS by sedation providers outside the operating room because of its side effect profile.[8,12] In this study, our objective was to describe the overall rates of adverse events (AEs) and serious adverse events (SAEs) when DEX is used by various pediatric subspecialists from a large multicenter database.

METHODS

Study Design and Data Collection

The Pediatric Sedation Research Consortium (PSRC) is a collaborative group of institutions dedicated to improving sedation/anesthesia care outside the operating room for children internationally.[13] Member institutions are self-selected and currently include 42 locations in the United States and Canada, including large freestanding children's hospitals, children's hospitals within hospitals, and general/community hospitals. Participating institutions (see Appendix 1) all received institutional review board approval (or equivalent) before sharing data with the PSRC. Members prospectively enrolled consecutive patients receiving sedation or anesthesia for all procedures (diagnostic and therapeutic) outside the operating room. Only deidentified data are collected. Also, data are intentionally deidentified by the institution.

We queried the PSRC database to identify all patients using DEX as their primary sedation agent for elective PPS from September 2007 to May 2014. In the first wave of data (September 2007 to October 2011), 24 of 40 sites reported DEX use, with an average number of cases per center of 365 (range 1–5968). Seven of these 24 centers reporting DEX use accounted for almost 97% of all DEX cases. In the second wave of data (November 2011 to May 2014), 37 of 42 sites reported DEX use, with an average number of cases per center of 116 (range 1–1221). DEX use during this time accounted for 4.0% of all sedations. Similar to the earlier period, seven centers accounted for 86% of all DEX cases.

Outcome and Event Measures

Successful completion of the procedure was documented as an outcome measure. We assessed the incidence of self-reported AEs and SAEs as outcome measures. A list of these adverse events is given in Appendix 2. Nonserious adverse events, however, are events that are easily managed by the sedation provider and do not appear to be associated with sequelae during procedural sedation. They have low potential to cause irreversible harm to the patient, with no adverse long-term outcome.

An SAE was defined as any one of the following events: (1) airway obstruction, (2) laryngospasm, (3) emergent airway intervention, (4) unplanned hospital admission or increased level of care, (5) aspiration, (6) emergency anesthesia consult, (7) cardiac arrest, or (8) death. These SAEs were defined by a consensus of the members of the PSRC at its inception. As with all outcomes associated with this effort, clear definitions for each event are available on the Web site for PSRC members (requires a login and password), and text of the definition of each event is available when members hover over the event on the data entry form on the Internet. The following as defined by the PSRC are considered part of emergent airway management: tracheal intubation, positive pressure ventilation, or placement of another airway device (oral airway, nasopharyngeal tube, or laryngeal mask airway). Airway obstruction was defined as lack of air movement in spite of respiratory effort for >10 s. Laryngospasm was defined as complete or near-complete lack of air movement with respiratory effort and/or stridor not relieved by chin repositioning or oral/nasal airway. Patients could have been sedated >1 time and appear multiple times in the dataset. For analysis, multiple sedations on the same patient were considered independent. Information was available on pre-, intra-, and immediate postprocedure events, but long-term follow-up and subsequent care related to an adverse event could not be obtained.

Statistical Methods

Descriptive statistics were calculated using counts, frequencies, medians, and interquartile ranges for patient demographics and sedation procedure characteristics. AE rates and SAE rates were calculated, and 95% confidence intervals (CIs) are provided. SAE rates were also calculated across primary sedation provider groups. Data are presented as event rate per 10 000 sedations. All statistical analyses were performed using SAS 9.3 (SAS Institute, Cary, NC).

RESULTS

Demographic and Sedation Characteristics

From September 2007 to May 2014, 13 072 procedural sedation cases using DEX were reported. The total number of sedation cases entered into the PSRC database at the same time was 246 419. DEX thus accounted for 5.3% (13 072/246 419) of all sedations during the study period.

Demographic and sedation characteristics are reported in Tables 1 and 2. The majority of patients sedated were <5 years of age, and >57% were <3 years old. Boys were slightly more prevalent than girls. Seventy-three percent of sedated patients were classified as American Society of Anesthesiologists physical status (ASA PS) class 1 or 2 at the time of sedation. A small proportion of patients (1.7%) had a documented nothing-by-mouth (NPO) time for solids of <6 h before sedation. The most

TABLE 1 Summary of Demographics of Patients Receiving PPS Using DEX

Characteristic	Value
n	13 072
Age, months	
Median	36.0
25th to 75th percentile	19.0–60.0
Weight, kg	
Median	15.4
25th to 75th percentile	11.1–22.0
Male gender[a]	7575 (58.0)
ASA PS[b]	
1	2160 (16.6)
2	7369 (56.6)
3	3447 (26.5)
4	44 (0.3)
≥5	4 (0.03)
NPO clear liquids, h[b]	
<2	111 (0.9)
≥2	12 789 (99.1)
NPO solids, h[d]	
<6	220 (1.7)
≥6	12 793 (98.3)

Data are *n* (%) unless noted otherwise.
[a] *n* = 13 069.
[b] *n* = 13 024.
[c] *n* = 12 900.
[d] *n* = 10 804.

common primary diagnoses for which DEX was used were (1) neurologic in 7946 cases (60.8%), (2) hematologic in 1300 cases (9.9%), (3) infection (4.7%), (4) orthopedic (3.6%), and (5) renal (3.4%). The majority of patients were sedated for a radiologic (83%) or neurologic (18%) procedure. The most common radiologic procedures for which DEX was used were magnetic resonance studies, various nuclear medicine studies, and peripherally inserted central catheter (PICC) placement. (Fig 1).

In the majority of cases, DEX was given by intravenous bolus, infusion, or a combination. Bolus only was noted in 4302 cases (32.9%), infusion only in 2937 cases (22.5%), and bolus and infusion in 3961 cases (30.3%). Additional routes of administration are presented in Table 2. Medications coadministered with DEX were benzodiazepines, most commonly midazolam and lorazepam (61.4%), followed by ketamine (5.7%) and opioids (3.8%).

Sedations were most commonly performed in radiology or a designated sedation unit (90.9% of cases). DEX was used in a very small number of painful procedures (3.9%). The painful procedures for which DEX was used are presented in Appendix 3. The painful procedures in PPS are defined by the PSRC and previously published.[14]

Sedation with DEX was performed by anesthesiologists (35.1%), followed by intensivists (34.1%), emergency medicine physicians (12.7%), and hospitalists (1.1%). This is shown in Table 2. Other providers were defined primarily as advanced practice provider, physician assistant, other pediatric subspecialists (radiologist, dentist), or resident/fellowship-level trainees.

Adverse Events

Of the 13 072 recorded sedations, 466 had ≥1 reported AE (3.6%; 95% CI 3.26% to 3.90%), with 547 total AEs reported. In 57 (0.43%) of the total 13 072 cases, >1 AE was reported. The AE rate per 10 000 sedations was 419 (95% CI 385 to 455). The most common AE was an unexpected change in heart rate or blood pressure >30% in 122 cases (0.93%). Among the five most common AEs, none was considered serious. Additional data on the most common AEs are listed in Table 3.

Serious Adverse Events

Of the 13 072 sedations, 45 sedations had ≥1 SAEs (0.34%; 95% CI 0.19% to 0.37%), with a total of 50 SAEs reported. The SAE rate per 10 000 sedations was 38 (95% CI 29 to 50). Additional data on SAEs are listed in Table 4.

No deaths or cardiac arrests were reported. Three patients had laryngospasm. One was a 3-year-old boy who received DEX in addition to ketamine and midazolam for a PICC line. The patient required suctioning, bag-mask ventilation, and emergent airway intervention. The second patient was an 11-year-old girl with hematologic malignancy who needed sedation for radiologic imaging (MRI and computed tomography) and received midazolam and DEX. The patient had laryngospasm after an episode of coughing and required suctioning and emergent airway intervention. The third patient was a 2-month-old girl with an underlying neurologic problem and sedated with DEX in addition to propofol and alfentanil for a lumbar puncture. The patient had laryngospasm that required emergent

TABLE 2 Summary of PPS Characteristics Using DEX

Characteristic	Value
n	13 072
DEX administration	
Bolus only	4302 (32.9)
Infusion only	2937 (22.5)
Bolus and infusion	3961 (30.3)
Intranasal only	1250 (9.6)
Intramuscular only	229 (1.8)
Sublingual only	211 (1.6)
Other	133 (1.0)
Orally only	44 (0.3)
No administration data	5 (0.04)
Location of sedation	
Radiology/sedation unit	11 880 (90.9)
Specialty clinic/floor	676 (5.2)
PICU	319 (2.4)
ED	43 (0.3)
Cardiac catheterization suite	5 (0.04)
Dental	2 (0.02)
Other	147 (1.1)
Painful procedures[a]	511 (3.9)
Adjunctive medications	
Lidocaine	103 (0.8)
Opioids (morphine/fentanyl)	494 (3.8)
Benzodiazepines (midazolam and ativan)[b]	8020 (61.4)
Anticholinergics (glycopyrrolate and atropine)	185 (1.4)
Ketamine	746 (5.7)
Chloral hydrate	44 (0.3)
Barbiturates (pentobarbital and methohexital)	60 (0.5)
Primary sedation provider	
Anesthesiologist	4585 (35.1)
Intensivist	4461 (34.1)
Emergency medicine	1662 (12.7)
Other	2223 (17.0)
Hospitalist	141 (1.1)

Data are *n* (%) unless noted otherwise.
[a] Painful procedures are defined in Appendix 3.
[b] The use of benzodiazepines may be underestimated because of changes in the data collection in 2011.

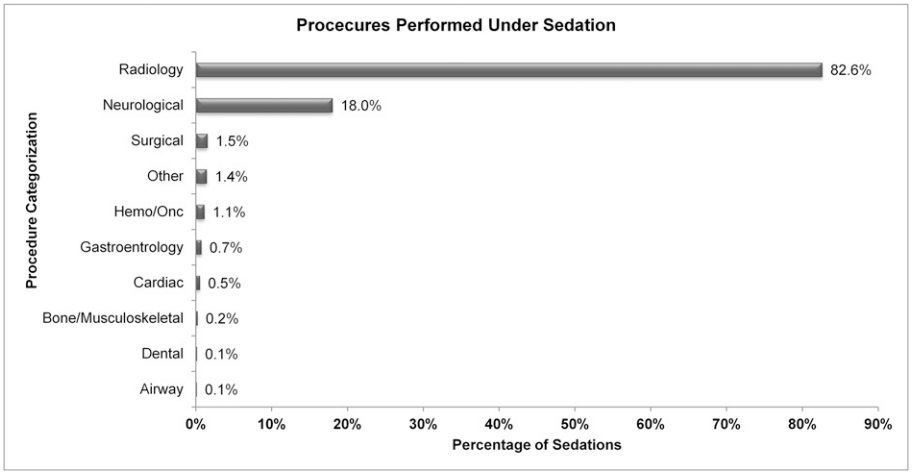

FIGURE 1 Procedures performed under sedation. Patients can be sedated for >1 procedure, so percentages do not total to 100. Airway (bronchoscopy, laryngoscopy, other); bone/musculoskeletal (Botox injection, cast placement/removal, fracture reduction, joint injections/reductions, pin removal, other); cardiac (cardiac catheterization, cardioversion, echo, electrophysiology study, ablation, pericardiocentesis, transesophageal echocardiography, other); dental (dental restoration, tooth extraction, other); gastroenterologic (cecostomy change/placement, colonoscopy, liver biopsy, manometry, percutaneous endoscopic gastrostomy/gastrostomy tube placement/change, pH probe, upper endoscopy, other); hematologic/oncologic (bone marrow aspiration/biopsy, lumbar puncture/intrathecal meds, radiation therapy, other); neurologic (brainstem auditory response test, electroencephalography, electromyography, epidural blood patch, lumbar puncture (diagnostic), magnetoencephalography, somatosensory evoked potential, other); radiologic (computed tomography, dual-energy x-ray, MRI, magnetic resonance angiography, magnetic resonance venography, magnetic resonance spectroscopy, nuclear scan, positron emission tomography, PICC placement, transthoracic echo, ultrasound body, voiding cystourethrography, venography/arteriography, other); surgical (anal dilatation, arterial line, Broviac catheter removal/placement, central line removal/placement, chest tube, circumcision, fine needle aspirate, foreign body removal, abscess incision and drainage, intraoral, laceration repair, peritoneal dialysis catheter placement, PICC placement, skin biopsy, renal biopsy, suture removal, wound burn care, other); other (other painful/nonpainful procedure, ophthalmology, exam under sedation, sexual assault exam, other not classified elsewhere).

airway intervention. All three survived neurologically intact. Sedations were successful in 99.7% of cases.

SAEs by Provider Type

SAE rates were similar between provider groups; however, because of the relatively small number of events, adjusted event rates were not calculated by provider type. The SAE rates per 10 000 sedations for each provider are shown in Table 5. SAE rates were not compared among providers due to the small number of events and limited information on providers.

DISCUSSION

This is the largest study cohort to date evaluating the risks associated with the provision of PPS by a variety of subspecialists using DEX. This study shows that within the PSRC, PPS performed using DEX has a very high success rate and is unlikely to yield a high rate of SAEs. The majority of patients receiving DEX were either ASA PS class 1 or 2 and <5 years of age. It is not surprising that most sedations using DEX were to facilitate radiologic studies. Radiologic imaging requires sedative effects more than analgesic properties of a drug.[15] DEX is an excellent sedative and anxiolytic, but given its limited analgesic properties, it may not be the ideal agent by itself for painful procedures.[16,17]

Requests for PPS outside the operating room have expanded to cover pediatric patients of different ages, with various medical conditions, for a variety of different procedures, in various locations of the hospital, and by a variety of different pediatric subspecialty providers.[18,19] The inability of pediatric anesthesiologists to meet the increasing demand for procedural sedation outside the operating room has resulted in other pediatric subspecialty providers performing PPS.[3]

Only 10% of all sedations in this cohort were performed using intranasal DEX. Experience with intranasal DEX is evolving to determine appropriate dosing and adequacy of sedation provision for completion of radiologic imaging.[10,17] Therefore, use of intravenous DEX is more prevalent for longer radiologic imaging studies such as MRI or nuclear medicine imaging, as the higher bolus dosing with or without the continuous infusion can provide the necessary depth of sedation.[9,20,21] This helps to explain why the majority of sedations are done using intravenous bolus, infusion, or a combination of both.

When we analyzed the subspecialty provider usage of DEX, our findings were consistent with previously published reports of higher usage of DEX by anesthesiologists and intensivists.[8,22] We found use of DEX to be highest in these groups (~35% anesthesiologists and 34% intensivists). DEX was given by pediatric emergency medicine physicians (PEMs) 12% of the time and by hospitalists 1.1% of the time. In most

TABLE 3 Overall AE Rate and Five Most Common Events

AE	*n* (%)	95% CI
Overall AE rate[a]	466 (3.6)	3.26–3.90
Total AEs	547	
Unexpected change in heart rate or blood pressure >30%	122 (0.93)	0.78–1.11
Other complication	76 (0.58)	0.46–0.73
Agitation/delirium	60 (0.46)	0.36–0.59
Desaturation	57 (0.44)	0.33–0.56
IV-Related complication	55 (0.42)	0.32–0.55

[a] Percent of sedations during which ≥1 AE occurred.

pediatric emergency rooms, invasive procedures are performed using ketamine or propofol, the latter alone or in combination with an opioid.[23] The prolonged induction and recovery time may be a deterrent to liberal use of DEX as a sole sedation agent in the busy pediatric emergency department (ED), in which quick patient turnover is necessary.[24] Furthermore, there are not many radiology studies (especially MRIs) requiring deep sedation performed on patients within the ED setting, and it is unlikely that the majority of radiologic procedures performed were for emergency department patients. However, it is possible that some PEMs may be a part of a sedation team that provides sedation outside the ED. Thus, not all sedations done by PEMs in this study using DEX are solely from the ED. It is not possible to distinguish, at this time, which sedations using DEX were performed by PEMs in the ED versus within a sedation service. It is possible that PEMs may be part of a sedation service and, thus, directly responsible for DEX sedations outside of the ED. A previously published survey, however, has shown that only 23% of sedation programs in the country are staffed by PEMs.[25]

TABLE 4 Overall SAE Rate and Individual Event Rates of Each SAE

SAE	*n* (%)	95% CI
Overall SAE rate[a]	45 (0.34)	0.19–0.37
Total SAEs	50	
Airway obstruction	35 (0.27)	0.19–0.37
Emergent airway intervention	7 (0.05)	0.03–0.11
Laryngospasm	3 (0.03)	0.01–0.07
Unplanned hospital admission/increased level of care	5 (0.04)	0.02–0.09
Aspiration	0	0–0.02
Emergency anesthesia consultation	0	0–0.02
Cardiac arrest	0	0–0.02
Death	0	0–0.02

[a] Percent of sedations during which ≥1 SAE occurred.

Our finding of the small percentage of DEX use by hospitalists (1%) is similar to a study by Monroe et al,[26] who found a similar low usage of DEX (compared with pentobarbital and chloral hydrate) among general pediatricians despite a relatively higher frequency of inadequate sedation in the non-DEX group. This may be due to the belief that additional training in the recognition and management of hemodynamic variability may be needed in patients sedated with DEX. The low rate of DEX use among hospitalists is also possible because some institutions may restrict the use of DEX to certain provider types.

The overall AE rate was 3.6%, with an unexpected change in heart rate or blood pressure >30% seen in only 0.93% of sedated patients. Previous studies have shown similar hemodynamic effects of DEX.[27–29] The decrease in heart rate and blood pressure with DEX are dose dependent and independent of age, do not require pharmacologic agents, and usually resolve within an hour of stopping DEX. A study by Mason et al[5] showed that high-dose DEX use was associated with 16% incidence of bradycardia and mean arterial blood pressure decrease with 20% of age-adjusted normal range. The PSRC database does not record a change in heart rate or blood pressure <30% as an AE. Furthermore, as providers who use DEX frequently know that these hemodynamic changes are common and expected, to call them unexpected might have led providers to fail to identify these changes as being an AE. This may account for the low overall incidence of hemodynamic effects seen in our study.

In this study, we found that sedation with intravenous DEX had a success rate of 99.7%, with low AE rates. There were no deaths or cardiac arrests. This low adverse event rate of <5% is similar to what is reported in other large studies from the PSRC using propofol for procedural sedation. Cravero et al[1] reported an overall AE rate of 5.9% (49 836 propofol-sedated patients), Mallory et al[2] reported an overall AE rate of 2.2% (25 443 patients sedated with propofol by PEMs), and Kamat et al[30] reported an overall AE of 5% (91 189 propofol-sedated patients by pediatric critical care physicians). The overall SAE rate for sedation using DEX by all providers was 0.34%, with airway obstruction (0.27%) being the most common SAE in this study, which is lower than reported by Mallory et al[2] (2.2%, 25 443 propofol sedations) and Kamat et al[30] (2.2%, 91 189 propofol sedations). The incidence of laryngospasm with DEX was 0.03%, much lower than that of propofol, with a reported incidence of 0.11% and 0.27% in the studies by Mallory et al[2] and Kamat et al,[30] respectively. This low SAE rate with DEX sedations is possibly due to its minimal effects on the pediatric airway and respiratory system compared with the airway effect of propofol during PPS.[31,32]

Table 5 SAE Rate by Provider

Provider	*n*	SAEs, *n*	SAE rate/10 000
Anesthesiologist	4585	16	34.9
Intensivist	4461	17	38.1
Emergency medicine	1662	8	48.1
Hospitalist	141	1	70.9
Other	2223	8	36.0

In this study, there was a very low rate of SAE overall, across all providers using DEX. Comparisons cannot be made between provider types given the small number of SAE events and limited information on the providers. Also, we did not compare nonserious adverse events by provider specialty. These are events during sedation that are easily managed by the sedation provider, are not expected to be associated with sequelae during procedural sedation, and have a low potential to cause irreversible harm to the patient. These events are ambiguous, and there is a lack of

consistency among sedation providers in identifying these events as AEs. We acknowledge that this study is underpowered to detect differences in SAEs between provider groups, and therefore, larger studies are needed to perform comparisons between such groups.

This study has several limitations. The data used in this study come from the PSRC database, which is observational and voluntary in nature and is based on self-report. Self-reporting can vary between individuals as well as between cohort provider groups. It is possible that motivation and organization in the 42 member centers reporting would lead to higher performance versus nonstudy centers. As a result, there could be selection bias similar to that present in all sedation/anesthesia studies from single centers reporting their outcomes. Additionally, selective data reporting and delay in reporting AEs for a particular study period by institutions is possible. However, blinded data submission and internal audits by the PSRC decrease the impact of these effects. Although 86% to 97% of DEX sedation cases from seven centers contributed to the overall dataset, resulting in some degree of institutional bias, the importance of this report is further highlighted, as it will inform centers that report somewhat limited usage. It can also greatly inform non-PSRC institutions less familiar with DEX.

Although many PSRC centers likely use similar monitoring approaches (heart rate, pulse oximetry, capnography, etc.) and protocols, the PSRC does not mandate specific standardized or mandated monitoring protocols.[33] Likewise, the PSRC database does not have a method for specific intraprocedure collection of hemodynamic parameters for an entire case. However, hemodynamic parameters are routinely monitored at all centers, and the centers report the unexpected change in heart rate (tachycardia, bradycardia) or blood pressure (hypertension, hypotension) that is >30% different from baseline. Finally, there are no national benchmarks for definitions of AE. We have used the definition for all AEs set forth by PSRC, which provides some standardization for the data reporting across the 40 centers. Furthermore, we did not take into account AEs in relation to the level of sedation. There is a possibility that the rate of AEs increases with increasing depth of sedation, and the PSRC does not capture the level of sedation. The PSRC also does not report the dosing of DEX (whether high or low) but only the route of administration.

Although our study found no difference in the incidence of SAEs between the different specialists (owing to the relatively small number of SAE events), we are not claiming that the skill with which this drug is given is equal. We have no data on the efficiency or detailed information on the effectiveness of the sedation that was provided. In addition, it is also difficult to control for patient selection and comorbidities across various provider types.

CONCLUSIONS

We report the largest series of PPSs outside the operating room using dexmedetomidine. Within the PSRC, sedation performed using dexmedetomidine has a very high success rate and is unlikely to yield a high rate of SAEs.

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APPENDIX 1
Participating Centers in the Pediatric Sedation Research Consortium

Akron Children's Hospital, Akron, OH
American Family Children's Hospital, University of Wisconsin School of Medicine and Public Health, Madison, WI
Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, IL
Avera McKennan Hospital, Sioux Falls, SD
American Family Children's Hospital, Madison, WI
Blank Children's Hospital, Iowa Methodist Medical Center, Des Moines, IA
Brenner Children's Hospital, Winston-Salem, NC
Cape Fear Valley Children's Hospital, Fayetteville, NC
Children's Hospital at Memorial University Medical Center, Savannah, GA
Children's Hospital Colorado, Aurora, CO
Children's Hospital Navicent Health, Macon, GA
Children's Healthcare of Atlanta (Egleston and Scottish Rite), Atlanta, GA
Children's of Alabama, Birmingham, AL
Children's Hospital of the Greenville Hospital System, Greenville, SC
Children's Hospital of the King's Daughters, Norfolk, VA
Children's Hospitals and Clinics of Minnesota, Minneapolis, MN
Children's Memorial Hospital, Chicago, IL
Connecticut Children's Medical Center, Hartford, CT
Dartmouth-Hitchcock Medical Center, Lebanon, NH
Doernbecher Children's Hospital, Portland, OR
The Children's Hospital, Denver, CO
East Tennessee Children's Hospital, Knoxville, TN
Eastern Maine Medical Center, Bangor, ME
Florida Hospital for Children, Orlando, FL
Gundersen Lutheran, LaCrosse, WI
Helen DeVos Children's Hospital, Grand Rapids, MI
Holtz Children's Hospital, Miami, FL
Kentucky Children's Hospital, Lexington, KY
Kosair Children's Hospital, University of Louisville, Louisville, KY
Maricopa Integrated Health System, Phoenix, AZ
Medical University of South Carolina, Charleston, SC
Memorial Children's Hospital, South Bend, IN
Monroe Carell Jr. Children's Hospital at Vanderbilt, Nashville, TN
Nationwide Children's Hospital, Columbus, OH
Nemours Alfred I. DuPont Hospital for Children, Wilmington, DE
North Central Baptist Hospital, San Antonio, TX
Palmetto Health Children's Hospital, Columbia, SC
Rainbow Babies and Children's Hospital, Cleveland, OH
St. Vincent Hospital, Green Bay, WI
The Children's Hospital at Providence, Anchorage, AK
UNC Healthcare, Chapel Hill, NC
UVA Children's Hospital, Charlottesville, VA
WakeMed Children's Hospital, Raleigh, NC
WakeMed Children's Hospital, Morgantown, WV

APPENDIX 2
Definition of Adverse Events From the PSRC Database

Agitation/delirium
Airway obstruction (no air movement for $\geq$15 s despite respiratory effort)[a]
Allergic reaction
Apnea $>$15 s

Aspiration*
Cardiac arrest*
Coughing
Death*
Desaturation: oxygen saturation <90 for >30 s
Emergency anesthesia consultation*
Emergent airway intervention*
Hypothermia
Inadequate sedation
IV-related complication
Laryngospasm*
Secretions excessive enough to require treatment
Stridor
Unexpected change in heart rate or blood pressure >30%[†]
Unplanned admission to hospital or increase in level of care*
Use of reversal agents—unplanned vomiting (nongastrointestinal procedure) or wheezing
Other

*Defined as serious adverse event.
[†]Hypertension, hypotension, tachycardia, bradycardia not present before sedation and temporally related to sedation.

APPENDIX 3
Painful Procedures for Which PPS Was Provided

Bone and joint/skeletal
Fracture reduction
Joint injection/aspiration
Joint reduction
Pin removal/placement
Other bone joint/skeletal procedure
Cardiac
Cardiac catheterization
Cardioversion
Electrophysiology study/ablation
Pericardiocentesis
Transesophageal echocardiogram
Other cardiology procedure
Gastroenterology
Cecostomy change/placement
Liver biopsy
Percutaneous endoscopic gastrostomy/gastrostomy tube placement/change
Upper endoscopy
Other gastroenterology procedure
Hematology/oncology
Bone marrow aspiration/biopsy
Lumbar puncture
Ommaya reservoir tap
Radiological
PICC placement
Other
Renal biopsy
Surgical procedure
Dental examination/treatment
Procedure deemed painful

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