Ideal use of Sedation Agents

Joseph Cravero MD FAAP
George T. Blike MD
James Hertzog, MD
National Patient Safety Foundation
AHRQ
Sedation Conference 2009

Outline

- **Thoughts on Safety/Efficacy**
- **Current literature, guidelines**
- **Dartmouth Sedation Studies**
- **Pediatric Sedation Research Consortium**

How do we choose the right drug? :

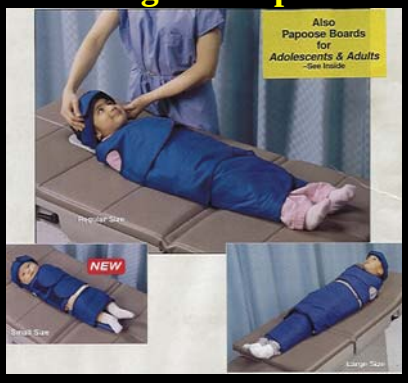
- Match needs of the procedure with the performance of the drug.
- ensure that providers have the critical competencies required to use the drugs - specifically rescue capability.

Recognize the Challenges of Each Case!

- Difficult Patients
- Difficult Environments
- Difficult Procedures

The Problem

No Longer Acceptable



Can Current Literature Guide Our Practice?

Current State of Sedation Literature

- Over eighty studies involving a variety of providers using anesthesia can be found on Medline search - last 5 years
- Studies most often retrospective or prospective and observational.
- Numbers = 30 to 1000 patients.
- Almost never find a serious incident

• Conclusions = Technique "x" is safe and efficient for procedure "y".

Current State of Sedation Literature

Is propofol safe for procedural sedation in children? A prospective evaluation of propofol versus ketamine in pediatric critical care*

Amir Vardi, MD; Yishay Salem, MD; Shay Padeh, MD; Gideon Paret, MD; Zohar Barzilay, MD, FCCM

Objectives: To compare propofol with ketamine sedation delivered by pediatric intensivists during painful procedures in the pediatric critical care department (PCCD).

Design: Prospective 15-month study.

Setting: An 18-bed multidisciplinary, university-affiliated PCCD.

Interventions: All children were randomized to the propofol or ketamine protocol according to prescheduled procedure dates. Propofol was delivered by continuous infusion after a loading bolus dose and a minidose of lidocaine (PL). Ketamine was given as a bolus injection together with midazolam and fentanyl (KMF). Repeated bolus doses of both drugs were given to achieve the desired level of anesthesia. The studied variables included procedures performed, anesthetic drug doses, procedure and recovery durations, and side effect occurrence. The patient's parents, PCCD nurse and resident physician, pediatric intensivist, and the physician performing the procedure graded the adequacy of anesthesia.

Measurements and Main Results: Of the 105 procedures in 98 children, PL sedation was used in 58 procedures, and KMF was used in 47. Recovery time was 23 mins for PL and 50 mins for KMF, and total PCCD monitoring was 43 mins for PL and 70 mins for KMF. Five children (10.6%) in the KMF group and in none in the PL group experienced discomfort during emergence from sedation. Transient decreases in blood pressure, partial airway obstruction, and apnea were more frequent in the PL than in the KMF sedation. All procedures were successfully completed, and no child recalled undergoing the procedure. The overall sedation adequacy score was 97% for PL and 92% for KMF ($p < .05$).

Conclusions: Both PL and KMF anesthesia are effective in optimizing comfort in children undergoing painful procedures. PL scored better by all evaluators, recovery from PL anesthesia after procedural sedation was more rapid, total PCCD stay was shorter with PL, and emergence from PL was smoother than with KMF. Because transient respiratory depression and hypotension are associated with PL, it is considered safe only in a monitored environment (e.g., a PCCD). (Crit Care Med 2002; 30:1231–1236)

Key Words: propofol; ketamine; anesthesia; sedation; procedures; pediatric critical care

Current State of Sedation Literature

- 12 of 58 propofol patients required airway manipulation. 10 required PPV.
- 3 of 47 in the ketamine group required PPV and one needed to be intubated because of "difficult ventilation".
- Recovery time 23 min for Prop, 50 min for ketamine.

• Conclusion - Propofol safe and effective…..

Preprocedural Fasting and Adverse Events in Procedural Sedation and Analgesia in a Pediatric Emergency Department: Are They Related?

Mark G. Roback, MD
Lalit Bajaj, MD, MPH
Joe E. Wathen, MD
Joan Bothner, MD

From the Department of Pediatrics and Section of Emergency Medicine, University of Colorado School of Medicine, Denver, CO.

Study objective: Fasting time before procedural sedation and analgesia in a pediatric emergency department (ED) was recently reported to have no association with the incidence of adverse events. This study further investigates preprocedural fasting and adverse events.

Methods: Data were analyzed from a prospectively generated database comprising consecutive sedation events from June 1996 to March 2003. Comparisons were made on the incidence of adverse events according to length of preprocedural fasting time.

Results: Two thousand four hundred ninety-seven patients received procedural sedation and analgesia. Four hundred twelve patients were excluded for receiving oral or intranasal drugs (n=95) or for receiving sedation for bronchoscopy by nonemergency physicians (n=317). A total of 2,085 patients received parenteral sedation by emergency physicians. Age range was 19 days to 32.1 years (median age 6.7 years); 59.9% were male patients. Adverse events observed included desaturations (169 [8.1%]), vomiting (156 [7.5%]), apnea (16 [0.8%]), and laryngospasm (3 [0.1%]). Fasting time was documented in 1,555 (74.6%) patients. Median fasting time before sedation was 5.1 hours (range 5 minutes to 32.5 hours). When the incidence of adverse events was compared among patients according to fasting time in hours (0 to 2, 2 to 4, 4 to 6, 6 to 8, >8, and not documented), no significant difference was found. No patients experienced clinically apparent aspiration.

Conclusion: No association was found between preprocedural fasting and the incidence of adverse events occurring with procedural sedation and analgesia.

[*Ann Emerg Med.* 2004;44:454-459.]

Adverse event rates vs. NPO time

Table 4.
Adverse events by fasting time.

	Respiratory Adverse Events		Vomiting		Any Adverse Event	
Fasting Time (No.)	No. (%)	OR (95% CI)	No. (%)	OR (95% CI)	No. (%)	OR (95% CI)
0–2 h (150)*	11 (7.3)	1	10 (6.7)	1	18 (12.0)	1
2–4 h (391)	30 (7.7)	1.05 (.51–2.15)	40 (10.2)	1.60 (.78–3.28)	64 (16.4)	1.44 (.82–2.51)
4–6 h (430)	31 (7.2)	.98 (.48–2.00)	30 (7.0)	1.05 (.50–2.20)	60 (14.0)	1.19 (.69–2.09)
6–8 h (281)	27 (9.6)	1.36 (.65–2.79)	18 (6.4)	.96 (.43–2.13)	41 (14.6)	1.25 (.69–2.27)
>8 h (303)	19 (6.3)	.85 (.40–1.80)	27 (8.9)	1.37 (.65–2.91)	44 (14.5)	1.25 (.69–2.26)
Not documented (530)	54 (10.2)	1.43 (.73–2.82)	31 (5.8)	.87 (.42–1.82)	82 (15.5)	1.34 (.78–2.32)

*Reference group.

Current State of Sedation Literature

Propofol for Procedural Sedation in Children in the Emergency Department

See related articles, p. 351 and p. 361, and editorial, p. 357

Kathleen F. Bassett, MD
Jane L. Anderson, MD
Charles G. Pribble, MD
Elizabeth Gardiner, MD, MPH

From the Division of Pediatric Emergency Medicine (Bassett, Gardiner), the Pharmacy (Anderson), and the Department of Pediatrics (Anderson), and Medical Care (Pribble), Primary Children's Medical Center; University of Utah School of Medicine, Salt Lake City, UT.

Study objective: We determine the safety and efficacy of propofol sedation for painful procedures in the emergency department (ED).

Methods: A consecutive case series of propofol sedations for painful procedures in the ED of a tertiary care pediatric hospital from July 2000 to July 2002 was performed. A sedation protocol was followed. Propofol was administered in a bolus of 1 mg/kg, followed by additional doses of 0.5 mg/kg. Narcotics were administered 1 minute before propofol administration. Adverse events were documented, as were the sedation duration, recovery time from sedation, and total time in the ED.

Results: There were [illegible] sedations with propofol were analyzed. Procedures consisted of the following: fracture reductions (54%), reduction of joint dislocations (47%), spica cast placement (2%), and ocular examination after ocular burn (1.3%). The median propofol dose was 2.7 mg/kg. Ninety-two percent of patients had a [illegible] decrease in systolic blood pressure, although [illegible] required bag-mask ventilation. No patients incurred endotracheal intubation.

Conclusion: Propofol sedation is efficacious and can be used safely in the ED setting, unlike the guidelines of a protocol. Transient cardiopulmonary depression occurs, which necessitates vigilant monitoring by highly skilled practitioners. Propofol is well suited for short, painful procedures in the ED setting.

[*Ann Emerg Med.* 2003;41:62-72.]

STATEMENT ON SAFE USE OF PROPOFOL
(Approved by ASA House of Delegates on October 27, 2004)

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Due to the potential for rapid, profound changes in sedative/anesthetic depth and the lack of antagonist medications, agents such as propofol require special attention. Even if moderate sedation is intended, patients receiving propofol should receive care consistent with that required for **deep sedation.**

The Society believes that the involvement of an anesthesiologist in the care of every patient undergoing anesthesia is optimal. However, when this is not possible, non-anesthesia personnel who administer propofol should be qualified to **rescue*** patients whose level of sedation becomes deeper than initially intended and who enter, if briefly, a state of general anesthesia.**

***Rescue** of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level. It is not appropriate to continue the procedure at an unintended level of sedation.

- The physician responsible for the use of sedation/anesthesia should have the education and training to manage the potential medical complications of sedation/anesthesia. The physician should be proficient in airway management, have advanced life support skills appropriate for the patient population, and understand the pharmacology of the drugs used.

The physician should be physically present throughout the sedation and remain immediately available until the patient is medically discharged from the post procedure recovery area.

- The practitioner administering propofol for sedation/anesthesia should, at a minimum, have the education and training to identify and manage the airway and cardiovascular changes which occur in a patient who enters a state of general anesthesia, as well as the ability to assist in the management of complications.

The practitioner monitoring the patient should be present throughout the procedure and be completely dedicated to that task.

- During the administration of propofol, patients should be monitored without interruption to assess level of consciousness, and to identify early signs of hypotension, bradycardia, apnea, airway obstruction and/or oxygen desaturation. Ventilation, oxygen saturation, heart rate and blood pressure should be monitored at regular and frequent intervals. Monitoring for the presence of exhaled carbon dioxide should be utilized when possible, since movement of the chest will not dependably identify airway obstruction or apnea.

STATEMENT ON GRANTING PRIVILEGES TO NONANESTHESIOLOGIST PRACTITIONERS FOR PERSONALLY ADMINISTERING DEEP SEDATION OR SUPERVISING DEEP SEDATION BY INDIVIDUALS WHO ARE NOT ANESTHESIA PROFESSIONALS

(Approved by the ASA House of Delegates on October 18, 2006)

Because of the significant risk that patients who receive deep sedation may enter a state of general anesthesia, privileges to administer deep sedation should be granted only to practitioners who are qualified to administer general anesthesia or to appropriately supervised anesthesia professionals.

PAIN MANAGEMENT/CONCEPTS

Clinical Practice Advisory: Emergency Department Procedural Sedation With Propofol

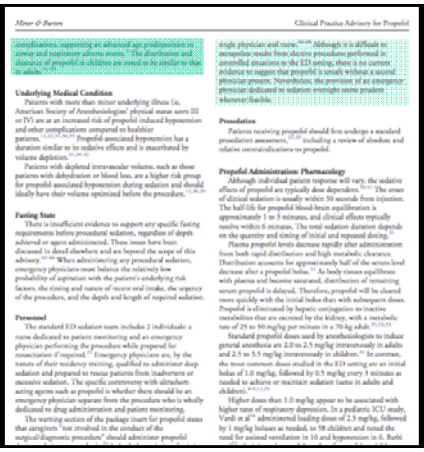
James R. Miner, MD
John H. Burton, MD

From the Department of Emergency Medicine, Hennepin County Medical Center, Minneapolis, MN (Miner); and the Department of Emergency Medicine, Albany Medical Center, Albany, NY (Burton).

We present an evidence-based clinical practice advisory for the administration of propofol for emergency department procedural sedation. We critically discuss indications, contraindications, personnel and monitoring requirements, dosing, coadministered medications, and patient recovery from propofol. Future research questions are considered. [Ann Emerg Med. 2007;50:182-187.]

0196-0644/$-see front matter

doi:10.1016/j.annemergmed.2006.12.017



Miner & Burton — Clinical Practice Advisory for Propofol

Underlying Medical Condition

Patients with more than minor underlying illness (ie, American Society of Anesthesiologists' physical status score III or IV) are at an increased risk of propofol-induced hypotension and other complications compared to healthier patients.[3,4,11,15,34,35] Propofol-associated hypotension has a duration similar to its sedative effects and is exacerbated by volume depletion.[11,36–38]

Patients with depleted intravascular volume, such as those patients with dehydration or blood loss, are a higher risk group for propofol-associated hypotension during sedation and should ideally have their volume optimized before the procedure.[11,36,39]

Fasting State

There is insufficient evidence to support any specific fasting requirements before procedural sedation, regardless of depth achieved or agent administered. These issues have been discussed in detail elsewhere and are beyond the scope of this advisory.[40–44] When administering any procedural sedation, emergency physicians must balance the relatively low probability of aspiration with the patient's underlying risk factors, the timing and nature of recent oral intake, the urgency of the procedure, and the depth and length of required sedation.

Personnel

The standard ED sedation team includes 2 individuals: a nurse dedicated to patient monitoring and an emergency physician performing the procedure while prepared for resuscitation if required.[45] Emergency physicians are, by the nature of their residency training, qualified to administer deep sedation and prepared to rescue patients from inadvertent or excessive sedation. The specific controversy with ultrashort-acting agents such as propofol is whether there should be an emergency physician separate from the procedure who is wholly dedicated to drug administration and patient monitoring.

The warning section of the package insert for propofol states that caregivers "not involved in the conduct of the surgical/diagnostic procedure" should administer propofol

single physician and nurse.[46–48] Although it is difficult to extrapolate results from elective procedures performed in controlled situations to the ED setting, there is no current evidence to suggest that propofol is unsafe without a second physician present. Nevertheless, the provision of an emergency physician dedicated to sedation oversight seems prudent whenever feasible.

Procedation

Patients receiving propofol should first undergo a standard procedation assessment,[17,49] including a review of absolute and relative contraindications to propofol.

Propofol Administration: Pharmacology

Although individual patient response will vary, the sedative effects of propofol are typically dose dependent.[50,51] The onset of clinical sedation is usually within 30 seconds from injection. The half-life for propofol blood-brain equilibration is approximately 1 to 3 minutes, and clinical effects typically resolve within 6 minutes. The total sedation duration depends on the quantity and timing of initial and repeated dosing.[52]

Plasma propofol levels decrease rapidly after administration from both rapid distribution and high metabolic clearance. Distribution accounts for approximately half of the serum level decrease after a propofol bolus.[53] As body tissues equilibrate with plasma and become saturated, distribution of remaining serum propofol is delayed. Therefore, propofol will be cleared more quickly with the initial bolus than with subsequent doses. Propofol is eliminated by hepatic conjugation to inactive metabolites that are excreted by the kidney, with a metabolic rate of 25 to 50 mg/kg per minute in a 70-kg adult.[51,52,55]

Standard propofol doses used by anesthesiologists to induce general anesthesia are 2.0 to 2.5 mg/kg intravenously in adults and 2.5 to 3.5 mg/kg intravenously in children.[56] In contrast, the most common doses studied in the ED setting are an initial bolus of 1.0 mg/kg, followed by 0.5 mg/kg every 3 minutes as needed to achieve or maintain sedation (same in adults and children).[4,9,12,19]

Higher doses than 1.0 mg/kg appear to be associated with higher rates of respiratory depression. In a pediatric ICU study, Vardi et al[36] administered loading doses of 2.5 mg/kg, followed by 1 mg/kg boluses as needed, to 58 children and noted the need for assisted ventilation in 10 and hypotension in 6. Rathi

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Current State of Pediatric Sedation Safety Research

- **Desperate need for prospective, controlled, randomized studies with real power.**
- **Desperate need for validated outcomes measures including intraoperative conditions and procedure outcomes.**
- **Need for multispecialty collaboration.**

Dartmouth Studies…..

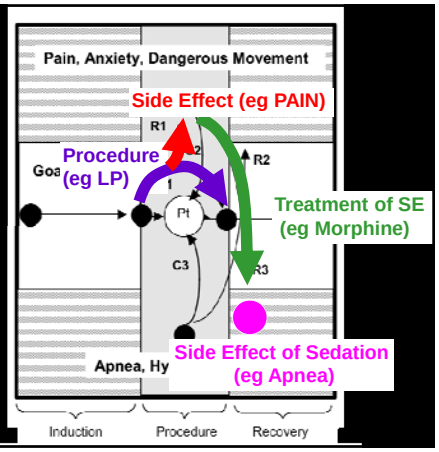
Human Factors Approach

- Characterize work domain
- Understand vulnerabilities/hazards
  - People, Tools, Environment, Problem
- Model system
- Design and prototype remedies
- Validate remedies

Characterizing Pediatric Sedation Work

- Video recorded 12 sedations
  - Radiology, oncology, ED, audiology, cardiology…
- Analyzed by 3 pediatric anesthesiologists
  - Work: demands and resources
  - Goals, problems, control tasks

Control over time



DOCS:

the Dartmouth Operative Conditions Scale

Patient State	Observed behaviors and clinical signs			
Pain/Stress	0 Calm expression	1 Grimace or frown	2 Crying, sobbing, screaming	
Movement	0 Still	1 Random little movement	2 Major purposeful movement	3 Thrashing, kicking, biting
Consciousness	0 Eyes open	-1 Ptosis, uncoordinated, "drowsy"	-2 Eyes closed	
Sedation SE's	-1 SpO2<92%	-1 Noise with respiration	-1 Respiratory pauses >10secs	-1 BP<5th percentile

DOCS validation

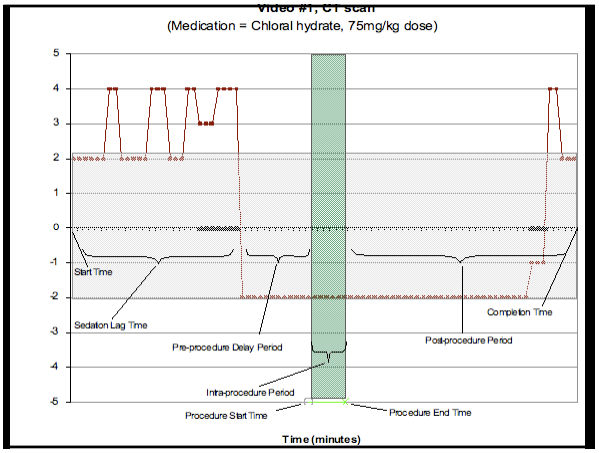
- We defined 3 "zones"
- Greater than 2 = procedural side effects
- 2 to –2 = acceptable
- Less than –2 = sedation side effects (over sedation)

Development and Validation of the Dartmouth Operative Conditions Scale

Joseph P. Cravero, MD, George T. Blike, MD, Stephen D. Surgenor, MD, and Jens Jensen, MS
Department of Anesthesiology, Dartmouth Hitchcock Medical Center, Lebanon, New Hampshire

Studies of pediatric sedation practice have suffered from the lack of an objective scale that would allow for a comparison of the effectiveness and safety of sedation provided by various providers and techniques. We present the Dartmouth Operative Conditions Scale (DOCS), which is designed as a research tool to codify the appropriateness of the procedural conditions provided by various sedation interventions. To begin, human factors methodology was used to develop a model of the pediatric sedation process and to define the criteria for measuring a patient's condition during a procedure (DOCS). To accomplish validation, 70 video clips (30-s duration) were then selected from more than 300 h of procedural video tape for testing/grading purposes. Inter-rater reliability was tested by comparing the score for each video clip among 10 different raters. Intra-rater reliability was evaluated by retesting all of the raters 1 yr after their initial rating. Construct validity was confirmed by analyzing the change in DOCS score relative to the time that sedation intervention was undertaken. Criterion validity was tested by comparing the DOCS to a modified COMFORT© score. The DOCS was completed with excellent inter-rater (kappa = 0.84) and intra-rater (kappa = 0.93) agreement by 10 health care providers with various backgrounds during the 1-yr study period. Criterion validity was supported by the close correlation between the DOCS and the modified COMFORT© scores for 20 distinct video clips (Spearman correlation coefficient = 0.98; $P < 0.001$). The distribution of DOCS scores 20 min after the anesthetic induction was significantly lower than the scores before initiation of sedation, and scores after emergence were consistently higher than those 20 min after sedation ($P < 0.001$), thus confirming construct validity of the scale. The DOCS is a validated research tool when used with video data for comparing the effectiveness and safety of pediatric sedation service, regardless of technique used for decreasing anxiety or pain during a procedure.

(Anesth Analg 2005;100:1614–21)



Sedation Study

- **One hundred and ten procedural sedations were then video taped – from time of medication administration to "back to baseline"**
- **DOCS score assigned for every minute of every video and data represented graphically.**

Results of the Study

- Failure to achieve sedation rate was 5%.
- 8% without expert providers.
- 0% with expert providers.

Results of the Study

- Time from beginning sedation to beginning the procedure varied from 2 minutes to 84 minutes

Results of Study

- High risk states were divided into two categories –
- 1) oversedation events with a DOCS of less that –2 and
- 2) undersedation states with a DOCS score of greater than 2.

Results of the Study

- Six of the 100 tapes were noted to have evidence of oversedated states.
- One newborn experience a prolonged oxygen desaturation state with pulse oximetry readings of less that 84% for 9 minutes during a CT scan under chloral hydrate sedation another had <80% for 6 minutes.

Results of the Study

- When asked to rate the safety and efficacy of the sedation, providers and parents in all cases with high risk states - rated the sedation 10/10.
- They would choose it again!!!

Results of the Study

- Undersedated states were extremely common - occurring in 68% of the videotapes.

Summary of the Study

- Drugs and Providers were poorly matched to provide needed sedation for procedures in this study.

What about core competencies for use of potent sedative medications?

Simulator as Crash Test Dummy

- "The Use of a Patient Simulator to Evaluate Rescue capability for Pediatric Sedation Critical Events." SPA 2003

Simulator as Crash Test Dummy

- METI simulator used in 3 different environments where sedation is given to children.
- Same scenario evaluated in each case.
- Video record and physiologic data collected in each case.

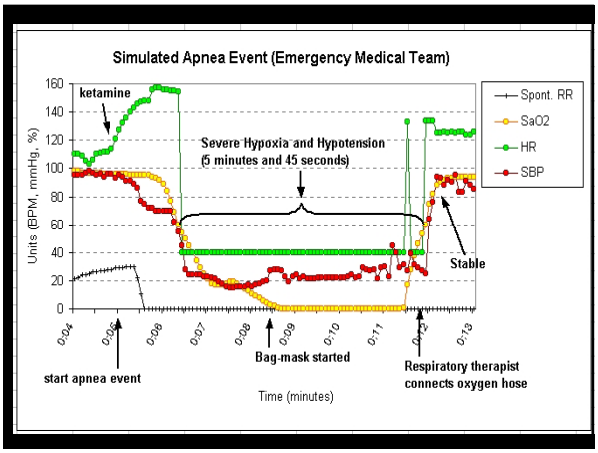
A Method for Measuring System Safety and Latent Errors Associated with Pediatric Procedural Sedation

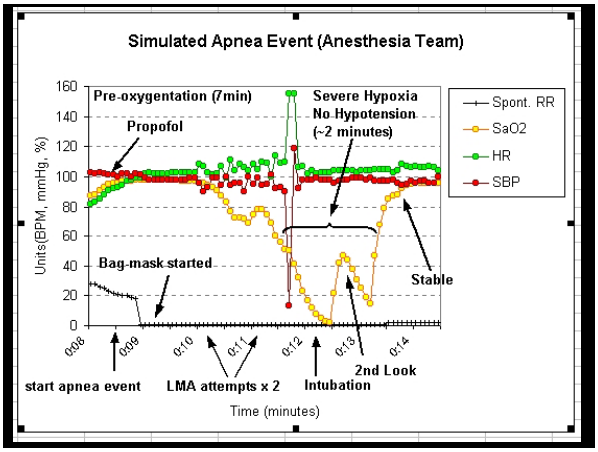
George T. Blike, MD, Klaus Christoffersen, PhD, Joseph P. Cravero, MD, Steven K. Andeweg, MD, and Jens Jensen, MS

Department of Anesthesiology, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire

The practice of sedating patients in the hospital for diagnostic and therapeutic procedures may be associated with life-threatening respiratory depression. We describe a method that uses a simulated event to identify latent system failures. A simulated scenario was developed that was reproducible with realistic physiology that degraded over time if no interventions occurred and improved when treated appropriately. Management of the scenario was observed in an ideal setting, a radiology department, and an emergency department. Event management was videotaped. The simulator's physiological data were saved automatically at 5-s intervals. Deviations from "best practice" were measured by using a set of video markers for event detection, diagnosis, and treatment. The simulator data files were used to calculate time out of range for critical variables. Hypoxia and hypotension lasted 4.5 and 5.5 min in the radiology and emergency departments, respectively, compared with 0 min in the gold standard setting. Many latent failures were identified by reviewing the video. This study supports the feasibility of using available human simulation as a crash-test dummy to more objectively quantify rescue system performance in actual sedation care settings. This method revealed vulnerabilities in personnel and in care systems even though sedation care regulatory requirements were met.

(Anesth Analg 2005;101:48–58)





Conclusions from Crash Tests

- Lack of an event does not prove "safety".
- Rare events need to be modeled and practiced to perform well.
- Good "back-up" and ongoing training are critical.

Summary from Crash Tests

- Competencies need to be defined and tested before using potent sedative medications.

Pediatric Sedation Research Consortium

Complication Data Collection

Apnea – *unintended pause in breathing for more than 20 seconds. Could be obstructive or central in nature.*
Aspiration – *gastric contents suctioned – respiratory sequellae documented.*
Cardiac Arrest
Death
Delirium during or after the procedure – *requiring restraint of medication.*
Oxygen desaturation – *further defined as mild, moderate or severe.*
Emergency consultation called for airway management
Hypothermia – *Temp < 35C in a previously normothermic patient.*
Required positive pressure ventilation when not intended.
Prolonged recovery time/prolonged sedation – *greater than 2X expected for drug and child.*
Unexpected change in heart rate, blood pressure or respiratory rate *> 30% change from baseline.*
Unintended deep level of sedation.
Unplanned intubation.
Vomiting – *during or after the (non-gastrointestinal) procedure.*
Unplanned admission to the hospital or increase in the level of care.
Other

Data Coming Out of the Consortium

Complications Paper

Incidence and Nature of Adverse Events During Pediatric Sedation/Anesthesia for Procedures Outside the Operating Room: Report From the Pediatric Sedation Research Consortium

Joseph P. Cravero, MD[a,b], George T. Blike, MD[a], Michael Beach, MD[a], Susan M. Gallagher, BS[c], James H. Hertzog, MD[a], Jeana E. Havidich, MD[a], Barry Gelman, MD[d], and the Pediatric Sedation Research Consortium

Departments of [a]Anesthesiology and [b]Pediatrics, Dartmouth Hitchcock Medical Center, Lebanon, New Hampshire; [c]Bioinformatics Group, Dartmouth College, Hanover, New Hampshire; [d]Department of Pediatrics, Division of Critical Care, Alfred I. duPont Hospital for Children, Wilmington, Delaware; [e]Department of Anesthesiology, Medical University of South Carolina, Columbia, South Carolina; [f]Department of Pediatrics, Division of Critical Care, University of Miami School of Medicine, Miami, Florida

The authors have indicated they have no financial relationships relevant to this article to disclose.

PSRC

- At this point we had recorded one "code" (bronchoscopy) in a child s/p lung transplant – no deaths.
- One aspiration in a child s/p visceral transplant.
- Most reported problems are minor – involving desaturation and need for bag-mask ventilation.
- Data on efficiency is still being evaluated.

Selected Results

Adverse Events	Incidence per 10,000	N	95% CI
Death	0.0	0	(0.0-0.0)
Cardiac Arrest	0.3	1	(0.0- 1.9)
Aspiration	0.3	1	(0.0- 1.9)
Hypothermia	1.3	4	(0.4- 3.4)
Seizure (unanticipated) During Sedation	2.7	8	(1.1- 5.2)
Stridor	4.3	11	(1.8- 6.6)
Laryngospasm	4.3	13	(2.3- 7.4)
Wheeze (new onset during sedation)	4.7	14	(2.5- 7.8)
Allergic Reaction (rash)	5.7	17	(3.3- 9.1)
Intravenous Related Problems/complication	11.0	33	(7.6- 15.4)
Prolonged Sedation	13.6	41	(9.8- 18.5)
Prolonged Recovery	22.3	67	(17.3- 28.3)
Apnea (unexpected)	24.3	73	(19.1- 30.5)
Secretions (requiring suction)	41.6	125	(34.7- 49.6)
Vomiting During Procedure (non-GI)	47.2	142	(39.8- 55.7)
Desaturation Š below 90%	156.5	470	(142.7-171.2)
Total Adverse Events	339.6 (1 per 29)	1020	(308.1- 371.5)

Selected Results

Unplanned Treatments	Incidence per 10,000	N	95% CI
Reversal Agent Required - unanticipated	1.7	5	(0.6- 3.9)
Emergency Anesthesia Consult for Airway	2.0	6	(0.7- 4.3)
Admission to Hospital Š unanticipated (sedation related)	7.0	21	(4.3- 10.7)
Intubation Required - unanticipated	9.7	29	(6.5- 13.9)
Airway (b) (unexpected requirement)	27.6	83	(22.0- 34.2)
Bag-mask Ventilation (unanticipated)	63.9	192	(55.2- 73.6)
Total Unplanned Treatments	111.9 (1 per 89	336	(85.5- 130.2)
Conditions Present During P	Incidence per 10,000	N	95% CI
Inadequate sedation, could not complete	88.9 (1 per 338	267	(78.6- 100.2)

Results-Serious AE's

- 0 Deaths
- 1 Cardiac Arrest
- 1 Aspiration
- 24 Stridor and Laryngospasm
- 21 Unplanned admissions
  - ~1 per 1,500 sedations

Results-Serious AE's

- 111 Stridor, Laryngospasm, Wheezing, Apnea
  - ~1 per 400 sedations
- 267 Vomiting, Secretions
  - ~1 per 100 sedations

Results-Unplanned Treatments

- 6 Emergency Anesthesia Consults
- 29 Emergent Intubation
- 83 Oral Airway Insertion
- 192 Positive Pressure BMV
- 310 Unplanned Major Airway Interventions
  - ~1 per 100 sedations

Discussion

- Primary Findings-
  - Critical AEs rare (Death, Cardiac Arrest, Aspiration);
  - serious AE's (Laryngospasm, Stridor, Apnea, Bronchospasm) LESS rare
    - ~1:400 sedations
  - Need for Emergent Airway Tx Common (depending on definition)
    - ~1:100 sedations

The Incidence and Nature of Adverse Events during Pediatric Sedation/Anesthesia with Propofol for Procedures outside the Operating Room
Report from the Pediatric Sedation Research Consortium

- Data submitted by 37 institutions - 49,836 sedation encounters utilizing primarily propofol.
- July 1 2004 - Sept 1, 2007
- Data evaluated for complications and effectiveness of sedation

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Provider Type	*Total # of Cases*	*Percent of Cases*
Anesthesiologist	5,117	10. 27
APRN/PNP/PA	15	0. 03
Emergency Medicine MD	18,034	36. 19
Fellow Level Trainee	1,215	2. 44
Intensivist	24,296	48. 76
Pediatrician	1,123	2. 25
Radiologist	5	0. 01

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Drug	*Total Uses*	*Incidence per 10K*	*Confidence Interval*
Ativan	33	6. 6	(4. 6, 9. 3)
Chloral hydrate	139	27. 9	(23. 5,32. 9)
Dexmedetomidine	22	4. 4	(2. 8, 6. 7)
Etomidate	42	8. 4	(6. 1,11. 4)
Ketamine	879	176. 4	(165. 0,188. 3)
Methohexital	14	2. 8	(1. 5, 4. 7)
Midazolam	3766	755. 7	(732. 6,779. 2)
Pentobarbital	135	27. 1	(22. 7,32. 1)
Pentothal	53	10. 6	(8. 0,13. 9)
Valium	5	1. 0	(0. 3, 2. 3)

Complication	*Number*	*Rate*	*CI*
Inadequate sedation	394	85. 0	(76. 8,93. 8)
Airway Obstruction	432	93. 2	(84. 6,102. 3)
Allergic reaction	14	3. 0	(1. 7, 5. 1)
Apnea	143	30. 8	(26. 0,36. 3)
Aspiration	4	0. 9	(0. 2, 2. 2)
Cardiac Arrest	2	0. 4	(0. 1, 1. 6)
Cough (interrupts procedure)	356	76. 8	(69. 0,85. 2)
Death	0	0. 0	(0. 0, 0. 8)
Desaturation (less than 90% > 30 secs)	716	154. 4	(143. 4,166. 1)
Emergency Anesthesia Consult **	7	1. 5	(0. 6, 3. 1)
Hypothermia	6	1. 3	(0. 5, 2. 8)
IV complications	113	24. 4	(20. 1,29. 3)
Laryngospasm	96	20. 7	(16. 8,25. 3)
Myoclonus (interrupts procedure)	11	2. 4	(1. 2, 4. 2)
Prolonged Recovery	42	9. 1	(6. 5,12. 2)
Prolonged Sedation	30	6. 5	(4. 4, 9. 2)
Secretions (Require Suction and interrupt procedure)	341	73. 6	(66. 0,81. 8)
Seizure – interrupts procedure	11	2. 4	(1. 2, 4. 2)
Stridor – interrupts procedure	50	10. 8	(8. 0,14. 2)
Change in HR, BP, RR of> or <30%	282	60. 8	(53. 9,68. 3)
Unintended Deep Sedation	4	0. 9	(0. 2, 2. 2)
Unexpected admission	33	7. 1	(4. 9,10. 0)
Reversal Agent Required.	2	0. 4	(0. 1, 1. 6)
Vomiting During Sedation	49	10. 6	(7. 8,14. 0)
Wheezing – interrupts procedure	44	9. 5	(6. 9,12. 7)

Cardiac Arrests

- 9 YO male undergoing bronchoscopy in an intensive care unit. H/O TEF. Laryngospasm episode led to hypoxia - bradycardia (profound). CPR plus epi bolus. He was reported at his baseline 2 hours later.
- 16 YO athletic male s/p episode of GI bleed. Colonoscopy 195 mg of propofol over 13 minutes. Apnea occurred with severe bradycardia (asystole) 30 seconds. CPR plus atropine and epi - back to baseline in 3 minutes.

Unplanned Airway Intervention	*N*	*Rate*	*95% CI*
Intubation.	53	11. 4	(8. 6,15. 0)
Jaw thrust	525	113. 2	(103. 8,123. 3)
LMA placement	50	10. 8	(8. 0,14. 2)
Nasopharyngeal Airway Placement	211	45. 5	(39. 6,52. 1)
Blow-by O2 required	1899	409. 6	(391. 7,428. 0)
Oral Airway Insertion Required	300	64. 7	(57. 6,72. 4)
Bag-mask Ventilation Required	513	110. 6	(101. 3,120. 6)
Repositioning of head	721	155. 5	(144. 4,167. 2)
Suctioning Required	341	73. 6	(66. 0,81. 8)
No data	17	3. 7	(2. 1, 5. 9)

Procedure Status	*Total Number of Cases*	*Percent*
Procedure Completed	49,395	99. 12
Procedure Not Completed (Due to Problems with Sedation)	294	0. 59
Procedure Not Completed (Problems Not Related to Sedation)	107	0. 21

Last Intake Status	*Total # of Cases*	*Percent*
Liquids Intake - Less than 2 hours	315	0. 63
Liquid Intake – More than 2 hours	49,521	99. 37
Solid Intake – less than 8 hours	8,679	17. 42
Solid Intake – more than 8 hours	41,157	82. 58

Aspiration Episodes

Age	*Diagnosis*	*Procedure*	*NPO status*	*Setting*
5 yrs	Ex-Premies/p visceral transplant	Colonoscopy	> 8 hours for clear fluids and solids.	Sedation Unit
31 mo	Seizure Disorder	MRI	2 hours - clear fluids 6 hours - solids.	Recovery Room
10 yrs	Hallucinations with intercurrent URI.	MRI	4 hours – clear fluids 6 hours - solids	Scanner
10 yrs	Leukemia	LP – Chemo	6 hours – clear fluids 6 hours - solids	Sedation Unit

Propofol Conclusions

- Lots of Propofol Sedation going on out there!
- Low morbidity and mortality in this mixed group.
- 1 in 65 associated with stridor, laryngospasm, airway obstruction, wheezing, or central apnea.
- Proves the effectiveness of good rescue systems!
- Argues for credentialing core competencies based on data

Discussion

- Does Data Generalize to Your Hospital?
  - This group of hospitals is likely better than average.
    - Selection Bias
    - Specialty services and programs
    - Dedicated resources

Discussion

- Is this the way to define Critical Competencies in Pediatric Sedation?
- Evaluate unexpected airway management - teach TO these skill sets.
- Come up with ways to credential and re-credential these competencies.

Safety Summary

- We need new thinking - more evidence.
- We need more detail and science behind the behaviors and practices that characterize safe and effective sedation.
- We need more cooperation among the various specialists that practice pediatric sedation.

Future

- Continue PSRC - refine tool
- Report data on various complications and effectiveness with various sedation methods.
- Use data to formulate critical competencies for priviledging.

Society for Pediatric Sedation

- Mission Statement: The Society for Pediatric Sedation (SPS) will strive to be the international multidisciplinary leader in the advancement of pediatric sedation by promoting safe, high quality care, innovative research and quality professional education.
- www.pedisedation.orgl