

Codman Awards

Improving Outcomes in Pediatric Procedural Sedation

Nina Lubisch, M.S.N., B.-C., A.R.N.P.

Rudolph Roskos, M.D.

Suzan M. Sattler, R.N., B.S.N.

The parent corporation of Broward General Medical Center (which contains the Chris Evert Children's Hospital [CECH]), Broward Health is a not-for-profit, tax-assisted community health system and one of the five largest public health systems in the nation. Broward General, a 716-bed facility, is the largest and most comprehensive regional referral medical center serving the northern residents of Broward County.

In October 2003, the Joint Commission survey at Broward General Medical Center and CECH resulted in recommendations for our pediatric sedation process, particularly as it related to the administration of sedation for outpatient diagnostic procedures. Although not a painful procedure, pediatric sedation can require children (3 weeks to 18 years of age) to remain immobile for up to three hours. The previous sedation protocol offered little case-by-case flexibility and was not accommodating to children. CECH performs approximately 1,000 exams a year, including computerized tomography (CT), positive emission tomography (PET), magnetic resonance imaging (MRI), ultrasound, nuclear medicine, electroencephalogram (EEG), brainstem auditory evoked response (BAER), echocardiography, and radiation therapy. When the improvement initiative began, the organization exclusively used chloral hydrate for moderate sedation. As procedures became longer and more complex, pentobarbital became the primary sedative used, with chloral hydrate reserved for EEG and BAER tests. Yet children receiving pentobarbital were awakening during the procedure from

Article-at-a-Glance

Background: In Fall 2003, Chris Evert Children's Hospital (CECH; Fort Lauderdale, Florida) exclusively used chloral hydrate for moderate sedation. As procedures became longer and more complex, pentobarbital became the primary sedative used. Yet children receiving pentobarbital were awakening during the procedure from paradoxical drug reactions or insufficient sedation. In 2003, the failed sedation rate was 12.29%—more than six times the national benchmark of 2%.

Methods: The pediatric sedation team created a pediatric sedation protocol, which reflected the designation of an α_2 -adrenergic agonist, dexmedetomidine (dex), as the drug of choice and spearheaded a variety of performance improvement changes, including creation of a stand-alone eight-bed sedation unit to accommodate the registration process and pre-assessment and postprocedure monitoring and to include the parent in the treatment continuum.

Results: Following the implementation of the new protocol in 2003, the failed sedation rate for children undergoing various diagnostic and therapeutic procedures decreased from 12.29% to 1.63% in 2004, 0.19% in 2005, and 0.28% in 2006; in 2007 the rate was 0.72%—reflecting an average 98% reduction in the failed sedation rate.

Discussion: The continued improvement and success in pediatric sedation over time indicates that the protocol has sustained benefits and lasting value.

paradoxical drug reactions or insufficient sedation.

Multiple centers reported a 15% sedation failure rate for radiological procedures in children related to excessive movement and outright delirium.¹⁻³ In 2003, the organization's failed sedation rate was 12.29%—more than six times the national benchmark of 2%.⁴ On the basis of these findings, pediatric sedation became a major priority for the organization and one of the highest ranked performance improvement initiatives. Our goal was to increase the efficiency and safety associated with the delivery of pediatric sedation and to create an inviting environment where children feel at ease. This was a challenging task, particularly relating to children with special needs. A secondary goal was to improve parent and physician satisfaction.

Methods

FORMATION OF PEDIATRIC SEDATION TEAM

In November 2003, a team composed of specialized clinicians and staff members, including an administrator, was formed at CECH on the basis of their competencies in pediatric sedation. The challenge was to standardize care, develop safety-in-sedation protocols, and achieve excellent customer satisfaction. The team conducted an extensive assessment of current protocols from nationally recognized best practice children's hospitals. It also examined pharmaceutical options, standards of monitoring, and various protocols. Finally, a root cause analysis (RCA) was conducted and a trilingual parent survey was distributed and analyzed to ascertain parental input.

PERFORMANCE IMPROVEMENT ACTIVITIES

The following performance improvement changes were implemented between October 2003 and April 2006:

- Development of sedation privileges defining minimum education and training requirements for staff hired to execute presedation assessment
- Achievement of advanced cardiac life support (ACLS) and pediatric advanced life support (PALS) licensure and sedation-trained staff on the basis of Joint Commission standards⁵
- Revision of sedation policy and procedure criteria on the basis of Joint Commission standards and American Society of Anesthesiologists⁶ and American Academy of Pediatrics (AAP)⁷ guidelines, resulting in a pediatric seda-

tion protocol*

- Creation of a stand-alone eight-bed sedation unit to accommodate the registration process and pre-assessment and postprocedure monitoring and to include the parent in the treatment continuum
- Employment of advanced registered nurse practitioners (A.R.N.P.s) and a pediatric physician champion [R.R.]
- Hiring of registered sedation-trained nurses and a child-life coordinator
- Implementation of a change in the scheduling process to accommodate children's NPO status (for example: clear liquids and breast milk two hours before procedure and six to eight hours for solids)
- Selection of α_2 -adrenergic agonist, dexmedetomidine (dex), as our drug of choice, decreasing the need for opioids and eliminating sedative narcotics
- Development of a methodology to monitor the process for improvement purposes
- Establishment of requirement that all children receive 4% topical lidocaine analgesia before intravenous (IV) insertion

MEASURES

Data were obtained from multiple internal sources. Early on in the initiative, there were no internal performance measurement tools available for use. Before 2004, pediatric sedation was not identified as an area of study at CECH. The lead program director of the pediatric sedation unit, an A.R.N.P. [N.L.], implemented a database, designed measurement tools, and worked in partnership with a statistician and collaborated with anesthesiologists to develop performance measurement tools to accurately measure the data. Since the inception of the pediatric sedation program, these tools have been proven reliable.

Failed sedation data are easily captured because the children are in the sedation unit and 100% of the data are documented before discharge. In addition, all abstracted data elements are derived directly from the child's medical record, so that there are no issues of recall or historical bias.

Results

FAILED SEDATION

A total of 3,376 cases were included in the failed sedation

* Available from the author by e-mail request.

Failed Pediatric Sedation, 2003–2006

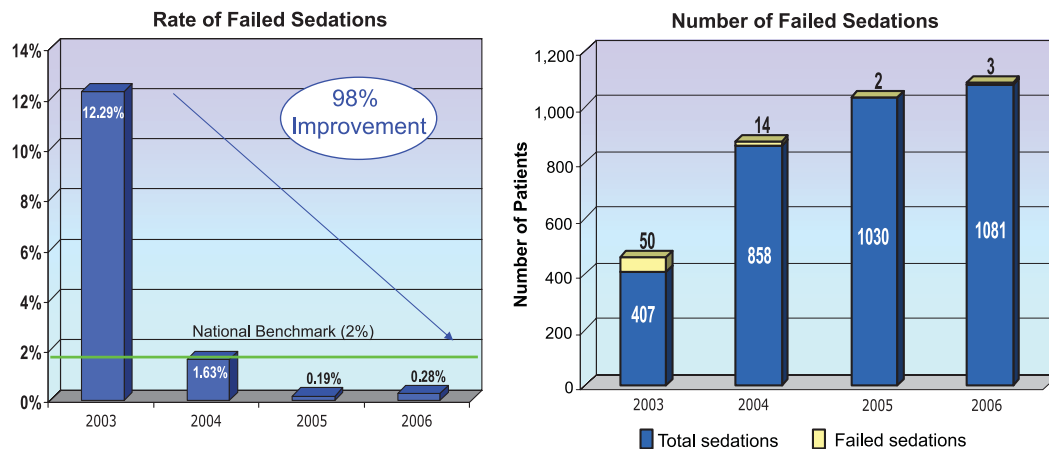


Figure 1. Following the implementation of the new protocol in 2003, the failed sedation rate decreased to 1.63% in 2004, 0.19% in 2005, and 0.28% in 2006; in 2007 the rate was 0.72%, still well below the national benchmark of 2%.

study. Following the implementation of the new protocol in 2003, the failed sedation rate decreased to 1.63% in 2004, 0.19% in 2005, and 0.28% in 2006; in 2007 the rate was 0.72%, still well below the national benchmark of 2% (Figure 1, above). The overall impact of the initiative was a 98% reduction in the failed sedation rate for children undergoing various diagnostic and therapeutic procedures.

Evaluation of the failed sedation data by a Chi-square analysis (4 [year] by 2 [sedation] matrix [degrees of freedom, 3]) resulted in a Chi-square statistic of 248.39 ($p \leq .001$).

TIME FOR PATIENT WAKENING DATA

A 2005 study focused on survival time, that is, time until the patient awoke from sedation. Values were compared for a random sample of (1) 138 children who received pentobarbital (age range, 3 months–13 years of age; mean age, 4.12 years (± 2.64)) and of (2) 551 children who received dex (age range, 2 weeks–18 years of age; mean age, 4.37 years (± 3.23)). The children receiving pentobarbital had longer recovery times than those receiving dex (Table 1, page 195). These results reflect dex's pharmacology and pharmacokinetics, which promote natural sleep stages I, II, and III (allowing the child to fall asleep just as he or she does at home).

Discussion

The continued improvement and success in pediatric sedation over time—as evidenced, for example, by exceeding the national benchmark for failed sedation for four years in a row—indicates that the protocol has sustained benefits and lasting value. Participation in the Pediatric Sedation Research Consortium (PSRC; <http://an.hitchcock.org/PediatricSedationRC/>) allows access to external comparative data.

A systematic approach to performance improvement has served the pediatric sedation program well. The most important factors for the program's developmental success were the designation of a high-level administrator and the hiring of a physician champion. The physician and the A.R.N.P. facilitated the rapid implementation of a plan of action, researching the literature and reviewing options for procedural sedation. Clearly, chloral hydrate was not an acceptable agent. The first choice was phenobarbital; however, the rage reactions and prolonged recovery times were inconsistent with the goal of safe, efficient, and effective sedation with minimal side effects or toxicities. In a major breakthrough, we explored the use of dex as a sedating agent, and the data revealed that rage reactions and prolonged recovery times were no longer observed.

A large population of children requiring procedural

Table 1. Time Distribution in the Kaplan Meier Nonparametric Model

Drug	Group Size	Mean Survival Time* (\pm SE) in Both Groups	
		(Time to be awake)	(Time to be asleep)
		Time to Sleep Failure	Time to Awake Failure
Dex	551	7.99 (\pm 0.12)	45.40 (\pm 0.94)
Pento-barbital	138	12.74 (\pm 0.82)	181.37 (\pm 2.31)

* No censorings: median time to event = mean time of events. SE, standard error; Dex, dexmedetomidine.

sedation have autism spectrum disorder; dex has been an ideal agent for them. Its use in conjunction with oral Versed has resulted in successful sedations. Recently, we have used intramuscular dex and oral Versed with similar success, with the advantage of avoiding placement of an intravenous line.

The use of dex (which is not administered in unmonitored units) has resulted in efficient scheduling, improved throughput in radiology, reduced wait times, reduced patient delays, and high-quality diagnostics. Physicians are extremely satisfied with the ease of the scheduling process, the timely and accurate reports, and the reduced need for rescheduled exams. For example, neurologists are pleased with the quality of EEGs without sedative interference. The pediatric MRI studies are noted for their exceptional clarity. The decreased wait times, elimination of the need to take additional days off from work, as well as the positive experiences, have all pleased the parents. Before the initiative and the implementation of the use of dex as a sedative agent, radiology's capacity was at a maximum of four children per day, which resulted in a wait time of up to six weeks for diagnostic procedures. The current capacity is now ten patients per day, with a wait time of less than five days.

The quality of care and patient safety improvements were so overwhelmingly evident that the pediatric sedation program would continue even if it were not financially profitable. Initially, pediatric sedation services were not charged. Instead, the organization first collected, interpreted, and analyzed the data.

Only after successful implementation with positive patient outcomes did the organization investigate the reimbursement aspects. With overwhelming positive

results, managed care providers now reimburse for our pediatric sedation services.

Postscript

In April 2006, the only pediatric sedation unit in the county was opened at CECH. Separated from the regular pediatric unit, it has a dedicated staff allowing for nurses, A.R.N.P.s, and physicians to concentrate only on the sedation of the child.

Since the hospital's adoption of a patient-centered care model in the same year, registration now occurs at the point of care. The family goes directly to the pediatric sedation unit to register in a child-friendly environment and is greeted by a child-life specialist.

We are currently researching other methods of delivery of α 2-adrenergic agonist sedatives to provide individualized unique alternatives for children who do not require IV access. **J**

Nina Lubisch, M.S.N., B.-C., A.R.N.P., is Lead Program Director, Pediatric Sedation Unit, Chris Evert Children's Hospital, Fort Lauderdale, Florida, and **Rudolph Roskos, M.D.**, is Medical Director, Pediatric Sedation Unit, and Chairman of the Department of Pediatrics. **Suzan M. Sattler, R.N., B.S.N.**, is Regional Manager of Performance Improvement, Broward General Medical Center, Fort Lauderdale, and Chris Evert Children's Hospital. Please address reprint requests to Suzan Sattler, Ssattler@browardhealth.org.

References

1. Malviya S., Voepel-Lewis T., Tait A.R.: Adverse events and risk factors associated with the sedation of children by non-anesthesiologists. *Anesth Analg* 85:1207–1213, Feb. 1997.
2. McCarver-May D.G., et al.: Comparison of chloral-hydrate and midazolam for sedation of neonates for neuro-imaging studies. *J Pediatr* 128:573–576, Apr. 1996.
3. Barst S.M., et al.: A comparison of propofol and chloral hydrate for sedation of young children during magnetic resonance imaging scans. *Paediatr Anaesth* 4:243–247, Jul. 1994.
4. Cravero J.P., Multicenter Prospective Analysis of Pediatric Sedation Practice: The Pediatric Sedation Research Consortium [abstract]. *Anesthesiology* 103:A1314, Oct. 2005.
5. The Joint Commission: *2005 Comprehensive Accreditation Manual for Hospitals: The Official Handbook*. Oakbrook Terrace, IL: Joint Commission Resources, 2004.
6. Gross J.B., et al.: Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology* 96:1004–1117, Apr. 2002.
7. American Academy of Pediatrics, Committee on Drugs: Guidelines for Monitoring and Management of Pediatric Patients During and after Sedation for Diagnostic and Therapeutic Procedures. *Pediatrics* 110:836–838, 2002.