Syllabus Material
## Wednesday, May 28

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:30 am</td>
<td>Registration Opens</td>
<td>Registration Booth, Second Floor</td>
</tr>
<tr>
<td>7:30 am-8:30 am</td>
<td>Continental Breakfast</td>
<td>Harborside Center East, First Floor</td>
</tr>
<tr>
<td>8:30 am-12:00 pm</td>
<td>Meeting of PSRC</td>
<td>Ballrooms AB&amp;C, Second Floor Joe Cravero, MD</td>
</tr>
<tr>
<td>12:00 pm-1:00 pm</td>
<td>Lunch on your own</td>
<td></td>
</tr>
<tr>
<td>1:00 pm-3:00 pm</td>
<td>Meeting of PSRC</td>
<td>Ballrooms AB&amp;C, Second Floor Joe Cravero, MD</td>
</tr>
<tr>
<td>3:00 pm-3:30 pm</td>
<td>Trolley Ride to Backus Children’s Hospital</td>
<td></td>
</tr>
<tr>
<td>3:30 pm-5:30 pm</td>
<td>Practical Sessions and Panel Discussion</td>
<td>Ballrooms AB&amp;C, Second Floor Joe Cravero, MD</td>
</tr>
<tr>
<td>5:30 pm-6:00 pm</td>
<td>Trolley Ride to Hyatt Regency Savannah</td>
<td></td>
</tr>
<tr>
<td>7:00 pm-8:30 pm</td>
<td>Welcome Reception</td>
<td>Scarbrough 1-3, First Floor All attendees are invited.</td>
</tr>
</tbody>
</table>

## Thursday, May 29

<table>
<thead>
<tr>
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<tbody>
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<td>Continental Breakfast</td>
<td>Harborside Center East, First Floor</td>
</tr>
<tr>
<td>8:00 am-8:15 am</td>
<td>Welcome</td>
<td>Ballrooms AB&amp;C, Second Floor Marty Scott, MD</td>
</tr>
<tr>
<td>8:15 am-9:15 am</td>
<td>Lecture: Pediatric Sedation Safety – The Big Picture</td>
<td>Ballrooms AB&amp;C, Second Floor George Blike, MD</td>
</tr>
<tr>
<td>9:15 am-10:45 am</td>
<td>The Safety of Potent Sedative Medications: Propofol, Ketamine</td>
<td>Ballrooms AB&amp;C, Second Floor Lia Lowrie, MD (Propofol) Mark Roback, MD (Ketamine)</td>
</tr>
<tr>
<td>10:45 am-11:00 am</td>
<td>Break/Questions and Answers</td>
<td></td>
</tr>
<tr>
<td>11:00 am-12:00 pm</td>
<td>Continued: The Safety of Potent Sedative Medications: Etomidate, and Dexmedetomidine</td>
<td>Ballrooms AB&amp;C, Second Floor Amy Baxter, MD (Etomidate) John Berkenbosch, MD &amp; Nina Lubisch, MD (Dexmedetomidine)</td>
</tr>
<tr>
<td>12:00 pm-1:15 pm</td>
<td>Inaugural Meeting and Lunch for the Society of Pediatric Sedation</td>
<td>Ballrooms AB&amp;C, Second Floor Joe Cravero</td>
</tr>
</tbody>
</table>

May 28-30, 2008 • Savannah, Georgia
1:15 pm-2:00 pm  Assessment of Sedation Depth and Discharge Readiness ........................................ Shobha Malviya, MD
2:00 pm-2:15 pm  Break/Questions and Answers
2:30 pm-3:30 pm  Breakout Session 1
3:35 pm-5:00 pm  Questions and Answers
Authors of Poster Sessions
5:00 pm  Adjourn

Friday, May 30

7:00 am  Sign-in Available ............................................................ Registration Booth, Second Floor
7:00 am-8:00 am  Continental Breakfast ................................................ Harborside Center East, First Floor
8:00 am-8:10 am  Welcome ................................................................. Ballrooms AB&C, Second Floor
8:15 am-9:00 am  Sedation Safety – The PSRC Data ................................ Ballrooms AB&C, Second Floor
9:15 am-10:00 am  Breakout Session 2
10:15 am-11:00 am  Breakout Session 3
11:15 am-12:00 pm  Breakout Session 4
12:00 pm  Conference Concludes

Breakout Sessions

1. Emergency Department-Based Sedation Team
   Amy Baxter, MD

2. ICU-Based Sedation Team
   Sally Webb, MD and Terry Watt, RN

3. Credentialing and Privileging for Sedation Providers
   Joe Cravero, MD & George Blike, MD

4. Traveling Sedation Team vs. Fixed Sedation Unit
   Marty Scott, MD and Charlene Dimond, RN

5. RN Administered Nitrous Oxide
   Mary Kay Ferrell, RN and Judith Zier, MD

6. The Use of Capnography to Monitor Adequacy of Ventilation During Procedural Sedation
   Constance Houck, MD

Abstracts
Title: Sedation Safety: “The Big Picture”

Biography of Plenary Speaker:
Dr. George Blike is a Professor of Anesthesiology and is a member of the Pediatric Section at the Dartmouth-Hitchcock Medical Center. He is also a member of the Human Factors and Ergonomic Society. He has practiced medicine for over 17 years at Dartmouth Hitchcock Medical Center. His scholarly work focuses on the research and practical applications of human factors science in the medical domain—a.k.a., patient safety. He established the Dartmouth Medical Interface Laboratory which conducts research to better understand how clinicians make decisions in medicine and how to improve the usability of medical devices and information displays. He has led system re-design efforts to create more reliable care systems departmentally and hospital-wide and is currently the Quality and Patient Safety Officer for Dartmouth Hitchcock Medical Center. The National Patient Safety Foundation has supported and funded Dr. Blike in the use of direct video-observation to model and design optimal pediatric procedural sedation systems; and, the National Institute of Child Health and Human Development supported Dr. Blike in his efforts to assess the utility of simulation to understand performance failures in the management of rare-events in pediatric sedation. He partnered with a team led by Dr. Joseph Cravero at the Children’s Hospital at Dartmouth to help put theory into practice by establishing the Pain Free Pediatric Sedation Unit that in a unique way has cared for more than 14,000 children for over seven years. He remains active in seeking to improve pediatric sedation and analgesia care in all settings through the optimal application of systems engineering, advanced training modalities and collaboration.

Dr. Blike’s plenary presentation will explore pediatric procedural sedation care in the greater context of the patient safety sciences. The microsystems, mesosystems and macrosystems of modern healthcare will be used to frame the many settings in which procedural sedation is required and the myriad ways our systems can fail. Lessons within the evolution of the practice of anesthesiology will be used to reflect on the challenges associated with the provision of pediatric sedation care. He will introduce the scientific field of human factors engineering and how practitioners of this science are seeking to optimize the fit between individuals and teams with the tools, technology and environments utilized in modern medical care. The current state-of-the-art in pediatric procedural sedation will be contrasted with ideal care. He will attempt to highlight the gaps in our people and systems which currently threaten patient safety, but that also represent major opportunities for improvement as we work together to eliminate the pain and anxiety associated with pediatric medical care.

Selected Bibliography:


Safety of Potent Sedative Medications: Propofol

Lia Loewie, MD
Chief, Division of Pediatric Critical Care
Associate Professor of Pediatrics
Case Western Reserve University School of Medicine
Rainbow Babies and Children's Hospital

SAFETY
What exactly does this mean?

Safety
• No perfect system
• No perfect drug
• Poor understanding of what sedation/anesthesia actually is physiologically
  • Continuums
• Lack of clarity of goals
  • Analgesia and sedation
  • Anesthesia
  • Risk vs. Benefits

Safety of Propofol
• Will talk about
  • Events associated with propofol use as an anesthetic
    • Adult
    • Pediatric
• Events associated with propofol use to achieve deep sedation
  • Single center
  • Multi-center
• Won’t talk about
  • Propofol used for "long term" sedation in ICU
  • Propofol infusion syndrome

Propofol
• Hypnotic agent
  • Enhances GABA-mediated transmission at a site removed from benzodiazepine binding site
    • Synergistic or additive effects with other hypnotics
  • Anesthetic properties but may be less strong than those of benzodiazepines
• Complicated pharmacokinetics
  • Rapid distribution from blood into tissues (rapid onset)
  • Rapid clearance from blood (short duration) into brain, muscle and fat
  • Slow return from peripheral compartment
    • Euphoria elimination — long third phase not considered clinically significant.
  • Children generally require higher initial and maintenance dosing

Propofol as Anesthetic
• Propofol approved by FDA and introduced into general anesthesia clinical practice in 1989
  • Over 300 articles in peer reviewed Anesthesia literature
  • Analyzed a post-marketing study
Propofol in 1990 Anesthesia Literature

- Notable observations
  - 53% of patients experienced 16-35% reduction in SBP usually around induction
  - 2% experienced bradycardia on induction
  - 32-52% experienced moderate to severe pain with injection
  - 83% experience reduced tidal volume and/or apnea
  - 20% of children induced with 2.5 mg/kg had apnea longer than 20 seconds
  - Propofol recipients 70% less likely to have postop nausea and vomiting than “other regimens.”

Propofol in 1990 Anesthesia Literature

- Pediatric use
  - Generally higher per kilogram dosing needed to achieve same effects as in adults
  - Similar cardiopulmonary depressant effects
  - Drug effects similar – pediatric airway and developmental issues affect how to use the drug
  - One study found more airway obstruction when inducing children with halothane (34%) than with propofol (10%) (Maier et al. Anesth Analg 1993;77:144–148)
  - Muscle relaxant delivery better with propofol because the IV was already present facilitating airway management

Post-marketing survey


- 25,981 patients, 1722 institution and 1819 anesthesiologists
  - ASA I–III
  - 18–80 years old
- Data collection
  - Patient history and illnesses
  - Medication history
  - Airway management
  - Anesthetic doses and administration times
  - Procedure time
  - Vital signs (BP and HR) recorded at 0, 2.5, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130 minutes

Post-marketing survey

- Adverse events occurred in 10.8% of patients
- Serious events 0.2%
  - Hypotension, Nausea/vomiting, bradycardia, hypertension
- Review authors noted that 0.2% incidence much lower than prospective trials
- Reports tend not to report expected and well characterized events in Phase IV trials

History and Politics

Pediatric sedation safety
Non-anesthesiologist use
Numbers and safety

Multi-center (PSRC)

- Not yet published data compiled from Pediatric Sedation Research Consortium
  - Joe Cravero, Michael Beach, George Blihe, Susan Gallagher, James Hertzig
- 37 institutions
- 49,836 sedation encounters using propofol
  7/1/04 – 9/1/07
### Procedure Type

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th>Total (n)</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Anesthesia</td>
<td>792</td>
<td>1.40</td>
</tr>
<tr>
<td>Other</td>
<td>412</td>
<td>0.83</td>
</tr>
<tr>
<td>Cardiovascular procedure</td>
<td>301</td>
<td>0.60</td>
</tr>
<tr>
<td>Medical procedure</td>
<td>367</td>
<td>0.70</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>8</td>
<td>0.02</td>
</tr>
<tr>
<td>Electromagnetic procedure</td>
<td>644</td>
<td>1.27</td>
</tr>
<tr>
<td>Catheter procedure</td>
<td>1472</td>
<td>28.30</td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>2696</td>
<td>51.39</td>
</tr>
<tr>
<td>Other</td>
<td>2909</td>
<td>55.06</td>
</tr>
<tr>
<td>N/A</td>
<td>327</td>
<td>0.63</td>
</tr>
</tbody>
</table>

### Adverse Events - Rate per 10,000

<table>
<thead>
<tr>
<th>Event</th>
<th>Rate/10,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspiration</td>
<td>0.9</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>0.4</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
</tr>
<tr>
<td>Unexpected admission</td>
<td>7.1</td>
</tr>
</tbody>
</table>

### Adverse Event Rate > 10/10,000

<table>
<thead>
<tr>
<th>Event</th>
<th>Rate (per 10,000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate sedation</td>
<td>85</td>
</tr>
<tr>
<td>Airway obstruction</td>
<td>93.2</td>
</tr>
<tr>
<td>Apnea</td>
<td>30.8</td>
</tr>
<tr>
<td>Cough interrupting procedure</td>
<td>76.8</td>
</tr>
<tr>
<td>Pulse ox &lt; 90% &gt; 30 sec</td>
<td>154.4</td>
</tr>
<tr>
<td>Laryngospasm</td>
<td>25.7</td>
</tr>
<tr>
<td>Secretions interrupting procedure</td>
<td>73.5</td>
</tr>
<tr>
<td>Stinger interrupting procedure</td>
<td>10.8</td>
</tr>
<tr>
<td>Het, Bp, RIf change &gt; 30%</td>
<td>65.8</td>
</tr>
<tr>
<td>Bag mask ventilation required</td>
<td>116.5</td>
</tr>
<tr>
<td>Intubation</td>
<td>11.4</td>
</tr>
<tr>
<td>Vomiting during sedation</td>
<td>10.6</td>
</tr>
</tbody>
</table>

### Conclusions PSRC data

- < 1% of sedation encounters using propofol led to conditions that did not allow procedure completion
- Approximately 1 in 65 sedation encounters using propofol required skilled intervention to prevent possible progression to a poor outcome
- Data obtained from highly motivated and organized healthcare centers

### Single Center

**RB&C Pediatric Sedation Unit**

- Opened in 1996
- Propofol is sedative of choice
- First 500 encounters described 1998
  - 19% “adverse event” reported
  - Confidently reported as “safe”
- Continued data collection
  - 1999-1999: N = 4104
    - ICU nurse cohort
  - 2001: N = 850
    - Physician cohort
**RB&C PSU Procedures**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>In PSU</th>
<th>AE</th>
<th>% of procedures w/AE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic resonance imaging</td>
<td>675 (33.3%)</td>
<td>1%</td>
<td>19%</td>
</tr>
<tr>
<td>Computed tomography</td>
<td>759 (21.2%)</td>
<td>1%</td>
<td>13%</td>
</tr>
<tr>
<td>Cardiac ultrasound</td>
<td>452 (21.2%)</td>
<td>1%</td>
<td>13%</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>408 (24.7%)</td>
<td>1%</td>
<td>13%</td>
</tr>
<tr>
<td>Arteriography</td>
<td>409 (31.9%)</td>
<td>1%</td>
<td>13%</td>
</tr>
<tr>
<td>Biochemical analysis</td>
<td>229 (25.4%)</td>
<td>1%</td>
<td>44%</td>
</tr>
<tr>
<td>Functional analysis</td>
<td>198 (6.8%)</td>
<td>1%</td>
<td>14%</td>
</tr>
<tr>
<td>Vital signs &amp; EKG</td>
<td>196 (6.1%)</td>
<td>1%</td>
<td>14%</td>
</tr>
<tr>
<td>Venous thoracic x-ray</td>
<td>182 (9.1%)</td>
<td>1%</td>
<td>14%</td>
</tr>
<tr>
<td>Transplantation</td>
<td>143 (7.2%)</td>
<td>1%</td>
<td>13%</td>
</tr>
<tr>
<td>Thyroid ultrasound</td>
<td>140 (6.7%)</td>
<td>1%</td>
<td>13%</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>133 (25.6%)</td>
<td>1%</td>
<td>13%</td>
</tr>
<tr>
<td>EKG</td>
<td>99 (6.4%)</td>
<td>1%</td>
<td>13%</td>
</tr>
<tr>
<td>Echocardiography</td>
<td>98 (5.7%)</td>
<td>1%</td>
<td>13%</td>
</tr>
<tr>
<td>Detailed procedure</td>
<td>95 (5.1%)</td>
<td>1%</td>
<td>13%</td>
</tr>
</tbody>
</table>

**RB&C PSU AE Definitions**

- Hypotension: Decreased BP 30%
- Oxygen desaturation: Pulse ox < 94%
- Airway obstruction: Airways management, BVM
- Aborted sedation: Incomplete procedure due to AE
- Apnea: BVM required
- Failed sedation: Canceled procedure
- Unanticipated hospital admission: Or upgrade in care for not
- Emergence: Post-sedation
- Perioperative agitation: Agitation after sedation given
- Hypotension: Requiring intervention
- Seizure: During sedation or recovery
- Aspiration: Respiratory distress after anemia
- Cardiac arrest: Compressions and/or drugs
- Death: Within 48 hours

**RB&C PSU Drug Related Conclusions**

- Recovery time increases with addition of benzodiazepine more than with opioid alone
- Addition of benzodiazepine does not increase rate of adverse events
- Addition of benzodiazepine and another drug does increase rate of adverse events
- Continual intensivist presence may or may not change rates of adverse events

**RB&C PSU Other Considerations**

- Graph showing data over time
- Graphs showing PSU year of operation
- Graph showing PSUs G1-G6
RB&C PSU Other Considerations

Adverse Event Timing
Sedation Delivery system
- All propofol as primary sedative
- 55% of AE occurred with induction
- 75% of AE occurred within 5 minutes of propofol dose adjustment
- Use of benzodiazepine or opioid did not change timing

Conclusions
- Safety is relative
  - Expected benefits
  - Risk tolerance
  - Knowledge
  - Skill
  - Experience
- Safety is a continuum
  - Sharing knowledge can only help
Ketamine Sedation
Safety Profile in Children

Mark G. Roback, MD
Pediatric Emergency Medicine
University of Minnesota Children’s Hospital, Fairview

Disclosure Information
• In the past 12 months, I have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in this CME activity.
• I do not intend to discuss an unapproved/investigative use of a commercial product/device in this presentation.

Objectives
• Ketamine effects
• Safety: Adverse Events and Ketamine
  ▪ Respiratory: Apnea & Laryngospasm
  ▪ Vomiting
  ▪ Emergence reactions
  ▪ Long term effects?
• Ketamine: Randomized Control Trials
• Ketamine and Propofol

Ketamine Properties
• Synthesized from Phencyclidine in 1963
• N-Methyl-D-Aspartate Antagonist
  ▪ Blocks NMDA-receptor glutamate binding in CNS
• “Dissociative” Agent
  ▪ Thalamoneocortical and limbic systems
  ▪ Prevents higher centers from perceiving stimuli
    ▪ Visual
    ▪ Auditory
    ▪ Painful
• Sedation, Analgesia, and Amnesia

Ketamine Effects
• Hypersalivation
• Nystagmus
• Increases heart rate and blood pressure
• Inc intracranial/intraocular pressure
• Skeletal muscle hypertonicity/rigidity
• Bronchodilator
• Protective airway reflexes intact

Ketamine Adverse Events
• Respiratory
  ▪ Oxygen desaturations
  ▪ Apnea
  ▪ Laryngospasm
• Vomiting
• Adverse Psychotomimetic Effects
  ▪ Emergence Reactions
  ▪ Schizophrenia-like syndrome: hallucinations, delusions, illogical thinking, agitation, disturbances of emotion, dissociation
Apoptosis

- Programmed cell death
  - Physiologic elimination of redundant neurons in normal brain development
- NMDA receptors: tonic stimulation appears vital for survival of developing nerve cells

NMDA Receptors

- Excessive stimulation (excitatory neurotoxicity) aggravates neuronal damage
  - Hypoxic-ischemic, hypoglycemic, epilepsy-related situations
- Protective effect of ketamine on CNS
  - Inadequate stimulation appears to trigger neuronal apoptosis
  - Ketamine may lead to neuronal degeneration in developing animal brains

Relative Contraindications

- Age less than 3 months
- Increased apnea
- Airway anomaly/procedure
- Hypertension
- Active respiratory infection
- Unstable asthma
- Cardiac or vascular disease
- Intracranial mass or increased ICP
- Acute glaucoma or globe injury
- Thyroid disease
- Porphyria
- Major psychiatric disorder

Ketamine

- Dosing:
  - IV: 1-2 mg/kg (max dose ?)
  - IM: 2-4 mg/kg (max dose ?)
- Atropine or Glycopyrrolate
  - Anti-sialagogue
  - Atropine: 0.02 mg/kg IV/IM
  - Glyco: 5 mcg/kg (max dose 250 mcg) IV/IM


Ketamine IV

- Onset sedation/analgesia 30-60 seconds
- Recovery beginning within 10-15 minutes
- Near complete recovery 60-120 minutes

Ketamine IM

- Onset sedation/analgesia 3-5 minutes
- Longer acting

Ketamine IV vs. IM

- Length of Sedation
  - Time ketamine administered to time ready for discharge (physiologic recovery)
  - Ketamine IV: median 80 minutes
  - Range: 27-210 minutes
  - Ketamine IM: median 129 minutes
  - Range: 55-365 minutes

Ketamine Indications

- Orthopedic reduction
- Laceration repair
- Incision & drainage of abscesses
- Wound and dressing care
- Other (many)


Ketamine Clinical Studies

- Adverse Events + Safety
- Randomized Control Trials (RCTs)
  - Ketamine/Midazolam vs. Midazolam/Fentanyl
  - Ketamine IV vs. IM
  - Ketamine +/- Midazolam
  - Ketamine +/- Ondansetron

Fentanyl + Midazolam vs. Ketamine + Midazolam

- Double-blind, RCT of FM vs. KM
- 260 patients, orthopedic procedures
- Ketamine/midazolam provides
  - More consistent sedation
  - Less respiratory adverse events
- 6 vs. 25% hypoxia


Fentanyl + Midazolam vs. Ketamine +/- Midazolam

<table>
<thead>
<tr>
<th>Sedation Drugs</th>
<th>Resp AE (rate)</th>
<th>Vomiting (rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(n=2127)</td>
<td>OR (95% CI)</td>
<td>OR (95% CI)</td>
</tr>
<tr>
<td>Ketamine (n=1492) (reference)</td>
<td>91 (6.1)</td>
<td>151 (10.1)</td>
</tr>
<tr>
<td>Ket/Midazolam (n=299)</td>
<td>30 (10)</td>
<td>16 (5.4)</td>
</tr>
<tr>
<td>Midaz/Fentanyl (n=336)</td>
<td>65 (19.3)</td>
<td>6 (1.8)</td>
</tr>
</tbody>
</table>


IV vs. IM Ketamine

- Prospective, randomized, controlled trial
  - Not blinded
  - Ketamine 1 mg/kg IV vs. 4 mg/kg IM
  - 208 patients


Ketamine IV vs. IM

- Respiratory adverse events similar
  - IV 9 (7.6%) vs. IM 4 (4.2%), OR 0.54, 95% CI 0.16, 1.8
- Vomiting more common in the IM group
  - IM 26 (27.4%) vs. IV 16 (13.4%), OR 2.43, 95% CI 1.21, 4.85.

**Ketamine IV vs. IM**

- Length of sedation longer in the IM group
  - 129 vs. 80 median minutes
- No adverse event managed with the IV
- Dose related?


**Respiratory Adverse Events**

<table>
<thead>
<tr>
<th>Study</th>
<th># Patients Ketamine</th>
<th>Hypoxia</th>
<th>Apnea</th>
<th>Laryngospasm</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>130</td>
<td>6%</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>266</td>
<td>4.5%</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>208</td>
<td>6.3%</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>604</td>
<td>5 (0.8%)</td>
<td>4 (0.7%)</td>
<td></td>
</tr>
</tbody>
</table>

*Respiratory depression; received BMV*


**Ketamine and Vomiting in the ED**

<table>
<thead>
<tr>
<th>Study</th>
<th># Patients Ketamine</th>
<th>Route +/- Midaz</th>
<th>Vomiting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>130</td>
<td>IV + Mid</td>
<td>9%</td>
</tr>
<tr>
<td>2</td>
<td>129</td>
<td>IV</td>
<td>19.4%</td>
</tr>
<tr>
<td>2</td>
<td>137</td>
<td>IV + Mid</td>
<td>9.6%</td>
</tr>
<tr>
<td>3</td>
<td>109</td>
<td>IV</td>
<td>11.9%</td>
</tr>
<tr>
<td>3</td>
<td>99</td>
<td>IM</td>
<td>26.3%</td>
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**Ketamine and Vomiting at Home**

<table>
<thead>
<tr>
<th>Study</th>
<th># Patients Ketamine</th>
<th>Route +/- Midaz</th>
<th>Vomiting</th>
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<tbody>
<tr>
<td>1</td>
<td>?% of 130</td>
<td>IV + Mid</td>
<td>12%</td>
</tr>
<tr>
<td>2</td>
<td>~112</td>
<td>IV</td>
<td>7.0%</td>
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<tr>
<td>2</td>
<td>~119</td>
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<td>83</td>
<td>IV</td>
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<tr>
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<td>73</td>
<td>IM</td>
<td>9.1%</td>
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</table>


**Ketamine and Vomiting in the ED**

- Ketamine/ondansetron vs. K/placebo IV
  - Prospective, double-blind, RCT
  - 255 patients: 127 placebo, 128 ondansetron
  - Vomiting: 16/127 (12.6%) vs. 6/128 (4.7%)
  - P=.02, difference 7.9% (95% CI 1.1%, 14.7%)
  - NNT to prevent 1 patient vomiting = 13
  - Vomiting increased in patients > 5 years


**Ketamine and Vomiting at Home**

- Telephone f/u successful in 211/255 (82.7%)
- 211 patients: 100 placebo, 111 ondansetron
  - Vomiting: 8/100 (8%) vs. 4/111 (3.6%)
- Total Vomiting (ED or Home), > 5 years
  - Placebo 23.5% vs. Ondansetron 9.5%
  - NNT = 7
- Consider ondansetron pretreatment > 5 years

Ketamine - Emergence Reactions

- Prospective observational study
- 716 patients ED ketamine IV or IM for PSA
- 699 children, 4.8 months to 17.8 years
- 199 (28.5%) E R
- 145 (20.7%) “significant” Emergence Rxn
  - Hallucinations
  - Nightmares
  - Agitation


Ketamine vs. Ketamine + Midazolam

- Equally effective sedation
- No difference in the incidence of emergence reactions
- Parental and Physician satisfaction was high


Ketamine - Emergence Reactions

- More common in children > 10 years
  - 42.6% vs. 23.2%, RR 1.8, 95% CI 1.4, 2.2
- Unpleasant Emerg Rxn more common > 10 years
  - 27.9% vs. 18.1%, RR 1.5, 95% CI 1.1, 2.0
- Did not effect incidence of Emergence Reactions
  - Gender
  - Dose of ketamine (mg/kg)
  - Route of administration


Ketamine vs. Ketamine + Midazolam

- Does midazolam prevent ketamine Emerg Rxn?
- Prospective, double bind, RCT
- IV ketamine PSA for ED procedures
  - 266 patients
  - ED emergence reactions: 71/266, 26.7%
  - Significant EP 18/266, 6.8%


Ketamine + Midazolam?

- Increase in oxygen desaturations
- Decrease in vomiting
- No change in emergence reactions
- Timing of midazolam administration?
- Selective population?
What about Propofol?

- Ketamine/Midazolam vs. Propofol/Fentanyl
- Ketamine + Propofol = Ketofol
  - Goals:
    - Less respiratory depression - safer
    - Less vomiting
    - Smoother offset (quicker recovery without emergence reactions)
- Ketamine/Propofol vs. Propofol/Fentanyl

Ketamine/Midazolam vs. Propofol/Fentanyl

- RCT: Orthopedic procedure in the ED
  - 113 patients: 3-18 years of age
  - Equally effective sedation
  - Recovery time less PF (23.2 vs. 33.4 mins)
  - Desats: KM 4/54 (7.4%), PF 18/59 (30.5%)
  - Vomiting: KM 2/54 (3.7%), PF 0

Ketamine/Propofol vs. Propofol/Fentanyl

- RCT: 32 patients, 5-60 months old
  - Site: In-house Burn Unit
  - Sedation for Burn wound dressing changes
  - Adverse events low in both groups
  - Both adequate sedation and analgesia
  - KP “superior” as patients “less restless”

Ketamine - Summary

- Commonly used for ED sedation
- Positive safety profile, however:
  - ~1% will need positive pressure ventilation
  - Many questions remain about best practice
  - Long-term effects? Behavior?
- Ketamine + Propofol = Ketofol
  - “Marriage made in heaven” or “beauty and the beast?”
  - Jury is still out

Questions?
The University of Virginia Pediatric Sedation Service: A Unique Approach to the Provision of Procedural Sedation to Children
Julie Haizlip and Patricia Scherrer.
Department of Pediatrics, Division of Critical Care Medicine, University of Virginia Children’s Hospital, Charlottesville, Virginia.

Background: Pediatric patients can require a number of different painful and/or frightening procedures as part of their ongoing medical care. While a number of different models exist to provide procedural sedation for these children, providing safe, organized, and appropriate interventions in a variety of settings and locations can prove challenging. Many programs have established pediatric sedation units; however, physically discrete units do not address the needs of pediatric patients who require sedation in more remote locations of the health care system.

Objective: This study was designed to evaluate the performance of a mobile pediatric sedation service in the provision of pediatric procedural sedation and analgesia and to compare its safety and effectiveness with other pediatric sedation programs from around the country.

Design/Methods: Since July 14, 2004, our service has submitted data from each pediatric sedation encounter to the database maintained by the Pediatric Sedation Research Consortium (PSRC), a collaborative group of 35 institutions who share prospective observational outcome data on procedural sedation. As of March 31, 2007, our organization had contributed 2132 sedations out of the total 74,280 records entered in the database. We compared our complications and outcomes with those of the greater PSRC member group.

Results: Our service provides pediatric procedural sedation in a much wider variety of locations as compared to the entire PSRC group, whose members provided 93% of sedations either in a centralized unit or in a radiology suite with a centralized pediatric sedation area. There was no statistically significant difference in unexpected airway management between our group and the PSRC as a whole. While the outcomes were not significantly different, our program did have a higher percentage of cases completed (99.3%) versus the PSRC group (98.9%).

Conclusions: A mobile sedation service can offer safe and effective pediatric procedural sedation and analgesia in a variety of locations and settings.
**Pediatric Sedation Program and Practice Characteristics among Pediatric Sedation Research Consortium Contributors**

Patricia D. Scherrer MD, Esther McClure RN, Joseph P. Cravero MD, and Members of the Pediatric Sedation Research Consortium

**Introduction:** The Pediatric Sedation Research Consortium (PSRC) was founded in 2004, with the purpose of improving pediatric sedation practice through sharing of prospective observational data on cases and outcomes. Since its inception, a total of 36 institutions have submitted prospective data on a total of 107,299 sedation encounters to the PSRC database. PSRC member institutions comprise many different environments of care, provider specialties, and sedation techniques.

**Methods:** Each participating program in the PSRC was invited to complete a descriptive questionnaire summarizing their sedation service. This survey included questions regarding: type of medical facility in which the service operates; degree of centralization of the program; common locations in which sedation services are provided; most commonly performed procedures requiring sedation; pediatric specialties and types of providers involved; availability of program services; commonly employed sedative and analgesic regimens; and, institutional requirements for training and credentialing of sedation providers. A total of 24 programs responded to the questionnaire.

**Results:** These 24 programs have contributed more than 91% of the sedation encounters catalogued in the PSRC database. The participating institutions include 10 free standing children’s hospitals, 12 children’s hospitals within hospitals, and 2 regional referral hospitals. Six programs provide completely mobile services, while the rest utilize a centralized pediatric sedation unit for some portion of their practice. All but one program provide sedation for radiologic procedures. Of the programs utilizing a pediatric sedation unit, procedures most commonly performed in these units include hematology/oncology procedures, sedated hearing evaluations, vascular access, and general surgical procedures. Nine of the surveyed programs have a pediatric critical care program base. Three are organized through pediatric emergency medicine and three through pediatric anesthesiology. One program is managed by a pediatric hospitalist program and one by the general pediatrics team. Five programs utilize a combination of providers. Two programs are led by advanced practice nurses. 15 programs offer regular services Monday through Friday only, but several are available 6 or 7 days a week and/or offer additional call coverage for sedation. Propofol, midazolam, ketamine, and fentanyl are the most commonly employed sedative and analgesic agents, although propofol is not being used by the surveyed pediatric hospitalist or general pediatric sedation services. Half of the responding programs still regularly use chloral hydrate for procedural sedation. Dexmedetomidine and etomidate are being used by providers from each of the represented specialties. Two programs are actively including nitrous oxide in their sedative regimens. Training and credentialing requirements are widely variable. 18 programs require PALS certification for sedation providers. Approximately half of the services include a written packet and/or a formal written or on line test, as well as direct patient care training with monitored patient care experiences. Three programs have incorporated simulation training. Most programs require recertification every two years.

**Discussion:** The many varied characteristics of PSRC programs provide significant insight into the current practice of pediatric procedural sedation.
A Comparative Evaluation of Patients with and without Cerebral Palsy Receiving Propofol Sedation for Non-Painful Radiologic Procedures

John W. Taylor, 1Pelin Cengiz, 2Jens C. Eickhoff & 1Gregory A. Hollman
University of Wisconsin Medical School, 1Department of Pediatrics and 2Department of Biostatistics, Madison, WI, USA

Background: A sizeable amount of literature regarding pediatric procedural sedation has accrued since the American Academy of Pediatrics first policy statement in 1985. Evaluation of the patient with cerebral palsy (CP) as a specific population frequently requiring procedural sedation for diagnostic evaluation has not occurred. Children with CP often have difficulty with airway control. This unique patient group is hypothesized to be at greater risk relative to non-CP patients during propofol sedation.

Objective: The purpose of this study was to compare the differences in frequency and type of adverse events in patients with CP versus non-CP patients receiving propofol sedation for non-invasive procedures.

Design/Methods: The study was a retrospective analysis of children age birth to 18 years sedated with propofol for nonpainful procedures presenting for the first time to the University of Wisconsin Pediatric Sedation Program between June 2000 and June 2006. Data collected included presence or absence of CP, risk factors, sedation medications with dosages and occurrence and types of adverse events. Adverse events were defined as oxygen saturation <94%, airway obstruction, hypoventilation, apnea, hypotension (blood pressure <5th% mean for age) and bradycardia. Complication rates were compared between the CP and non-CP patients using Chi-square analysis and Fishers Exact Test for Count Data.

Results: A total of 1623 patients were studied with and without a diagnosis of CP (n=45 and n=1578, respectively). Adverse respiratory events occurred in 17 (38%) patients with CP versus 274 (17.4%) patients without CP (p<0.005). In children with CP who had adverse events, oxygen saturation <94% (12/17), airway obstruction (12/17) and hypoventilation (5/17) were the most frequent respiratory complications. Patients with CP tended to have hypotension compared to non-CP patients (6.5% vs. 1.8%, p=0.055).

Conclusions: Children with cerebral palsy have a greater likelihood of respiratory complications when receiving propofol sedation for a non-painful procedure when compared to children without CP. Careful screening of these patients and preparation for increased respiratory adverse events is essential to providing safe procedural sedation.
Title: Impact of Caffeine for Post-dural puncture headache on Propofol Dosage for Lumbar Puncture Sedation

Author(s): McElvery H, Baxter AL.

Affiliation(s): Pediatric Emergency Medicine Associates, Children’s Healthcare of Atlanta;

ABSTRACT BODY:

Objective: To compare the dosage of propofol needed to sedate for routine lumbar puncture with and without IV caffeine administration.

Methods: Two children sedated for routine lumbar punctures between July 2006 and December 2007 were identified from hematology/oncology sedation records. Both children had developed recurrent post lumbar puncture headaches (PLPH) requiring caffeine boluses 500mg in 1 L prior to the procedures. Data from LPs during which the patients were currently taking steroids were excluded. Outcomes included total dose of propofol in mg/kg/minute of sedation duration (time from drug administration until completion of procedure) for the three LPs prior to initiation of caffeine and the three LPs after cessation, and number of re-boluses needed to complete the procedure.

Results: Average mg/kg of propofol for patient KS was 0.14mg/kg/min before caffeine, 0.23 mg/kg/min, and for patient KT 0.172 versus 0.265mg/kg/min (p=.0104). One LP was excluded for patient KT due to concurrent steroids. KS averaged 3 reboluses with caffeine sedations, versus 0.5 per sedation without. KT required 1 rebolus per sedation with caffeine, versus 0.33 without.

Conclusions: Caffeine boluses given prior to an LP increase the dose of propofol required for adequate sedation.
PROPOFOL WITH OR WITHOUT FENTANYL FOR LUMBAR PUNCTURE IN CHILDREN WITH CANCER: COMPARISON OF SAFETY, RECOVERY TIMES AND FAMILY PREFERENCE

Gregory A Hollman, Meredith M Schultz, Jens C Eickhoff and Devon K Christenson. Pediatrics, University of Wisconsin Children's Hospital, Madison, WI, United States.

Objectives: We sought to compare safety, recovery times and family preference of propofol alone to propofol with fentanyl for lumbar puncture (LP) in children with acute hematologic malignancies.

Methods: The study was a randomized, controlled, double blind, crossover study. Study patients were children with acute hematologic malignancies receiving sedation for LP. Each patient received two sedations in random order, one with propofol/placebo and one with propofol/fentanyl. The study investigator and patient/parent were blinded to placebo or fentanyl. Data collected included patient age and diagnosis, propofol dose, recovery times, adverse events and family preference. Adverse events included oxygen saturation < 94%, airway obstruction, apnea, hypotension and bradycardia (<5% mean for age). Logistic regression analysis was utilized to assess probability of adverse events and the Wilcoxon Signed Rank and McNemar’s tests were used for paired comparisons.

Results: Twenty-two patients were enrolled. Fourteen patients were male and 8 were female. Each patient was studied twice for a total of 44 sedations. The mean age was 6.4± 4.2 (mean ± SD) years. The mean total dose of propofol was 5.24±1.79 mg/kg for propofol/placebo versus 3.42±1.87 mg/kg for propofol/fentanyl (p <0.001). Adverse events occurred in 11 of 22 patients (50.0%) propofol/placebo compared to 6 of 22 (18.2%) propofol/fentanyl (p=0.02). Mean recovery time was 36.86±17.1 min propofol/placebo and 23.36±16.4 min propofol/fentanyl (p=0.0047). Sixteen families (72.7%) preferred propofol/fentanyl.

Conclusions: Propofol/fentanyl for LP sedation in children with acute hematologic malignancies resulted in fewer adverse events and faster recovery times than propofol alone. Most families preferred the combination of propofol/fentanyl for future LP sedations.
RESPIRATORY DEPRESSION IN CHILDREN WITH PRADER WILLI SYNDROME FOLLOWING CLONIDINE AS A PROVOCATIVE AGENT FOR GROWTH HORMONE STIMULATION

Gregory A. Hollman, Jens C. Eickhoff, and Aaron L. Carrell. University of Wisconsin Children's Hospital, Madison, WI, United States.

Objectives: We sought to determine the sedative and respiratory affects of clonidine in children with Prader Willi Syndrome (PWS) when used as a provocative agent for growth hormone (GH) secretion.

Methods: The study was a prospective evaluation conducted over a three-year period. Study patients were children with PWS scheduled to receive a clonidine (0.15 mg/m²) stimulation test to assess GH responsiveness. Each patient was studied up to four times. Heart rate, respiratory rate, blood pressure, oxygen saturation and sedation level were recorded at baseline and every five minutes following clonidine. Patients were monitored continuously with pulse oximetry by a sedation study nurse. Changes between baseline and post clonidine treatment assessments were evaluated using a non-parametric Wilcoxon Signed Rank test.

Results: Seventeen patients were enrolled. Ten patients were female and 7 were male. All 17 patients were studied at least once for a total of 60 studies. The mean ± SD dose of clonidine was 0.074±0.027 mg (5.3±1.72 mcg/kg). All patients achieved a sedation score of 4 to 5 (drowsy to asleep). The mean time to sleep was 34.3±12.3 minutes. The mean decline from baseline in heart rate was 19.6±14.6, respiratory rate 9.3±6.1, blood pressure 19±12 and oxygen saturation 2.2±2.0 (p<0.001). Five patients experienced oxygen saturations ≤94% on nine separate occasions. Three episodes of oxygen desaturation were accompanied by mild to moderate airway obstruction and were treated with airway repositioning.

Conclusions: Clonidine administration to assess GH responsiveness resulted in significant respiratory depression in some children with PWS. Doses of clonidine calculated in mcg/kg for GH stimulation typically exceed standard doses used for sedation.
ANALYSIS AND PERFORMANCE IMPROVEMENT MEASURES FOR THE PEDIATRIC SEDATION SERVICE

Carrie E. Makin, RN; Cheri D. Landers, MD; Heinrich A. Werner, MD
Kentucky Children’s Hospital, Lexington, KY

Background: Children undergoing medical procedures and tests frequently require sedation for anxiety control and cooperation. Pediatric sedation services are in increasing demand. Members of the sedation service at Kentucky Children’s Hospital observed an increase in the number of requests for sedation. Most requests were for medically complex patients who incur a higher sedation risk. This posed the need to evaluate the rate of adverse events during sedation and implement safety measures.

Methods: All of 2005 and five months of the 2006 sedation data were reviewed. Data was sorted into 2 patient groups: high risk/complicated vs low risk while looking at yes/no adverse events. Sedation service functions that were analyzed included documentation, selection of high risk patients, communication between sedation practitioners, potential for medication errors, availability of necessary functional equipment, and database records.

Results: A sedation request sheet was developed to assess sedation risk and is utilized by the pediatric sedation nurse or intensivist to approve sedation requests. The body mass index (BMI) is calculated and values that are over the 95th percentile for age and sex are further evaluated and potentially referred to the department of anesthesia. An emergency drug sheet was developed allowing drug doses to be calculated in advance. Monthly sedation M&M meetings were implemented to facilitate communication between practitioners. Cardiac catheterization sedation patients have their chart reviewed by an intensivist and a sedation plan is filled out in advance. Emergency equipment is chosen for each patient immediately before the start of the sedation.

Conclusion: In our experience evaluation and implementation of safety and quality assurance measures for sedation services are a necessary part of daily functioning and will improve outcomes for patients and practitioners. Implementing M&M meetings improved communication and provided a common ground for practice review and collaboration between all sedation practitioners.
Comparison of Risk of Oxygen Desaturation during Propofol Sedation in Children for Bronchoscopy, Upper Endoscopy and Lower Endoscopy

Novotny W, Nguyen K, Fiordalisi I, Lilley K, Holbert D, Perkin R. Brody School of Medicine, Department of Pediatrics, Greenville, NC

Objectives: To determine the relative incidence of desaturation (<90%) by pulse oximetry during sedation with propofol for the performance of bronchoscopy, upper endoscopy and lower endoscopy.

Background: Procedural sedation to minimize motion and discomfort in the pediatric age group can easily result in respiratory insufficiency. The relative risks for oxygen desaturation during instrumentation of the upper airway versus instrumentation by lower endoscopy are not known.

Methods: Retrospective chart reviews of sedations from December 2002 through November 2007 were undertaken. Sedations were conducted by staff with pediatric critical care training and experience. Monitoring included electrocardiography, pulse oximetry, blood pressure and capnography. During sedations supplemental oxygen had been routinely provided at 1 to 2 liters/minute via nasal cannula. Oxygen delivery rate via nasal cannula or mask was increased as indicated by low pulse oximetry readings.

Results: Propofol was the drug of choice in 93/100 lower endoscopies, 311/326 upper endoscopies, 197/203 bronchoscopies. When propofol was used desaturation occurred in 11/93 (11.8%) of lower endoscopies, 99/311 (31.8%) of upper endoscopies and 76/197 (38.6%) of bronchoscopies. The odds ratios for desaturation during upper endoscopy (3.81) and bronchoscopy (3.92) suggest higher risk when compared to lower endoscopy. The frequency of desaturations was less in older children during bronchoscopy and upper endoscopy; however during lower endoscopy, the incidence of desaturation was greater in older children.

Conclusions: Use of propofol is associated with moderate risk of desaturation during pediatric bronchoscopy and upper endoscopy. Routine delivery of higher oxygen concentrations to groups at risk may be warranted. Alternative sedative agents may be associated with less risk.
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**Title: Dexmedetomidine for pediatric procedural sedation: Results from the Pediatric Sedation Research Consortium (PSRC).**

John W Berkenbosch, MD¹, Nina Lubisch, ARNP², Susan Gallagher, BS³ and Joe P Cravero, MD.¹ Pediatrics, University of Louisville, Louisville, KY, United States, 40202; ²Pediatrics, Chris Evert Children's Hospital, Ft. Lauderdale, FL, United States, 33316 and ³Anesthesiology, Dartmouth Hitchcock Medical Center, Lebanon, NH, United States, 03756.

**Background**

Dexmedetomidine (dex) is an $\alpha_2$ receptor agonist with potent sedative and modest analgesic properties but minimal respiratory depression and represents the newest sedative agent available to procedural sedation practitioners. Preliminary experience with dex in this arena is promising but limited. The current series expands significantly on this experience.

**Methods**

Members of the PSRC, a group of 37 institutions providing procedural sedation to children, have been prospectively contributing to a pediatric sedation-related practices and outcomes database since July, 2004. Children sedated with dex from July 1, 2004 through Sept 1, 2007 were identified from this database. Sedation-related data were extracted including demographics, provider information, doses, adjunct agents, efficacy and complications.

**Results**

2309 patients aged 57.2±47.0 mos and weighing 22.2±16.3 kg received dex, primarily for radiologic procedures (n=2026, 87.7%), especially MRI (63.6%). Dex was administered as a bolus alone (n=164), infusion alone (n=360), po alone (n=215), bolus + infusion (n=1566), or po + bolus + infusion (n=4). Adjunct sedation, primarily midazolam, was used in 1546 cases (67.0%). The mean total dex dose was 3.1±2.1 mcg/kg over 54±32 min. The mean recovery time was 56±31 min. Dex was administered by physicians (n=112), APN's (n=1485) and/or RN's (n=1347). Adverse events were recorded in 141 sedations (6.1%). Inadequate sedation and/or agitation occurred in 48 (2.1%) cases. Cardiorespiratory events were rare (n=44, 1.9%) with 34 episodes of hypotension and/or bradycadia (1.5%), 3 episodes of desaturation (0.1%) and 4 of airway obstruction (0.2%). 3 patients required assisted ventilation (BVM x2, intubation x1). There were 17 sedation failures (0.7%), 11 of which were sedation-related (0.5%).

**Conclusion**

The present series represents the largest description of dex use for pediatric procedural sedation to date. Dex appeared to be effective, with a high success rate, and minimal associated adverse cardiorespiratory or behavioral events compared to other agents. Dex represents a viable option for non-invasive pediatric procedural sedation, particularly for appropriately trained, non-physician, sedation providers.
Background: Esophagogastroduodenoscopy (EGD) in children is mostly performed under sedation. Short-acting sedatives, such as propofol, appear to allow for more expedient and less expensive procedures, compared to general, inhalational anesthesia with endotracheal intubation. Propofol is reported as safe and effective in adult endoscopy. However, adult experience is not readily applicable to children, as deeper levels of sedation are required for often uncooperative children, and unique anatomic and physiologic characteristics put children at higher risk for sedation-related complications. In this study, we report our 8 year experience with a pediatric intensivist-led sedation program using propofol.

Methods: The procedural sedation service at Kentucky Children’s Hospital is staffed by pediatric intensivists and sedation nurses. We reviewed all EGD sedations since introduction of propofol in 1999, through March 2007. We recorded demographics, interventions, events and complications. Definition of adverse events and interventions follows guidelines by the Pediatric Sedation Research Consortium (PSRC).

Results: 1001 pediatric patients underwent EGD under propofol sedation during the study period. We observed the following events: Desaturation < 90% (n=101, 10.1% of all EGDs), cough (n=56, 5.6%), airway obstruction (n=54, 5.4%), laryngospasm (n=12, 1.2%), stridor (n=7, 0.7%), apnea (n=7, 0.7%), and wheezing (n=4, 0.4%). The following unplanned airway interventions were required: Repositioning of head, neck and jaw (n=61, 6.1% of all EGDs), bag-valve-mask ventilation (n=48, 4.8%), suctioning for secretions (n=33, 3.3%), insertion of oral airway (n=14, 1.4%), and intubation (n=6, 0.6%). Frequency of events and interventions were markedly higher than those reported by the PSRC for sedations in all types of procedures.

Conclusion: In our experience with propofol sedation during pediatric EGD, airway associated events and interventions occurred more frequently than expected from national experience with all types of pediatric procedures. Pediatric airway expertise and great vigilance are required while sedating children for EGD.
If You Build It They Will Come: Pediatric Intensivist Run Sedation Service
Development and Challenges

Cheri Landers, MD; Horacio Zaglul, MD; Dawn Turner, MD; Philip Bernard, MD and Carrie Makin, RN. Kentucky Children’s Hospital, Lexington KY

Background: Pediatric sedation by non-anesthesiologists is now common among hospitals performing procedures on children. Little has been written on the development and growth of such services and the challenges that come with expansion.
Objective: Describe the development of a pediatric intensivist run sedation service from its inception in 1999 and address the challenges such a service poses to maintain efficiency and safety.
Methods: Descriptive study of the Kentucky Children’s Hospital (KCH) Pediatric Sedation Service from 1999 to 2007.
Results: The pediatric sedation service at KCH began in 1999. Yearly volume has increased from 384 in the first 12 months to 1850 in 2007. Sedations changed from predominantly LPs and BMAs with a few EGDs, MRIs and cardiac catheterizations to a more even mix of LPs/BMAs, GI endoscopy and non-invasive radiology. Staffing was initially an intensivist alone but a dedicated RN now participates in all sedations. Complex scheduling of multiple procedures and locations is done by a dedicated sedation scheduler. Patient safety measures have grown to include comprehensive pre-scheduling assessment and peer review at monthly M&Ms. Startup equipment was initially funded through a charitable grant, now further equipment requirements are provided through KCH. Additional intensivist FTEs can be supported by small increments of weekly sedations. Billing is via anesthesia codes after education of Kentucky Medicaid leaders on the need for pediatric sedation and the skills provided by pediatric intensivists. Current challenges include lack of space to reliably provide sedation for all requests and limited existing faculty to provide the two full time sedation teams needed.
Conclusions: A non-anesthesiologist run pediatric sedation service can grow in numbers and types of procedures quickly and presents challenges in providing needed space, manpower and ongoing safety initiatives.
Implementation of New Directions in Pediatric Procedural Sedation in Interventional Radiology

Carolyn Rigg, RN
Evelyn Dyck, RN
Image Guided Therapy
Diagnostic Imaging Department
The Hospital for Sick Children
Toronto, Ontario, Canada

Abstract: The “Image Guided Therapy Center” is a busy pediatric interventional practice in an academic hospital setting in Canada. This centre performs approximately 10,000 procedures per year and continues to grow at an approximately 10% annual increase in procedure volume since it opened its doors in 2001. A large percentage of our procedures are performed under general anesthesia, but as the shortage of pediatric anesthesiologists worsens, access to this support is expected to diminish. The IGT department is facing a problem of how best to care for our patients.

An interdisciplinary team consisting of a Radiologist, Anesthesiologist, IGT Manager and Nurses worked together to look at the present sedation program. It was felt the overall program was somewhat outdated and inadequate with the range of drugs and depth of sedation achieved. The team worked in collaboration to develop a new sedation protocol introducing agents such as Fentanyl, Ketamine and Nitrous Oxide that were not previously permitted to the Radiologists.

This poster presentation will introduce the development, education, implementation and evaluation of this program.
Initial experience with single dose dexmedetomidine for procedural sedation in pediatric patients.

Background: Several studies have evaluated the efficacy of continuous infusion of dexmedetomidine for procedural sedation of pediatric patients. This study sought to evaluate the efficacy of single dose dexmedetomidine for procedural sedation of pediatric patients.

Methods: Retrospective chart review and case reports of pediatric patients who received intravenous dexmedetomidine for procedural sedation at Kentucky Children’s Hospital.

Results: Dexmedetomidine was administered as a single dose bolus of 1-2 mcg/kg over 10-15 minutes. In the clinical scenarios, effective sedation was achieved in order to perform MRI examinations and/or lumbar punctures. The only side effect related to administration was hypotension, which did not require intervention.

Conclusion: Single dose dexmedetomidine is an effective agent for procedural sedation in children.

Keywords: dexmedetomidine; procedural sedation

Rubén J. Nazario. Assistant Clinical Professor. Section of Inpatient Pediatrics. University of Kentucky College of Medicine, Lexington, Kentucky.
Disparity between Pediatric Procedural Sedation Event/Complication Rates between Centers: Need for Development of Pediatric Risk of Sedation Predictor

Cheri Landers, Horacio Zaglul, M. Dawn Turner, Philip Bernard, Carrie Makin, Joe Cravero and the Pediatric Sedation Research Consortium

Background: Multiple factors likely impact the relative risk of complications for a child undergoing procedural sedation. We noted that the complication/event rate for patients at Kentucky Children’s Hospital (KCH) enrolled in the Pediatric Sedation Research Consortium (PSRC) were higher than those of the entire PSRC population. We hypothesized that this was in part due to the differences in the patient population sedated and procedures performed.

Methods: Retrospective comparison of frequency of complications and patient characteristics for KCH patients with the PSRC as a whole.

Results: KCH has enrolled 1593 individual sedations in the first 12 months ending February 2008. The PSRC comparison group included 65,220 patients entered prior to KCH enrollment. The incidence of complications/events in the PSRC group was 5.5% with the KCH incidence of 17%. The most common event for the PSRC group was desaturation in 1.4%; with upper airway obstruction most common (5.7%) in the KCH patients. The KCH patient population was predominantly ASA III (55%) followed by ASA II (35%) whereas the PSRC was mostly ASA I and II. The most common KCH primary diagnosis was hematology/oncology (39%) followed by neurologic and gastrointestinal diagnoses in 18% each. The PSRC’s top 2 primary diagnoses were neurologic (37%) then hematology/oncology (17%). The most common procedures in the KCH group were hematologic/oncologic and radiologic (30 and 28%, respectively) followed by GI (19%). The PSRCs procedures, however, were primarily neurologic at 62%.

Conclusions: Complication/event rates for pediatric procedural sedation vary between institutions and patient populations. It may be possible to develop a Pediatric Risk of Sedation Score (PRISS) incorporating multiple patient and procedure variables (age, weight, ASA, diagnosis, procedure, etc.) and validate the score using the PSRC database.
LIGHTS, CAMERA, ACTION!
VIDEO CONSENT-TAKE ONE!

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Abstract

To meet the vision of the 21st century, nursing will rise to new levels with the growth of technology. New creative strategies need to be developed to improve quality of care through patient/physician/nurse communication.

For quality improvement through evidenced based practice, our pediatric radiology department has instituted an innovative concept of video teaching for procedural sedation.

The purpose of our initial survey was to integrate our physicians and nurses to determine the need for video teaching.

Follow-up surveys have indicated video teaching has improved the quality of care for our pediatric patients and families. The poster will focus on the collaboration present between the nurse and physician. In managing the video teaching process, the nurse consistently evaluates for patient/family knowledge and satisfaction. This provides a safe and legal venue for procedural sedation.
Sedation Abstract

Title: Nil per os Time and the Incidence of Adverse Events During Pediatric Sedation

Authors: Buckmaster, MA; Callans, B; Tofil, N; Winkler, MK

Objective: Comparison of sedation encounters at Children’s Health System (CHS) with the Pediatric Sedation Research Consortium (PSRC) prospective database on pediatric sedation to determine whether longer nil per os (NPO) times are associated with a lower incidence of adverse sedation events.

Methods: Data was collected from 403 consecutive sedation encounters at CHS from September to December 2007 where our standard NPO time is routinely greater than 8 hours for solids and liquids. This was compared to data from the PSRC which consists of 53 member institutions dedicated to improving sedation/anesthesia care for children internationally. The consortium prospectively enrolls all consecutive pediatric patients presenting for sedation/anesthesia for a variety of procedures. Data is gathered regarding demographics, American Society of Anesthesiologists (ASA) classification, sedation provider, NPO status, outcomes, airway interventions, and adverse events which are reported via a web-based data collection tool.

Results: A total of 26 institutions including CHS submitted 11497 data records for sedation encounters for a 4 month period. NPO times at CHS were >8 hours for liquids in 94.8% of cases (n=403) and >8 hours for solids in 99.3% (n=403) of encounters. PSRC member institutions had NPO times >8 hours in 46.1% of encounters (n=11004) and >8 hours in 70.4% of cases (n=11004) for solids. There were 21 complications (5.2%) in the Children’s Hospital population and 559 complications (5.0%) reported by PSRC members during the data collection period. Events potentially relating to NPO status included aspiration (CHS= 0, PSRC =0), laryngospasm (CHS= 0, PSRC= 19), and vomiting (CHS= 1, PSRC= 27). Serious events were rare with episode of CPR and 1 death beging reported during the study period by the PSRC.
Conclusion: Review of our data compared to similar institutions from the PSRC show that prolonged NPO times are not associated with a lower overall complication rate compared to shorter periods. Consideration should be given to modify NPO time to be more reflective of current practice methods.

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Background
Procedural sedation has become a routine part of pediatric diagnosis and treatment. Many studies have documented the frequency of adverse cardiorespiratory events during the sedation process including hypotension, hypoxemia, and hypoventilation. However, the effect of these events on actual tissue oxygen delivery remains unknown. We evaluated the status of cerebral oxygenation (rSO2) using near infrared spectroscopy (NIRS) and its correlation to changes in cardio-respiratory parameters during pediatric procedural sedation.

Methods
rSO2, SpO2 and ETCO2 were continuously monitored and recorded in 100 children undergoing procedural sedation. Values were recorded from baseline until 30 minutes after sedative administration and simultaneous values recorded. Other sedation-related data were recorded including sedative agents, procedure performed, and adverse cardiorespiratory events. Correlations between rSO2, SpO2, and ETCO2, specifically during adverse cardiorespiratory events, were performed. Cerebral desaturations were defined as an absolute rSO2 value <50% or a >20% decrease from baseline.

Results
100 patients, aged 5.9±4.7 yrs were sedated, yielding 1515 simultaneous rSO2/SpO2/ETCO2 measurements. Primary procedures included oncologic (n=44), radiologic (n=31) and vascular access (n=6). rSO2 remained normal in 1488/1515 measurements (98.2%). rSO2 was unaffected during 5 adverse cardiac events (hypertension x3, hypotension x 1, bradycardia x 1). During 13 hypoxemic episodes, rSO2 decreased only once (7.7%) while rSO2 decreased during 5 of 9 (55.6%) hypercarbic episodes. 23 significant cerebral desaturations were not associated with cardiorespiratory changes. In 55 measurements, rSO2 actually increased >20% from baseline.

Conclusions
Cerebral oxygenation as measured by NIRS was rarely compromised (1.8%) during pediatric procedural sedation. Transient cardiorespiratory events were uncommonly associated with cerebral desaturation, with hypercarbia appearing to have a greater effect than hypoxemia. Conversely, conventional respiratory monitors did not detect all significant cerebral desaturations. NIRS monitoring may represent a useful adjunct during pediatric procedural sedation, particularly to identify events that current monitors may not detect.
Effectiveness and Safety of a New Pediatric Nurse Administered Nitrous Oxide Program

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Background: MeritCare Children’s Hospital started a nurse administered nitrous oxide sedation program in May 2007.

Objective: To assess effectiveness and safety of newly established nurse administered nitrous oxide program.

Methods: Retrospective chart and sedation log-book review of 255 pediatric nitrous sedation episodes. Cases excluded - physician administered sedation or where data was lacking. There were 234 eligible cases. Data collected - patient age and gender, type of procedure, maximum concentration and duration of nitrous oxide administered, NPO status, presence of side effects, and the depth of sedation as measured by the Modified Ramsey Sedation Scale.

Results: Demographics - 62.8% female, 37.2% male; 81.6% outpatients, 18.4% inpatients; age - mean/median 5.5/5 years (range 1 - 20). Total of 252 procedures were done during 234 sedations, including 69 (27.4%) VCUGs, 54 (21.4%) IV placements, 40 (15.9%) Botulinum toxin injections, 16 (6.3%) Port accesses, 13 (5.2%) Lumbar punctures, 13 (5.2%) EEG electrode placements, 11 (4.4%) bladder catheterizations, 9 (3.6%) blood draws, 7 (2.8%) laceration repairs. Mean/median duration of sedation was 15.1/14 minutes (range 2 - 57). Nitrous oxide concentrations during procedure varied but in most cases reached 70%. Sedation was documented as successful in 219 (93.6%) of cases. Side-effects: no apneas, 1 episode (0.4%) of desaturation to 91%, 8 vomiting episodes (3.4%) without respiratory complications, 1 episode (0.4%) of deeper than intended (moderate) level of sedation. Minor side-effects: drooling 7 (3%), flushing 4 (1.7%), hiccups 3 (1.3%), coughing 2 (0.8%); headache, dizziness, stomach ache, tachycardia, gagging, dry mouth and “bad dream” each had 1 occurrence (0.4%).

Conclusion: With appropriate training and oversight a nurse administered nitrous oxide program for minimal sedation can be safely and effectively implemented in a pediatric setting.
Title: Nurse Practitioners Providing Pediatric Procedural Sedation: A Good Fit.

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Background
As the holistic theory of comfort is a distinguishing characteristic of the nursing profession, and procedural sedation intimately involves the provision of anxiolysis, analgesia and other comfort measures, APN’s with appropriate airway management and other rescue skills would appear to be ideally suited for participation in and provision of pediatric procedural sedation. We describe here the success of our NP-driven sedation service.

Methods
Since it’s inception we have maintained a detailed database of our sedation practices. From this database, demographic and sedation-related information were abstracted including provider type, medication regimens, procedures performed, complications and failure rates. Outcome comparisons between physician and NP sedations were limited to sedations performed with medications available to NP’s and analyzed using contingency tables.

Results
We received 3816 consults and sedated 3527 patients. 2844 (80.6%) patients were sedated by NP’s. 68 consults (1.9%) were refused due to risk. Most patients were ASA 2 (62.4%) or 3 (36.0%). The most common regimens were ketamine/midazolam (43.9%), pentobarbital/midazolam (12.7%), and dexmedetomidine/midazolam (12.4%). Primary procedure types included radiographic (50.1%), especially MRI (29.0%) and oncology (36.7%). There were 45 cardiorespiratory complications (1.4%) and 21 sedation failures (0.6%). Complications and failure rates were no different between physician and NP performed sedations.

Conclusion
To our knowledge, this is the first data describing an independent, NP-driven model for pediatric procedural sedation/analgesia. Our results support the assertion that appropriately trained NP’s can independently provide these services as safely and effectively as Board Certified Pediatric Intensivists. The affinity and disciplinary focus of nurses and APN’s to effect comfort for their patient further testifies to the “goodness of fit” of their active involvement in this activity.
An aged and sex-based comparison of the effectiveness of oral anxiolytics (Versed) in young children having a VCUG (Voiding Cysto Uretero Gram)

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**Abstract**
Oral versed is often used in children undergoing VCUG to reduce the anxiety and emotional trauma associated with the procedure. A retrospective data review was conducted to evaluate age and sex based responses to pre-procedural sedation using oral versed. 128 cases were reviewed over 8 months in 2007. The ages of children ranged from 18 months to 10 years, with the mean age of 4.75 years. 2 of the 128 children did not successfully complete the VCUG, requiring deeper sedation. The patient’s response during the VCUG procedure, as documented by the nurse attending the child, was analyzed for the remaining 126 cases. A four-point scale was used by the investigator to categorize the nurse’s documentation. A score of 1 indicated best performance (did well, very well, great) during radiological study and score of 4 indicated worst performance (extreme anxiety, crying and fighting) during the procedure. Considering a score of 1 or 2 as positive performance, males (88%) generally scored more positively than females (71%). In the 18 month to 2 year old group (n=27), 74% had positive performance scores (41% score = 1 and 33% score = 2). In this same group, 11% of the toddlers had performance scores of 3 and 15% scored 4. In the 3–4 year old group (n=54) 76% of children scored positively (37%=1, 39%=2, 11%=3, 13%=4). In children 5 to 6 years (n=29) 69% of children had positive scores (52%=1, 17%=2, 21%=3, 10%=4). 75% of the 7-10 year old group (n=20) scored positively (31%=1, 44% = 2, 25%=2 and 0%=4). Regardless of age, the nurse documentation was rated as a positive response in 74% of children who received oral versed prior to undergoing a VCUG. Future opportunities for study would be to expand upon the evaluation of behavior and recall across these same age groups.
Pediatric Critical Care Procedural Sedation Experience with Pediatric Gastroenterology Procedures

Lynn Sciu to ARNP, G. Patricia Cantwell MD, Barry Gelman MD, Michael A Nares MD, John Thompson MD, N. James Halliday, MD

Background: Literature regarding best practice for procedural sedation is extensive. The composition of procedural sedation services is mostly driven by institutional needs and required personnel who have airway maintenance skills, expertise in safely providing sedation, comprehensive knowledge of sedatives, and an ability to recognize the need for anesthesia referral. Our experience as a pediatric critical care directed procedural sedation service is described with respect to gastroenterology procedures.

Methods: Data submitted to the Pediatric Sedation Research Consortium (PSRC) was analyzed. Sedation policy and procedures were followed as developed by the Hospital Pediatric Sedation Committee, co-chaired by Pediatric Anesthesia and Pediatric Critical Care. The procedural sedation service is comprised of a pediatric intensivist, ARNP or pediatric critical care fellow and nurse who are present throughout the procedure. Data has been entered into the PSRC data bank since 1/2/04. Deep sedation is achieved with propofol by bolus and infusion for essentially all procedures; ketamine or fentanyl may be added as deemed necessary for analgesia. Glycopyrrolate is generally used preceding upper endoscopies.

Results: Our critical care procedural sedation service has existed since 1994; data submission to the multicenter PSRC commenced 1/2/04. Our group provides sedation for the largest percentage of gastrointestinal (59% - all sites 8%) and transplant patient population (20.1 – all sites 0.6%). Total GI procedures (n = 986) included upper endoscopy (42.4%), colonoscopy (22.6%), upper endoscopy plus colonoscopy (18%), liver biopsy (16.6%), and rectal dilatation (0.3%). Complications were documented (7.1% - all sites 5.8%); unexpected hemodynamic changes 3% and unexpected airway intervention 2.9%. No long term morbidity or mortality was seen.

Conclusion It is clear that practical experience and communication with the consultant service ensure optimal patient safety and outcome. Our data lends additional support to safe practice by pediatric intensivists providing deep sedation specific to patients requiring gastroenterology procedures.
Experience of a Pediatric Sedation Team and Pediatric Sedation Safety
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Objectives: To determine the incidence of desaturation by pulse oximetry in a hospital-based sedation service staffed by pediatric critical care physicians, nurses and acute care nurse practitioners.

Background: “Deep” procedural sedation in the pediatric age group can easily result in respiratory insufficiency. The relative risk of oxygen desaturation during various procedures performed during sedation is unknown.

Methods: From January 2003 through December 2007, 3903 sedations were completed (mean 65/month). Sedation objectives were to minimize motion and procedure-related discomfort. Complications of those sedations were retrospectively reviewed. Propofol was the drug of choice in most sedations. Sedations were performed at various locations throughout the hospital to accomplish procedures such as MRI, CT, endoscopy, EEG, BAER, lumbar puncture, bone marrow aspirate/biopsy, bronchoscopy, endoscopy, radiologic intervention, radiation therapy, catheter insertion or dressing change. Anesthesia was consulted to perform an average of 2 to 3 high risk sedations/month including patients with enlarged tonsils, obstructive sleep apnea, stridor, obesity, craniofacial defects, swallowing dysfunction, prior airway problems associated with sedation or anesthesia. A subgroup of consecutive sedations (n=505) conducted between June 2007 and November 2007 for bronchoscopy, endoscopy, MRI and CT were evaluated separately for incidence of oxygen desaturation.

Results: Desaturation by pulse oximeter (<90%) occurred in 356 (9.3%) of all sedations. Manual bag-mask or bag-tracheostomy ventilation was performed in 75 instances (1.9%). Neither tracheal intubation nor cardiopulmonary resuscitation was needed in any case. Procedure specific sedation demonstrated desaturation by pulse oximeter as follows: 22% of bronchoscopies (7/32), 35% of endoscopies (36/102), 3% of MRI (7/213) and 0% of CT (0/46).

Conclusions: Use of propofol for pediatric sedations is associated with low risk of desaturation. Bronchoscopy and endoscopy may be at increased risk for desaturation during procedural sedation in children.
Propofol Procedural Sedation in Children: The Experience in a Rural, Non-Academic, Tertiary Referral Hospital


Objective: The objective of this study was to determine the safety profile of propofol procedural sedation (PPS) for children in a non-academic, rural, tertiary referral medical center. As the use of PPS is extended to additional medical settings, is safety maintained?

Methods: Records of all patients who were given PPS for diagnostic/treatment procedures between Jan 2005 and Dec 2007 at EMMC, as provided by the PSRC, were reviewed. Data included age, sex, wt, ASA score, primary diagnosis, procedure done, location of PSS, NPO status, PPS start to procedure finish time, propofol dose, PPS finish to discharge time, complications and unexpected airway interventions.

Results: There were 1521 cases of PPS in children at EMMC, mean age (± st dev): 5.28 ± 4.51 years, range: 0 to 24 years, 53% girls, mean weight: 23.8 ± 19.3 kg, range 2.6 to 189 kg, mean ASA score: 1.42 (1: 912, 60%, 2: 573, 38%, 3: 36, 2%), NPO for food > 6 hr in 1470 (97%) and clears > 2 hr in 1513 (99%). The diagnostic categories: neurologic 550 (36%), renal 371 (24%), hematology/oncology 242 (16%), airway 55 (4%), infection 53 (4%), orthopedic 49 (3%). The procedural categories: radiology 1029 (68%), hematology/oncology 226 (15%), nerve/brain/ear 150 (10%), surgical 80 (5%), airway 29 (2%), dental 29 (2%). Induction location was PICU/Ward 458 (30%), PSU 333 (22%), radiology 730 (48%). PPS included induction dose followed by bolus/infusion: mean total dose 169.5 ± 128.7 mg, PPS start to procedure end mean 40.5 ± 27.5 min, average infusion dose 102 to 127 mcg/kg/min, average total dose 7.12 mg/kg. No complications were noted in 1471 cases (97%). Complications in 25 cases (1.6%) included airway obstruction 5, secretions/vomiting 5, apnea/bag/mask ventilation 2, agitation 2, O2 desat (>30 sec) 7, HR, BP drop > 30%, 3. In an additional 25 cases (1.6%), unexpected O2 administration, repositioning including jaw thrust or suctioning was noted. No cardiac arrest or ET intubation was noted. PPS finish to discharge from PSU care was mean 25.5 ± 44.9 min. Cases included HR, BP, O2 sat (MRI: EtCO2) done by PICU intensivists.

Conclusion: In a rural, non-academic tertiary care facility, with an organized PSU service, the safety features of PPS reported in other settings can be duplicated.
Case Report

Dexmedetomidine as an alternative when propofol fails during procedural sedation
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Introduction
Sedation failure although rare when present represents a challenge for the practitioner. (1) The first question asked is why did this person fail the “standard” agent(s) and could this have been anticipated. We report a case of an individual on anti-epileptics which are known to modulate GABA\textsubscript{A} receptors (GAR) in whom propofol failed. (2) When dexmedetomidine a highly selective alpha 2 agonist was given, deep sedation was achieved. (3,4,5) What is the role of GAR and in which patients should we consider a drug with an alternative path from the start? (6,7)

Case Presentation
26 year old male ,BSA 41\text{m}^{2}, ASA 3 with severe mental retardation and seizure disorder required deep sedation for scheduled radiation therapy treatment of a right anterior orbit malignant small cell neoplasm. Medications include: topiramate, levetiracetam, quetiapine and divalproex sodium. Past surgical history significant for chemoport placement.

Initial sedation attempt with standard propofol dosing of 2mg/kg IV bolus followed by 200mcg/kg/minute infusion was unsuccessful as patient remained awake and combative. Next day, general anesthesia provided with 5mg/kg thiopental IV and 8% sevoflurane requiring LMA placement to complete radiation therapy. Subsequently another attempt was made at deep sedation with dexmedetomidine 0.6 mcg/kg/dose IV and was able to achieve deep sedation with no respiratory nor hemodynamic compromise.

Discussion
Perhaps this is a case of chronic exposure to other GAR positive modulators (anti-epileptics) resulting in sedative-hypnotic tolerance by decreasing chloride influx and downregulating GAR.(6) When propofol was given targeting the same receptors no sedation was achieved. Dexmedetomidine was given with no effect on GAR, it activates pre- and postsynaptic alpha 2 adrenoreceptors to achieve sedation which resembles light sleep.(8,9) It has the advantage of minimal respiratory and hemodynamic compromise with rapid onset and clearance.(10) When standard therapies fail consider mechanism of action and dexmedetomidine as a safe alternative for procedural sedation.

Keywords: dexmedetomidine, procedural sedation, GABA\textsubscript{A} receptors, propofol, seizure disorder
References


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Dexmedetomidine mechanism of action

- Synaptic Vesicle
- Noradrenaline (NOREPINEPHRINE)
- Alpha_2 receptor
- Alpha_1 receptor

Negative Feedback

- Dexmedetomidine
Propofol Dosing for MR Imaging in Pediatric Patients with Liver Failure

Bell, Keisha MD; Carmel Bogle RN; Marion Goldman RN; Valeriy R. Korostyshevskiy; Deborah LaViolette RN

Study Design: Retrospective chart review of pediatric patients between 3 months and 12 years with and without chronic liver failure who were sedated with propofol for MR imaging

Methods: The study group included patients with chronic liver failure; the age-matched control group included patients with no history of liver disease. A patient was determined to have liver failure if he/she had a bilirubin ≥ 4mg/dL and/or a total alanine transferase (IU/L) level at least twice the accepted level for age tested within the thirty day period preceding the sedation.

All patients received propofol for induction and via infusion, with rescue aliquot doses for movement, for the duration of the imaging study. No other drug was administered. Routine induction dose is 2mg/kg and infusion dose of 7mg/kg/hour with titration as needed. Total propofol dose given per body weight (kg) over the duration of procedure was evaluated in both study and control groups. The mean doses of propofol in units of mcg/kg/min for both study and control groups were compared using Student’s t-test, considering a p-value of < 0.05 as significant.

Results: Fifteen patients were evaluated in this pilot chart review: seven in the study group and eight in the control group. The average propofol dose for the control group was 244 +/- 37.6 mcg/kg/min and for the study group, 253 +/- 18.53 mcg/kg/min. When evaluated using the Student’s t-test, the difference was not statistically significant (p = 0.8321).

<table>
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<th>Study Patients</th>
<th>Age</th>
<th>Bilirubin</th>
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<tr>
<td>7</td>
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<tr>
<td>8</td>
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</table>
Conclusion: In this pilot retrospective chart review, we found no significant difference in the dose of propofol used in pediatric patients with chronic liver failure compared to age-matched controls. This pilot study has urged us to expand this review to the larger population of pediatric patients with liver failure to explore, with more statistical power, whether a difference in propofol dosing exists.

<table>
<thead>
<tr>
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<tr>
<td>S.E.M.</td>
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</table>

Propofol Dose in Micrograms/Kg/Min (Table 2)
RCT for Intermittent versus Continuous Propofol Sedation for Pediatric Brain and Spine MRI Studies

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Abstract
Children often require sedation to successfully complete radiological studies such as bone scans and MRI’s. Without sedation there is an increased risk of inadequate study results and often an increased expense for repeated imaging. Propofol given by intermittent bolus has emerged as an effective agent for pediatric procedural sedation. The risk of complications related to propofol increase as the dose and level of sedation increase. With the advent of MRI compatible infusion pumps, it is possible to continuously infuse propofol during MRI studies achieving a steady level of sedation. A randomized controlled study of the use of intermittent propofol sedation versus continuous propofol sedation in children 1 month to 18 years undergoing sedation for MRI studies was conducted. The Intermittent group received a loading bolus of propofol (2-4 mg/kg/dose) followed by a repeat bolus (0.5-2 mg/kg/dose) as needed. The Continuous infusion group received the same initial loading bolus of propofol (2-4 mg/kg/dose) followed by a continuous infusion (100mcg/kg/min) titrated to effect. A total of 149 children were enrolled in the study with 68 (45.6%) in the Continuous group and 81 (54.4%) in the Intermittent group. The two groups were compared on five quantitative variables: total dose of propofol, total sedation time, total recovery time, complications, and quality of the MRI scan. Means, standard deviations, and medians for the quantitative variables within each treatment group were analyzed. There was statistically significant difference in the total dose (mcg/kg/min) for the two groups (loading dose included = p-value 0.018; loading dose excluded = p-value was 0.008). The Intermittent group required higher total amounts of Propofol (163.5 mcg/kg/min) versus the Continuous group (130.2 mcg/kg/min). There were not significant differences in the other variables. When compared to intermittent infusions, continuous propofol infusion using MRI-safe pumps provided less dose exposure and increased ease of administration.
Babies and children who cannot remain still during their echocardiogram are given light sedation by a registered nurse and cardiologist. Preschoolers are difficult to sedate because they spit up the medicine, are agitated after ingestion and do not fall asleep or cooperate for testing. Several medications were attempted with this age group to find the most effective drug combination.

The objective of this chart review was to compare oral midazolam, chloral hydrate, or chloral hydrate plus benadryl to determine the most effective drug. All patient charts of children 2-4 years old who presented to the Heart Station for a sedated echocardiogram in 2001-2003 were reviewed for:

- Underlying cardiac physiology
- Drug used
- Dosage
- Route
- Age
- Weight
- Sex
- Time of day
- Minutes from dose administration to onset of sedation
- Minutes sleeping
- Complications
- Incomplete echocardiograms due to patient agitation
- Prolonged/unanticipated deep sedations

Only 10% of patients given midazolam fell asleep. Sixteen of the midazolam patients had incomplete echocardiograms and awoke in the least amount of time. Patients given chloral hydrate alone achieved sedation the fastest. Patients given a single dose of either chloral hydrate alone or with benadryl fell asleep faster than those given divided doses. Fifteen of the chloral hydrate plus benadryl patients experienced prolonged sedation.

Chloral hydrate at doses of 75 mg/kg or above had the highest success rate. Adding benadryl to the chloral hydrate produced unwanted, prolonged sedation and did not hasten the onset of sleep.
Sedation with Propofol – A review of 46,363 multispecialty cases from the Pediatric Sedation Research Consortium.

Introduction: Propofol sedation is delivered to children by a wide variety of medical specialists and nurses. Over the last 2 years a significant amount of controversy has been generated concerning the appropriateness of this practice. Professional organizations have published a number of statements to condemn or promote the use of this sedative when anesthesiologists are not involved (1,2). This study is a review of the data generated by a large collaborative group – the Pediatric Sedation Research Consortium (PSRC). We specifically evaluated propofol sedation performed by all specialists who are part of the PSRC and analyzed the data with respect to the demographics of the providers and the patients and who received propofol sedation. In addition, we wished to look at the incidence of adverse events related to propofol sedation in order to help individuals who are charged with training and credentialing deep sedation providers.

Methods: The PSRC consists of 28 participating institutions - each with IRB approval for collecting deidentified, prospective, observational data on pediatric sedation practice. Each institution records data on consecutive cases - on a web-based data collection tool that includes information in 18 separate screens. Data elements include patient demographics, procedure type, sedation medications/technique, procedure outcomes and adverse events. All data is stored in a secure data base at the Dartmouth College Bioinformatics Group. Each center must provide periodic audits of both quantity and quality of reports to assure accuracy of the data. For this study, the data base was queried for all data on propofol sedations. We analyzed the demographics of the patients, procedures, and providers related to propofol sedation. Data for this abstract were collected between 7/14/2004 through 8/19/2007.

Results: See Tables Below.

Discussion: We report the largest series of propofol-based sedations by a variety of sedation providers. Our data indicates that there is a small but significant rate of adverse events and unexpected airway interventions during sedation activities. Data such allows us to better understand the nature and safety of sedation practice allowing to design training and credentialing criteria for programs that choose to deliver this care.


Table 1. Provider types and frequency of cases.

<table>
<thead>
<tr>
<th>Provider Type</th>
<th># of Cases</th>
<th>Percent of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesiologist</td>
<td>5,063</td>
<td>10.92</td>
</tr>
<tr>
<td>APRN/PNP/PA</td>
<td>14</td>
<td>0.03</td>
</tr>
<tr>
<td>Emergency Medicine MD</td>
<td>16,887</td>
<td>36.43</td>
</tr>
<tr>
<td>Fellow Level Trainee</td>
<td>1,202</td>
<td>2.59</td>
</tr>
<tr>
<td>Intensivist</td>
<td>22,086</td>
<td>47.64</td>
</tr>
<tr>
<td>Pediatrician</td>
<td>1,076</td>
<td>2.32</td>
</tr>
<tr>
<td>Radiologist</td>
<td>5</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Table 3. Unplanned Airway Interventions. N=46,363; Rates per 10,000

<table>
<thead>
<tr>
<th>Unplanned Airway Intervention</th>
<th>N</th>
<th>Rate</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intubation</td>
<td>50</td>
<td>10.8</td>
<td>(8.0,14.2)</td>
</tr>
<tr>
<td>Jaw thrust</td>
<td>525</td>
<td>113.2</td>
<td>(103.8,123.3)</td>
</tr>
<tr>
<td>LMA placement</td>
<td>50</td>
<td>10.8</td>
<td>(8.0,14.2)</td>
</tr>
<tr>
<td>Nasopharyngeal Airway Placement</td>
<td>211</td>
<td>45.5</td>
<td>(39.6,52.1)</td>
</tr>
<tr>
<td>Blow-by O2 required</td>
<td>1899</td>
<td>409.6</td>
<td>(391.7,428.0)</td>
</tr>
<tr>
<td>Oral Airway Insertion Required</td>
<td>300</td>
<td>64.7</td>
<td>(57.6,72.4)</td>
</tr>
<tr>
<td>Repositioning of head</td>
<td>721</td>
<td>155.5</td>
<td>(144.4,167.2)</td>
</tr>
</tbody>
</table>
Table 2. Complications During Propofol Sedation N=46,363: Rates per 10,000

<table>
<thead>
<tr>
<th>Complication</th>
<th>Number</th>
<th>Rate</th>
<th>CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate sedation</td>
<td>394</td>
<td>85.0</td>
<td>(76.8,93.8)</td>
</tr>
<tr>
<td>Airway Obstruction</td>
<td>432</td>
<td>93.2</td>
<td>(84.6,102.3)</td>
</tr>
<tr>
<td>Allergic reaction</td>
<td>14</td>
<td>3.0</td>
<td>(1.7, 5.1)</td>
</tr>
<tr>
<td>Apnea</td>
<td>143</td>
<td>30.8</td>
<td>(26.0,36.3)</td>
</tr>
<tr>
<td>Aspiration</td>
<td>4</td>
<td>0.9</td>
<td>(0.2, 2.2)</td>
</tr>
<tr>
<td>Cardiac Arrest</td>
<td>2</td>
<td>0.4</td>
<td>(0.1, 1.6)</td>
</tr>
<tr>
<td>Cough (interrupts procedure)</td>
<td>356</td>
<td>76.8</td>
<td>(69.0,85.2)</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0.0</td>
<td>(0.0, 0.8)</td>
</tr>
<tr>
<td>Desaturation (less than 90% &gt; 30 secs)</td>
<td>716</td>
<td>154.4</td>
<td>(143.4,166.1)</td>
</tr>
<tr>
<td>Emergency Anesthesia Consult **</td>
<td>7</td>
<td>1.5</td>
<td>(0.6, 3.1)</td>
</tr>
<tr>
<td>Hypothermia</td>
<td>6</td>
<td>1.3</td>
<td>(0.5, 2.8)</td>
</tr>
<tr>
<td>IV complications</td>
<td>113</td>
<td>24.4</td>
<td>(20.1,29.3)</td>
</tr>
<tr>
<td>Laryngospasm</td>
<td>96</td>
<td>20.7</td>
<td>(16.8,25.3)</td>
</tr>
<tr>
<td>Myoclonus (interrupts procedure)</td>
<td>11</td>
<td>2.4</td>
<td>(1.2, 4.2)</td>
</tr>
<tr>
<td>Prolonged Recovery</td>
<td>42</td>
<td>9.1</td>
<td>(6.5,12.2)</td>
</tr>
<tr>
<td>Prolonged Sedation</td>
<td>30</td>
<td>6.5</td>
<td>(4.4, 9.2)</td>
</tr>
<tr>
<td>Secretions (Require Suction and interrupt procedure)</td>
<td>341</td>
<td>73.6</td>
<td>(66.0,81.8)</td>
</tr>
<tr>
<td>Seizure – interrupts procedure</td>
<td>11</td>
<td>2.4</td>
<td>(1.2, 4.2)</td>
</tr>
<tr>
<td>Stridor – interrupts procedure</td>
<td>50</td>
<td>10.8</td>
<td>(8.0,14.2)</td>
</tr>
<tr>
<td>Unexpected change in HR, BP, RR of &gt; or &lt; 30%</td>
<td>282</td>
<td>60.8</td>
<td>(53.9,68.3)</td>
</tr>
<tr>
<td>Bag Mask Ventilation Required</td>
<td>513</td>
<td>110.6</td>
<td>(101.3,120.6)</td>
</tr>
<tr>
<td>deep</td>
<td>4</td>
<td>0.9</td>
<td>(0.2, 2.2)</td>
</tr>
<tr>
<td>Unexpected admission</td>
<td>33</td>
<td>7.1</td>
<td>(4.9,10.0)</td>
</tr>
<tr>
<td>Intubation</td>
<td>53</td>
<td>11.4</td>
<td>(8.6,15.0)</td>
</tr>
<tr>
<td>Reversal Agent Required.</td>
<td>2</td>
<td>0.4</td>
<td>(0.1, 1.6)</td>
</tr>
<tr>
<td>Vomiting During Sedation</td>
<td>49</td>
<td>10.6</td>
<td>(7.8,14.0)</td>
</tr>
<tr>
<td>Wheezing – interrupts procedure</td>
<td>44</td>
<td>9.5</td>
<td>(6.9,12.7)</td>
</tr>
</tbody>
</table>

** indicates emergency airway consultation – does not apply to cases delivered by anesthesiologists.

Table Age Categories for Propofol Sedations

<table>
<thead>
<tr>
<th>Age Category</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>8 + years</td>
<td>11,381</td>
<td>24.55</td>
</tr>
<tr>
<td>1-8 years</td>
<td>29,623</td>
<td>63.89</td>
</tr>
<tr>
<td>4-12 months</td>
<td>4,488</td>
<td>9.68</td>
</tr>
<tr>
<td>0-3 months</td>
<td>871</td>
<td>1.88</td>
</tr>
</tbody>
</table>

Table. ASA status and frequency

<table>
<thead>
<tr>
<th>ASA Status</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>13,904</td>
<td>30.59</td>
</tr>
<tr>
<td>II</td>
<td>24,390</td>
<td>53.65</td>
</tr>
<tr>
<td>III</td>
<td>6,741</td>
<td>14.83</td>
</tr>
<tr>
<td>IV</td>
<td>297</td>
<td>0.65</td>
</tr>
<tr>
<td>V</td>
<td>2</td>
<td>0.00</td>
</tr>
<tr>
<td>IE</td>
<td>83</td>
<td>0.18</td>
</tr>
<tr>
<td>IIE</td>
<td>11</td>
<td>0.02</td>
</tr>
<tr>
<td>IIIE</td>
<td>23</td>
<td>0.05</td>
</tr>
</tbody>
</table>
SEDATION PRACTICES IN PEDIATRIC EDs

Introduction: pediatric sedation has changed significantly. More medications are used for a variety of procedures.

Objectives: to discover the most common sedation practices in the PED.

Methods: a survey regarding sedation practices and the credentialing and QI processes for sedation providers was mailed to the 99 children’s hospitals that are members of NACHRI.

Results: the response rate was 73%. The most common sedation providers are PED attending physicians and fellows at 88% and 3% of PEDs, respectively. The most common medications used for sedation in PEDs are ketamine, ketamine-midazolam, and midazolam at 34%, 33%, and 19% of PEDs, respectively. 67% of PEDs can administer propofol, but it is only the 4th most common medication used.

The top 2 categories utilizing sedation in PEDs are orthopedics and general PED patients at 77% and 21% of PEDs, respectively. The top 2 conditions requiring sedation in PEDs are fracture reduction and laceration repair at 76% and 17% of PEDs, respectively.

61% of the responding PED’s hospitals have a sedation service. Only 19% of these PEDs consult it, and all of these use it for <10% of their sedation cases.

36% of PEDs sedate patients outside of the PED, mostly in radiology for CT scans, the 4th most common condition requiring sedation.

36% of PEDs have formal guidelines and 22% have informal guidelines that differ from the ASA pre-procedure fasting guidelines.

41% of PEDs follow the ASA guidelines >90% of the time, 18% follow them ~75% of them time, 18% follow them ~50% of the time, 4% follow them ~25% of the time, and 19% follow them < 10% of the time.

Conclusions: this study provides a current overview of procedural sedation practices in PEDs.
SEDATION PRIVILEGES AT CHILDREN’S HOSPITALS

Introduction: pediatric sedation has changed significantly. Professional societies have developed similar guidelines. JCAHO requires credentialing and QI processes for granting privileges to non-anesthesiologists.

Objective: to learn how credentialing and QI for sedation privileges vary at different hospitals.

Methods: a survey regarding sedation practices and the credentialing and QI processes for sedation providers was mailed to the 99 children’s hospitals that are members of NACHRI.

Results: the response rate was 73%. APLS or PALS is required by 73% of hospitals for moderate sedation privileges. ACLS is required by 27%. No life support course is required by 23%. BC or BE in PEM or EM is required by 54%. The observation of sedation cases is required by 14%. The requirements for deep sedation privileges differ at 28%. 20% of hospitals require a minimum number of cases for the renewal of sedation privileges with a range of 5 to 50 cases in 2 years. Other requirements are: maintaining PALS at 25%, maintaining BC or BE in PEM or EM at 13%, a hospital review of cases at 37%, a peer review at 25%, a cognitive evaluation at 30%, and a competency evaluation at 10%. Sedation cases are reviewed at 90% of hospitals by different entities. This may affect the renewal of privileges.

Conclusions: the requirements for obtaining sedation privileges vary at children's hospitals. Many require certification in life support. Some require BC or BE. Most do not require the observation of cases. The requirements for renewing privileges vary, also. Most do not require a minimum number of cases. Some require maintaining certification. Some require a peer review and/or a hospital review of cases. Some require a cognitive evaluation. Most do not require a competency evaluation.
*Nil per os* (NPO) duration and calculated residual gastric volumes by computed tomography in sedated children

Baker K, Cohen D, Leder M, Long F

Background: Growing attention has focused on fasting recommendations for pediatric procedural sedation. Current guidelines are supported by limited evidence on the relationship between *nil per os* (NPO) duration, gastric volume (GV) and risk of emesis or pulmonary aspiration.

Objective: To evaluate the relationship between NPO duration and GV as calculated by computed tomography (CT) and complications.

Methods: Records of children sedated for lung CT at a Children’s Hospital over three years were reviewed. Excluded were: those acutely ill, requiring intravenous sedation, with inadequate CT images and requiring additional scans. All children were sedated with oral chloral hydrate. CT scans were reviewed by a pediatric emergency medicine physician in conjunction with a pediatric radiologist. Cross-sectional areas of the stomach were measured and volume calculations performed using the GE Advantage Workstation version 4.2. Statistical analyses were performed to determine the relationship between NPO duration and GV, NPO duration and complications, and the association between cystic fibrosis (CF), a common diagnosis among study subjects, and GV.

Results: We evaluated 111 patients, 1 month to 4 years. NPO duration ranged from 2.5 to 13.5 hours. The mean GV was 1.21 +/- 0.83 ml/kg. Ninety-five patients (86%) had GV > 0.4 ml/kg and 72 (65%) volumes > 0.8 ml/kg. GV did not differ significantly between patients with (1.14 +/- 0.89 ml/kg) and those without (1.29 +/- 0.89 ml/kg) CF, *p* = 0.7. Complications were vomiting in 12 cases and transient oxygen desaturation in 5. There was no recorded aspiration. GV and NPO duration did not predict patients with complications.

Discussion: In this study, NPO duration correlated poorly with GV calculated by CT scan and did not alter the risk of complications. Most patients exceeded recommended GV despite compliance with current NPO guidelines. Further study is needed to determine the optimum fasting interval for procedural sedation.
The University of Virginia Pediatric Sedation Service: A Unique Approach to the Provision of Procedural Sedation to Children
Julie Haizlip and Patricia Scherrer.
Department of Pediatrics, Division of Critical Care Medicine, University of Virginia Children’s Hospital, Charlottesville, Virginia.

**Background:** Pediatric patients can require a number of different painful and/or frightening procedures as part of their ongoing medical care. While a number of different models exist to provide procedural sedation for these children, providing safe, organized, and appropriate interventions in a variety of settings and locations can prove challenging. Many programs have established pediatric sedation units; however, physically discrete units do not address the needs of pediatric patients who require sedation in more remote locations of the health care system.

**Objective:** This study was designed to evaluate the performance of a mobile pediatric sedation service in the provision of pediatric procedural sedation and analgesia and to compare its safety and effectiveness with other pediatric sedation programs from around the country.

**Design/Methods:** Since July 14, 2004, our service has submitted data from each pediatric sedation encounter to the database maintained by the Pediatric Sedation Research Consortium (PSRC), a collaborative group of 35 institutions who share prospective observational outcome data on procedural sedation. As of March 31, 2007, our organization had contributed 2132 sedations out of the total 74,280 records entered in the database. We compared our complications and outcomes with those of the greater PSRC member group.

**Results:** Our service provides pediatric procedural sedation in a much wider variety of locations as compared to the entire PSRC group, whose members provided 93% of sedations either in a centralized unit or in a radiology suite with a centralized pediatric sedation area. There was no statistically significant difference in unexpected airway management between our group and the PSRC as a whole. While the outcomes were not significantly different, our program did have a higher percentage of cases completed (99.3%) versus the PSRC group (98.9%).

**Conclusions:** A mobile sedation service can offer safe and effective pediatric procedural sedation and analgesia in a variety of locations and settings.
**Use of Dexmedetomidine (Dex) in PICU Patients**

Archana V Dhar MD, Thomas Spentzas MD, Stephanie Storgion MD  
Division of Pediatric Critical Care  
UTHSC, Memphis

**Introduction:** Dex is a novel sedative/analgesic (s/a) that controls stress, anxiety and pain without causing respiratory depression or hemodynamic instability.

**Objective:** To evaluate the use of Dex as a s/a in PICU patients.

**Methods:** Patients in our university affiliated PICU who received Dex over a 8 month period were identified for a retrospective review. Their HR, RR and BP - 6 hours prior to starting Dex and for 6 hours during its infusion were compared. All the s/a agents that the patient was on prior to and during the Dex infusion along with their dosages were reviewed. The sedation scale used by nurses was used to assess the depth of sedation.

**Results:** 14 patients aged 5 months-18 years were included. 3 patients (21%) were under the age of 1 year. All the patients were receiving more than one s/a agent. Dex was used as a second-line, rescue agent when the initial regimen with an opioid, benzodiazepine or propofol was judged to be unsuccessful because of the need for frequent boluses or need for increase in the dosage of the infusion. Dex was substituted for another s/a agent and was administered by a continuous intravenous infusion 0.20-1.50 mcg/kg/hr with a median of 0.5 mcg/kg/hr. The need for bolusing with other agents like midazolam, fentanyl, morphine or propofol was reduced with the Dex infusion. The reduction was statistically significant with propofol p<0.05. Before and during Dex infusion, there was no significant change in the BP, RR or HR.

**Conclusion:** Dex is a hemodynamically well-tolerated and safe s/a for PICU patients. A randomized, controlled study where Dex is used as a monotherapeutic, first line agent needs to be undertaken.
Safety of Etomidate for Pediatric Procedural Sedation

It’s not just for RSI anymore!

Amy L. Baxter, MD FAAP FACEP
Division of Emergency Pediatrics
Pediatric Emergency Medicine Associates

Overview
- Pharmacology
- History
- Current Literature
- Adverse events
  - Apnea
  - Adrenal Supression
  - Myoclonus
- Finesse

Pharmacology
- Imidazole hypnotic
- $0.2 - 0.4$ mg/kg
- Onset 5-15 seconds
- Pain at injection
- Negligible hemodynamic effects
- No Analgesia
- Not FDA approved <10 years

Pharmacology
- Initial half-life 2.7 minutes
- Hepatic > plasma
- 75% protein bound
- Wake in 5-14 minutes
- Rectal 6.5mg/kg
- Maintains CPP
- Reduces IOP

History
- 1972 introduced in Europe
- 1976 series in children for RSI
- 1983 approved in USA
  - Same year ICU deaths reported
- 2000 first outpatient reduction
- 2001 ED series, adults & children

Painful Procedures-Lumbar Puncture/BMA
- N=101
- age 11.6
- Retrospective
- Bolus $0.3$ mg/kg
  - $0.43$ mg/kg
  - Fentanyl $1$ μg/kg

McDowell J Clin Anesth 1995
Painful Procedures - Fracture Reduction

- N=53, age 9.7
- Retrospective
- 0.2mg/kg over 60 sec.
  - 0.24 mg/kg
  - All with Fentanyl
- Re-bolus 13/53
- 83% successful

Dickinson Acad Em Med 2001

Painful Procedures - Fracture Reduction

- N=100, age 9.7
- PRCT
- 0.2 mg/kg 60-90 sec
  - Fentanyl up to 2 μg/kg
- 92% successful
- Recovery 11.8 min.
- Myoclonus 22%

Di Liddo Ann Em Med 2006

Painless Procedures - Head CT

- N=61 (24 etomidate)
- PRCT
- N=7, 0.1mg/kg
  - 57% success
- N=17, 0.2mg/kg
  - 76% success

Kienstra PEC 2004

Painless Procedures - CT

- 444 etom, 396 pentobarb
- Age 23 months
- 0.3 mg/kg fast push
  - 0.38 mg/kg
- Success 99%
- Sedation duration 34 min

Baxter PEC 2007

Sedative Dosing by Age

Graphs by Etomidate Vs Pentobarb
### Pentobarb v. Etomidate

#### Adverse Events

<table>
<thead>
<tr>
<th>Event</th>
<th>Pentobarbital</th>
<th>Etomidate</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Event*</td>
<td>18 (4.5%)</td>
<td>6 (0.9%)</td>
<td>1.03 (1.01, 1.05)</td>
</tr>
<tr>
<td>Desaturation</td>
<td>4</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Inadequate sedation</td>
<td>3</td>
<td>2</td>
<td>NS</td>
</tr>
<tr>
<td>Apnea</td>
<td>2</td>
<td>1</td>
<td>NS</td>
</tr>
<tr>
<td>Allergy/cough/secretions</td>
<td>4</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Prolonged sedation</td>
<td>3</td>
<td>1</td>
<td>NS</td>
</tr>
<tr>
<td>Stridor</td>
<td>1</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Emesis</td>
<td>0</td>
<td>1</td>
<td>NS</td>
</tr>
<tr>
<td>Too Deep</td>
<td>1</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>IV complication</td>
<td>0</td>
<td>1</td>
<td>NS</td>
</tr>
<tr>
<td>Other</td>
<td>7</td>
<td>5</td>
<td>NS</td>
</tr>
</tbody>
</table>

---

#### Adverse Events - Apnea

- **Mini-bier block**
  - 1 mg/kg up to 25 mg
  - Tourniquet below nearest joint
  - Slow push, leave in 1 min

#### Adverse Events - Burning at injection

- **Deaths from long-term infusions**
- **1 dose suppresses cortex**
- **Dose dependent**
  - Inhibits chol → cortisol
- **Starts 30 min, lasts 5-15 hours**
- Tested via ACTH;
  - serum cortisol normal

---

#### Adverse Events – Adrenal Insufficiency

- **Risk factor in ICU AI**
  - 71% with v. 52% without (p<.01)
- **Etomidate et sepsis: une accusation sans preuve, un proces sans victime.**
- **Meningococcemia deaths**
  - 7/8 etom v. 1/8 without etomidate

Den Brinker Int Care Med 2008
Adverse Events - Myoclonus

- “Aesthetic rather than functional”
- Focal seizure threshold
- Antiepileptic
- Myoclonus not seizures

Percent Incidence of Myoclonus by Age

Adverse Events - Myoclonus

- By push times
  - Kienstra 0/17 0.2mg/kg 30 sec
  - Di Liddo 11/50 0.2mg/kg 60 – 90 sec
  - Gilles 13/30 0.3mg/kg 20 sec
  - 21/30 0.3 80 sec

Adverse Events - Myoclonus

- Sufentanil – 0.3 mcg/kg
  - 0/20 v. 16/20
- Magnesium 60 mg
  - 6/25 v. 18/25
- Midazolam – 0.015 v. etomidate 0.05
  - 4/20 v. 18/20 p<0.01

Finesse

- Good!
  - Possible increased ICP
  - Any airway issue
  - CT or LP with contraindication
  - Fast oral or ocular procedure
- Bad!
  - Bacterial sepsis
  - Duration > 5 minutes

Bottom Line

- Push fast
- Safer (but faster) than propofol
- Children not little adults
  - Rare apnea
  - Decreased myoclonus
- Not for Sepsis
- It’s not just for RSI anymore


THE SAFETY OF POTENT PROCEDURAL SEDATIVE MEDICATIONS: DEXMEDETOMIDINE

John Berkenbosch, MD
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Associate Professor
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University of Louisville
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GOALS

• Understand the pharmacology, physiology, and clinical properties of dexmedetomidine

• Review clinical experience with dexmedetomidine for pediatric procedural sedation
  • Adverse Events/Safety Profile
  • Coadministrations
  • Discuss practical issues related to use

DISCLAIMER

• No financial interest in any medication or company discussed

• Substantial interest in ensuring all children have access to appropriate sedation and/or analgesia

• Thoughts and opinions expressed are not intended to represent official positions of any governing bodies, including the SPS and/or the conference organizers

BACKGROUND

• Despite recognition of sedation importance, few agent developments in recent past

• Significant issues with current agents
  • Opiate/benzodiazepine – tolerance, efficacy
  • Chloral hydrate - predictability
  • Pentobarbital – agitation, duration
  • Propofol – limited access
  • Ketamine – emergence, tolerance
  • α₂-adrenoreceptor agonism

α₂ RECEPTOR AGONISTS

• Prototype agent is clonidine

• More recent applications in clinical practice
  • Sedation
  • Behavior disorders (ADHD)
  • Drug withdrawal
  • Hypertension

• Problem - α₁ effects - hypotension

• Solution – 2nd generation - ↑ α₂ specificity

DEXMEDETOMIDINE

• Precedex®, Hospira

• Pharmacologically active D- isomer of medetomidine

• 1st synthesized in late 1980’s, Phase 1 studies in early 1990’s, clinical trials late 1990’s

• ~ 8-fold greater α₂:α₁ selectivity than clonidine
  • 1620:1 vs 200:1

• Shorter elimination half-life than clonidine
  • 2-3 vs 8-12 hr

• FDA approved for ICU sedation in adults
PHARMACOKINETICS
- Intravenous:
  - Distribution $t_{1/2} = 6$ minutes
  - Elimination $t_{1/2} = 2$ hrs
  - $V_{DSS} = 118$ liters
- Intramuscular (2μg/kg):
  - Peak plasma conc 13±18 min (variable)
    - Concentration 0.81±0.27 ng/ml
    - ~ 70% bioavailability
  - Enteral: less well studied – buccal>>>gastric
  - Pediatrics – preliminary – similar to adults
    - ? neonates

METABOLISM
- Almost 100% biotransformation
  - Glucuronidation
  - Cytochrome P450 mediated
  - Metabolites all inactive
- Highly protein bound (94%)
- Significant $t_{1/2}$ in hepatic failure (7.5 hr)
- 95% of elimination is urinary
- <1% excreted as unchanged
- No significant effect of renal impairment

CNS ACTIONS
- Sedation – central, G-proteins (inhibition)
- Analgesia – spinal cord, Substance P

NON-CNS EFFECTS
- Hypertension:
  - peripheral $\alpha_1$-agonism
- Bradycardia/hypotension:
  - Sympathetic inhibition - medullary VMC
- ↓ shivering:
- Diuresis:
  - ↓ renin, vasopressin; ↑ ANP

RESPIRATORY EFFECTS
- Promoted as minimal respiratory depression
  - 0.17% incidence on monogram
- Most data suggest no change in $SaO_2$, $PaCO_2$
  - Belleville, 1992 – 0.25-2 μg/kg bolus
    - Mild ↑ $PaCO_2$ (42→46 mmHg)
    - ~ 45% ↓ ventilatory response to hypercarbia
- Numerous reports during spontaneous ventilation
**OR/ PERIOPERATIVE OBSERVATIONS**

- ↓ hypotension vs propofol
- Blunted tachycardia during controlled hypotension
- ± ↓ PACU analgesia requirements
- Blunted catecholamine response
  - Potential importance with vascular procedures
- Respiratory - non-intubated

**ICU OBSERVATIONS**

- Peds doses slightly higher, esp infants
- Effective bridge through extubation
- Parent satisfaction high
  - Lighter but less agitated
  - No recovery-related “wooziness”
- Appears useful in non-intubated pts
- Not necessarily 1st line
  - reserve for difficult, long-term
  - Analgesic effects not insignificant

**CLINICAL EXPERIENCE**

- Limited resp depression – ? role in procedural sedation
  - Sedation of 5 children failing chloral hydrate/midazolam
  - Dex bolus (0.8±0.4 ug/kg) over 10 min, gtt 0.6ug/kg/hr
  - Procedures completed
  - Modest ↓ HR, BP; no significant respiratory effects

**CLINICAL EXPERIENCE**

- Prospective case series, non-invasive procedures
- Candidates:
  - >4 y.o.
  - Previous chloral hydrate failure/poor candidate
  - Rescue from failed sedation
- Induction bolus: (0.5 ug/kg over 5 min)
- Maintenance: 0.5 ug/kg/hr
- Monitor - Physiologic
  - Effectiveness
  - Recovery-related behavior

**CLINICAL EXPERIENCE**

- 48 patients, 6.9±3.7 yrs - 15 rescues
  - Primarily MRI sedation
  - Induction 0.9±0.4 ug/kg over 10.3±4.7 min
  - Maintenance 0.7±0.3 ug/kg/hr
  - Modest ↓ in HR, BP
  - Clinically insignificant ↓ RR (3/min)
  - ET-CO₂ >50 in 1.7% (max 52 mmHg)
  - All procedures completed
  - No recovery-related agitation

**CLINICAL EXPERIENCE**

- Paucity of comparative trials:
  - Dex vs midazolam for MRI, n=80 – 1-7 yrs
    - Dex: 1ug/kg bolus, then 0.5 ug/kg/hr
    - Midazolam: 0.2 mg/kg, then 0.36 mg/kg/hr
    - ↑ efficacy (80% vs 20%), similar CV
    - Dex vs propofol for MRI, n=60 – 1-7 yrs
    - Sedation adequate in 83% vs 90%
    - ↑ rec time, similar CV, ↓ desaturations (0% vs 13%)
**CLINICAL EXPERIENCE**


- Dexmedetomidine for NB disorders
  - Many need EEG, MRI but sedation options limited
- Combined databases from KCH, CECH
  - Demographics, adjuncts, procedures, efficacy
  - Limited by differences between databases
- 315 pts, KCH (n=74), CECH (n=241)
  - Age: 6.8 ± 3.9 yrs (8 mo-24 yr)

### Diagnosis Number Percent

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Number</th>
<th>Percent</th>
</tr>
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<tbody>
<tr>
<td>Autism</td>
<td>262</td>
<td>83.1</td>
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<tr>
<td>Aggression</td>
<td>18</td>
<td>5.7</td>
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<tr>
<td>ADHD</td>
<td>16</td>
<td>5.1</td>
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<tr>
<td>Other</td>
<td>19</td>
<td>6.0</td>
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</table>

### Procedure Number Percent

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number</th>
<th>Percent</th>
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</thead>
<tbody>
<tr>
<td>MRI</td>
<td>245</td>
<td>77.8</td>
</tr>
<tr>
<td>Neurophysiology</td>
<td>20</td>
<td>6.3</td>
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<tr>
<td>Neurophys/Radiol</td>
<td>24</td>
<td>7.6</td>
</tr>
<tr>
<td>Other</td>
<td>26</td>
<td>8.3</td>
</tr>
</tbody>
</table>

**CLINICAL EXPERIENCE**


- Sedation:
  - Dex alone (n= 32), dex + midaz (n=283)
  - Induction - 1.4±0.6 µg/kg,
  - Total - 2.7±1.7 µg/kg
- Efficiency: Ind - 8.2±4.7 min, rec - 47±27 min
- Adverse:
  - >30% ↓ SBP (n=30, 9.6%), HR (n=64, 20.3%)
  - Glycopyrollate x4, N5 bolus x1
  - UAOstr in 1 - nasal trumpet
  - Sedation failures (n=4, 1.3%)
  - Recovery-related agitation – severe: n=2 (0.6%)

**CLINICAL EXPERIENCE**


- Multidisciplinary collaborative of 37 institutions
  - Mission – large database of procedural sedation-related practices to better evaluate important safety, efficacy questions
  - 2003 – Initial meeting - data collection tool
  - 2004 - Data collection tool revisions
  - July 1, 2004 – Data collection begun
  - Through 9/2007 – 90,000+ sedation entries
  - Multiple working groups established 2005

**CLINICAL EXPERIENCE**


- 2309 sedations, 7 Institutions
- Age: 57±47 mos
- ASA I=618, ASA II=738, ASA III=431
  - Co-morbidities in 1038 (47%)
- 1° diagnoses:
  - Neurologic (n=1389, 60%), Hem-Onc (n=328, 14%)
- 1° procedures = radiology (n=2026, 88%)
  - MRI (1469, 64%), CT (460, 20%), NM (133, 6%)

**CLINICAL EXPERIENCE**


- Administration: Bolus alone - n=164 (7.1%)
  - Infusion alone - n=360 (15.6%)
  - PO alone - n=215 (9.3%)
  - Bolus+infusion - n=1566 (68%)
- Total dose - 3.1±2.1 µg/kg
- Adjunct midazolam in 1535 (66.4%)
  - Analgesics (n=42), Sedatives (n=107)
- Administration: Physician: n=112 (4.8%)
  - APRN: n=1485 (64.3%)
  - RN: n=1347 (58.3%)
CLINICAL EXPERIENCE
Berkenbosch JW, Lubisch N, PSRC (in preparation)

Conditions produced:
- Ideal (2212, 95.7%)
- Suboptimal (80, 3.4%)
- Failures (n=17, 0.7%)
  - Inadequate (n=8)
  - Complications (n=3)
  - Unrelated (n=6)
- Level of Care (n=2, 0.1%)
  - PICU (n=2)
  - Underlying Dx (n=2)

Complication # %
- Inadequate 48 2.1
- VS >30% 44 1.9
- Respiratory 7 0.3
- Inadequate 8
- Complications 3
- Unrelated 6

CONCLUSIONS
• Effective for non-invasive procedures
  • Co-administered with analgesics for invasive??
• Dose moderately higher than for ICU sedation
  • 2-3 µg/kg/hr well tolerated medium-term
• Major benefit is recovery-related agitation
  • Minimal compared to chloral, barbiturates
• Role of adjunct benzodiazepines unclear
• Similar CV, ↓ resp vs propofol - availability!!
• Ongoing paucity of comparative trials

• Highly effective
  • Dex alone – 724/729 (99.3%)
  • Dex + Midazolam – 1334/1440 (99.6%)
  • Dex + any adjunct – 2298/2309 (99.5%)
• Adverse events favorable compared to PSRC
  • Respiratory – 1:329 vs 1:49
  • Airway Intervention – 1:770 vs 1:89
  • Failed sedation – 1:210 vs 1:338
• Availability to/administration by non-physicians

Co-administration with ketamine – cath lab
- Tosun et al, J Cardiovasc Vasc Anesth, 2006
  • Dex/propranolol + ketamine – n=44, acyanotic CHD
  • Induction – 1 µg/kg dex, 1 mg/kg ketamine – 10 min
  • Maint – 0.7 µg/kg/hr dex/1 mg/kg/hr ketamine
  • Dex/ketamine – n=16
  • Induction – 1 µg/kg dex, 2 mg/kg ketamine – 3 min
  • Maint – 2 µg/kg/hr dex, ketamine 1 mg/kg prn
• Effective, minimal HR/BP Δ, minimal resp effects
Chris Evert Children’s Hospital Pediatric Sedation Unit

Buccal vs Intravenous Serum Concentrations

Antilla Study

Buccal doses varied from 0.49 to 1.75 µg i.v., i.m., buccal p.o.

Methods

Demographics

Diagnoses

Introduction

A. The different routes of Dex utilized

B: What are the guidelines in monitoring safety parameters of vital signs

C. What is the clinical criteria to determine who gets what mode of delivery...IV, Buccal or IM

Sedation Protocols Utilized

- Dexmedetomidine Intravenous Protocol
- Dexmedetomidine Transmucosal Protocol
- Dexmedetotomidine Intramuscular Protocol

Intravenous Protocol

- 2 micrograms per kg bolus over 10 min (average)
- If the child becomes sedated before 10 minutes stop the bolus and set the hourly infusion.
- If the child requires greater than 10 min set the hourly rate at the dose the child becomes sedated.

- Document Baseline V.S.
- HR, MAP, S/D
- Precalculate 70% of baseline.
- Glycopyrrolate at MD discretion
- Versed at MD discretion
- Goal is to maintain V.S within parameters < ~70% of baseline
- 20 kg Bolus of RL or NS
- 20 kg/h post sedation
RESULTS

Lowest hemodynamic measurements by treatment type

<table>
<thead>
<tr>
<th>Treatment (mean values)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEX</td>
<td>DEX+midazolam</td>
</tr>
<tr>
<td>SBP 88.36</td>
<td>92.6</td>
</tr>
<tr>
<td>DBP 47.13</td>
<td>50.69</td>
</tr>
<tr>
<td>HR 83</td>
<td>80.57</td>
</tr>
<tr>
<td>MAP 60.11</td>
<td>64.93</td>
</tr>
</tbody>
</table>

Table 6
The mean lowest values of the vital signs are significantly different for children treated with DEX vs. DEX+midazolam for SBP, DBP and MAP.

DISCUSSION

- Data suggests Dex via an extravascular routes is efficacious.
- Dex alone have lower SBP, DBP, MAP.
- Anxious children respond well to Dex and midazolam.
- This dosing regimen resulted in predictable times of onset and duration independent of the ages or weights studied.
- Buccal Dex as an alternative to IV Dex for pediatric procedural sedation.
- This regimen resulted in temporary reductions in blood pressure and heart rate that were within acceptable limits.

DISCUSSION

Intramuscular dosing

- 1.5-4.5 mcg/kg dose ranges (average dose 2.5 mcg/kg)
- Ages 6 mth-13 years
- Wgt ranges 5.7 kg-43kg
- Failures none
- Repeated doses (6)
- Time to sedation
- 3 minutes – 60 min(1)
- Ranges of wakeup time
  - 7min-1:10 minutes
  - Average wake up time
  - (15-20 minutes actively drinking fluids)
  - # of IV Starts (2) + (2) child not drinking fluids
  - # 1 remote to 6 hours post sedation.
  - 9 y/o child went community ED for dehydration Had been d/c'd home with no p.o fluids******

CONCLUSION

- Buccal Dex may be a viable option in children requiring sedation in lieu of intravenous routes.
- Intramuscular routes may be a viable option
- Implementation of an Anxiety scale would be beneficial.
- Further randomized and pharmokinetic studies are warranted.

REFERENCES


REFERENCES

Lubisch, N., Roskos, R., Personal data and prior reports from Broward General Medical Center pediatric sedation, North Broward Hospital District. 2006.


Assessment of Sedation Depth and Discharge Readiness

Shobha Malviya, MD
Professor of Anesthesiology
University of Michigan Health System

Disclosure
- Currently receiving research funding from Aspect Medical Systems for a study unrelated to the current presentation
- Received BIS sensors but no financial support for previous studies

Objectives of Monitoring Sedation Depth
- To titrate sedative agents to a target sedation depth
- To ensure that the patient is not at deeper than intended levels of sedation
- To determine discharge readiness and ensure patient safety in unmonitored settings

Why Target Sedation Depth?
- Unpredictability of response to sedatives in children
- Undersedation – pain and anxiety
- Oversedation – serious adverse events, prolonged recovery times
- Because the JCAHO said so!!

Continuum of Sedation Analgesia
- The practitioner must have skills to rescue the patient from 1 level deeper than target sedation depth
- Need to titrate sedatives to effect

Observational Sedation Scales: Modified Ramsey Sedation Scale
1. Anxious, Agitated, Restless
2. Cooperative, Oriented, Tranquil
   Accepts mechanical ventilation.
3. Responds to commands only.
4. Brisk response to light glabellar tap or loud noise.
5. Sluggish response to light glabellar tap or loud noise.
6. No response.
Observational Sedation Scales:
University of Michigan Sedation Scale

0  Awake and alert
1  Minimally sedated: tired/sleepy, appropriate response to verbal conversation and/or sound
2  Moderately sedated: somnolent/sleeping, easily aroused with light tactile simulation or a simple verbal command
3  Deeply sedated: deep sleep, arousable only with significant physical stimulation
4  Unarousable


Is there a tendency to underestimate the depth of sedation?


Effect of Age and Sedative Agent on the Accuracy of Bispectral Index in Detecting Depth of Sedation in Children

Malviya S, Voepel-Lewis T, Tait AR, Watcha MF, Sadhasivam S, Friesen RH

Pediatrics 2007; 120: e461-e470

Anesthesia Depth Monitors

- Bispectral Index
- Spectral Entropy
- Cerebral State Index
- Auditory Evoked Potentials
- Narcotrend

Observational Sedation Scales

- Despite good psychometric properties, observational scales remain subjective and allow room for observer interpretation and bias.
- Most observational scales measure response to a stimulus and if used during a procedure may awaken the child and disrupt the procedure.


Effect of Age and Sedative Agent on the Accuracy of BIS

- Moderate and significant inverse correlations between UMSS and BIS for all age groups ($\rho = -0.63$ to $-0.69$)
- BIS was reasonably sensitive in differentiating mild (UMSS 0-1) from deeper sedation (UMSS 3-4)
- BIS poorly differentiated between moderate and deep sedation in all age groups


Sedative Agents and BIS values

- Significant inverse correlations between BIS and UMSS during use of all sedative agents except ketamine
- Correlations between BIS and UMSS were poor to low in the presence of opioids
- BIS values were significantly higher in children who received opioids as a secondary agent with CH and midazolam


BIS vs. Ramsey

- 86 children sedated with pentobarb alone for CT, MRI
- Children with RSS 4-4 in PACU monitored with BIS
- No significant difference in mean BIS values between Ramsay groups ($p=0.64$)
- Wide variation in BIS values (31 – 90)

Mason K et al Pediatr Anesth 16:1226, 2006

- 217 paired RSS and BIS values in 20 children sedated with midazolam and fentanyl or pentobarbital
- ROC analysis revealed moderate to high discriminatory power of BIS scores in predicting level of sedation throughout the sedation continuum.


Pitfalls of BIS Monitoring for Sedation

- BIS is insensitive to narcotics – increasing doses of opioids may not change BIS values despite increasing narcosis
- Unreliable association between BIS and sedation scores during ketamine sedation
- Age related differences
- May be a useful tool in selected patients but would require extensive education to ensure correct interpretation

Level of Sedation evaluation with Cerebral State Index and A-line Arx in Children Undergoing Diagnostic Procedures

- Correlation between CSI and AAI with UMSS during propofol sedation evaluated in 20 children for MRI or EGD
- Propofol given every 10 sec until UMSS score was 3-4
- CSI, AAI and UMSS data recorded every 10 sec until UMSS 3-4 and every 3 min until awake

CSI and AAI vs. UMSS

- CSI and AAI data showed a strong correlation with UMSS scores
  - CSI: \( r = -0.861, p < 0.0001 \)
  - AAI: \( r = -0.823, p < 0.0001 \)


“…. knowledge of its boundaries and constraints is essential to the safe use of any monitor.”

Sleigh JW, et al. BJA 92:159, 2004

Use of BIS to Target Sedation Depth

- Caution: May result in deeper than intended levels of sedation if used to titrate sedation regimens that include opioids or ketamine
- Very limited data in children, largely limited to propofol with target BIS values of 45-50
- Further studies are needed before BIS can be recommended for this indication

Imprecise evaluation of discharge readiness and premature discharge to the unmonitored setting or to the home remain the weakest links in the care of sedated children.

Patient Risk after Discharge

- Prolonged sedation
  - Keengwe, Anaesthesia 1999;54:1069
  - Malviya, Pediatrics 2000;105:e42
- Delayed adverse events
  - Respiratory event at home or general care
    - Malviya, Anesth Analg 1997;85:1207
    - Engelhoff, AJR 1997;168:1259
  - Return to ED
    - Malviya, Pediatrics 2000;105:e42
    - Rooks, AJR 2003;180:1125

Prolonged Recovery and Delayed Effects from Sedation

- 376 children sedated for MRI/CT
- Discharged when institutional criteria met
- Telephone F/U with parents in 24-48 hours
- Escalation of care
  - In hospital: 1%
  - Following discharge: 4%
- Return to baseline activity
  - within 24 hours: 89%
  - second day after procedure: 5%

Patient Risk after Discharge

- Adverse events reports to FDA
  - 11/118 reports revealed premature discharge.
  - 8 patients died or suffered permanent neurologic injury at home or in an automobile after a procedure.
  - “These cases clearly point out the need for very rigorous recovery procedures and DC criteria.”


Recommended Discharge Criteria

- AAP Sedation Guidelines, 2006
  - The patient is easily arousable and protective reflexes are intact
  - “For the young or handicapped child…the presedation level of responsiveness or a level as close as possible to the normal level for that child should be achieved.”

Pediatrics 118:2587, 2006

Depth of Sedation at Discharge

- UMSS Scores Over Time


Assessment of Discharge Readiness

- Specific objective criteria
- Scores on observational scales
  - Ramsey
  - University of Michigan Sedation Scale
- Duration of wakefulness when unstimulated

Discharge Criteria

Standard
- “…level of consciousness is stable compared to the pre-sedation baseline state.”

Revised
- UMSS of 0 or 1
- Maintains wakefulness for ≥ 20 minutes

Instruments

Modified Maintenance of Wakefulness Test (MMWT)
MWT is a polysomnographic technique, similar to the Multiple Sleep Latency Test, used to evaluate excessive daytime somnolence.

We adapted principles from this test in devising a clinically applicable measure of the ability to stay awake in a quiet, soporific environment.
Results

Positive Predictive Value of Revised Criteria

• Revised criteria correctly predicted the child with BIS > 90 in 88% of cases

Standard Criteria
• 7 children (29%) had BIS values ≤ 76 at DC

Revised Criteria
• All children had BIS values ≥ 81 at DC

Results

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<thead>
<tr>
<th></th>
<th>Standard Criteria</th>
<th>Revised Criteria</th>
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<tr>
<td>DC time (mins)</td>
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<tr>
<td>Procedure end</td>
<td></td>
<td></td>
</tr>
<tr>
<td>From sedative</td>
<td>17 ± 13</td>
<td>88 ± 19</td>
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<tr>
<td></td>
<td>75 ± 76</td>
<td>75 ± 76</td>
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<tr>
<td></td>
<td></td>
<td>145 ± 78*</td>
</tr>
<tr>
<td>DC &lt; 30 mins</td>
<td>21 (88%)</td>
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<tr>
<td>30-60 mins</td>
<td>3 (12%)</td>
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<tr>
<td>&gt; 60 mins</td>
<td>7 (29%)</td>
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<tr>
<td></td>
<td>10 (40%)</td>
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</table>

*p = 0.001

Summary

• Depth of sedation monitoring is an important part of ongoing assessment of the sedated patient.
• Depth of sedation monitoring does prolong recovery time while enhancing the safety but not the predictability of sedation.
• Anesthesia depth monitors may be useful in very selected patients but their use in this setting will require extensive education to ensure appropriate interpretation.
Solving the Conundrum of Pediatric Deep Sedation Practice - Results from the Pediatric Sedation Research Consortium
Joseph Cravero MD FAAP
George T. Blike MD
National Patient Safety Foundation - AHRQ
Children’s Hospital of Philadelphia

Outline
• Why Create a Collaborative Database on Pediatric Sedation?
• Current literature, guidelines
• Pediatric Sedation Research Consortium - selected results

Consider the Variation – sign of lack of understanding best practice?
• Laparoscopic Cholecystectomy – Dartmouth vs. UPENN. Same types of anesthesia providers, same monitors, same drugs, similar recovery etc.
• MRI scan – Dartmouth vs. CHOP. Different provider type, different monitors, diff drugs

Sedation Research:
• Given: Pediatric sedation is practiced by multiple specialties in many different environments even within a given institution/office.
• Given: Serious problematic events are rare – and thus difficult to detect in standard sedation studies (50 – 1000 patients).

Sedation Research:
• Given: In most institutions that deliver pediatric sedation – the practice does not approach the “ideal” sedation we know is possible.
• Given: In most instances there is minimal or non-existent exchange of research and sedation process ideas between different specialties.

Current Practice
• Survey of 116 Children’s Hospitals found:
• 50% had a dedicated sedation service
• Most common model of practice was physician oversight of nurse delivered sedation - NOT Anesthesia.
• 87% of institutions reported barriers to creating a sedation service – lack of personnel.
Current Practice


- Level of care varies – particularly when it comes to “undersedation” issues.
- Survey compared US institutions to that in Europe
- 30% of US respondents reported no sedation for Bone Marrow Bx’s 50% of the time – 0% reported from Europe.

The Problem

No Longer Acceptable

Growth Industry!

- At DHMC and around the Pediatric Sedation Research Consortium - reported growth of sedation requests have averaged 10-15% per year after sedation service is established.

Current State of Sedation Literature

- Over eighty studies involving a variety of providers using deep sedation/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
  - Vardi et al. Critical Care Medicine. 30(6): 1231-6, 2002
  - Actually a comparison of high dose propofol to combination ketamine, midazolam and fentanyl anesthesia in the ICU.
**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.

**Adverse event rates vs. NPO time**

<table>
<thead>
<tr>
<th>NPO Time (hr)</th>
<th>Injepnyor A/nz &amp; Evnt</th>
<th>Vehidng</th>
<th>Any Adverse Event</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%)</td>
<td>No. (%)</td>
<td>No. (%)</td>
</tr>
<tr>
<td>0-2</td>
<td>10/53</td>
<td>1/08</td>
<td>10/53</td>
</tr>
<tr>
<td>2-4</td>
<td>17/120</td>
<td>1/08</td>
<td>17/120</td>
</tr>
<tr>
<td>&gt;4</td>
<td>13/145</td>
<td>1/08</td>
<td>13/145</td>
</tr>
</tbody>
</table>

**Current State of Sedation Literature**

- Some anesthesiologists will maintain that studies the size of those existing for general anesthesia, literally hundreds of thousands of cases, are necessary to validate the profile of newer procedural sedation and analgesia agents. Most established therapies are based on hundreds rather than thousands or patients, and ED practice patterns and standard of care must of necessity be based on smaller samples.

**Guidelines**

- For the good of the patients? or for the good of the specialty?
- Based on consensus?
- Based on incomplete data?
- Which is worse?
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 more numbers - multi-specialty data
Collaborative Work on Pediatric Sedation Safety

- We must all recognize that no one "owns" pediatric sedation.
- Individuals trying to accomplish the same outcomes for the same patient population should (logically) share data and attempt to move toward best practice in a collaborative manner.

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- Theme 6: Education in Sedation Safety

Pediatric Sedation Newsletter – Winter 2006

Department of Anesthesiology and Pediatrics, Children's Hospital of Dartmouth, "Farnsworth" 9th Floor, 100 Monmouth St., Lebanon, NH
Editor: Joseph Caruso MD (jcaruso@dartmouth.edu)
Published: Winter 2006 (Pediatric Sedation Newsletter)

Pediatric Sedation Newsletter

- Email only sedation newsletter
- Format – editorial or interview followed by literature review and sentinel event review.

- Wide distribution – exact circulation hard to know.

Pride, Prejudice, and Pediatric Sedation:
A Multispecialty Evaluation of the State of the Art

Report from a Dartmouth Summit on Pediatric Sedation

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Dartmouth Medical School
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Dartmouth Medical School
Pediatric Sedation Research Consortium

Can we cooperate and give ourselves a large “n”?

Can we make outcomes research part of our every day work?

Pediatric Sedation Research Consortium – Aviation Model

• Can we learn from each flight (encounter)?
• Membership solicited through the readership of the *Pediatric Sedation Newsletter* – readership approximately 5000 internationally. (no selection criteria for institutions)
  - Each site has a PI (multi-specialty) – obtains IRB approval – maintains the integrity of the data (audits).
  - NO informed consent needed.

Structure

• 27 institutions submitting data on web-based data collection tool – data stored at Dartmouth Bioinformatics Group – secured – all data is de-identified meeting HIPPA regulations
  - Participants include 10 free standing children’s hospitals, 7 children’s hospitals within hospitals, 6 general hospitals/medical centers, and 3 community hospitals.
Structure and Participation

- Each member institution must identify a PI - responsible for data gathering and integrity.
- Must have IRB consent for data gathering.
- Must submit a plan for data gathering.
- No individual consent required.
- Data audits for quality and number of records submitted are required.

Specialties

- 1/3 Anesthesiologist
- 1/3 Intensivists
- 1/3 Emergency Medicine
- Growing group of Hospitalists

Participating Institutions

Alfred I. duPont Children’s Hospital
Avera McKennan Hospital
Cape Fear Valley Medical Center
Children's Healthcare of Atlanta Egleston Campus
Children’s Healthcare of Atlanta Scottish Rite Campus
Children's Hospital of Philadelphia
Children's Hospital Omaha
Children’s Mercy Hospital
Chris Evans Children’s Hospital
Columbus Children’s Hospital
Dartmouth Hitchcock Medical Center
Denver Children's Hospital
DeVos Children’s Hospital
Eastern Maine Medical Center
Gundersen Lutheran
Jackson Memorial Hospital, University of Miami School of Medicine
Kaiser Children’s Hospital, University of Louisville
LeBonheur Children’s Medical Center
Medical University of South Carolina
Meharry Medical College
Rainbow Babies and Children's Hospital
Tod Children's Hospital
UMass Memorial Medical Center
University of Florida
University of Virginia
Yale New Haven Children’s Hospital

Data Elements Collected

- The result of over 20 hours of discussion and 3 general meetings of the active participants over 1.5 yr period.
- Balance between what we want to know and what is possible to complete in 2-3 minutes.

Structure

- Equal partners – use data for QA purposes and research.
- Data is entered on a web-based tool that takes approximately 2 minutes to complete depending on complexity of the child and the experience of the data entry technician.

Data Elements Collected

- Age
- Weight
- Gender
- ASA status
- Primary medical condition
- Coexisting medical problems
- NPO status of the patient
- Procedure performed
- Location of procedure
- Medications used for sedation
- Monitors employed during sedation
- Provider type responsible for the sedation
- Provider type monitoring the patient
- Planned airway management strategy
- Planned depth of sedation
- Actual depth of sedation
- Sedation start time
- Procedure end time
- Complications encountered during sedation
- Unexpected airway management required
- Transport during sedation
- Assessed patient state during the procedure

Care Provider Factors

- Sedation Technique
- Observer Care
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.

Unplanned admission to the hospital or increase in the level of care.

Other

Quarterly Reports

- Each institution receives quarterly reports that report the results of the individual institution vs. the consortium.

- Each institution can see its own data but not that of any other individual institution. - We are blinded!!
### Pitfalls

- Data Collection is Prospective and Observational.
- Hypothesis (original) to understand the incidence and nature of adverse events in sedation/anesthesia for children – model ideal practice.
- Invariably people (including me) want to do more with the data.

### Possible Accusations - Problems

- Data Mining
- Selective Data Reporting
- Integrity of the Data
- Variation in Reporting Data (definitions)
- Variation in practice situations
- So many relational possibilities!

### 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

JENNIFER L. EVANS, MD, MPH, LISA J. RHINE, MD, PHD, R. PETER SHANK, MD, DAWN L. KAPLAN, MD, JENNIFER M. HARRIGING, MD, FRCPC, MARILYN B. KIRK, MD, Anna-Karin Ahlström, Department of Pediatrics, University of Louisville, Louisville, Kentucky; HENDRICKsohn, Department of Anesthesiology, Indiana University, Indianapolis, Indiana; Chantal Collina Almeida, Department of Anesthesiology, Massachusetts General Hospital, Boston, Massachusetts; and William P. Miranda, University of Miami School of Medicine, Miami, Florida. This report is based on data collected by the Pediatric Sedation Research Consortium (PSRC), a multidisciplinary collaboration of 17 pediatric anesthesia organizations and 68 academic centers across the United States, that includes practice sites in all 50 states and 5 Canadian provinces.

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

<table>
<thead>
<tr>
<th>Event</th>
<th>Incidence per 10,000</th>
<th>N</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0.0</td>
<td>0</td>
<td>(0.0-0.0)</td>
</tr>
<tr>
<td>Cardiac Arrest</td>
<td>0.3</td>
<td>1</td>
<td>(0.0-1.9)</td>
</tr>
<tr>
<td>Aspiration</td>
<td>0.3</td>
<td>1</td>
<td>(0.0-1.9)</td>
</tr>
<tr>
<td>Hypothermia</td>
<td>1.3</td>
<td>4</td>
<td>(0.4-5.6)</td>
</tr>
<tr>
<td>Desaturation (below 90%)</td>
<td>27.6</td>
<td>83</td>
<td>(14.4-48.8)</td>
</tr>
<tr>
<td>Stridor</td>
<td>4.3</td>
<td>11</td>
<td>(1.8-15.1)</td>
</tr>
<tr>
<td>Wheeze</td>
<td>2.7</td>
<td>7</td>
<td>(1.1-5.4)</td>
</tr>
<tr>
<td>Intravenous Related Problems</td>
<td>11.8</td>
<td>35</td>
<td>(7.4-24.2)</td>
</tr>
<tr>
<td>Prolonged Sedation</td>
<td>22.3</td>
<td>63</td>
<td>(15.6-30.1)</td>
</tr>
<tr>
<td>Prolonged Recovery</td>
<td>39.7</td>
<td>117</td>
<td>(31.7-53.1)</td>
</tr>
<tr>
<td>Apnea (unpredicted)</td>
<td>24.1</td>
<td>72</td>
<td>(16.7-37.5)</td>
</tr>
<tr>
<td>Secretions (requiring suction)</td>
<td>41.6</td>
<td>125</td>
<td>(86.9-166.0)</td>
</tr>
<tr>
<td>Vomiting During Procedure (non-GI)</td>
<td>47.2</td>
<td>142</td>
<td>(39.8-55.7)</td>
</tr>
<tr>
<td>Desaturation (below 90%)</td>
<td>156.5</td>
<td>470</td>
<td>(142.7-171.2)</td>
</tr>
<tr>
<td>Total adverse events</td>
<td>339.6</td>
<td>1020</td>
<td>(308.1-371.5)</td>
</tr>
</tbody>
</table>

Unplanned Treatments

<table>
<thead>
<tr>
<th>Unplanned Treatments</th>
<th>Incidence per 10,000</th>
<th>N</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Airway (oral)</td>
<td>9.7</td>
<td>20</td>
<td>(6.61-12.9)</td>
</tr>
<tr>
<td>Airway (oral)</td>
<td>26.7</td>
<td>83</td>
<td>(22.04-32.1)</td>
</tr>
<tr>
<td>Intravenous Related Problems</td>
<td>63.9</td>
<td>192</td>
<td>(55.23-71.6)</td>
</tr>
<tr>
<td>Total Unplanned Treatments</td>
<td>111.9 (1 per 88)</td>
<td>336</td>
<td>(85.5150.2)</td>
</tr>
</tbody>
</table>

Conditions Present During P

<table>
<thead>
<tr>
<th>Conditions Present During P</th>
<th>Incidence per 10,000</th>
<th>N</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desaturation (below 90%)</td>
<td>88.9 (per 35)</td>
<td>267</td>
<td>(79.40-202)</td>
</tr>
</tbody>
</table>

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
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

Discussion

- Next Steps
  - Data will allow for focused Research.
    - Serious AEs; Unplanned major airway interventions
      - Patient Factors? (Age, ASA, Dz)
      - Procedure Factors? (Bronchs, PICC lines, etc.)
      - Provider Factors? (Anesthesiologists, Intensivists, Emergency med, Other)
      - Sedation technique? (Propofol, ketamine, Midaz/Fentanyl, Pentobarb, Chlorohydrate, etc.)
Discussion

• Is this the way to define Critical Competencies in Pediatric Sedation?
• Evaluate unexpected airway management - teach TO these skill sets. Data - not consensus.
• Come up with ways to credential and re-credential these competencies.

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

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 30 minutes.
Aspiration Episodes

<table>
<thead>
<tr>
<th>Age</th>
<th>Diagnosis</th>
<th>Procedures</th>
<th>NIV status</th>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>97 y</td>
<td>Ex-Prematurity, visual impairment</td>
<td>Bronchoscopy</td>
<td>&lt; 8 hours for clear fluids and solids</td>
<td>NICU</td>
</tr>
<tr>
<td>30 mo</td>
<td>Sickle Cell</td>
<td>MRI</td>
<td>3 hours - clear fluids</td>
<td>Recovery Room</td>
</tr>
<tr>
<td>10 y</td>
<td>Allergies, cystic fibrosis</td>
<td>MRI</td>
<td>6 hours - soft solids</td>
<td>Recovery Room</td>
</tr>
<tr>
<td>10 y</td>
<td>Leukemia</td>
<td>LP - Chemo</td>
<td>6 hours - clear fluids</td>
<td>NICU</td>
</tr>
</tbody>
</table>

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.
Propofol Sedation
Classification of Issues

- Major Events
- Moderate Events
- Minor Events

Major Events

- a. Aspiration
- b. Death
- c. Cardiac Arrest
- d. Unintended increase in level of care required.
- e. Emergent need for “code team” response.
- f. Emergent unexpected need for intubation.

Moderate Events

- a. Airway Obstruction
- b. Inadequate Sedation
- c. Seizure Activity
- d. Stridor – Laryngospasm
- e. O2 desaturation <70% for >30 seconds or <80% for more than 2 minutes

Minor Events

- a. Apnea
- b. Cough
- c. Hypothermia
- d. IV related events
- e. Myoclonus
- f. Prolonged Sedation
- g. Prolonged Recovery
- h. Secretions
- i. Unintended Deep Level of Sedation
- j. Unplanned intubation
- k. Vomiting
- l. Wheezing
- m. Minimal hypoxia

Provider Specific Data - Major Events

<table>
<thead>
<tr>
<th>Provider</th>
<th>Cases</th>
<th>Events</th>
<th>Rate</th>
<th>Lower 95% CI</th>
<th>Upper 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesiologist</td>
<td>5,063</td>
<td>5</td>
<td>9.88</td>
<td>(3.21, 23.03)</td>
<td></td>
</tr>
<tr>
<td>ER MD</td>
<td>16,887</td>
<td>10</td>
<td>5.92</td>
<td>(2.84, 10.89)</td>
<td></td>
</tr>
<tr>
<td>Intensivist</td>
<td>22,086</td>
<td>21</td>
<td>9.51</td>
<td>(5.89, 14.53)</td>
<td></td>
</tr>
<tr>
<td>Pediatrician</td>
<td>1,076</td>
<td>0</td>
<td>0.00</td>
<td>(0.00, 34.22)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1,246</td>
<td>2</td>
<td>16.0</td>
<td>(1.94, 57.86)</td>
<td></td>
</tr>
</tbody>
</table>

Provider Specific Data - Minor Events

<table>
<thead>
<tr>
<th>Provider</th>
<th>Rate</th>
<th>Lower 95% CI</th>
<th>Upper 95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ER MD</td>
<td>1.31</td>
<td>(0.75 - 2.31)</td>
<td>.35</td>
<td></td>
</tr>
<tr>
<td>Intensivist</td>
<td>1.76*</td>
<td>(1.11 - 2.80)</td>
<td>.02</td>
<td></td>
</tr>
<tr>
<td>Pediatrician</td>
<td>0.90</td>
<td>(0.58 - 1.38)</td>
<td>.62</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>0.97</td>
<td>(0.56 - 1.67)</td>
<td>.91</td>
<td></td>
</tr>
</tbody>
</table>
### Age Specific Data - Major Events

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Sedations</th>
<th>Total Events</th>
<th>CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-3 months</td>
<td>871</td>
<td>4</td>
<td>45.92 (12.53,117.16)</td>
</tr>
<tr>
<td>4-12 months</td>
<td>4,488</td>
<td>9</td>
<td>20.05 (9.17,38.03)</td>
</tr>
<tr>
<td>1-8 years</td>
<td>29,623</td>
<td>15</td>
<td>5.06 (2.83,8.35)</td>
</tr>
<tr>
<td>8 years +</td>
<td>11,381</td>
<td>10</td>
<td>8.79 (4.21,16.15)</td>
</tr>
</tbody>
</table>

### ASA status data - major events

<table>
<thead>
<tr>
<th>ASA Status</th>
<th>Total Sedations</th>
<th>Major Events</th>
<th>Sed per 10K</th>
<th>CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>I - II</td>
<td>38,388</td>
<td>29</td>
<td>7.55</td>
<td>(5.06,10.85)</td>
</tr>
<tr>
<td>III - IV</td>
<td>7,975</td>
<td>9</td>
<td>11.29</td>
<td>(5.16,21.41)</td>
</tr>
</tbody>
</table>

### Emergency Status and Major Event Rate

<table>
<thead>
<tr>
<th>Status</th>
<th>Total Cases</th>
<th>Events</th>
<th>Events per 10K</th>
<th>CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-emerg</td>
<td>45,334</td>
<td>37</td>
<td>8.16</td>
<td>(5.75,11.25)</td>
</tr>
<tr>
<td>Emergent</td>
<td>1,029</td>
<td>1</td>
<td>9.72</td>
<td>(0.25,54.03)</td>
</tr>
</tbody>
</table>

### Emergency Status and Moderate Events

<table>
<thead>
<tr>
<th>Status</th>
<th>Sedations</th>
<th>Events</th>
<th>Events per 10K</th>
<th>CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-emerg</td>
<td>45,334</td>
<td>994</td>
<td>219.26</td>
<td>(205.98,233.16)</td>
</tr>
<tr>
<td>Emergent</td>
<td>1,029</td>
<td>20</td>
<td>194.36</td>
<td>(119.12,298.59)</td>
</tr>
</tbody>
</table>

### Pulmonary Complications

#### Methods:
- The Pediatric Sedation Research Consortium (PSRC) has 24 participating institutions and multidisciplinary membership. Members submit detailed reports of all sedations performed. From 08/04 to 08/05, 13,778 sedations were recorded. Patients were stratified by weight status using the American Society of Anesthesiologists (ASA) classification system ([ASA I-II] vs. [ASA III-IV]) and by age. A pulmonary complication was defined as any episode of desaturation, unexpected bag mask ventilation intubation. Generalized linear models with Poisson errors were used to estimate relative risk of a complication with focus on effects of age and ASA status. Quasi-poisson was incorporated into variance estimate. Procedures were categorized as: radiologic (16%), invasive/surgical (8%), GI (7%), other (6%), neurologic (5%), and other (5%).

#### Effect of Age and Severity of Illness on Risk of Pulmonary Complications During Sedation

**Authors:** (All): Gelman, Barry; Carrell, S.; Patrick; K. J.; John W.; Maluglin, Cowan C.; Torre, Michael; Guelf, Lynn; Neber, Michael; C. C.; Joseph P. T.

**Institutions:** (All): 1. Pediatrics, UM Miller School of Medicine, Miami, FL, USA, 2. Anesthesiology, Dartmouth Hitchcock Medical Center, Lebanon, NH, USA.

**Abstract Body:**

Introduction: Few data exist to estimate the risk of pulmonary complications during sedation and to stratify this risk by age and health status.

Hypothesis: The risk of pulmonary complications during sedation is related directly to severity of illness, and inversely to age.
Pulmonary Complications

Results: There were 308 (2.1%) pulmonary complications. These were more common for ASA status III. Among ASA I-II patients, the highest complication rate was in patients ≤ 6 months old (3.3%).

Conclusions: Children with ASA III have a greater risk of pulmonary complications during surgery. ASA I-II patients ≤ 6 months old may also have higher risk. Further work is needed to understand the etiology of the complications.
Nil per os (NPO) Times & Pulmonary Complication Rates in Pediatric Sedation

Results from the Pediatric Sedation Research Consortium (PSRC)


National Patient Safety Foundation Funding

DATA

- NPO status was known for 28,941 patients.
  - 6,857 had liquids within 2 hours or solids within 8 hours of sedation
- One pulmonary aspiration was recorded in 30,037 records.

Methods (continued)

- We adjusted for ASA level, emergency status, provider type, and age using generalized linear models to estimate relative risk (RR).

Discussion

- The rate of pulmonary aspiration events in pediatric sedations is unknown, though clearly rare.
  - In this data set, we found one pulmonary aspiration event in 30,037 sedations.
  - Patient had pre-existing pathology relating to GI tract.


Results (continued)

- In multivariable modeling, pulmonary complications were not associated with NPO guideline rule violation solids < 8 hours or liquids < 2 hours.
  - Age less than 6 months (RR=1.82; 95% CI 1.38-2.41)
  - ASA classification greater than II (RR=2.41; 95% CI 1.93-3.02)
  - And, provider specific differences (p <0.0001) remained statistically significant
• Remarkably, NPO status was not associated with pulmonary complications, as were age, ASA status and provider type.
• This suggests that patient characteristics may be of primary importance, not necessarily the duration of NPO for this group of sedation encounters.

Etomidate versus Pentobarbital for CT Sedations: Report from the PSRC

Amy L Baxter, MD, Michael D Mallory, MD, MPH, Sujit Sharma, MD, Steven H Freilich, MD, Philip R Spandorfer, MD, MSCE1
Pediatric Emergency Care 2007 Oct (23(10):690-5.

Results

Table 1. ADVERSE EVENTS ASSOCIATED WITH SEDATION

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Pentobarbital</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
</tr>
<tr>
<td>Reaction</td>
<td>r (%)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>0 - 0</td>
</tr>
<tr>
<td>Hypotension</td>
<td>0 - 0</td>
</tr>
<tr>
<td>Apnea</td>
<td>0 - 0</td>
</tr>
<tr>
<td>Allergy</td>
<td>0 - 0</td>
</tr>
<tr>
<td>Gag</td>
<td>0 - 0</td>
</tr>
</tbody>
</table>

Problems - Etomidate cases were from one institution using ED providers, Pentobarbital cases from a variety of institutions with a variety of providers.

Efficiency Data

• Etomidate recovery = 34 minutes (32,36) vs Pentobarbital 144 minutes (85,109)
• One case cancelled (etomidate) due to apnea - one study Pentobarbital “not ideal”.
• Problems - Etomidate cases were from one institution using ED providers, Pentobarbital cases from a variety of institutions with a variety of providers.

PSRC Summary

• We report on establishment of the PRSC and a multi-specialty pediatric procedural sedation registry – outgrowth of previous research and our view of the research needs for the field of pediatric sedation.
• We believe the use of this registry will allow us to understand the broader nature of pediatric sedation practice.
• Ultimately we hope the study of outcomes will improve pediatric sedation delivery internationally.

Summary

• Deep sedation is growing - we must choose how to respond - now
• We need to recognize the ability of other specialists to deliver deep sedation - collaborate and educate.
• 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 privileging.
- Maintain Anesthesia profile as the leader in this area of patient care.

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.pedsedation.org
Sedation for Pediatric Imaging
Who and How?
The Emergency Physician’s Perspective

David M Banks, MD
Amy Baxter MD
David Werner MD
Director, Pediatric Sedation Services, LLC
Children’s Healthcare of Atlanta, Scottish Rite Campus

Pediatric Sedation Services, LLC is a physician company owned by Pediatric Emergency Medicine Associates, LLC

PEMA

• 52 Full-time providers
• 27 BE/BC Pediatric Emergency Physicians
• Total of over 120,000 ED visits per year
  – ED@ Scottish Rite, CHOA>80,000 visits/yr

PSS

• Radiology (CT, MRI, NM, IR)
• Free Standing Radiology Clinic
• ABR/Audiology
• Hematology/Oncology
• Special Procedures
• Emergency Department
• Total
  – 350/month
  – 80/month
  – 30/month
  – 40/month
  – 30/month
  – 120/month
  – 650/month

PSS, LLC

• Late in 2000
  – Discussions with CHOA regarding need for radiology sedation services
    • Inefficient scanner use
    • Repeated scans
    • Failed studies
  – Anesthesia, Critical Care, Hospitalists had all declined

PSS, LLC

• Early 2001
  – PEMA Committee of 5 PEM’s and Business Manager
• Business Manager
  – Negotiated third party payers contracts
  – Credentialed physicians
  – Expanded professional liability coverage
PSS, LLC

• PEMA Physician Committee
  – Researched sedation literature
  – Site visits
  – Updated policies/procedures
  – Rewrote protocols

JCAHO Standards

• Sedation is a continuum
• Difficult to predict how patients will respond
• Hospitals are to develop specific and appropriate protocols

JCAHO Standards

• “These protocols are consistent with professional standards and address at least the following:”
  – Sufficient Qualified Individuals
  – Appropriate Equipment
  – Appropriate Monitoring
  – Appropriate Documentation
  – Review of Outcomes

JCAHO Standards

• The Right People
• The Right Equipment
• The Right Procedures & Monitoring
• The Right Documentation
• Monitor the Outcomes for QI

The Right People

• “… have at a minimum had competency-based education, training, and experience in … evaluating patients … and performing moderate or deep sedation and anesthesia, including rescuing patients who slip into a deeper-than-desired level of sedation or anesthesia.”
The Right People

- JCAHO does not specifically state who are the Right People
- Anesthesiologists?
- Other physicians/subspecialists?
- Non-physician providers?

Children's Healthcare of Atlanta

- Moderate Sedation Privileges
  - Physicians required to successfully complete online sedation module
- Deep Sedation Privileges
  - Considered “Core” for BC/BE in
    - Peds EM,
    - Critical Care

The Right People

- Solid Support Staff
  - Existing Sedation Nursing Staff
    - Highly Experienced
  - Excellent Radiology Technicians
  - Strong “Child Life” presence in radiology

The Right Equipment

- Monitoring Equipment
  - Standard Cardio/Respiratory
  - Blood Pressure
  - Pulse Oximetry
- Addition of Capnography
- Standard Resuscitation Equipment

Right Procedures

- Continued with existing initial process
  - Scheduling is arranged through radiology
  - Nurse Phone Call 2 days prior
    - Confirm appointment
    - Review recent illnesses
    - Review of NPO guidelines
  - Initial nursing history and assessment

Right Procedures

- Sedation Physician
  - Review of nursing assessment
  - Review history, previous sedates
  - Physical exam
  - Assessment and sedation plan
  - Informed consent
Right Procedures

- Physician administers all sedation medications and
- CT, Interventional Radiology
  - Remains with the patient until procedure is complete
- MRI and Nuclear Medicine
  - Remains with patient until in steady state of sedation, monitored by nurse, with physician in immediate area
- Reassesses patient prior to discharge

Right Documentation

- Initial assessment form
- Sedation monitoring record
- EMR for physician documentation
  - Duplicates the initial assessment form
  - Contains essential clinical data of the sedation
  - Web based, easily accessed for subsequent review
  - Contains all billing data

Monitor Outcomes

- Continued existing QI program established by sedation nurses
- PSRC affiliation
  - track our data compare to national data
- Mallory Form
  - tracks events and interventions
    - clinical significance
    - impact on study/procedure

Potential Obstacles

- Credentialing for hospital privileges
- Gaining access to sedation medications
- Reimbursement for services

PSRC

- Pediatric Sedation Research Consortium
  - Multicenter database of sedation clinical data
  - Established by Joe Cravero at Dartmouth
  - Began collecting data in 2003

PSRC

- >30 member institutions that provide pediatric sedation
- Web based data entry tool
- Has >100,000 entries
- Ripe with data for clinical investigation
PSRC


SPS

- The Society for Pediatric Sedation was formed at the Spring Meeting of the PSRC this year in Atlanta.

- 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.

Web Sites

- PSRC
  - http://an.hitchcock.org/PediatricSedationRC/index.htm

- SPS
  - http://www.pedsedation.org/

JCAHO, one more thing

- Apply the same standards for quality of care in all areas throughout the system

Sedation Service

- Sedation services are destined to extend beyond the radiology department
- Many different models have evolved
  - Fixed
  - Mobile
  - Mixed

PSS

- Radiology (CT, MRI, NM, IR)
- Free Standing Radiology Clinic
- ABR/Audiology
- Hematology/Oncology
- Special Procedures
- Emergency Department
PSS Staffing

• 4 to 5.5 shifts (9hr) each weekday
• 1 shift each weekend day/holiday
• Hours of coverage
  – 6:30a-1:00a weekdays
  – 1:00pm-1:00am weekends/holidays
• 12,000 MD-hours of clinical coverage/yr
• Physician FTE’s
  – 8 clinical, 1/4 administrative

PSS Staffing

• PEM practiced in a high acuity, high volume tertiary care facility is a young physician’s profession.

• The sedation service provides a professional change of pace and has had a significantly positive impact on work satisfaction among our physicians.
PICU Based Pediatric Sedation Teams
Sally A. Webb, MD
Teresa Watt, RN
MUSC Children’s Hospital
May 2008

Objectives
• Summarize necessary steps to create PICU based sedation service
• Describe appropriate skills for team personnel
• Compare and contrast effectiveness of sedation regimens in use

Sample of Literature
• Pediatric ED teams
  – Pershad & Gilmore (Pediatr 2006; 117:e413-e422)
• PICU teams

Sample of Literature
• Anesthesiology based or trained teams
• Overviews
  – Cravero, Blike (Anesth Analg 2004; 99:1355-1364)

Before you start….
• Where is procedural sedation performed outside the operating room at your institution?
• Who are the providers?
• What are your institutional policies re: moderate and deep sedation?
• What is the estimate of the numbers of pediatric sedations/year?
• What is the cost? Reimbursement?

Before you start…
• Determine patient numbers & needs
  – Inpatient
    • Types of procedures, Referral sources, Degree of urgency, Setting for optimal safe sedation
  – Outpatient
    • Types of procedures, Referral sources, Setting for optimal safe sedation
Before you start.... determine staffing needs
For MRI/CT areas:
• Who screens the patients for GA vs. Deep sedation vs. No Sedation Needed?
• Who schedules the sedations?
• Who organizes meds, supplies, monitoring equipment?
• Who starts the IV for outpatients?
• Who monitors the patient during the procedure?
• Who recovers and discharges the patient?
• What is the role of the Radiology staff/RNs in provision of procedural sedation?
• How many RNs, MDs, and techs do you need to make it work (with sick leave, vacations, etc)?

Before you start.....determine staffing needs
• For sedations outside Radiology:
  – Will you be a mobile service or will you be based out of a sedation “unit”?
  – What is the role of the staff/RN on site (e.g. PICU, Endoscopy, Bronchoscopy lab) in provision of procedural sedation?
  – Who screens & schedules the patients?
  – How many RNs, MDs, and techs do you need to make it work?

Planning
• Hospital funded service vs. fee for service ..... Do the math and negotiate contract
  – Meet with hospital administrator and business manager
  – Appoint a Medical Director of Sedation Team
  – Meet with Nursing administrator, Radiology administrator
  – Meet with Anesthesia Department

Planning
• Development of screening triage via telephone for Sedation Team or General Anesthesia
• Obtain transport monitors (ETCO2 & SaO2 compatible), mobile cart, other equipment
• Determine drug regimens and convenient method to have controlled substances and other drugs with the team
• Training, credentialing of sedation providers
• Marketing (brochure, video, website, letters)
• Develop Performance Improvement and tracking system for AE and outcomes
• Peer review process

Doing it!
• MUSC experience
  – Numbers
  – Staff
  – Comparison of most common drugs used in pediatric procedural sedation
  – Outcomes/performance improvement
Assuring High Quality Procedural Sedation for All Practitioners
Joseph P. Cravero MD

Our Problem
- Lalwani and Michel – survey of 116 Children’s Hospitals
  - 66% run credentialing service for non-anesthesiologists.
- Anesthesiologists sole sedation providers in 26%.
- Propofol was used regularly by non-anesthesiologists for sedation of non-intubated patients in 42%.

Further Problems
- The availability of new, potent, short acting agents has generated a huge call for more deep sedation/anesthesia care. Providers of all types want to deliver this care. PSRC data > 25K propofol sedations this year.
- The question remains as to who can/should give sedation using these agents and how does anyone document the ability of a given provider to deliver this care?

Still More Problems........
- Sedation providers represent a spectrum of education and expertise RN, vs primary care MD vs Critical Care MD vs Anesthesiology.
- How does one design a training course that is appropriate for all of these individuals – when many believe they do not need any training at all?

Our Choices
- Ignore it - hope it goes away.
- Do not participate - but try to legislate against the use of potent medications by other providers.
- Take on all deep sedation.
- Take on the most challenging cases - help design credentialing courses that assure critical competencies and remain engaged.
Sedation Training – Guidance from JCAHO

- Material is directive but not specific.
- Sedation levels are defined.
- Need to be able to rescue from one level deeper than intended level of sedation.
- No guidance for how training should be provided.
- Accountability initially linked to anesthesiology departments – now weakened.

Credentialing

- Hospitals assure patient safety and quality of care by verifying from primary sources that individual practitioners meet the organization’s minimum requirements for appointment to the medical staff and have the training, education and experience outlined in their application.
- Appointment should be for no more than 2 years.

Privileging

- Defines scope of practice. Gives permission to provide areas of care.
- Healthcare facility must
  1) approve a plan to provide a service and
  2) determine the criteria for determining which practitioners are qualified to provide the service.

Minimal Sedation

- No granting of privileges required – normal cardiovascular and ventilatory function are part of this level of sedation.

Moderate Sedation

- Ventilatory function may be impaired.
- Credentials must be demonstrated and privileges must be granted for this care.
- Practitioners must be able to rescue from one level deeper than that intended.
- ACLS (PALS) may be a requirement
- Alternatively “other courses” that teach airway management may be specified.

Deep Sedation

- Practitioners must be able to manage an unstable cardiovascular system as well as inadequate spontaneous ventilation.
- ACLS or other courses are acceptable
- Performance improvement data demonstrating good patient care verify that policies are effective.
Privileging guidelines for Moderate/Deep Sedation

- Completion of Anesthesiology Residency
- Completion of Nurse Anesthesia Training
- Completion of a residency where training in sedation and experience in supervising sedation is part of the program. Includes cardiology, GI, EM, pulmonologists, surgeons etc.

AAP guidelines for Deep Sedation

- Must have a monitor.
- “At least one person must be present who is trained in pediatric basic life support and who is skilled in airway management and cardiopulmonary resuscitation”.
- Training in Advanced Pediatric Life Support is recommended.

So How Do We Do This?

Sedation Training PALS

- Levels of Sedation
- Presedation Assessment (AMPLE)
- NPO Status
- Airway examination described – not detailed.
- Monitoring and record keeping is mentioned
- Medications described.

Sedation Training PALS

- Drugs mentioned in detail – barbiturates, benzodiazepines, opiates. Ketamine, propofol, and Chloral Hydrate each get a paragraph. Reversal agents discussed.
- Discharge criteria mentioned.
- In all, 10 pages of instruction.
- The sedation module is often not included as part of the course at many institutions. To be recreated in 2007.

Sedation Training PALS

- Megacode usually involves unanimated mannequin resuscitation – cardiac arrest.
- No practical sedation related hands on training is included.
Sedation Training APLS

- Includes ACEP terminology for sedation (PSA).
- Includes ASA status.
- Monitoring discussed.
- Extensive Drug list with all meds imaginable – Local to Etomidate etc.
- Specific explanation of drugs and possible combinations for specific procedures are included.
- Recovery Criteria are mentioned.

Sedation Training at Individual Institutions

- Didactic knowledge +/- hands on competence
- Almost all include a course that contains info like that of PALS/APLS – preop assessment, monitoring, meds, and recovery criteria.
- Many also include some hands on observation – either in the unit (Rainbow Babies) OR, on a simulator (Dartmouth and others).
- Some have graduated competencies (Walter Reed AMC)

What Are We Left With?

- Each institution must decide what is appropriate in terms of training and skill level to provide sedation.
- JCAHO gives no guidance on use of specific drugs or what (exactly) is required for training when deep sedation is involved.
- Many models exist that are now in place to meet the need to credential sedation providers

Dartmouth Sedation Credentialing

- Begin with a didactic course that can be read and test taken online.
- Content can include video training or interactive material. Updates are easy.
- Test of knowledge is embedded in the course material with explanations.
- Emphasize high risk patient factors and high risk procedure factors.

Pediatric Sedation Course:

- Version 1.0
- Required course for all RN and MD providers of Pediatric Sedation
Assuring Quality Care

- Question remains – What are the critical competencies related to sedation provision and how do we document them?
- Can we use evidence to determine these competencies.

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

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

<table>
<thead>
<tr>
<th>Unplanned Treatments</th>
<th>Incidence per 1000 N</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reversal Agent Required - unanticipated</td>
<td>1.7</td>
<td>(0.6-3.9)</td>
</tr>
<tr>
<td>Emergency Anesthesia Consult for Airway</td>
<td>2.0</td>
<td>(0.3-3.3)</td>
</tr>
<tr>
<td>Advance intubation - unanticipated</td>
<td>2.0</td>
<td>(1.1-3.8)</td>
</tr>
<tr>
<td>Admission to Hospital - unanticipated</td>
<td>7.0</td>
<td>(4.2-10.7)</td>
</tr>
<tr>
<td>Intubation Required - unanticipated</td>
<td>9.7</td>
<td>(6.5-13.9)</td>
</tr>
<tr>
<td>Airway (oral) (unanticipated)</td>
<td>27.6</td>
<td>(22.0-34.2)</td>
</tr>
<tr>
<td>RegardlesSedation (unanticipated)</td>
<td>63.9</td>
<td>(55.2-73.6)</td>
</tr>
<tr>
<td>Total Unplanned Treatments</td>
<td>111.9 (1 per 89336)</td>
<td>(85.3-130.2)</td>
</tr>
</tbody>
</table>

Conditions Present During Treatment

<table>
<thead>
<tr>
<th>Incidence per 1000 N</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate Sedation, could not complete</td>
<td>88.9 (1 per 338267)</td>
</tr>
</tbody>
</table>

Discussion

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

Results-Serious AE’s

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

Critical Competencies

- Combine Database Results with Direct Video Observation
Critical Competencies

- Assess patient - stratify risk.
- Obtain IV access.
- Understand drug dosing - titration to effect.
- Understand monitors - pro's vs con's - understand how to place - troubleshoot.
- Understand how to recognize apnea using several methodologies esp capnography.

Critical Competencies

- Open Airway - multiple methodologies - oral airway, nasal airway, jaw thrust, chin lift.
- Clear airway - suction, clear physical obstruction etc.
- Choose appropriate mask. Place appropriately
- Deliver positive pressure ventilation with bag and mask.

Critical Competencies

- Call for help.
- Recognize all equipment needed for intubation.
- Familiarity with intubation technique.
- Appropriate Bag-tube ventilation technique.

Dartmouth Sedation Training

- Hands on training with sedation crisis situations using the simulator. 1) 3 YO with laryngospasm 2) Infant with airway obstruction 3) Adolescent medication error.
- Feedback on critical events using the simulator to recreate events and accompanied by didactic material.
Ongoing Training and Updating

- Critical events are reported and reviewed
- Model events in the simulator
- Reenact the incident
- Overlay with instructional video.

Summary

- Intellectual training – detailed – video enhanced...
- Critical competencies, hands on training – OR or simulator based.
- Tiered sedation delivery privileging.
- Ongoing testing of systems
- Use QI process to model errors and reenact to educate on an ongoing basis.

www.dhmcstedation.com
It’s a Gas! – Nitrous Oxide for Procedural Sedation

3rd International Multidisciplinary Conference on Pediatric Sedation
May 28 – 30, 2008

Judy Zier, MD
Medical director, Nitrous oxide sedation program
Mary Kay Farrell, RN-BC
Clinical nurse educator, Radiology, ED – St. Paul campus

Objectives

• List 3 properties of nitrous oxide which make it attractive for procedural sedation in children
• Name at least 3 contraindications to nitrous oxide sedation
• Describe the steps necessary to develop a nitrous oxide sedation program

Nitrous oxide history

• discovered along with oxygen by Joseph Priestly in 1771
• first used as a dental anesthetic by Horace Wells in 1845
• currently used in 88% of pediatric dental offices

Pediatric sedation literature

• Extensive dental literature
• JAMA, 1981
• >3000 pediatric patients in private pediatric office in Bountiful, Utah
• Europe, Israel, Australia
• St. Louis Children’s Hospital
  – Luhmann, Kennedy, et al
• Miami Children’s Hospital
  – Burnweit, et al

Nitrous oxide properties

• sweet-smelling, colorless gas
• rapid onset of clinical action
  – relatively insoluble, rapid equilibrium between alveolus and capillary
  – crosses blood-brain barrier quickly
• rapid return to normal function
  – no significant metabolism by the liver
  – no significant excretion by the kidneys
  – remains unchanged in blood
  – not stored in tissues
  – eliminated through the lungs

Inhaled “anesthesia”

• weak anesthetic
  – minimal alveolar concentration (MAC)
  – amount of drug necessary to prevent movement in 50% of subjects responding to surgical incision
  – 104% for N2O, ~2% for sevoflurane
• airway reflexes remain intact with nitrous oxide alone
**N₂O properties**
- anxiolytic
- analgesic
- amnestic
- rapid onset of action
- titration possible
- rapid and complete recovery

**Side effects**
- most common
  - nausea
  - vomiting
  - diaphoresis
- other
  - hallucinations
  - vasodilatation

**Gas expansion**
- N₂O replaces N₂ in any closed gas space
- N₂O diffuses in more rapidly than N₂ diffuses out
  - trapped gas will expand...
    - pneumothorax
    - bowel obstruction
    - pulmonary blebs, congenital lobar emphysema
    - craniotomy, eye surgery
    - or increase pressure if it can't expand...
    - middle ear obstruction
    - sinus or ear discomfort with sinusitis or URI

**Other issues/contraindications**
- inactivates vitamin B₁₂ and methionine synthase
  - potential for:
    - megaloblastic anemia
    - myeloneuropathy
    - impaired fetal development, particularly in first trimester
- vasodilatation
  - increased intracranial pressure
- diffusion hypoxia
- abuse potential

**Nitrous oxide sedations at Children’s, Minnesota**
- bladder catheterization for VCUG/RNC – trial population
- CT scan
- IV start
- peripherally inserted catheters (PICC)
- MRI – patient with chronic pain
- intra-carotid sodium amytal test (ISAT)
- gastrostomy/GJ tube change
- nasogastric tube insertion
- botulinum toxin injection
- electromyogram
- incision and drainage
- laceration suturing
- lumbar puncture
- barium enema
- joint injection
- abuse exam

**Limitations**
- sedation may be inadequate for procedure
  - expectations must match capabilities of N₂O
  - just “one more tool in the toolbox”
  - occasional failure
- some specific contraindications
- occasional side effects, but still well accepted by patients and families
**Children’s nitrous oxide sedation program**

**Hurdles identified from the beginning**
- nursing scope of practice
- education
- equipment needs
- regulatory issues
- policies and procedures
  - what will anesthesia say?

**Nursing scope of practice**
- Minnesota statutes cover dentists and dental hygienists
- State Board of Nursing
  - Meeting held to ensure compliance with nursing scope of practice
- Care delivery committee, nursing union

**Building our education program**
- didactic program developed for in-house training of nurses and physicians
- core group of “super-user” nurses provide hands-on training in a supervised setting
- change from time-based (statutory) to competency-based (Nursing Board)

**Nitrous equipment**
- Nitronox systems (Matrx)

**Dental analgesia systems**
Nitrous oxide/oxygen sedation setup

- Standard “off the shelf” equipment
- Simple to use
- Built in safety features
- Scavenging system
- Now involve respiratory care department

Regulatory issues

- National Institute for Occupational Safety and Health
- Scavenging system is essential
- Determine facility adequacy for waste anesthesia gas disposal
- Biomedical department involvement
- Safety office: environmental exposure checks
  - Badge dosimetry

Policies and procedures

- Anesthesiologists “kept in the loop”
- Sedation committee oversight
- Sedation policy updated
- Credentialing developed
- Documentation developed
  - Orders
  - Administration
  - EMR
- Parent education sheets
- Quality assurance process specifically targeted to monitor adverse effects

Lessons learned

- A successful program involves much more than simply equipment purchase
- Essential components:
  - Leadership by physician and nurse “champions”
  - Training of a small, dedicated core group of nurses
  - Manager and medical director support

Lessons learned

- Expectations must match the capabilities of nitrous oxide sedation
  - Not the answer to all patients, just “one more tool in the toolbox”
  - Successful administration is a learned skill
  - Attitude is everything!
Impact of nitrous oxide sedation program - staff

Impact of nitrous oxide sedation program - families

“Overall it was a fantastic experience! There was not one thing that could of gone better. We used Nitrous for sedation and it made the whole procedure pain and anxiety free.”

“Use of Nitrous Oxide for sedation was fabulous—positive effective both during and after the procedure.”

“Extremely nice to use only Nitrous Oxide for sedation in place of Propofol.”

“This was an extremely stressful procedure (VCUG) for our daughter until today. The switch from Versed to Nitrous was an extremely positive change.”

“We participated in the nitrous oxide trial in Nuclear Medicine. While Heather vomited and experienced a headache from the gas, it was quite helpful until the time she got sick. I would recommend its usage.”

Why isn’t nitrous used more?

“Why isn’t nitrous used more?

That’s dental…

That’s anesthesia…. We tried that before, it never works.

It takes too much time and we’re too busy (those kids don’t really need sedation anyway).

Nitrous “Catch-22”

It’s minimal sedation…

– fasting guidelines taken from national standards
– http://guidelines.gov (search “nitrous”)
– no history and physical required
– still do pre-sedation assessment

Can’t bill for minimal sedation…

For more information

General nitrous oxide

Children’s nitrous oxide sedation program:

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Monitoring Requirements: Is There a Role for Routine Capnography in Pediatric Sedation?

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“Routine” Monitoring for Procedural Sedation

• “Competent individual shall observe patient continuously”
• Continuous pulse oximetry and heart rate monitoring
• Intermittent RR and BP monitoring
• Time-based documentation q.5 min

Which one of these tells you about adequacy of ventilation?

What’s wrong with respiratory rate monitoring and pulse oximetry?

• A respiratory rate in the normal range does not guarantee that respiratory function is adequate
• Visual inspection of respiration is a poor indicator of adequacy of ventilation
• Periods of apnea are easy to miss

Why do we need a better monitor of ventilation?

• For many procedures, children require more than moderate sedation
• Deep sedation is associated with more
  - Upper airway obstruction
  - Hypoventilation
  - Apnea
• Visual inspection of ventilation is not always possible

Monitoring for Procedural Sedation

“The use of a precordial stethoscope or capnograph for patients who are difficult to observe (e.g., MRI or in a darkened room) to aid in monitoring of ventilation is encouraged”
JCAHO Standards for Deep Sedation

"Respiratory frequency and adequacy of pulmonary ventilation should be continually monitored"

Monitoring for Procedural Sedation

- "The use of these combined technologies (oximetry and capnography) for ED propofol sedation is strongly recommended."
- "... it would behoove emergency physicians to add capnography to their propofol protocols to better mirror the propofol practices of anesthesiologists"

Noninvasive measurement of ventilation

- Graphical representation of expired CO2
- Breath to breath analysis of alveolar ventilation
- Accurate respiratory rate monitoring when continuous visual inspection is not feasible (e.g. MRI)

Types of capnographs
- Mainstream
- Sidestream
- Microstream

Capnographic Waveform

- Nasal cannula with aspiration tubing
- Mouth breathing can be a problem
- Dilutional effect with supplemental O2
- Nasal secretions can interfere with readings
Capnographs

- Smaller and more portable devices
- Low flow rates for smaller tidal volumes
- Nasal/oral devices

What capnography can tell you

- Respiratory rate (breath-to-breath)
- Apnea
- Airway obstruction
- Hypoventilation
Hypoventilation

Hypoventilation with shallow breathing followed by deep breath

Capnography Studies
Hart, Berns, Houck et al, 1997
- 42 patients, sedation in ER
- Three sedation regimens
  - Fentanyl
  - Fentanyl/Midazolam
  - DPT (Demerol, Phenergan, Thorazine)
- No supplemental O2

Capnography Studies
Hart, Berns, Houck et al, 1997
- ETCO2 > 50
  - Fentanyl alone – 20%
  - Fentanyl/midazolam – 23%
  - DPT = 11%

Capnography Studies
Tobias JD, 1999
- 50 children, emergency room
- Sedation with ketamine and midazolam
- Airway obstruction detected by cessation of ETCO2 waveform in 1 patient
- Hypoventilation detected in 3 patients: 2 w/ trisomy 21 and 1 w/ recent URI and tonsillar hypertrophy

Capnography Studies
McQuillen KK, et al., 2000
- 106 patients, mean age 6.8 years
- Fentanyl, ketamine, morphine, midazolam, No O2 supplementation
- ETCO2 increases (mm Hg):
  - Midazolam = 3.2
  - Midazolam and ketamine = 5.4
  - Midazolam and opioid = 8.8
Capnography during ketamine sedation
Kim G, et al., 2003
• 20 patients, mean age 6.5 years
• Ketamine 1.5 mg/kg over 1 min
• Continuous monitoring of ETCO2
• Placement of nasal cannula prior to sedation was generally well tolerated
• No evidence of hypoventilation in this small study

Capnography Studies
• 165 patients, mean age 3.4 years, MRI
• IV pentobarbital w/ and w/o fentanyl
• 28 foot nasal cannula
• 2L O2 per nasal cannula
• No significant change in ETCO2 values but higher mean ETCO2 w/ fentanyl

Capnography studies
Yildizdas, D, et al, 2004
• 126 children, sedation in PICU
• Five groups
  – Ketamine (K)
  – Midazolam (M)
  – Ketamine/ Midazolam (KM)
  – Midazolam/Fentanyl (MF)
  – Propofol (P)
• No supplemental O2

Capnography studies
Yildizdas, D, et al, 2004
• Hypercarbia noted only in the MF and propofol groups
  – Propofol – 52%
  – Midazolam/fentanyl – 28%

Capnography Studies
Soto RG, et al, 2004
• 39 adult patients, MAC
• Oral/nasal capnography
• Transthoracic Impedence monitor
• O2 flow rates = 0, 2, 4, 6 L
• 26% had apnea > 20 seconds detected by both ETCO2 and impedance monitor

Capnography Studies
Soto et al, 2004
• None of these episodes was detected by the anesthesia provider
• Oxygen flow rate affected the amplitude of the capnograph but not the detection of apnea
• Desaturation noted only when no supplemental O2 was administered
Capnography Studies
Lightdale, J, et al, 2006
- 163 patients, mean age 14 years
- Midazolam/fentanyl sedation in GI suite
- 2L O2 by nasal cannula
- “Blinded” Microstream® capnography
  - Intervention arm – apnea > 15 sec
  - Control arm – apnea > 60 sec

Capnography Studies
Lightdale J, et al, 2006
- Endoscopy nurses documented poor ventilation in 3% of patients
- Capnography showed:
  - Alveolar hypoventilation 56%
  - Apnea 24%
- Patients in intervention arm less likely to have O2 desaturation 11% vs 24% (p<0.03)

Capnography Studies
- 60 adult & pediatric patients (1 – 89 yrs)
- Study stopped due to 20 acute respiratory events in 60 patients (33%)
- Most patients (85%) had ETCO2 suggesting hypoventilation or apnea
- ETCO2 findings were documented before ↓ O2 sat or hypoventilation noted in 70%

Summary
- Capnography is an early indicator of respiratory inadequacy
- Apnea and airway obstruction are easily detected with capnography
- Supplemental O2 has a mild “dilutional” effect on ETCO2

Summary
- Sedation regimens involving ketamine, pentobarbital, midazolam have a low incidence of respiratory depression
- Sedation regimens involving the use of opioids either alone or in combination and propofol have a higher incidence of respiratory depression

Bispectral Index Monitoring (BIS®)
Summary

• BIS levels correlate well with sedation scores for many agents used for procedural sedation
• Poor correlation is seen with sedation regimens that employ ketamine, pentobarbital and chloral hydrate

Thank you for your attention