What are the Risks of Sedation for Children?

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When Things Go Wrong

- Why do things go wrong?
- What adverse events should you anticipate?
- Preparing for adverse events
- Take home message
Adverse Events and Pediatric Sedation

- Children - highest risk, lowest error tolerance
- Sedation must be deeper than that given to adults to achieve acceptable conditions during procedure
- Higher risk of hypoxia, respiratory depression
- Adverse events are unavoidable but occur rarely
- Acceptable rates of adverse events should exist
- Sedation providers and institutions should be able to compare outcomes
- Benchmarks for sedation-related adverse events have not been established
  - is desaturation always an adverse event?

Adverse Events Model
Adverse Sedation Events in Pediatrics: A Critical Incident Analysis of Contributing Factors

Cote CJ, Notterman DA, Karl HW, Weinberg JA, McCloskey C:
Pediatrics Vol. 105, No. 4
April 2000

Database of FDA adverse drug events, USP, pediatric specialists

- 118 reports examined by 4 physicians
- 95 reports had consensus on cause
- 51 deaths, 9 permanent CNS injury, 21 prolonged hospitalization without injury, 14 no harm
- Critical incident analysis indicates that human error accounted for most mishaps
- Order of observed events:
  > 80% respiratory depression, then bradycardia, then cardiac arrest
- Strong positive relationship between successful outcome and use of pulse oximetry and unsuccessful outcome and no monitoring


Distribution of Cases by Age

Majority of patients were 6 years old or less - no relationship between age and adverse outcome

Poorer outcome for events occurring outside the hospital

- Cardiac arrests: 79% versus 21%
- Death/CNS injury: 93% versus 37%
- Inadequate resuscitation major factor: 57% versus 2%
- In hospital: patients monitored with pulse oximetry had successful outcomes (15)
- Outside hospital: pulse oximetry not helpful (4 of 5 had adverse outcomes)


Excerpts

- “A disproportionate number of cases (32 of 95) involved sedation/anesthesia for dental procedures”
- “9 were identified as being oral surgeons who have the most training of dental specialties for administering anesthetics/sedative agents.”

Excerpts

- “Conscious sedation is an oxymoron for many children < 6 years old.”

- “Some indicator of respiratory compromise was the initially observed clinical event in >80% of patients.”


Conclusions and Recommendations

- Our interpretation is that dental insurance coverage should be available for all children not simply those with underlying medical conditions
- Our data suggest the need for improved training and monitoring standards for dental practitioners who treat children with sedation
- Recommendations:
  - Pulse oximeter
  - Second observer
  - Precordial stethoscope and capnograph could aid in early recognition of a respiratory event


Adverse Events during Pediatric Dental Anesthesia and Sedation: A Review of Closed Malpractice Insurance Claims

Maggie C. Chicka, DDS, MS • Jeffrey B. Dembo, DDS, MS • Kavita R. Mathu-Muju, DMD, MPH • David A. Nash, DMD, MS, EdD • Heather M. Bush, PhD

Abstract:

Purpose: The purpose of this study of closed malpractice insurance claims was to provide descriptive data of adverse events related to child sedation and anesthesia in the dental office.

Methods: The malpractice claims databases of two professional liability carriers were searched using predetermined keywords for all closed claims involving anesthesia in pediatric dental patients from 1993-2007.

Results: The database searches resulted in 17 claims dealing with adverse anesthesia events of which 13 involved sedation, 3 involved local anesthesia alone, and 1 involved general anesthesia. Fifty three percent of the claims involved patient death or permanent brain damage; in these claims, the average patient age was 3.6 years, 6 involved general dentists as the anesthesia provider, and 2 involved local anesthesia alone. Local anesthetic overdoses were observed in 41% of the claims. The location of adverse event occurrence was in the dental office where care was being provided in 71% of the claims. Of the 13 claims involving sedation, only 1 claim involved the use of physiologic monitoring. Conclusions: Very young patients (< 3 years-old) are at greatest risk during administration of sedative and/or local anesthetic agents. Some practitioners are inadequately monitoring patients during sedation procedures. Adverse events have a high chance of occurring at the dental office where care is being provided.

Pediatr Dent 2012;34:231-8
Chicka et al. Study Commentary

- Adverse event occurrence rate is impossible to determine given the evidence presented
- Lack of physiologic monitoring - a huge concern
- Local anesthesia overdose - a huge concern
- Study conclusion: “Adverse events have a high chance of occurring at the dental office where care is being provided” is not supported by the evidence presented
- When sedation guidelines are followed the likelihood of an adverse event is decreased substantially

Risk Factors for Complications

- Polypharmacy sedations without understanding possible drug interactions
- Overdosages of narcotics and/or LAs
- Failure to recognize respiratory depression
- Inadequate resuscitation
- Inadequate monitoring intra- and post-procedure
- Inadequate medical evaluation before treatment
- Poor patient selection
- Lack of age & size appropriate emergency equipment


Depth of Sedation Continuum of Consciousness

Awake Minimal Moderate Deep General Anesthesia
We seem to have it “sdrawkcab”

• It’s not the route, it’s the depth
  • How do we distinguish between sedation levels?
• It’s not the drug(s), it’s the depth
  • Why are certain drugs restricted if most drugs we use can produce deep sedation/GA?
• Is it time to reformulate the sedation continuum?
  • Should we monitor patient physiology instead of subjective assessments of sedation depth?
• Stratify sedation levels using objective physiologic data?

Possible Adverse Sedation Events: “Modern” Data

“All: Pediatric Sedation Research Consortium

“Minor?”
Agitation/delirium
Coughing
Desaturation: \(\text{SpO}_2\) below baseline for >30s
Hypothermia
Inadequate sedation
Prolonged recovery time
Secretions requiring treatment
Use of reversal agents
Wheezing

“Severe?”
Airway obstruction
Allergic reaction
Apnea >15s
Aspiration
Cardiac arrest
Death
Laryngospasm
Stridor
Unintended deeper level of sedation
Unplanned hospital admission
Unplanned intubation
Vomiting

Frequency of Adverse Events in Pediatric Sedation

• Significant disparities exist in adverse event reporting
  • Differences in drugs used
  • Different providers with different training/education/skill sets
  • Different procedures - painful vs. not painful, duration
  • Acuity of illness of subjects
  • Definitions of adverse events (eg. - desaturations)
• Adverse events occur infrequently; large study populations required to assess accurately the “true” frequency
  • Sample sizes in dental sedation studies are too small to capture
• Pediatric Sedation Research Consortium 2006 data; 30,037 records:
  • 1,601/30,037 reported a complication - 5.3% overall incidence of complications
  • 1:89 sedations associated with “a complication”
  • 1:400 sedations associated with stridor, wheezing, laryngospasm, apnea
  • 1:200 sedations required airway interventions
  • 1:200 sedations associated with vomiting
  • 1:1500 sedations associated with admission to hospital
• Significant caveats associated with these data
  • Co-existing illnesses in majority of patients
  • Voluntary participation and self-reporting; selection bias!

### Predictors of Adverse Events - Pediatric ER Data

<table>
<thead>
<tr>
<th>Predictor Variable</th>
<th>Odds Ratio</th>
<th>95% CIs for Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary diagnosis upper respiratory disease</td>
<td>4.69</td>
<td>2.51-8.75</td>
</tr>
<tr>
<td>Primary diagnosis prematurity</td>
<td>4.02</td>
<td>1.42-11.43</td>
</tr>
<tr>
<td>Adjunctive benzodiazepine</td>
<td>3.09</td>
<td>2.14-4.46</td>
</tr>
<tr>
<td>Adjunctive ketamine</td>
<td>2.56</td>
<td>1.51-4.33</td>
</tr>
<tr>
<td>Adjunctive opioid</td>
<td>2.23</td>
<td>1.48-3.34</td>
</tr>
<tr>
<td>ASA ≥ 3</td>
<td>1.95</td>
<td>1.60-2.37</td>
</tr>
<tr>
<td>NPO solids for &lt; 6 hours</td>
<td>1.43</td>
<td>0.81-2.51</td>
</tr>
</tbody>
</table>

### Intervention-based definitions for sedation-associated adverse events

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Intervention performed in response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygen desaturation</td>
<td>Vigorous tactile stimulation, Airway repositioning</td>
</tr>
<tr>
<td>Apnea: Central vs. Obstructive (partial versus complete)</td>
<td>Administration of reversal agents, Supplemental oxygen, Tracheal intubation</td>
</tr>
<tr>
<td>Retching/Vomiting</td>
<td>Administration of antiemetic agent(s), Suctioning</td>
</tr>
<tr>
<td>Clinically apparent pulmonary aspiration</td>
<td>Extended observation or admission to hospital</td>
</tr>
<tr>
<td>Excitatory movements</td>
<td>Procedure delayed, interrupted or not completed</td>
</tr>
<tr>
<td>Paradoxical response to sedation</td>
<td>Administration of reversal agents, Administration of sedative agents</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>Chest compressions</td>
</tr>
<tr>
<td>Hypotension</td>
<td>Administration of medications</td>
</tr>
<tr>
<td>Unpleasant recovery reactions</td>
<td>Allocation of additional staff to care for patient/family</td>
</tr>
</tbody>
</table>

### Risk Reduction in Pediatric Procedural Sedation

- **Methods:**
  - Focused review of sedation records from Children’s Hospital of Wisconsin after implementation of a uniform sedation process
  - Guided Risk Assessment (GRA) tool developed to identify risk of sedation
  - Primary outcome was any adverse event (AE) or complication

- **Results:**
  - 960 records reviewed; 89% were ASA 1 or 2; 54.2% radiology; 18.3% cardiology
  - Adverse event incidence: 4.2% overall; CS - 3.8%; DS - 12%
  - Patients who underwent GRA and achieved DS had significantly lower AE rate (1.7%) than those in DS who did not have GRA performed (7%).
  - Polypolypharmacy (≥ 3 drugs) risk of AE
  - Chloral hydrate (50-75 mg/kg) ALONE was associated with most inadvertent DS and AE - hypoxemia, hypotension, airway obstruction

- **Take Home Messages:**
  - Adherence to guidelines and a structured process reduces occurrence of AE during pediatric procedural sedation
  - Guided Risk Assessment is the most important element in risk reduction

Preparing for Adverse Events

The obvious, eh?

- Practice within the Guidelines
  - PS9 (2010) - Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures
- Educate and train staff in:
  - Sedation procedures
  - Rescue and resuscitation
- Adequate staff available during procedure; recovery
- Appropriate equipment, drugs and monitors available
- Appropriate physical assessment:
  - Guided risk assessment
- Informed consent
- Appropriate discharge criteria:
  - Two responsible adults to accompany child home

Slit Rubber Dam - Caution

Entry points to airway for fluids/foreign bodies
Shortcomings in Training/Education
Core Competencies

Moore/Cote papers

- Inadequate medical evaluation before treatment
- Poor patient selection
- Polypharmacy sedations without understanding possible drug interactions
- Overdoses of narcotics and/or LAs
- Inadequate resuscitation
- Failure to recognize respiratory depression
- Inadequate monitoring intra- and post-procedure
- Lack of age & size appropriate emergency equipment

SPS Core Competencies

- Physical assessment skills
- Managing patients in ALL levels of sedation
  - using a variety of drugs
  - using a variety of routes of administration
- Emergency management skills and knowledge
  - Simulation training - “practice on plastic”
- Clinical requirements which are competency-based
  - Multidisciplinary sedation team training - RNs, RTs
  - Standardized sedation curriculum
  - Qualified Faculty

Accreditation Requirements

Teach “to the skills” NOT “to the specialty”

“Rather than limit sedation to specific specialties, the program teaches skills and concepts needed by any sedation provider to safely provide sedation, irrespective of the depth of sedation intended, as patients have a nasty habit of sometimes becoming more (or less) sedated than intended.”

Michael J. Verive, MD, FAAP
Medical Director - Pediatric Intensive Care
St. Mary’s Hospital for Women and Children

Monitoring for......?

- Hypoventilation
- Apnea
- Airway obstruction
- Laryngospasm
- Cardiopulmonary impairment
- Rescue
Control of Ventilation

**Oximetry**
- 
- Peripheral hypoxemic drive

**Capnography**
- 
- \( CO_2 + H_2O \rightarrow H_2CO_3 \)
  - \( H^+ + HCO_3^- \rightarrow H_2CO_3 \)

Becker, D; Bradley B.: Basic Physiologic Considerations; In: Principles of Pain and Anxiety Control; Dionne, Phero, Becker, eds.; Saunders, 2002

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**Does Supplemental Oxygen Prevent Hypoxia?**
- All agents used for sedation have the potential to cause respiratory depression and hypoxia
- ASA has recommended that all patients receiving deep sedation should receive supplemental \( O_2 \) (moderate may benefit)
- In theory, \( O_2 \) supplementation causes a longer interval between apnea and oxygen desaturation

- Keidan et al., 2008 (credentialing sedation course with simulation)
  - Simulated apnea in a 6 year old, three groups:
    - A: 15 pediatricians with supplemental \( O_2 \)
    - B: 15 pediatricians without supplemental \( O_2 \)
    - C: 10 anesthesiology residents with supplemental \( O_2 \)
  - Time interval from simulated apnea to BVM ventilation recorded
  - Those in group A took significantly longer to recognize and treat apnea than groups B and C.
- Conclusion: Supplemental oxygen does not prevent desaturations and delays recognition of apnea

- Why use a measure of oxygenation to assess ventilation?


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**Supplemental Oxygen Administration**
- Deitch et al., 2008, reported that supplemental oxygen did not reduce the incidence of hypoxia in adults moderately sedated with midazolam/fentanyl
- Leelataweewud et al. 2000, reported no difference in desaturation incidence in children sedated with CH,M,H and either \( N_2O \) or supplemental oxygen
- When using ETCO2, use of supplemental oxygen would give MORE time to manage apnea prior to desaturation, once noticed


- Standard oxygen tubing, saliva ejector
- Effective if mouth breathing
- 2-5 litres per minute
- Can be moved to accommodate procedure
- Less irritating to patient than nasal prongs

Milnes A: Delivering supplemental oxygen during sedation via a saliva ejector; *Pediatr Dent* 2002; 24(4):340-2
Capnography: Key Factors

- Measures concentration of expired CO₂ (usually via infrared technology).
- Indicates airway compromise & rate of breathing.
- Sensitive to:
  - probe placement
  - mucous blockage
  - rate of sampling of air
  - patient behaviors (e.g., crying)
- Gold standard for monitoring with pulse oximetry.
- Alarm for apnea within 15-20 seconds.

What can capnography tell us?

Low end-tidal CO₂ - hypoventilation
Normal respiratory rate; ↓ tidal volume
displaced CO₂ cannula
partial airway obstruction

Microstream Capnography - Enhanced Safety?

- Prospective, randomized, double-blind trial - 2 arms
  - 163 children; underwent 174 endoscopic procedures; moderate sedation
- Both arms: microstream capnography + independent observer
  - Intervention arm: signal if monitor detected alveolar hypoventilation/apnea for > 15 sec.
  - Control arm: signal if monitor detected alveolar hypoventilation/apnea for > 60 sec.
  - Primary outcome - SpO₂ <95 for > 5 sec, all subjects received supplemental O₂
- Patients in intervention arm were significantly less likely to have an intraprocedural desaturation:
  - Earlier recognition of hypoventilation
  - Stimulation to breathe +/- adjustment of head position upon notification of hypoventilation

Discharge: When is it safe?

• Which scale?
  • University of Michigan Sedation Scale (www.anesthesia-analgesia.org/content/102/2/389.full)
  • Wisconsin Sedation Scale (www.pediatricdigest.mobi/content/109/2/236.full)
  • Modified Ramsay Sedation Scale (spranac.umin.ac.jp/How to use the Ramsay score to assess the level of ICU sedation.htm)
  • Modified Maintenance of Wakefulness Test®
  • COMFORT scale (Ambuel et al. 1992) (jpepsy.oxfordjournals.org/content/17/1/95.abstract)
  • AVPUS (PALS)

• Incorporating specific, objective discharge criteria with a measure of wakefulness (MMWT®) may ensure a status closer to baseline
• May delay discharge of sedated children - Cost? Space? Staff?


<table>
<thead>
<tr>
<th>Parameter</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level Of Consciousness</td>
<td>Not responsive</td>
<td>Responds to pain only</td>
<td>Eyes open on command</td>
<td>Light sleep, eyes open intermittently</td>
<td>Fully awake, eyes open, conversing, oriented, aware</td>
</tr>
<tr>
<td>Activity</td>
<td>Not moving</td>
<td>Non-purposeful movement</td>
<td>Raises head/ extremity on command</td>
<td>Sitting unaided</td>
<td>Standing, walking unaided</td>
</tr>
<tr>
<td>Airway</td>
<td>Obstructs without support</td>
<td>Obstructed on neck flexion; clear with extension</td>
<td>Maintain airway without support, no cough</td>
<td>Opens mouth, able to breathe deeply</td>
<td></td>
</tr>
<tr>
<td>Oxygen Saturation</td>
<td>&lt;92 on room air</td>
<td>&gt;92 but &lt;96 on room air</td>
<td>&gt;96 on room air</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total Score Must Equal 9 Prior to Discharge


What Happens When They Go Home?

Table 1. Number of children who slept in the car as a function of drug regimen.

<table>
<thead>
<tr>
<th>Drug Category</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Triple Combination</td>
</tr>
<tr>
<td>Slept in car</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

$\chi^2 = 18.2, p < 0.001$

Table 2. Number of children who were difficult to awaken as a function of drug regimen.

<table>
<thead>
<tr>
<th>Difficult to awaken</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Triple Combination</td>
<td>10</td>
</tr>
<tr>
<td>Versed</td>
<td>0</td>
</tr>
</tbody>
</table>

$\chi^2 = 2.6, p = 0.087$

Medical Simulation

Thank You!

Danke
Gracias!
Merci!

Do Jeh!
Arigato!
Schön!

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