To Sleep, perchance to Dream…

Pediatric Procedural Sedation Update

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Objectives

• Describe the goals and means for management of procedural pain and anxiety in children
• Describe the elements of a quality, safe, evidence based Pediatric Procedural Sedation service
• Discuss current evidence surrounding a variety of controversial topics in Pediatric Procedural Sedation

Why

• Younger ages and lower cognitive abilities may require deeper levels of sedation to accomplish procedural goal
• Increased recognition that pain, anxiety are contributors to future outcomes
• Improve resource utilization in complex systems
• Decrease risks of long term unanticipated consequences of anesthesia
• Family and patient centered

History

1992: AAP Definition
– A depressed state of consciousness where patients nonetheless are able to retain protective reflexes and “respond appropriately to stimuli.”

1998: ACEP
– Statement noted that procedural sedation’s goal is to medicate patients until they can tolerate unpleasant procedures – an otherwise inappropriate response for a non-sedated person.

1995 consecutive series of deep sedation:
– 279/971 oncology patients
– Adverse events
  • Vomiting, tachycardia, agitation: Ketamine
  • Hypoxemia: Propofol
  • Myoclonus: Etomidate
– 2003 series of 1000 children for PSA in ED
  – 2144 cases with 17.8% complication
  • Hypoxemia
  • No aspiration, intubation or death (despite preprocedural fasting)

Pediatric Sedation Research Consortium

• Collaborative group of institutions dedicated to improving sedation practice through sharing of prospective observational outcome data on pediatric procedural sedation encounters.
• 2006: first 30,000 cases published
  – 3 Cardiopulmonary resuscitation
  – NO aspirations
  – NO deaths
• Current: over 300,000 cases
• Safety and Quality driven by data
AAP 2006 Guidelines

- Selection/Screening
  - Identify high risk groups, procedures, limitations

- Monitoring: preparedness to rescue from an unintended depth
  - Deep: a dedicated monitor in addition to sedationist
  - Moderate: Sedationist may perform procedure with a monitor/assistant

- Recovery: highlighting patient discharge criteria and home care
  - Aldrete

Sedation outside of the OR

Diagnostic:
- Imaging: CT, MRI, US, Nuclear scans
- Lumbar Puncture, Bone marrow aspirates/biopsies, endoscopies, solid organ biopsies, ABR's
- Cardiac exams: echo, catheterizations
- VCUG

Therapeutic:
- Laceration repair, abscess I & D, FB removal
- Wound & burn care
- Fracture/Orthopedic
- Central or PICC line placement
- Dental

Location, location, location

Broader range of locations for procedural interventions
- Outpatient radiology studies
- Outpatient procedures (Heme Onc, GI, Orthopedic, ENT)
- Emergency Center
- Inpatient Studies/Interventions

- Reduction in resource utilization - cost convenience
- Safety and skills must be verified for each location

Goals Of Sedation

- Anxiolysis
- Analgesia
- Amnesia
- Safety
- Control Behavior
- Return to baseline

<table>
<thead>
<tr>
<th>RESPONSE</th>
<th>MINIMAL</th>
<th>MODERATE</th>
<th>DEEP</th>
<th>GENERAL ANAESTHESIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIRWAY</td>
<td>Unaffected</td>
<td>Intervention maybe required</td>
<td>Intervention is required</td>
<td>Intervention required</td>
</tr>
<tr>
<td>VENTILATION</td>
<td>Unaffected</td>
<td>Adequate</td>
<td>May require support</td>
<td>Frequently inadequate</td>
</tr>
<tr>
<td>CV FUNCTION</td>
<td>Unaffected</td>
<td>Usually maintained</td>
<td>Usually maintained</td>
<td>May be impaired</td>
</tr>
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</table>
Regardless of intended level of sedation, sedation represents a dynamic continuum. Any level of sedation may "suddenly and unexpectedly become deep or general and precipitate loss of protective airway reflexes.

Understanding pain

- Untreated pain
  - Short term derangement of vital, stress response
  - Long term effects including sensitization to pain episodes in later life.
- Repeated painful episodes
  - Trigger anxiety and behavioral changes acutely and with amplification on subsequent re-exposure
- Emotional and psychological implications for both the child and the family
  - Potentially detrimental effect on clinical course
  - Long term impact – particularly in chronic disease conditions

Hospitalized children have multiple painful interventions daily

- Infants: average 10 (0-51)/day
- Children average 6.3/day

Anatomy of a Sedation

- Pre Sedation
  - Type of procedure that will be performed
  - Screening of candidate
- Intra Sedation
  - Personnel
  - Monitoring
  - Drug choices
- Post Sedation
  - Recovery
  - Follow up
  - Quality Surveillance

Pre Sedation

- Guidelines
- Policy and Procedure adherence
- Pre Sedation assessment
  - Patient a good candidate?
  - Procedural needs?
  - anFormulate sedation plan
**Safety**

**Pre-sedation Assessment**
- Patient’s name, age, weight (kg), and gender
- Medical history: underlying medical conditions or Risk Factors
- Previous sedation/anesthetic history or problems
- Allergies
- Current medications
- Family history of anesthetic complications
- Dietary history (NPO status)
- Why is sedation required?
- Physical examination
  - Baseline vital signs, room air saturation
  - Airway exam
  - Cardiorespiratory examination
  - Neurologic exam
- Laboratory (if appropriate)
- ASA status
- Plan
- Risks discussed/Consent obtained

**NPO Policy**
- Age 0 – 5 Months:
  - No milk or solid food for 4 hours prior to sedation
  - Clear liquids up to 2 hours prior to sedation
- Age 6 Months To 36 Months:
  - No milk or solid food for 6 hours prior to sedation
  - Clear liquids up to 2 hours prior to sedation
- Age Older Than 36 Months:
  - Clear liquids up to 2 hours prior to sedation
  - Milk or light meal up to 6 hours prior to sedation
  - Regular meal up to 8 hours prior to sedation

**ASA**

<table>
<thead>
<tr>
<th>ASA</th>
<th>Description</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A normally healthy patient</td>
<td>Unremarkable medical history</td>
</tr>
<tr>
<td>2</td>
<td>A patient with mild systemic disease (excludes the trivial limitation)</td>
<td>Mild asthma, controlled allergies, anemia, controlled hypertension</td>
</tr>
<tr>
<td>3</td>
<td>A patient with severe systemic disease/limited functional capacity</td>
<td>Severe congestive heart failure, poorly controlled anemia, poorly controlled diabetes, mild obesity</td>
</tr>
<tr>
<td>4</td>
<td>A patient with severe systemic disease that is a constant threat to life</td>
<td>Severe COPD, severe chronic pulmonary disease, cardiac, hepatic, renal, or endocrine disease</td>
</tr>
<tr>
<td>5</td>
<td>A moribund patient who is not expected to survive without immediate care</td>
<td>Septic shock, severe trauma</td>
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ASA 0 - 3: minimal risk
ASA IV - V: high risk

**Airway Assessment**
- Modified Mallimpati
  - Sitting upright
  - Tongue out
  - No vocalization
- Best oropharyngeal view (BOV)
  - Mouth open
  - No tongue protrusion

**High Risk Conditions**
- >ASA III
- URI
- Abnormal airways
- Craniofacial deformities
- Pulmonary disease
- Cardiovascular disease
- Hemodynamic instability
- Hypoxemia/Dehydration
- Neurologic dysfunction/instability
- Myopathy
- Obesity
- GE reflux
- Full stomach
- Abdominal distension
- Hepatic dysfunction
- Renal dysfunction
- Prematurity or former preterm infants
- Neonates
Contraindications

- Premature (<60 weeks gestation)- Infants born < 37 weeks EGA who are < 60 weeks post conception
- Uncontrolled seizures or multiple medications- particularly neuroleptic or psychotropic
- Raised ICP
- ASA physical status ≥ 4
- Neuromuscular disease
- Severe GERD/Vomiting

Screening of Candidates to ensure appropriate
- Must have immediate pre sedation reassessment documented- focused on current status
- Consent must be obtained

Airway differences in kids
- Big heads
- Anatomy- large tongue, anteriorly displaced airways, turbulent flow, high larynx, cricoid narrowing
- Resistance increased
- Ventilation differences
- Positioning matters

INTRA SEDATION

On site Checklist

- Size-appropriated suction catheters
- Adequate oxygen supply and functioning flow meters
- Size appropriate airway equipment
- All basic pharmacy drugs needed to support life during emergency
- Monitors: pulse oximeter, right sized probe, end-tidal carbon dioxide monitor, and other monitors as appropriate for the procedure (ECG, non invasive blood pressure, stethoscope)
- Special equipment or drugs for a particular case (e.g., defibrillator)
Monitoring

- PALS certified nurse
- Heart Rate, Respiratory Rate, Blood Pressure
- Continuous pulse oximetry- supplemental O2
- Capnography- ETCO2
- ECG
- Perfusion
- Neurologic status
  - State of consciousness
  - Pupillary responses

Non-pharmacological interventions

- Child life specialists
  - Play
  - Music
  - Distraction
  - Guided imagery
  - Massage
- Cognitive-behavioral
- Hypnosis
- Sucrose

Pharmacological Interventions

- Topical
  - Vapo-coolant (ethyl chloride/fluromethane) transient numbness evaporative cooing - <60 sec
  - Creams- EMLA: passive diffusion thru skin surface to inhibit transmission in sensory neurons of dermis/epidermis- occlusion and time applied. Contraindicated in preterms
- Local
  - Nerve blocks
- Systemic
- Inhalational

Medication Categories

- Sedative – decrease activity, excitability, calming
- Hypnotic - induce sleep (mobility)
- Anxiolytic- decrease anxiety
- Amnestic- impair memory
- Analgesic- decrease perception of pain – alteration of mental status may occur
- Anaesthetic - A substance that causes reversible loss of sensation or loss of consciousness

Route

- IV
  - Reliable and precise for titration
  - Access for variable reactions, complications
- IM
  - Unpredictable- easy to overshoot or need additional dosing.
  - Longer to onset, often longer recovery
- Transmucosal
  - Accessible
  - Poor titration
  - Ceiling of efficacy due to variable absorption, clearance.

Benzodiazepine

- Midazolam
  - GABA agonist
  - Amnestic (antegrade & retrograde)

Advantage:

- Predictable onset
  - IV 60 seconds / IN 5-10 min
- Faster recovery, elimination half life
- Reversible – Flumazenil

Disadvantage:

- Paradoxical excitation
- Hypoventilation
- Hypotension

Indications:

- Minor procedures: IV, VCUG, pre procedural

Relative Contraindications:

- Upper airway obstruction
- Swallowing abnormalities
- Muscular disorders (hypotonia)
Delivered with Oxygen
- 30-50% concentrations - “minimal sedation”
- Higher concentration is “moderate sedation”
- Caution if combined with opioids
- Onset in minutes, effect wears off quickly, easily titratable
- Minimal CV, respiratory effect when used alone
- Return to baseline quickly

Contraindicated in increased ICP patients

Equipment/infrastructure needs

- Nitrous Oxide
- Delivered with Oxygen
- 30-50% concentrations - “minimal sedation”
- Higher concentration is “moderate sedation”
- Caution if combined with opioids
- Onset in minutes, effect wears off quickly, easily titratable
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Contraindicated in increased ICP patients

Equipment/infrastructure needs

Pentobarbitol

- Disadvantages:
  - Respiratory depression and irregularity, apnea
  - Laryngospasm
  - Hypotension
  - Myocardial depression (pulmonary edema at high doses)
  - No analgesia, might enhance pain perception
  - Paradoxical reaction
  - Clinical effects shorter than elimination
  - No reversal agent

Advantage:
- Motion Control
- Anticonvulsant effect
- Long history of use

Dexmedetomidine

- Highly selective central α2-adrenergic agonist
- Cooperative sedation - “natural” sleep simulation

- Advantage:
  - Less respiratory depression
  - IV, IN, SM, Oral
  - Advantages in autiistic children, EEG (not interfere with interpretation)

- Disadvantage:
  - Sinus and AV node effects - bradycardia
  - Cost Formulary restrictions

Etomidate

- Hypnotic preferred in ED
- GABA receptor

- Advantage:
  - Onset <1 min, duration 10-15 min
  - Can be combined with analgesics

- Disadvantage:
  - Marked hypotension, severe asthma, severe CV disease
  - Side effects: pain on injection, myoclonus, agitation

Propofol

- Anaesthetic GABA receptor Agonist

- Advantages
  - Rapid onset, quick recovery, easy titration.
  - 30-60s
  - 2-10 min duration
  - “Clear-headed” emergence
  - Dose dependent weak antiemetic, lower incidence of nausea, amnestic
    less than with benzos

- Disadvantages
  - NO ANALGESIA
  - Respiratory depression / reduced airway tone Dose dependent decrease in ventilatory drive and tidal volume
  - Hypotension, hypoxemia (up to 30-
    safe reduction from baseline)
  - IV route only! Pain on injection

Indications:
- Bolus vs Drip
- Alone for noninvasive imaging
- Combined for brief painful procedures
- Brief periods of deep sedation

Contraindications:
- Hypersensitivity to propofol or any of its constituents (soybean oil, egg lecithin)
- Preexisting airway obstruction
- Increased ICP
- Pulmonary hypertension
- Hypoventilation/hypocarbia
**Opioid Agonists**

- **Bind Mu receptors**
  - **Fentanyl**
    - **Advantage**: Fast onset (4 to 5 min), duration 20-30 min
    - Resp depression is dose dependent
    - Less histamine and CV impact
    - Synergistic with Propofol, Midazolam
    - Reversible
  - **Disadvantage**
    - Facial pruritus, rarely hypotension
    - NV
    - Muscular rigidity - with high doses or rapid injection - “Steel chest” or “rigid chest” phenotype
- **Morphine**
  - Slower onset (5-10 min) and prolonged effect (3-4 hrs)

**Ketamine**

- Lipid-soluble; crosses BBB quickly
- NMDA receptor antagonist - leading to dissociation between thalamoencephalocortical system & limbic system
  - Low dose - anxiolysis/analgesia
  - High dose - dissociative sedation
  - Advantages
    - Maintain respiratory and airway reflexes - preservation of respiratory efforts and of muscular tone of tongue and pharynx, laryngeal reflexes
    - Increase HR, BP, CO
    - Bronchodilatation, direct smooth muscle dilatation
    - IV, Oral/IM, IN
    - VERY SAFE EFFICACIOUS RECORD

**Disadvantages**

- +/- ICP concerns - globe injury
- Visual hallucinations, emergence phenomena/vegetation
- Salivation
- Laryngospasm - VNS
- Emetis up to 10-25%
- Ketamine should be avoided in infant ≤ 4 month
- Muscle tone uninhibited (purposeful movements may occur)

**Relative contraindications**

- Head injury
- Airway abnormalities
- Procedures where posterior pharynx will be stimulated
- Glaucoma, acute globe injury
- Psychosis

**Ketamine**

- Anxiolysis
- Analgesia

**Naloxone** - opiate antagonist (mu, kappa, sigma)

- Lipid soluble, crosses blood brain
- IV, IM, SL, SC
- 1 hour duration

**Reversal**

- **Flumazenil** - antagonist benzodiazepines
  - lasts 1 hour

**Adverse Outcomes**

- Lack of monitoring
- Lack of titration
- Impatience
- Unfamiliarity with pediatric dosing
- Multiple medications
- Failure to rescue (recognize)
- Failure or delay in detecting apnea

**POST SEDATION**
**Post Procedure**

- **Immediate**
  - Respiratory impairment
  - Removal of noxious stimulus
- **Early**
  - Agitation, dysphoria, delirium
  - Laryngospasm
- **Late**
  - Somnolence
  - Motor impairment
  - Vomiting
  - Hours to Days: inattention, poor sleep, poor memory

**Recovery & Discharge**

Score > 8

30 min

**Case 1**

- 2 year old with 5% BSA burns 5 days ago to hands, torso and back requiring burn dressing change after discharge.

**Case 2**

- 7 yo with neutropenia, anemia and stable vital signs – needs LP and Bone Marrow aspirate and biopsy for evaluation. Previously healthy.

**Specific instructions should be given to the family of the child**

- Monitor for persistent sedation or adverse events
- Phone number for contact in event of concerns
- Information about the drugs received

**Post-sedation instructions should be age based.**

- Return to activity/school
- Sleep disruption
- Emesis

**Considerations**

- Painful procedure – does not require immobilization but given age may need more hypnosis
- Likely to need repeat procedures
- Midazolam
- Ketamine
Case 3

- 8 yo child with history of developmental delays and absence seizures needs an MRI of the brain.
- While getting the history you learn that he snores so loudly mom makes him sleep on a cot in her room

**Controversies**

- **Providers**
  - Data confirms safety of non anaesthesia providers
- **Contraindications**
  - Obesity
  - OSA
  - Term/Preterm
- **Long Term implications**

Obstructive Sleep Apnea

- **Sleep Study to determine dx, severity**
  - Adena tonsillar hypertrophy vs obesity
- **In cases with symptoms but no study**
  - Such pts should be treated as moderate unless clearly more severe symptoms
  - OSA Scoring to define perioperative risk – based on severity, invasiveness of procedure and requirement for opioids
  - General Anesthesia with secured airway is preferred practice for any patient with moderate or worse OSA undergoing procedure involving upper airway or if any possibility of deep sedation
    - Avoid spine positioning step in recovery
    - Discharge criteria may be different

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### Considerations

- **ASA**
- Prior history
- Current vitals and labs

- EMLA to areas
- Anxiolysis in anticipation
- Ketamine / Propofol vs Propofol / Fentanyl

### History

- Has he been sedated before – how did it go?
- Clear of contraindications

### Plan

- Consider intranasal versed/ oral if time prem ed to IV
- Dexmedetomadine vs Propofol drips

http://www.pedsedation.org/
**Obesity**

- Obesity defined as BMI 95th percentile for age and gender.
- Sedation-related outcomes, adverse events, and therapeutic interventions were compared between obese and nonobese patients.
  - 25899 control (median wt 25kg), 5253 obese (median wt 34kg)
  - Median ages: 72 months in both groups.
- Obesity-independent risk factors for adverse respiratory events during procedural sedation & associated with an increased frequency of airway interventions.
- Suggesting that additional vigilance and expertise are needed when sedating these patients.

*Paediatr Anaesth. 2015 Jul;25(7):689-97*

**Long Term Outcomes**

- **2014 FDA “Drug Safety Communication”**
  - Warning that general anesthesia and sedation drugs used in children less than 3 years of age or in pregnant women in their third trimester who were undergoing anesthesia for more than 5 hours or repeated use of anesthetics “may affect the development of children’s brains.”
  - Common general anesthetics and sedative agents that bind to GABA or NMDA receptors, including all anesthetic gases such as sevoflurane, and the intravenous agents propofol, ketamine, barbiturates, and benzodiazepines.

**NPO**

  - 393,421 procedural sedation/anesthesia encounters - 25,410 (6.5%) were not NPO
  - 0 deaths, 30 deaths, and 75 major complications
- Aspiration
  - NPO (5.92 events per 10,000) vs.
  - Non-NPO (12.94 events per 10,000)
  - OR (95% CI): 1.39 (95% CI: 1.07 to 1.80).
  - Major complications
  - NPO (25.57 events per 10,000) vs.
  - Non-NPO (34.39 events per 10,000)
  - OR (95% CI): 1.84 (95% CI: 1.51 to 2.23).
- Multivariate adjustment did not appreciably impact the effect of NPO status.

**CONCLUSIONS:**

The analysis suggests that aspiration is uncommon. NPO status for liquids and solids is not an independent predictor of major complications.

**Long Term Outcomes**

- **(GAS) study - General Anesthesia vs. Spinal Anesthesia**
- **(PANDA) study - Pediatric Anesthesia and Neurodevelopment Assessment**
  - involved formal neurodevelopmental testing
  - brief, single exposure to general anesthesia was not associated with poorer neurodevelopmental outcomes.

**Preterm**

- Prospective observational study
  - Children <23yo. receiving sedation/anesthesia for diagnostic and/or therapeutic procedures outside of the operating room
  - 57,127 patients
- Patients born preterm are nearly twice as likely to develop sedation/anesthesia adverse events, and this risk continues up to 23 years of age.
- Recommend obtaining birth history during the formulation of an anesthetic/sedation plan, with heightened awareness that preterm and former preterm children may be at increased risk.
OUR EXPERIENCE - PEDI PROS

Pedi Pros Sedation Service

- Founded 2014
  - 713-7183
  - PEDI.Sedation@uhs-sa.com
- Sedation Request Order set
  - Includes screening questionnaire
  - Must be cleared by a member of sedation team
  - Scope of Practice
- Surveillance Data

Case 3

- 8yo child with history of developmental delays and absence seizures needs an MRI of the brain.
- While getting the history, it is noted that he snores so loudly that妈妈 makes him sleep on a cot in her room.

Recommended Discharge Criteria

- Stable and satisfactory CV and airway status
- Easily arousable and sustained
- Talk if age appropriate
- Sit up alone if age appropriate
- Baseline responsiveness in preverbal child
- Hydration adequate

Summary

- Pre Sedation Assessment
  - SAFE patient
  - SAFE procedure
  - SAFE location
  - ALTERNATIVES?
- Intra Sedation
  - Monitoring
  - Skills
  - Choosing the right drug
- Post Sedation
  - Recovery time and criteria
  - Discharge education
We are such stuff as dreams are made on; and our little life is rounded with a sleep.

William Shakespeare