Ideal use of Sedation Agents

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

Outline

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

How do we choose the right drug?

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

Recognize the Challenges of Each Case!

• Difficult Patients
• Difficult Environments
• Difficult Procedures
The Problem

No Longer Acceptable

Can Current Literature Guide Our Practice?

Current State of Sedation Literature
- Over eighty studies involving a variety of providers using anesthesia can be found on Medline search - last 5 years
- Studies most often retrospective or prospective and observational.
- Numbers = 30 to 1000 patients.
- Almost never find a serious incident
  * Conclusions = Technique “x” is safe and efficient for procedure “y”.

Current State of Sedation Literature
- Is propofol safe for procedural sedation in children? A prospective evaluation of propofol versus ketamine in pediatric critical care®
  - 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.
  - 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….
Preoperative Fasting and Adverse Events in Procedural Sedation and Analgesia in a Pediatric Emergency Department: Are They Related?

Essentially all of this literature comes from the emergency medicine field.

Table 4

<table>
<thead>
<tr>
<th>Sedation Method</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prolonged Fasting</td>
<td>15%</td>
</tr>
<tr>
<td>Short Fasting</td>
<td>5%</td>
</tr>
</tbody>
</table>

Current State of Sedation Literature

Propofol for procedural sedation in children in the Emergency Department

Adverse event rates vs. NPO time

Conclusion: Propofol is safe and effective for EM provided elective sedation

Statement on Granting Privileges to Non-Anesthesiologist Practitioners for Personally Administering Deep Sedation or Supervising Deep Sedation by Individuals Who Are Not Anesthesia Professionals

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

Exemptions to the statement that the practitioners who receive deep sedation may either be of general anesthesia, privileges to administer deep sedation should be granted only to practitioners who are qualified to administer general anesthesia or to appropriately supervised anesthesia professionals.
Current State of Pediatric Sedation Safety Research

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

Human Factors Approach

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

Characterizing Pediatric Sedation Work

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

Dartmouth Studies....
Treatment of SE (eg Morphine)

Procedure (eg LP)

Side Effect (eg PAIN)

Control over time

Treatment of SE (eg Morphine)

Side Effect of Sedation (eg Apnea)

DOCS:
the Dartmouth Operative Conditions Scale

Patient State | Observed behaviors and clinical signs
---|---
Pain/Stress | Calm expression, Grimace at items, Crying, sobbing, screaming
Movement | Still, Random body movement, Major purposeful movement
Consciousness | Eyes open, Pins, uncoordinated, "drowsy"
Sedation SE's | Slight -70%, Noise with respiration, Apnea, Hypospasm, Low BP, Low SpO2

DOCS validation

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

Sedation Study

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

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

Results of the Study

• Time from beginning sedation to beginning the procedure varied from 2 minutes to 84 minutes.

Results of Study

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

Results of Study

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

Results of the Study

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

Results of the Study

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

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

What about core competencies for use of potent sedative medications?

Simulator as Crash Test Dummy

• “The Use of a Patient Simulator to Evaluate Rescue capability for Pediatric Sedation Critical Events.” SPA 2003

Simulator as Crash Test Dummy

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

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

George T. Blake, MD, Klaus Christoffersen, MD, Joseph P. Cravero, MD, Steven K. Andeweg, MD, and Jens Jensen, MD
Department of Anesthesiology, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire

The practice of sedating patients in the hospital for diagnostic and therapeutic procedures has led to an increased awareness of the need for high quality anesthesia care. We describe a method for using a simulation to study the inter- and intraprofessional skills of sedation nurses, anesthesiologists, and surgeons. The simulator was used to model different scenarios in a controlled environment. The sedation nurses were able to perform the task of sedation successfully without any adverse events. The same scenario was evaluated in each case. Video record and physiologic data were collected in each case. Severe hypotension and hyperthermia were noted in 2 of the 3 cases. The sedation nurses were able to manage the situation successfully. The simulator was able to identify critical variables in the sedation process and to provide feedback to the providers. The simulator was able to identify critical variables in the sedation process and to provide feedback to the providers.
Conclusions from Crash Tests

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

Summary from Crash Tests

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

Pediatric Sedation Research Consortium

Complication Data Collection

Apnea – unintended pause in breathing for more than 20 seconds. Could be obstructive or central in nature.
Aspiration – gastric contents suctioned – respiratory sequelae 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 < 35°C 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.
Unintended change in heart rate, blood pressure or respiratory rate > 30% change from baseline.
Unexpected deep level of sedation.
Unplanned intubation.
Vomiting – during or after the (non-gastrointestinal) procedure.
Unplanned admission to the hospital or increase in the level of care.
Other

Data Coming Out of the Consortium
### Complications Paper

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

- Data was submitted from 30,037 sedation encounters between July 1, 2004 and October 1, 2005.
- Current number is over 75,000 encounters.

**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>Adverse Event</th>
<th>Incidence per 10,000</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0.0</td>
<td>(0.0-0.0)</td>
</tr>
<tr>
<td>Cardiac Arrest</td>
<td>0.5</td>
<td>(0.0-1.5)</td>
</tr>
<tr>
<td>Hypoxemia</td>
<td>1.2</td>
<td>(0.9-1.5)</td>
</tr>
<tr>
<td>Hypoxemia during sedation</td>
<td>4.3</td>
<td>(3.6-5.0)</td>
</tr>
<tr>
<td>Prolonged recovery</td>
<td>4.5</td>
<td>(3.8-5.3)</td>
</tr>
<tr>
<td>Aspiration</td>
<td>0.3</td>
<td>(0.0-1.0)</td>
</tr>
<tr>
<td>Hypotension</td>
<td>2.9</td>
<td>(1.8-3.9)</td>
</tr>
<tr>
<td>Hypothermia</td>
<td>10.9</td>
<td>(7.8-14.4)</td>
</tr>
<tr>
<td>Bronchoscopy (unplanned)</td>
<td>11.0</td>
<td>(7.6-15.4)</td>
</tr>
<tr>
<td>Inadequate sedation, could not complete</td>
<td>88.9</td>
<td>(78.6-100.2)</td>
</tr>
</tbody>
</table>

#### Selected Results

<table>
<thead>
<tr>
<th>Unplanned Events</th>
<th>Incidence per 10,000</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reversal Agent Required - unexpected</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>(0.7-4.3)</td>
</tr>
<tr>
<td>Admission to Hospital - unplanned</td>
<td>7.0</td>
<td>(4.3-10.7)</td>
</tr>
<tr>
<td>Intubation Required - unplanned</td>
<td>9.7</td>
<td>(6.5-13.9)</td>
</tr>
</tbody>
</table>

#### Conditions Present During Procedure

<table>
<thead>
<tr>
<th>Condition</th>
<th>Incidence per 10,000</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate sedation, could not complete</td>
<td>88.9</td>
<td>(78.6-100.2)</td>
</tr>
</tbody>
</table>

### 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 AEs (Laryngospasm, Stridor, Apnea, Bronchospasm) LESS rare
  - ~1:400 sedations
  - Need for Emergent Airway Tx Common (depending on definition)
  - ~1:100 sedations

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

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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Total Cases</th>
<th>Incidence per 100</th>
<th>Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ativan</td>
<td>33</td>
<td>0.6</td>
<td>(4, 6, 9, 3)</td>
</tr>
<tr>
<td>Chlordiazepoxide</td>
<td>199</td>
<td>27.9</td>
<td>(23, 532, 9)</td>
</tr>
<tr>
<td>Dexmedetomidine</td>
<td>22</td>
<td>4.4</td>
<td>(2, 8, 6, 7)</td>
</tr>
<tr>
<td>Etomidate</td>
<td>42</td>
<td>8.4</td>
<td>(6, 11, 4)</td>
</tr>
<tr>
<td>Ketamine</td>
<td>879</td>
<td>176.4</td>
<td>(165, 188.3)</td>
</tr>
<tr>
<td>Midazolam</td>
<td>3766</td>
<td>755.7</td>
<td>(732, 779.3)</td>
</tr>
<tr>
<td>Pentobarbital</td>
<td>335</td>
<td>27.1</td>
<td>(22, 732.1)</td>
</tr>
<tr>
<td>Propofol</td>
<td>53</td>
<td>10.6</td>
<td>(8, 0.03, 9)</td>
</tr>
<tr>
<td>Valium</td>
<td>5</td>
<td>1.0</td>
<td>(6, 3, 2, 3)</td>
</tr>
</tbody>
</table>
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.
- 16 YO athletic male s/p episode of GI bleed. Colonoscopy 195 mg of propofol over 13 minutes. Apnea occurred with severe bradycardia (asystole) 30 seconds. CPR plus atropine and epi - back to baseline in 3 minutes.

Aspiration Episodes

<table>
<thead>
<tr>
<th>Age</th>
<th>Diagnosis</th>
<th>Procedure</th>
<th>BMI status</th>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 yrs</td>
<td>Esophageal varices repair</td>
<td>Esophagey</td>
<td>&gt; 8 hours for clear fluids</td>
<td>Isolation Unit</td>
</tr>
<tr>
<td>31 yrs</td>
<td>Sinus disorder</td>
<td>MRI</td>
<td>2 hours - clear fluids, 6 hours - solids</td>
<td>Recovery Room</td>
</tr>
<tr>
<td>10 yrs</td>
<td>Bilharzism with E. coli</td>
<td>MRI</td>
<td>4 hours - clear fluids 6 hours - solids</td>
<td>ICU</td>
</tr>
<tr>
<td>10 yrs</td>
<td>Leukemia</td>
<td>LP-Chemo</td>
<td>6 hours - clear fluids 6 hours - solids</td>
<td>Isolation Unit</td>
</tr>
</tbody>
</table>
**Discussion**

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

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

**Safety Summary**

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

**Future**

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

**Society for Pediatric Sedation**

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

- www.pedisedation.org