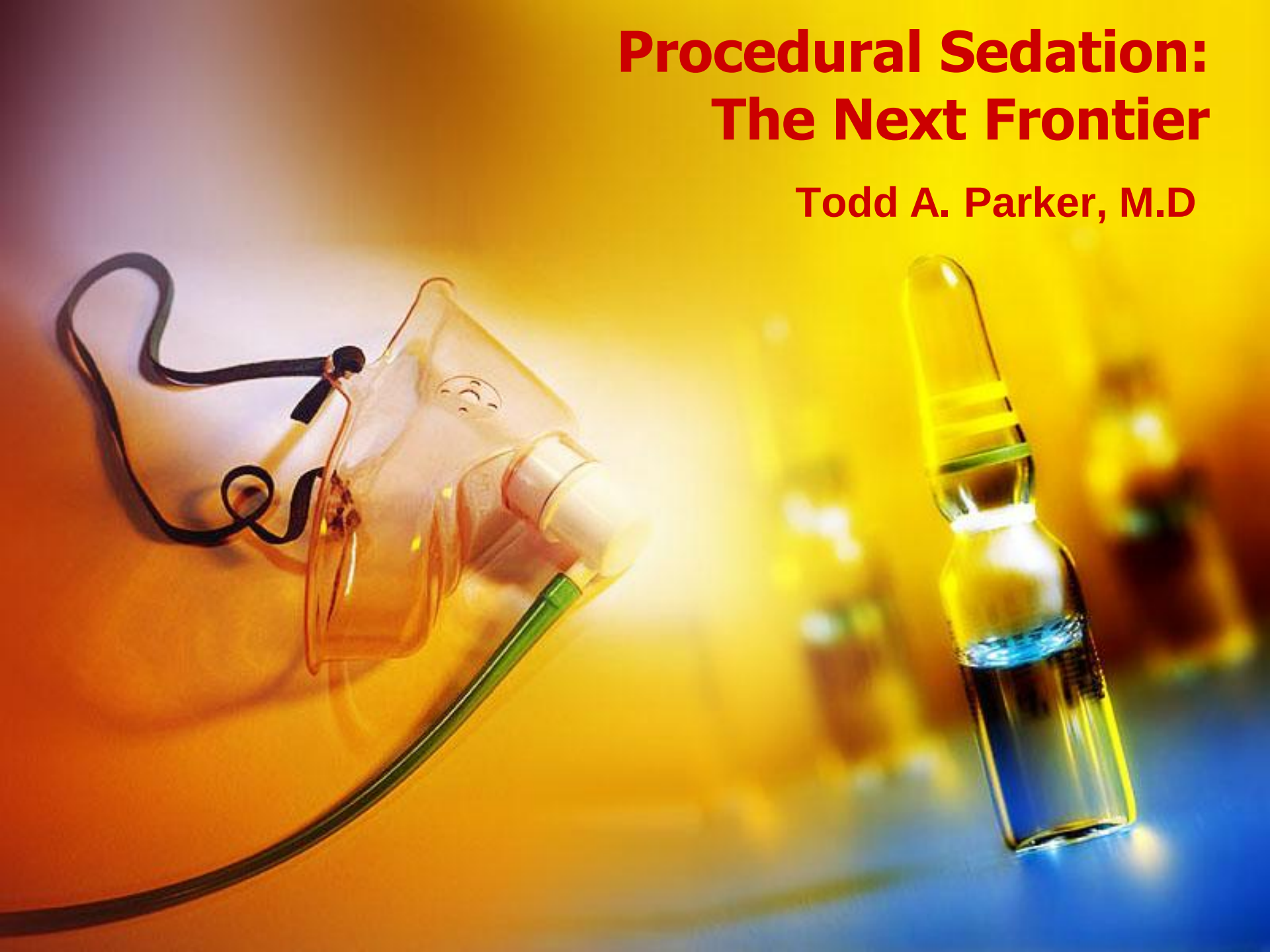
Procedural Sedation: The Next Frontier

Todd A. Parker, M.D



Procedural Sedation

- Procedural Sedation and Analgesia (PSA) in the ED is a Core Competency of ED physicians
  - But we're still not very knowledgeable!
- Part 1: Overview of current PSA practice
- Goals today (Part 2):
  - **Review key points from Pt 1**
  - **Monitoring**
  - **The Quebec Guidelines**
  - **New drugs and combos of old drugs**
  - **New methods of PSA**
  - **Recommendations**

Sedation Continuum

	Anxiolysis/ Min Sedation	Moderate Sedation	Deep Sedation	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful to verbal/ light tactile stimulation	Purposeful to repeated / deep stimulation	No response to painful stimulation
Airway	Maintained	Maintained	May need intervention	Usually needs intervention
Ventilation	Normal	Adequate	May need assistance	Usually needs assistance
Cardio-vascular Function	Normal	Maintained	Usually Maintained	May be impaired

ACEP Recommendations

- Strength of Evidence – Classes
  - Class I – Interventional Trials, prospective studies
  - Class II – Observational, retrospective, case-controlled studies
  - Class III – Observational reports, Case series, etc

- Level of Recommendations
  - Level A: Generally accepted principles based on Class I or overwhelming Class II evidence
  - Level B: Recommendations with moderate clinical certainty based on Class II or strong Class III evidence
  - Level C: Other strategies based on inconclusive/conflicting evidence, required panel consensus

Pre-sedation Assessment

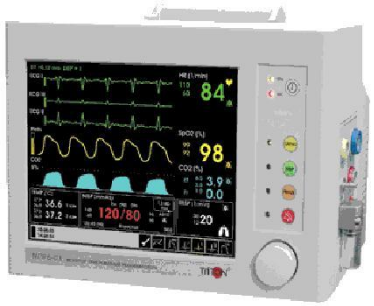
- Who should we sedate?
  - ASA I – Normal healthy patient
  - ASA II – Mild systemic disease
  - ASA III – Severe systemic disease
  - ASA IV – Severe disease / constant life threat
  - ASA V – Moribund, not expected to survive

ACEP-P Recommendations

- Fasting
  - Most data from Gen Anesthesia
    - Not manipulating airway
    - Higher ASA level
    - No inhalationals
  - Recent food intake not contraindication to PSA
    - Weigh urgency of procedure against intake
    - Level C (adults) / Level B (Peds)
    - NMCP – ASA guidelines (unless urgency dictates)
- Monitoring (Level C)
  - Continuous monitoring by a qualified support person
  - Sedation supervised by EP or other trained provider
  - Able to manage complications from *next highest* level
  - NMCP
    - ACLS and PALS certified!
    - Must take PSA online course

Monitoring Respiratory Status

- Monitoring
  - Pulse Ox if at risk of hypoxemia (Level B)
  - Supplemental O2 undetermined benefit, but helps pt tolerate brief apnea
  - Capnography likely beneficial (Level C)



- $EtCO_2$ best predictor of respiratory depression
  - Faster/more reliable than pulse ox

- $EtCO_2$ monitoring (increase of 10 or $EtCO_2$ < 30 or >50) predicted all cases of resp depression

Significance of EtCO2 Values

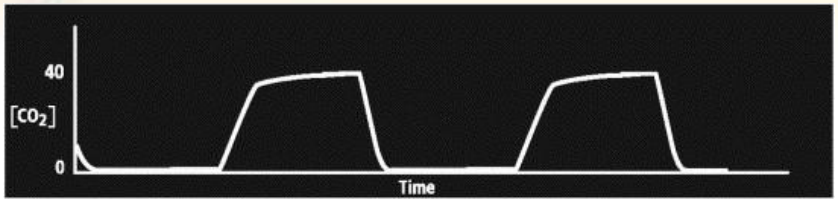
- Physiology
  - Change in 10, > 50 obvious…But <30?
  - Bradypneic vs. Hypopneic hypoventilation
    - Bradypneic: RR slow more than TV increases (Opioids)
    - Hypopneic: TV decreases more than RR slows (Sedatives)

Hypoventilation Type	Resp Rate	Tidal Volume	Tidal Vol/ Dead Space	EtCO2	PaCO2
Bradypneic	↓↓↓	↓	Slight ↓	↑	↑
Hypopneic	↓	↓↓↓	↑↑↑	↓ to no change	↑

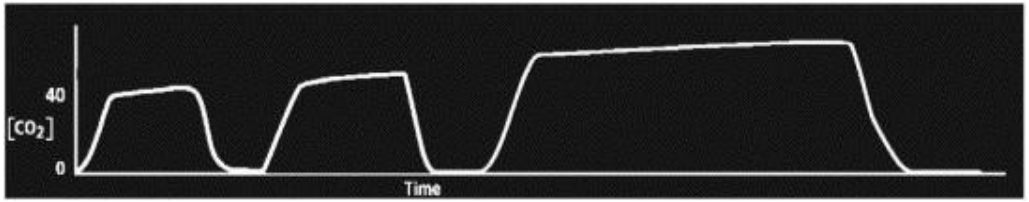
  - Therefore, Hypopneic hypoventilation results in decreased or unchanged EtCO2 but increased PaCO2

Significance of EtCO2 Values

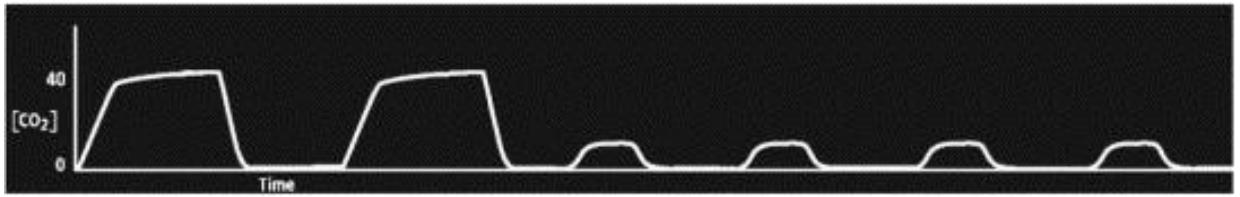
- Normal capnography



- Bradypneic Hypoventilation



- Hypopneic Hypoventilation



- Waveform just as important as value!
  - Recognizing waveform change may provide warning

"The Quebec Guidelines"

- Difficulty reconciling existing studies
  - Wide disparity in terminology and definitions
  - Leads to wide disparity in reported "events"

- Two large trials
  - PERC (Pediatric Emergency Research Canada)
  - PECARN (Pediatric Emergency Care Applied Research Network)

- Met to standardize terminology, definitions
  - Attempt to make future research comparable
  - Bhatt, M et al. Consensus-Based Recommendations for Standardizing Terminology and Reporting Adverse Events for ED PSA in Children, Pending Publication

“The Quebec Guidelines”

- Intervention oriented
  - i.e. not an “event” unless intervention required
  - Still some subjectivity, but essentially removes variability
  - Intervention may be just airway repositioning
- Will decrease reporting of “events”
  - Only clinically significant
- Differentiate between physiologic processes and anatomic processes
  - i.e. laryngospasm vs apnea

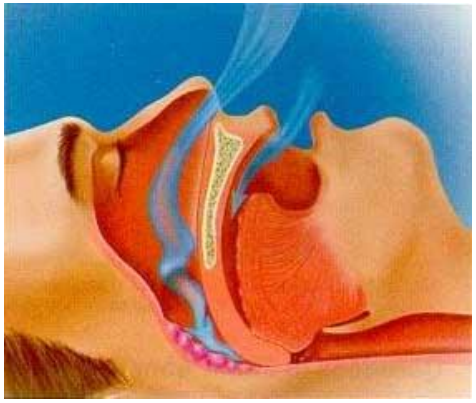
"The Quebec Guidelines" – New Definitions

1. Efficacy of Sedation
   a. No sedation related adverse event
      i. Abandonment of procedure
      ii. Permanent complication
      iii. Unplanned admission
   b. Pt does not have unpleasant recall of event
   c. Pt did not actively resist or require restraint

2. Oxygen Desaturation
   a. Any desaturation requiring:
      i. Vigorous tactile stimulation
      ii. Airway repositioning or suctioning
      iii. Supplemental O2
      iv. Oral or Nasal Airway
      v. PPV or Assisted BVM Ventilation
      vi. Intubation
   b. Not just < 90% - Can be any desaturation

"The Quebec Guidelines" – Adverse Events

3. Central Apnea – ventilatory cessation / pause requiring:
   a. Vigorous tactile stimulation
   b. Assisted BVM Ventilation
   c. Intubation
   d. Administration of Reversal Agent



4. Partial / complete airway obstruction
   a. Stridor, snoring, retractions (or absence of) requiring:
      i. Airway repositioning or suctioning
      ii. Oral or Nasal Airway
      iii. PPV or Assisted BVM Ventilation
      iv. Intubation
      v. Administration of additional sedation/neuromuscular blockers
   b. Note laryngospasm is separate event

"The Quebec Guidelines" – Adverse Events

5. Suspicion or Confirmation of Aspiration
   a. Suspicion by clinical signs (cough, crackles, wheeze, etc)
   b. Confirmation by laryngoscopy / bronchoscopy

6. Retching / Vomiting – during sedation or recovery

7. Bradycardia and Hypotension
   a. Only if an intervention is required (i.e. IVF, Meds, Airway maneuvers, etc)

8. Excitatory Movements – only if requires intervention or interferes with procedure completion
   a. Myoclonus – brief muscle contraction with body part movement (Hiccups)
   b. Muscle Rigidity – Stiffening in extension

9. Permanent complication or Death

The Quebec Guidelines

- Created for Peds EM - apply to all
- Why discuss?
  - Ensures understanding what you are looking for
  - Helps clarify what is “adverse” and what is not
  - Enhance our understanding of sedation
  - Provide uniformity and speak intelligently

ACEP-P Recommendations - Medications

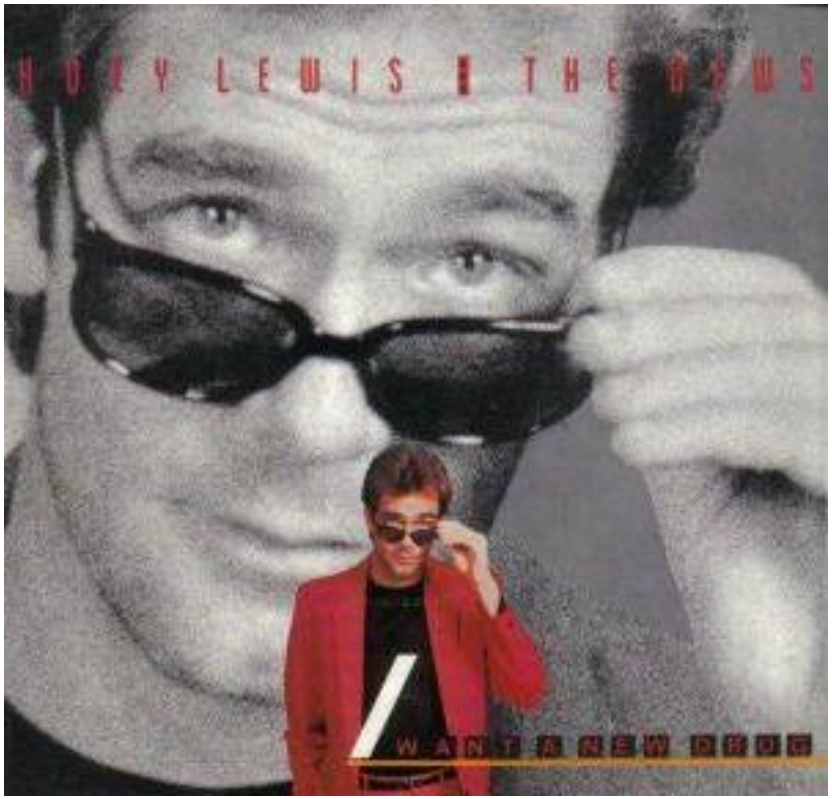
- Medications:
  - Fentanyl analgesic of choice (no amnesia)
  - Morphine / Dilaudid longer acting – more side effects
  - IV Versed – best benzo for amnesia/anxiolysis
    - Fentanyl / Versed Level B Recommendation
    - In combo, give opioid first

ACEP-P Recommendations - Medications

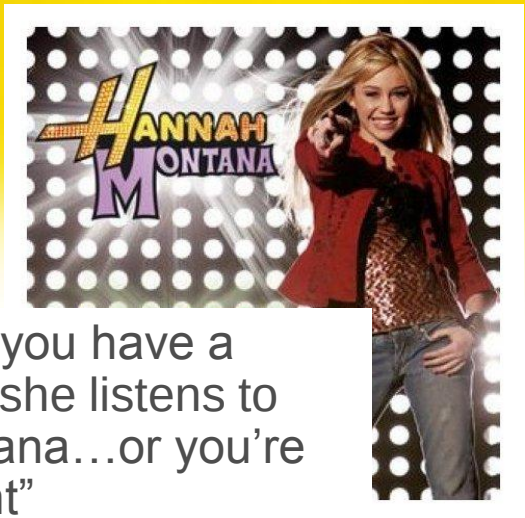
- Medications:
  - Ketamine – sedation, amnesia, analgesia
    - Emergence / pukogenic / hypersalivation / tachycardia
    - Level A Recommendation in children
  - Etomidate (Level C)
    - Amnesia and sedation – no analgesia
    - Cardiac stable but myoclonus
  - Propofol (Level B)
    - Sedative – hypnotic, no analgesia
    - May cause hypotension
    - Highest procedure success rate!

“I Want a New Drug”

- What could we be doing differently?
- What is out there now?
- What is coming?



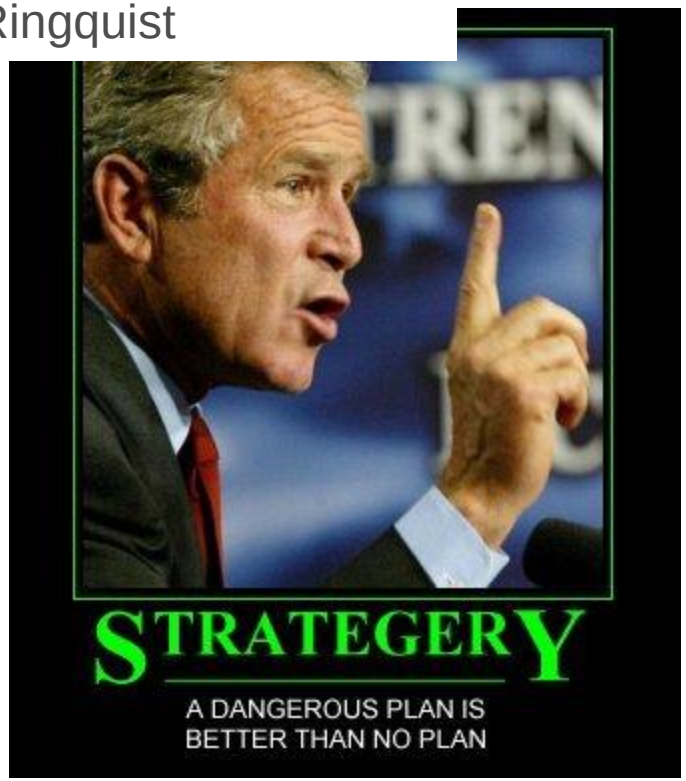
Ketofol



"It's not gay if you have a daughter and she listens to Hannah Montana…or you're on deployment"

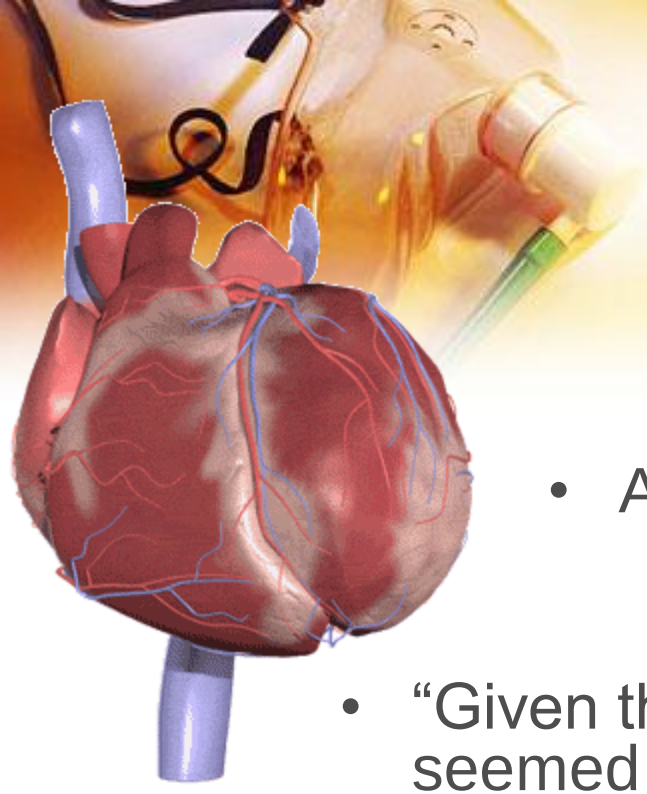
- John Ringquist

- "Best of Both Worlds"
  - Ketamine
    - Analgesia
    - Counters cardioresp effects
  - Propofol
    - Blunts psychomemetric effects
    - Minimizes nauseant effects
    - Blunts hypertension



Ketofol

- **Willman, E. et al. A prospective evaluation of "Ketofol" for PSA in the ED, Jan 2007**
  - Dosed in 1:1 ratio (10mg/ml of each)
  - Median dose of 0.75mg/kg of each (EP discretion)
  - 114 pts – median age 36 (25 < 16 years old)
  - 110 completed without additional meds (113/114 total successful)
  - 12 "adverse events"
    - By Quebec Guidelines – only 7
      - Four airway repositions
      - Two vigorous tactile stimulations
      - One BVM x 2 minutes
  - One emergence, treated successfully with midazolam
  - No hypotension, no vomiting
  - Median recovery time 15 minutes
  - Median physician, nurse, and pt satisfaction scores 10 (out of 10)



Ketofol

- Average pulse +6, average MAP +13.2

- “Given that the hemodynamic effects of ketamine seemed to overbalance those of propofol, a study using less ketamine would help clarify the optimal ratio”

- Anesthesia protocol
  - 1:5 ratio (100mg ketamine:500 mg propofol)
  - Dose based on propofol (0.75-1.0mg/kg, titrate)
  - All the benefits, less hemodynamic change
  - NOT prospectively validated (pilot studies, etc)

Ketofol – Why?

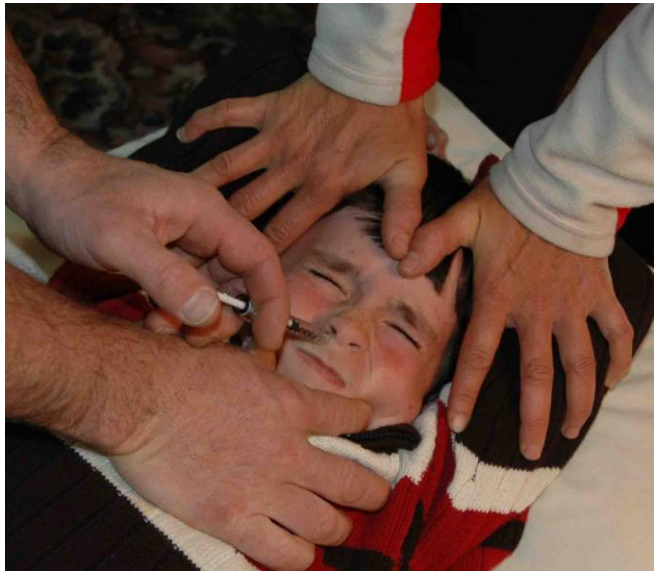
- What's the benefit?
- Needs comparison studies
- Theoretical benefit over opioid/propofol
- Ketamine alone (peds) or with benzo (adult)
  - Cardiovascular effect shouldn't be important
  - Perhaps in elderly or baseline hypertensive pts
  - What about anti-emetic effect of propofol?

Ondansetron with Ketamine

- Langston, W. et al. Effect of Ondansetron on the Incidence of Vomiting Associated with Ketamine Sedation in Children, July 2008
  - 255 children receiving IV ketamine for PSA
  - IV ondansetron 0.15mg/kg (max 4mg) vs placebo
  - Vomiting during and up to 12 hours post sedation
  - During procedure: 6/128 vs. 16/127 with placebo
    - NNT 13
  - During or after procedure: 10/128 vs. 24/127
    - NNT 9
  - No difference in ED LOS or parental satisfaction

Ketamine – IM vs IV

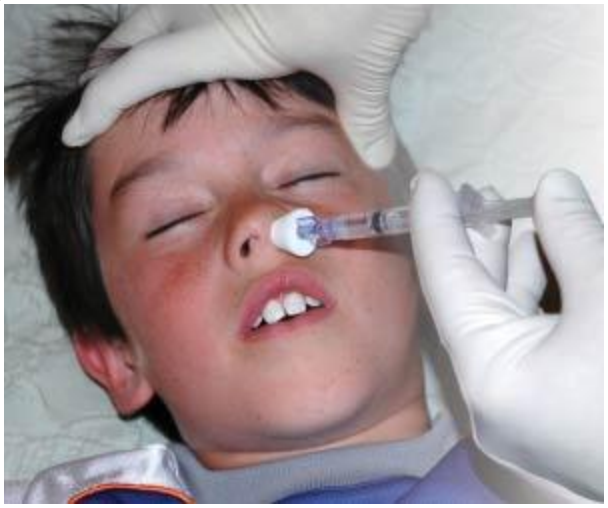
- Three key articles (Annals 2006, AEM 2009)
  - IV
    - Recovery faster
    - Enables repeated dosing
    - Optimal if IV in place / longer procedure
  - IM
    - Longer recovery, BUT…
    - No difference in ED stay
    - Optimal for shorter procedures



  - Bottom line:
    - No reported cases of adverse outcomes from not having IV
    - No difference in total ED stay if starting from scratch
    - If nurses proficient, or already have IV in place, IV better

Dexmedetomidine

- Alpha-2 agonist (8x > clonidine)
  - Sedation and analgesia
- Dose 1mcg/kg loading dose, repeat does 0.2-0.5 mcg/kg as needed
- Predictable sedation with no respiratory compromise
- Poorly studied for PSA (Mostly ICU)
  - Increase in “rescue” sedation
  - Bradycardia/hypertension common
  - Longer recovery
  - So why consider?
- Intranasal/Buccal administration
  - Absorption 82-91% vs IV



On the horizon….

- Fospropofol (Phase 3 trials)
  - Water soluble prodrug of propofol
  - More easily titrated than propofol
  - Harder to achieve gen anesthesia
  - Fewer adverse events

- Remifentanyl (same class as fentanyl)
  - Pilot studies only
  - Excellent hemodynamic profile
  - Rapid onset/short duration of action (6-8 mins)
  - Dense analgesia with procedural recall
    - No “unpleasant” recall
  - One study, one episode of BVM

Oral Sucrose

- Level **A** Recommendations
  - Oral sucrose can be used to reduce distress due to minor painful procedures in neonates (<28 days old)

- Level **B** Recommendations
  - Effective dose 2 ml of 24% or 50% sucrose
  - Better effectiveness with pacifier
  - Safe for full term neonates and infants

- Level **C** Recommendations
  - Less effective in infants between 1-6 months
  - Higher effective doses in these infants (up to 2ml 75% sucrose)
  - Should be given 2 minutes prior to procedure
  - Safe to give to low birth weight preterm neonates

Procedural Sedation Dosing

- How do we know how much to give?

- What are the goals of PSA?
  - Adequate sedation to facilitate procedure
  - Minimal recall (at least unpleasant)
  - Adequate analgesia
  - No adverse events or outcomes

- Similar problems in post-surgical pain mgt
  - Solution?

Patient Controlled Sedation (PCS)

- Primarily studied using propofol
  - Also remifentanil

- PCS – initiated and maintained by patient

vs

- PMS – initiated by provider/maintained by pt

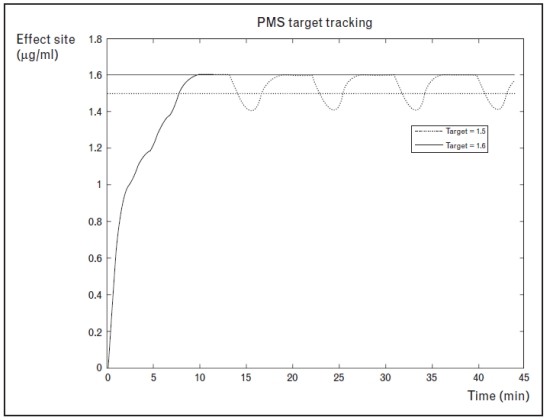
- Generally “Zero Lockout”
  - Quantity controlled, rate self-limiting
  - 2-3 ml/min (20-30mg/min for propofol)
  - Boluses of 0.25mg/kg

Patient Controlled Sedation (PCS)

- Results:
  - Effective sedation
  - Higher patient recall but equal pt satisfaction
  - Fewer adverse events
  - Lower peak plasma concentrations

- Thoughts:
  - This is likely coming
  - Technology catching up
  - Great choice for some pts
    - “Control” issue
  - Probably safer with fewer risks

Figure 2 The figure shows the functioning of patient-maintained sedation



Other options? (Ripe for Research!!)

- Regional anesthesia

- New Delivery systems
  - Intranasal
  - Buccal
  - Topical anesthesia

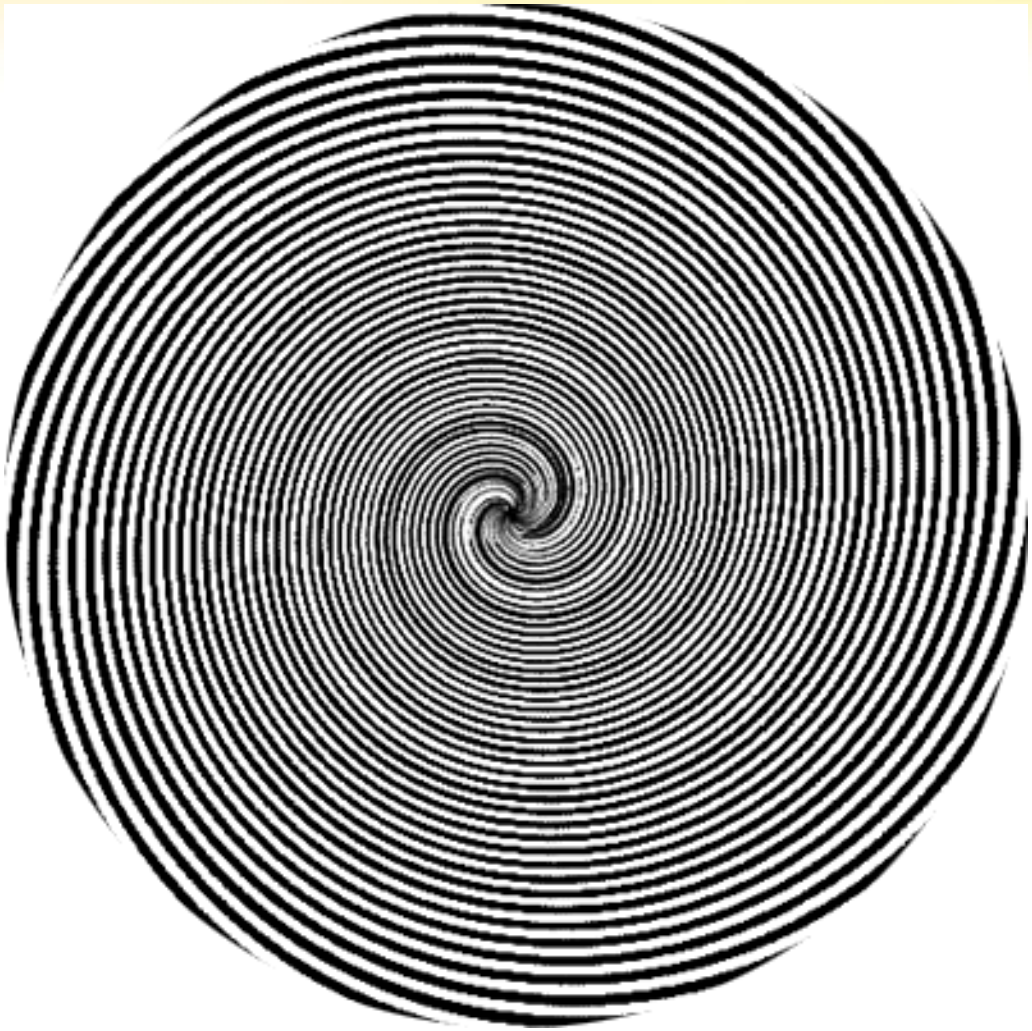
- Integrated multiparameter oxygenation/ ventilation systems with PCS

Other options? (Ripe for Research!!)

- New agents
  - Dexmedetomidine
  - Alfentanil
  - Remifentanil
- Post-discharge studies
- Psychological techniques
  - Cooperative child = less sedation
  - Child life specialists

There's always other options…

Hypnotist has surgery in a trance without anaesthetic



QUESTIONS?

New Procedural Consent Form

OF 522 OVPT #110
(REV 1/2009)
MEDICAL RECORD

CONSENT FOR PERFORMANCE OF OPERATIONS AND OTHER PROCEDURES AND / OR BLOOD TRANSFUSION

A. IDENTIFICATION

DESCRIPTION	SIDE (Mark One)	
	☐ Right	☐ Bilateral
	☐ Left	☐ Not Applicable

B. STATEMENT OF REQUEST:

2. The nature and purpose of the operation or procedure, possible alternative methods of treatment, the risks involved, and the possibility of complications have been fully explained to me. I acknowledge that no guarantees have been made to me concerning the results of the operation or procedure. I understand the nature of the operation or procedure to be (describe operation or procedure in laymen's language)

which is to be performed by or under the direction of Dr.

3. I request the performance of the above-named operation or procedure and of such additional operations or procedures as are found to be necessary or desirable, in the judgement of the professional staff of the below-named medical facility, during the course of the above-named operation or procedure

4. I request the administration of such anesthesia as may be considered or advisable in the judgement of the professional staff of the below-named medical facility

5. Exceptions to surgery or anesthesia, if any are:

(If "none", so state)

6. I request the disposal by authorities of the below-named medical facility of any tissue or parts which it may be necessary to remove.

7. I understand that photographs and movies may be taken of this operation, and that they may be viewed by various personnel undergoing training or indoctrination at this or other facilities. I consent to the taking of such pictures and observation of the operation by authorized personnel, subject to the following conditions

a. The name of the patient and his/her family is not used to identify said pictures.
b. Said pictures be used only for purposes of medical/dental study or research.

8. **BLOOD PRODUCTS**

During your procedure the likelihood of using a blood product is ☐ Yes ☐ No ☐ N/A

While many precautions are taken to make blood products safe, there are some known risks, including but not limited to those outlined below:

RISKS	INCIDENCE
Hepatitis B	1:220,000
Hepatitis C	1:1,800,000
HIV	1:2,300,000
HTLV (Human T-Cell Lymphotropic Virus)	1:2,993,000
West Nile Virus (WNV)	Rare despite WNV-NAT testing
TRALI (Transfusion related acute lung injury)	up to 1:5,000
Hemolytic reaction due to ABO / RH mismatch	up to 1:6000
Sepsis due to bacterial contamination	1:75,000 platelets 1:500 red blood cells
Delayed hemolytic reaction	up to 1:2,500
Alloimmunization (HLA antigens)	1:10
Alloimmunization (red blood cell antigens)	1:100
Anaphylactic reaction	up to 1:20,000
Allergic reaction (urticarial)	3:100
Febrile, nonhemolytic reaction	up to 1:100
Circulatory (volume) overload	less than 1%
Reference: AABB Technical Manual, 16th edition, 2008	

PATIENT IDENTIFICATION (For typed or written entries, give: Name - last, first, middle, ID no. DOB (SSN or other); hospital or medical facility)

REGISTER NO.	WARD NO.

CONSENT FOR THE PERFORMANCE OF OPERATIONS AND OTHER PROCEDURES AND / OR BLOOD TRANSFUSION
Medical Record
OPTIONAL FORM 522 (REV 8/2003)
Prescribed by GSA/ICMR FMR (41 CFR) 102-194030(i)

New Informed Consent for Sedation

INFORMED CONSENT FOR SEDATION

1. **Information.** I understand that there are several ways to provide sedation, which is a type of artificial sleepiness that occurs when drugs are given for the purpose of easing the discomfort of a procedure. Often sedation consists of local anesthetics (numbing medicines) in combination with other drugs that can produce varying levels of sleepiness to include minimal sedation (anxiolysis), moderate sedation/analgesia ("conscious sedation"), and deep sedation/ analgesia. **Regional anesthesia** (nerve blocks, epidural, spinal) refers to the injection of a local anesthetic near majornerves to "numb" specific areas of the body and can be combined with the levels of sedation mentioned above. The possibility of major nerve damage is no different than that following general anesthesia. **General anesthesia** is a technique using medications given through a vein and gases to keep you deeply asleep. This will often be combined with medications to relax muscles and methods to provide adequate oxygen. Some operations can only be performed under General Anesthesia.
   The current plan for my sedation is for _____
2. **Complications and Risks.** I understand that in addition to the risks of surgery and sedation of any type carries its own risks. Complications that may arise include, but are not limited to the following: nausea/vomiting, headache, back pain, damage to blood vessels, teeth, eyes, nose and skin, sore throat, vocal cord injury, windpipe injury, urinary retention, changes in smell and taste, reactions to drugs, failure to recover from sedation, respiratory problems, drug reaction, infection, nerve injury, paralysis, kidney damage, brain damage, death, and injury to an unborn fetus. I understand I should not engage in activities requiring unimpaired physical and mental ability (e.g. driving) for 24 hours after completion of the procedure.
3. **Understanding.** I understand that my sedation will be given by or under the supervision of someone who is trained and permitted to provide sedation. If this is a teaching facility, I understand that other personnel such as residents, interns, medical students, and student nurse anesthetists may be involved in my sedation care and will be supervised by a fully trained staff member. I understand that during my procedure additional monitoring may be necessary, which includes but is not limited to, arterial lines (small plastic needles placed in an artery to measure blood pressure) and central venous catheterizations (special type of plastic needle placed in a large vein).
4. **Consent.** I have been given an explanation of the proposed sedation plan, and have been given the chance to ask questions about it as well as other options. The risks and hazards have been explained to me, and I feel I have enough information to give this consent. I consent to have sedation provided by appropriate medical personnel. I understand that during the administration of my sedation, conditions may arise which require change in the sedation plan, up to and including a general anesthetic. I therefore consent to procedures that good medical judgment considers wise and reasonable if it is medically not a good idea to delay the procedure until after my further written consent has been obtained.

DO NOT SIGN THIS FORM UNLESS YOU HAVE READ IT, UNDERSTAND IT, AND AGREE WITH WHAT IT SAYS.

Patient Name or Name of person authorized to consent for patient	Signature	Date/Time
Witness	Signature	Date/Time
Counseling Physician / CRNA / Dentist	Signature	Date/Time
Patient Identification *(For typed or written entries, give: Name - last, first, middle; ID No or SSN; Sex; DOB; Rank/Grade.)*	Hospital or Medical Facility	
	Sponsor's Name	
	SSN/ID No.	

NAVMED 6710/12 (11-2007)

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