PROCEDURAL SEDATION

How deep are you willing to go?

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Coastal Emergency Medicine Conference
June 2013

YOU CAN'T USE KETAMINE AND PROPOFOL IN THE EMERGENCY DEPARTMENT!!!!

“Anesthesia exists along a continuum. For some medications there is no bright line that distinguishes when their pharmacological properties bring about the physiologic transition from the analgesic to the anesthetic effects. Furthermore, each individual patient may respond differently to different types of medications”

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group, January 14, 2011

ASA DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA

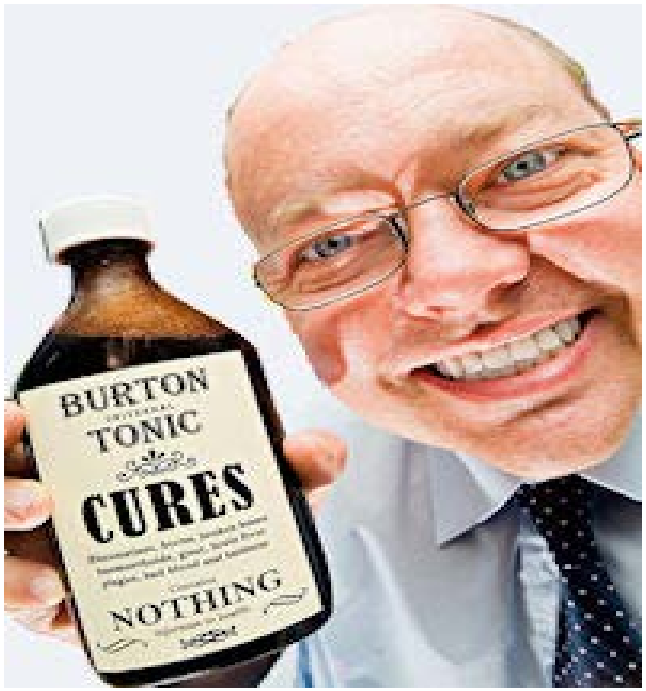
Continuum of Depth of Sedation

	Minimal Sedation (anxiolysis)	Moderate Sedation/ Analgesia	Deep Sedation/ Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful response to speech or touch	Purposeful response to repeated or painful stimulation	No response, even to pain
Airway	Unaffected	Remains open	May need help to maintain airway	Often needs help to maintain airway
Breathing	Unaffected	Adequate	May not be adequate	Often require ventilatory support
Heart Function	Unaffected	Usually maintained	Usually maintained	May be impaired

NITROUS OXIDE

Nitrous Oxide

- **char·la·tan**
- [shahr-luh-tn]
- noun - a person who pretends or claims to have more knowledge or skill than he or she possesses; quack.



Nitrous oxide

- N_2O used for decades in pediatric dentistry
- N_2O used widely in Australia and New Zealand for ED procedural sedation
- Newer portable units with scavenging system are making this an attractive sedation adjunct in US Emergency Departments

Nitrous Oxide – Methods of Delivery

Nitrous Oxide

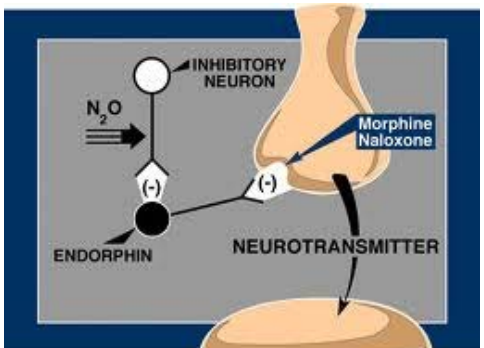
- Nitrous Oxide is an odorless, colorless gas
- Nitrous Oxide is used as a mixture of nitrous oxide AND oxygen
- It is ALWAYS delivered with oxygen
- Nitrous oxide is not metabolized
- It is excreted unchanged by exhalation via the lungs

Nitrous oxide

- When nitrous oxide is inhaled, it is absorbed by the body and has a calming and analgesic effect
- Onset is 2-3 minutes
- Duration is about 3-5 minutes
- CNS depressant
- Acts on Opioid receptors

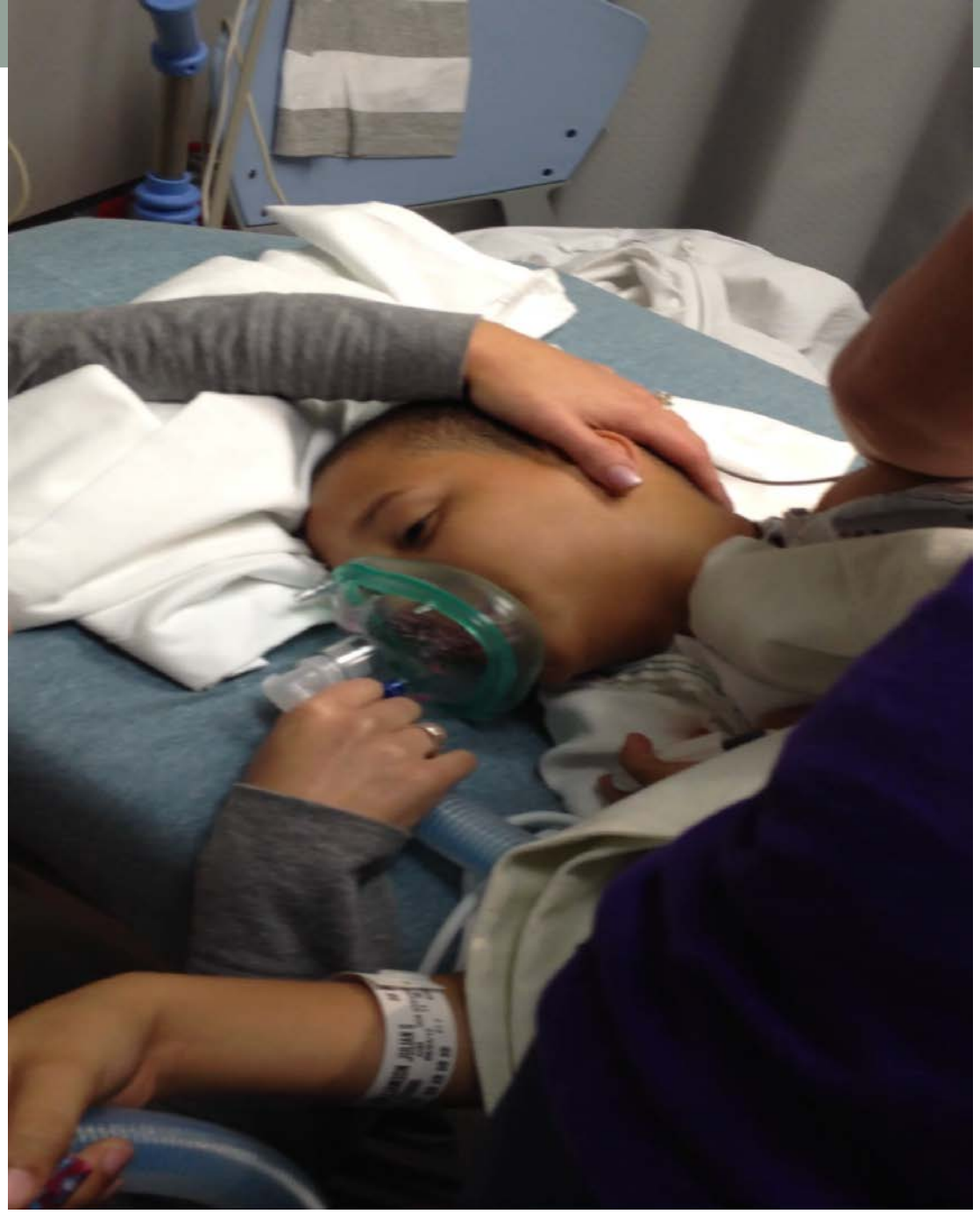
Nitrous oxide

- Gas exchange occurs across the alveolus
- **When nitrous is inhaled it moves from the alveolus (high partial pressure) to the capillary (low partial pressure) until equilibrium is reached**
- Nitrous carried to the brain where it acts on opioid receptors
- **When nitrous flow is terminated, partial pressure of nitrous increases in the blood, then it moves down concentration gradient back into the lungs and is excreted**



Nitrous Oxide

- Very few side effects
- CV – decrease in pulse and BP due to relaxation
- Nitrous oxide “expands” - avoid in use in patients with PTX or SBO



KETAMINE

Why is it different???

Ketamine

- Dissociative anesthetic
- “dissociates” CNS from outside stimuli
- Trancelike state of “sensory isolation”
- Does NOT exhibit dose response continuum like other sedatives (only give repeated doses to lengthen the time of dissociation)
- Maintain protective reflexes
- Dissociative threshold reliably reached at dose of 1-1.5mg/kg IV or 3-4mg/kg IM

ASA DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA

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Heart Function	Unaffected	Usually maintained	Usually maintained	May be impaired

Ketamine

- Explain side effects to families to ease anxiety
  - Tears , hypersalivation
  - Mild elevations in HR and BP
  - Histamine reaction
  - Muscle twitching
  - Emergence reaction
  - Vomiting

2011 ACEP Ketamine Guidelines

Clinical Practice Guideline for Emergency Department Ketamine Dissociative Sedation: 2011 Update

Steven M. Green, MD, Mark G. Roback, MD, Robert M. Kennedy, MD, Baruch Krauss, MD, EdM

From the Department of Emergency Medicine, Loma Linda University Medical Center and Children's Hospital, Loma Linda, CA (Green); the Department of Pediatrics, University of Minnesota, Minneapolis, MN (Roback); the Division of Emergency Medicine, St. Louis Children's Hospital, Washington University, St. Louis, MO (Kennedy); and the Division of Emergency Medicine, Children's Hospital Boston and Department of Pediatrics, Harvard Medical School, Boston, MA (Krauss).

We update an evidence-based clinical practice guideline for the administration of the dissociative agent ketamine for emergency department procedural sedation and analgesia. Substantial new research warrants revision of the widely disseminated 2004 guideline, particularly with respect to contraindications, age recommendations, potential neurotoxicity, and the role of coadministered anticholinergics and benzodiazepines. We critically discuss indications, contraindications, personnel requirements, monitoring, dosing, coadministered medications, recovery issues, and future research questions for ketamine dissociative sedation. [Ann Emerg Med. 2011;57:449-461.]

A **podcast** for this article is available at www.annemergmed.com.

0196-0644/$-see front matter

doi:10.1016/j.annemergmed.2010.11.030

INTRODUCTION

The dissociative agent ketamine has been the single most popular agent to facilitate painful emergency department (ED) procedures in children for nearly 2 decades.[1-3] Current ketamine protocols, including indications, contraindications, and dosing, are frequently based on a widely cited 2004 clinical practice guideline,[2] which in turn was an update of a 1990 protocol.[4] This latter article was cited in 1999 as an "example of compliance" by The Joint Commission.[5] The 2004 guideline, however, is now substantially out of date and in need of revision because subsequent ketamine investigations have questioned, disproved, or refined several of its assertions and recommendations. During this same period, there has also been sufficient ED research in adults to support expansion of ketamine use beyond children. In addition, animal research describing neurotoxicity with ketamine raises important new questions that must be considered and further investigated in humans.

To describe the best available evidence and perspectives about optimal dissociative sedation practice, we reviewed the newer ketamine literature and updated the 2004 clinical practice guideline.

WHY A SEPARATE CLINICAL PRACTICE GUIDELINE FOR KETAMINE?

Emergency physicians already have access to various standards,[6] policies,[7] guidelines,[8,9] and review articles[10,11] dealing with the general practice of procedural sedation and analgesia. However, ketamine displays unique features that warrant considering it separately from other sedatives.

The underlying pharmacology of ketamine is fundamentally different from that of other procedural sedation and analgesia agents. This drug exerts its effect by "disconnecting" the thalamocortical and limbic systems, effectively dissociating the central nervous system from outside stimuli (eg, pain, sight, sound). The resulting trancelike cataleptic state of "sensory isolation"[12] is characterized by potent analgesia, sedation, and amnesia while maintaining cardiovascular stability and preserving spontaneous respirations and protective airway reflexes.[4,12-16] Complete analgesia permits performance of extremely painful procedures.

Rather than displaying the dose-response continuum observed with all other procedural sedation and analgesia agents, ketamine dissociation appears at a dosing threshold of approximately 1.0 to 1.5 mg/kg intravenously (IV) or 3 to 4 mg/kg intramuscularly (IM). In smaller doses, ketamine exhibits analgesia and disorientation. Once the dissociative threshold is reached, administration of additional ketamine does not enhance or deepen sedation, as would be the case with opioids, sedative-hypnotics, or inhalational agents.[4,17] For these other agents, the more drug administered, the more the patient progresses along the sedation continuum, with increasing probability of ventilatory depression. In contrast, the quantity of ketamine administered has no clinically important effect on airway integrity and respirations within the range of clinically administered doses and using standard administration methods.[2-4,14,17-20] Accordingly, dissociative sedation can be readily achieved by administration of a single IV or IM loading dose, and the only need for titration, in contrast to other sedatives, is to maintain the dissociative state over time.

This unique mechanism of action has made it challenging to reconcile ketamine with the traditional stages of the sedation continuum.[17] Dissociated patients are unable to respond to external stimuli (including repeated or painful stimulation), and

2011 Ketamine Clinical Practice Guidelines

Absolute Contraindications

- Age < 3 months
  - Infant specific differences in airway anatomy, reactivity and laryngeal excitability
- Known or suspected schizophrenia
  - Exacerbates schizophrenia

2011 Ketamine Clinical Practice Guidelines Relative Contraindications

- Age
  - Safe for use in 3 – 12 months
  - Expands use to adults lacking HTN, heart disease or risk factors for CAD
- Laryngeal Stimulation
  - No increased risk of laryngospasm with simple ED procedures (intraoral laceration, dental procedures)
- Anatomy
  - Use with caution in patients with tracheomalacia, laryngomalacia
- Upper Respiratory Infection
  - May increase laryngospasm

2011 Ketamine Clinical Practice Guidelines

- Increased Intracranial Pressure
  - *Head trauma removed as contraindication*
  - Ketamine causes cerebral vasodilation which may improve perfusion
  - Reports of patients with obstructive hydrocephalus or masses/abnormalities

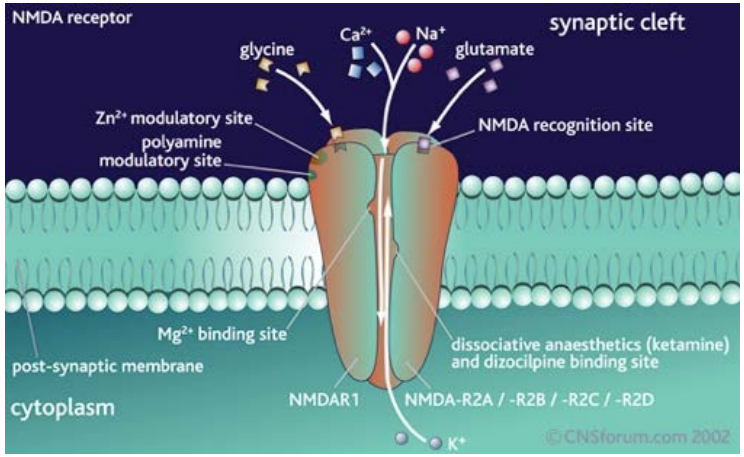
2011 Ketamine Clinical Practice Guidelines

- Expanded Guidelines to Include Adults
  - Avoid in patients with CHF, HTN, CAD
  - Inhibits reuptake of catecholamines resulting in sympathomimetic effect

⇧Heart Rate

⇧Blood Pressure

⇧Cardiac Output



2011 Ketamine Clinical Practice Guidelines

IV

- Faster onset of action (60 seconds)
- Less vomiting
- Easy to redose for longer procedures
- Pediatrics – 1.5-2mkg/kg
- Adults – 1 mg/kg

IM

- Onset about 5 minutes
- More vomiting
- Repeated IM injections
- Longer recovery
- No need for IV placement
- 4-5mg/kg

2011 Ketamine Clinical Practice Guideline Adverse Events

- Laryngospasm – 0.3%
  - risk factors include active asthma or URI
  - Tx = BVM and rarely intubation
- Respiratory Depression
  - ***Case reports of apnea if administered too quickly. Should be administered over 30-60 seconds***
  - Occurs after peak concentration (1-2 minutes after administration)
- Emesis
  - Early adolescence is peak
  - Usually occurs when late in recovery and patient can clear airway
- Emergence Reactions
  - Rarely disturbing in children or adults
  - Can give benzos if pronounced reaction

2011 Ketamine Clinical Practice Guideline

"Favorite Things"

- ***Should I coadminister an anticholinergic to decrease oral secrections and decrease airway adverse events?***
  - NO. Literature shows no benefit
- ***Do coadministered benzodiazepines decrease emergence reactions in children??***
  - NO. Literature shows no benefit in children
  - May have benefit in adults

- ***Does my patient have to eat before they are discharged?***
  - NO. Repeated attempts might unnecessarily provoke emesis
- ***Does may patient have to be able to walk without assistance?***
  - NO. Patients may have ataxia after ketamine for several hours.
  - Patients should be monitored to prevent falls at home

PROPOFOL

Propofol

- Why is it a great sedative-hypnotic?
  - Classified as nonopioid, nonbarbiturate
  - Fast onset of action 30-60 seconds
  - Half life is 1.3 - 4.1 minutes
  - Ultra short acting…..effects wear off in minutes
  - Dosage in literature for pediatrics: 1mg/kg IV bolus; additional doses of 0.5mg/kg
  - Adult dosing varies depending on age, comorbidities, and if patient has had narcotics. 1mg/kg IV bolus initially, but may need to decrease based on above.
- Adverse Reaction
  - Hypotension
  - Respiratory Depression

Propofol

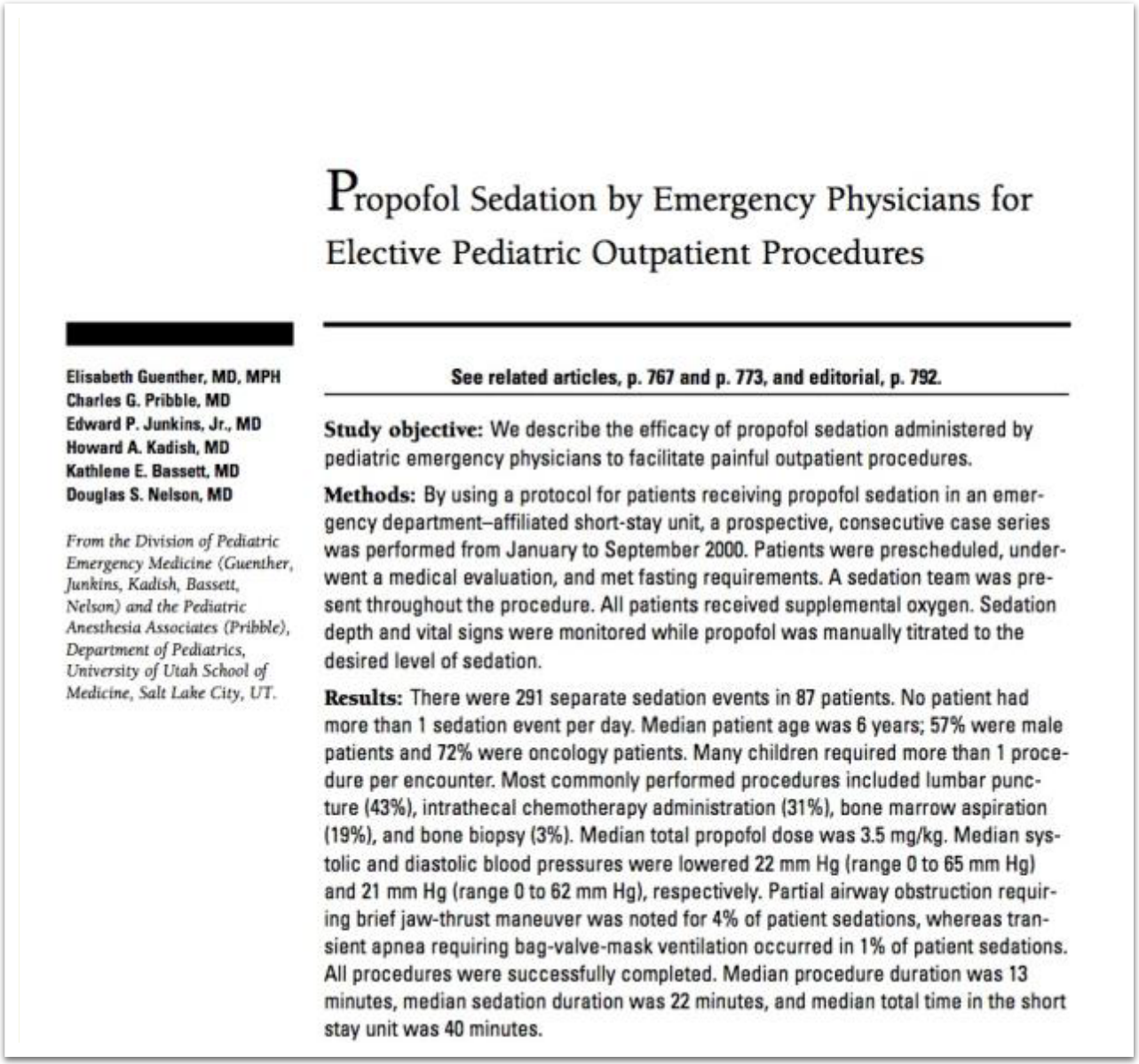
Ann Emerg Med 2003
N=291
Hypoxia =5%
Partial Airway Obstruction = 4%
Apnea with BVM =1%
All adverse events were promptly identified and readily managed without further complication

Dosage:
1mg/kg IV initial bolus
0.5mg/kg IV additional doses
(pretreated w/ fentanyl 1-2mcg/kg)

All but 4 patients had transient hypotension, but no evidence of poor perfusion

All studies completed successfully
1 provider administering propofol; 1 performing procedure

Limitations:
Did not record depth of sedation
No ETCO2
Multiple MDs administered propofol
Not all patients rec'd IVFs



Propofol Sedation by Emergency Physicians for Elective Pediatric Outpatient Procedures

Elisabeth Guenther, MD, MPH
Charles G. Pribble, MD
Edward P. Junkins, Jr., MD
Howard A. Kadish, MD
Kathlene E. Bassett, MD
Douglas S. Nelson, MD

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See related articles, p. 767 and p. 773, and editorial, p. 792.

Study objective: We describe the efficacy of propofol sedation administered by pediatric emergency physicians to facilitate painful outpatient procedures.

Methods: By using a protocol for patients receiving propofol sedation in an emergency department–affiliated short-stay unit, a prospective, consecutive case series was performed from January to September 2000. Patients were prescheduled, underwent a medical evaluation, and met fasting requirements. A sedation team was present throughout the procedure. All patients received supplemental oxygen. Sedation depth and vital signs were monitored while propofol was manually titrated to the desired level of sedation.

Results: There were 291 separate sedation events in 87 patients. No patient had more than 1 sedation event per day. Median patient age was 6 years; 57% were male patients and 72% were oncology patients. Many children required more than 1 procedure per encounter. Most commonly performed procedures included lumbar puncture (43%), intrathecal chemotherapy administration (31%), bone marrow aspiration (19%), and bone biopsy (3%). Median total propofol dose was 3.5 mg/kg. Median systolic and diastolic blood pressures were lowered 22 mm Hg (range 0 to 65 mm Hg) and 21 mm Hg (range 0 to 62 mm Hg), respectively. Partial airway obstruction requiring brief jaw-thrust maneuver was noted for 4% of patient sedations, whereas transient apnea requiring bag-valve-mask ventilation occurred in 1% of patient sedations. All procedures were successfully completed. Median procedure duration was 13 minutes, median sedation duration was 22 minutes, and median total time in the short stay unit was 40 minutes.

Propofol

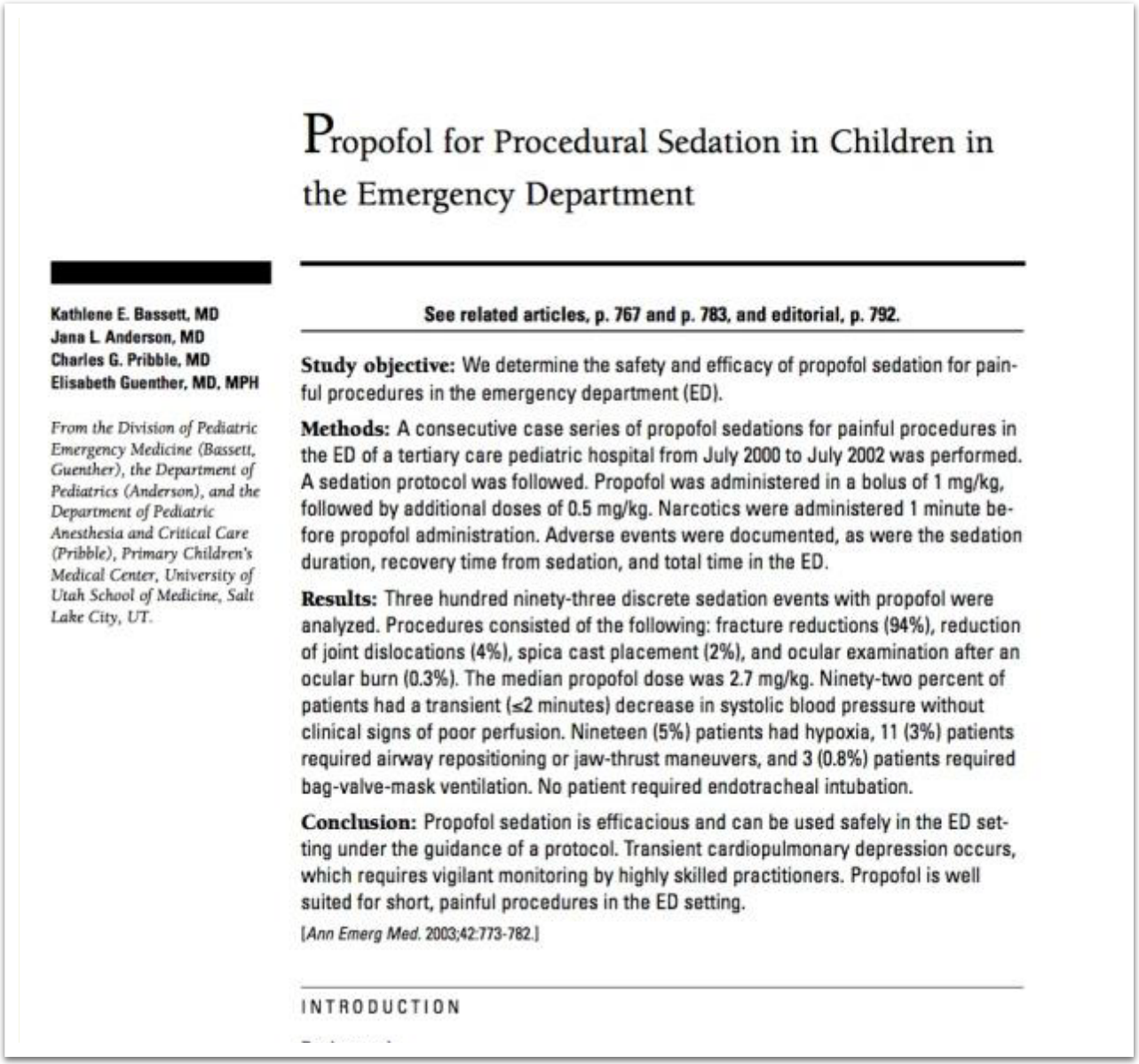
N= 393
Mainly ortho procedures

Hypotension >2 min = 8%; no episodes of poor perfusion
Hypoxia = 5%
Partial Airway Obstruction = 3%
Apnea with BVM = 0.8%
Bradycardia = 6%

Dosage:
1 mkg/kg IV initial bolus
0.5mg/kg add'l doses
Fentanyl or MSO4 given 1 minute prior to procedure
Mean propofol dose = 2.9mg/kg

ED MD monitored sedation
Orthopedist performed procedure

Limitations:
ETCO2 not used
Depth of sedation not scored
Multiple MDs administered propofol
Not all patients rec'd IVFs



Propofol for Procedural Sedation in Children in the Emergency Department

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From the Division of Pediatric Emergency Medicine (Bassett, Guenther), the Department of Pediatrics (Anderson), and the Department of Pediatric Anesthesia and Critical Care (Pribble), Primary Children's Medical Center, University of Utah School of Medicine, Salt Lake City, UT.

See related articles, p. 767 and p. 783, and editorial, p. 792.

Study objective: We determine the safety and efficacy of propofol sedation for painful procedures in the emergency department (ED).

Methods: A consecutive case series of propofol sedations for painful procedures in the ED of a tertiary care pediatric hospital from July 2000 to July 2002 was performed. A sedation protocol was followed. Propofol was administered in a bolus of 1 mg/kg, followed by additional doses of 0.5 mg/kg. Narcotics were administered 1 minute before propofol administration. Adverse events were documented, as were the sedation duration, recovery time from sedation, and total time in the ED.

Results: Three hundred ninety-three discrete sedation events with propofol were analyzed. Procedures consisted of the following: fracture reductions (94%), reduction of joint dislocations (4%), spica cast placement (2%), and ocular examination after an ocular burn (0.3%). The median propofol dose was 2.7 mg/kg. Ninety-two percent of patients had a transient (≤2 minutes) decrease in systolic blood pressure without clinical signs of poor perfusion. Nineteen (5%) patients had hypoxia, 11 (3%) patients required airway repositioning or jaw-thrust maneuvers, and 3 (0.8%) patients required bag-valve-mask ventilation. No patient required endotracheal intubation.

Conclusion: Propofol sedation is efficacious and can be used safely in the ED setting under the guidance of a protocol. Transient cardiopulmonary depression occurs, which requires vigilant monitoring by highly skilled practitioners. Propofol is well suited for short, painful procedures in the ED setting.

[*Ann Emerg Med.* 2003;42:773-782.]

INTRODUCTION

Propofol

3 sites: Maine Medical Center, Hennepin (MN), ***Overlake WA (**no resident coverage)***

N= 792

Indications: ortho, cardioversion, abscess I&D

Hypotension = 3.5%

Oxygen Desaturation = 7.7%

BVM = 3.9%

All adverse events resolved with brief supportive measures

Dosage:

1mg/kg initial bolus

0.5mg/kg additional boluses

Propofol for Emergency Department Procedural Sedation and Analgesia: A Tale of Three Centers

John H. Burton, MD, James R. Miner, MD, Eric R. Shipley, MD, Tania D. Strout, RN, BSN, Chris Becker, MD, Henry C. Thode Jr., PhD

Abstract

Objectives: To characterize propofol procedural sedation and analgesia (PSA) encounters for a large patient population at multiple emergency department (ED) sites. The authors sought to assess the frequency of respiratory and cardiovascular events during propofol PSA within these settings.

Methods: This study was a prospective, descriptive series of a consecutive sample of ED patients receiving propofol for PSA at three study sites. Patients were monitored for PSA-related events, including predefined clinically relevant cardiovascular and respiratory events. Data collection was performed during PSA with a standardized data collection sheet unique to each site.

Results: Propofol was administered during PSA to 792 patients during the respective reporting period at each center. Indications for sedation included dislocation reduction (38%), cardioversion (10%), fracture reduction (35%), abscess incision and drainage (8%), computed tomography imaging (2%), and tube thoracostomy (1%). The cumulative rate of oxygen desaturation events for all study sites was 7.7% with a brief period of assisted ventilation with bag-valve mask in 3.9%. The cumulative rate of PSA-related hypotensive events was 3.5%. Increasing patient age and specific clinical procedure were clinical variables most associated with any propofol-related respiratory event. All PSA-related events resolved with supportive interventions during the PSA encounter. No patients required endotracheal intubation, prolonged observation, or admission for PSA-related complications.

Conclusions: Propofol typically confers a deep sedation experience for ED PSA. The most common PSA events associated with propofol are respiratory related and appear consistent across these three practice settings. All propofol-related PSA events resolved with brief supportive interventions in the ED with no adverse sequelae.

ACADEMIC EMERGENCY MEDICINE 2006; 13:24–30 © 2006 by the Society for Academic Emergency Medicine

Keywords: propofol, procedural sedation and analgesia, conscious sedation

Propofol

No statistical significant differences in airway/respiratory adverse reactions among study sites

Limitations:

No rigid guideline for propofol dosing (some docs administered smaller initial bolus based on age, BP etc. from usual dosing)

2 different PSA scores used

Multiple providers

Table 2
Number (%) of Procedures Performed with Propofol Procedural Sedation and Analgesia at Each Study Site

Site	*n*	Dislocation Reduction	Fracture Reduction	Cardioversion	Abscess Incision and Drainage	Other*
HCMC	371	141 (38)	156 (42)	0	57 (15)	17 (5)
MMC	201	90 (45)	57 (28)	26 (13)	5 (3)	23 (11)
OMC	220	71 (32)	64 (29)	51 (23)	5 (3)	29 (13)
Total	792	302 (38)	277 (35)	77 (10)	67 (8)	69 (9)

HCMC = Hennepin County Medical Center; MMC = Maine Medical Center; OMC = Overlake Hospital Medical Center.
* Other (number of procedures) = computed tomography imaging (16), lumbar puncture (2), Foley catheter placement (2), chest tube placement (8), laceration repair (4), foreign body removal (6), endoscopy (6), unclassified (23), hernia reduction (1), and dilatation and curettage (1).

Table 3
Number (%) of Cases with Respiratory Events, Hypotension, or Emesis Associated with Propofol Procedural Sedation and Analgesia at Each Study Site

Site	*n*	SpO_2 <90%	Bag-valve Mask Ventilation	Oral Airway	Hypotension	Emesis
HCMC	371	31 (8.4)	14 (3.8)	1 (0.3)	10 (2.7)	0 (0)
95% CI		5.9, 11.0	1.9, 5.9	0.1, 0.5	1.1, 4.3	0, 0.8
MMC	201	19 (9.4)	6 (3.0)	0 (0)	13 (6.5)	0 (0)
95% CI		5.0, 13.9	1.0, 5.0	0, 1.5	2.5, 10.4	0, 1.5
OMC	220	11 (5.0)	11 (5.0)	1 (0.5)	5 (2.2)	1 (0.5)
95% CI		1.8, 8.2	1.8, 7.7	0.1, 0.9	0.9, 3.6	0.1, 0.9
Total*	792	61 (7.7)	31 (3.9)	2 (0.3)	28 (3.5)	1 (0.1)

HCMC = Hennepin County Medical Center; MMC = Maine Medical Center; OMC = Overlake Hospital Medical Center.
* Some patients had more than one event.

Table 4
Number (%) of Cases with Respiratory Events and/or Emesis by Procedural Sedation and Analgesia Procedure

Event	Dislocation Reduction	Fracture Reduction	Cardioversion	Abscess Incision and Drainage	Other*	p-value
SpO_2 <90%	28 (9.3)	17 (6.1)	10 (13.0)	1 (1.5)	5 (7.2)	0.07
Bag-valve mask ventilation	16 (5.3)	6 (2.2)	4 (5.2)	1 (1.5)	4 (5.8)	0.21
All†	36 (11.9)	20 (7.2)	10 (13.0)	2 (3.0)	7 (10.1)	0.08

* *Other* includes computed tomography imaging, lumbar puncture, Foley catheter placement, chest tube placement, laceration repair, foreign body removal, endoscopy, unclassified, hernia reduction, and dilatation and curettage.
† Includes SpO_2 <90%, bag-valve mask-assisted ventilation, oral airway (two patients), and/or emesis (one patient). Some patients had more than one event.

Propofol

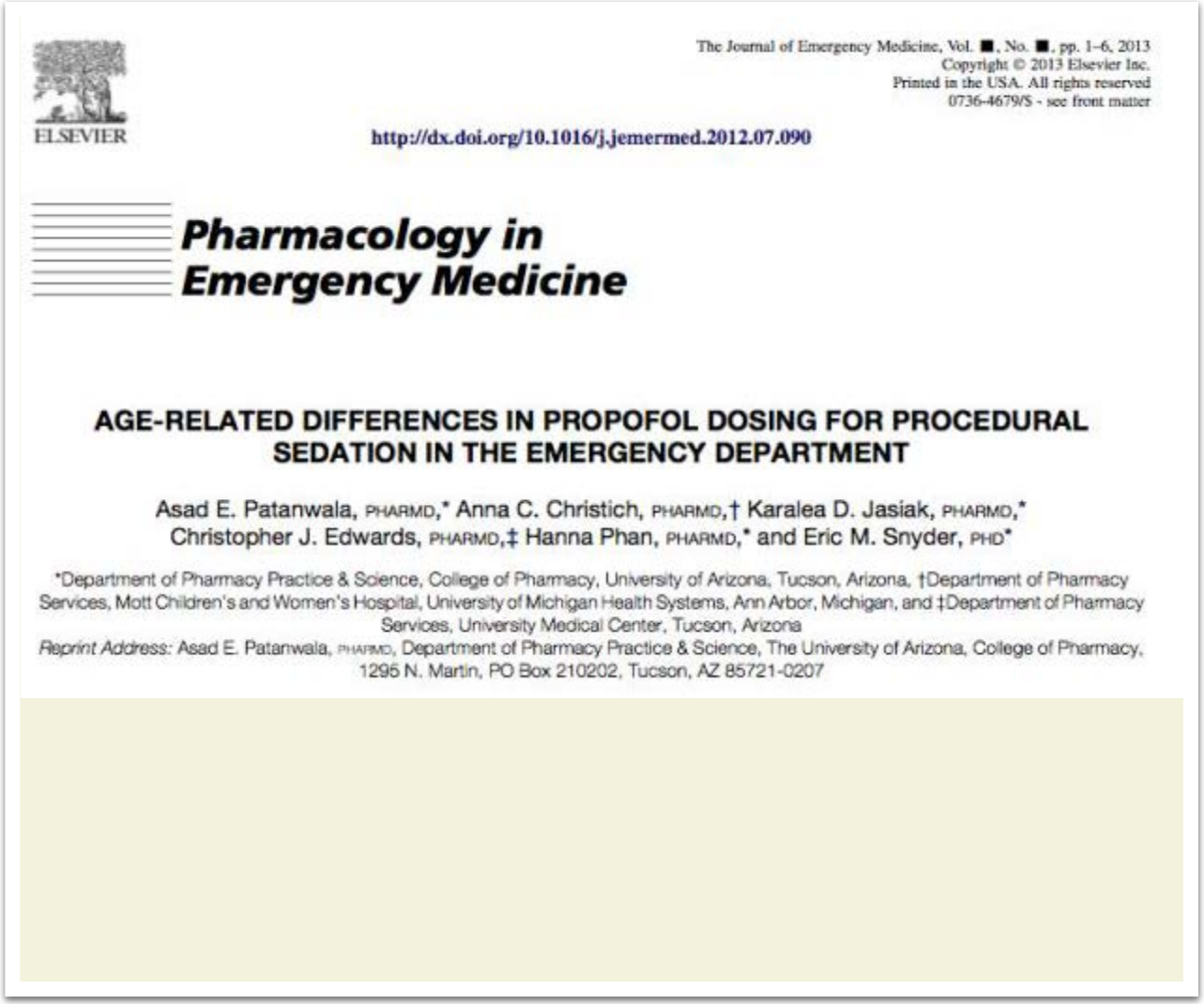
Retrospective cohort study

Determine the effect of patient age on propofol dose

N=170; divided into 3 cohorts
18-40 years
41-64 years
>65 years

Opioid use before procedure was similar in all groups

Unique elderly characteristics:
Higher serum concentrations
Greater sensitivity to hypnotic effects



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ELSEVIER

http://dx.doi.org/10.1016/j.jemermed.2012.07.090

Pharmacology in Emergency Medicine

AGE-RELATED DIFFERENCES IN PROPOFOL DOSING FOR PROCEDURAL SEDATION IN THE EMERGENCY DEPARTMENT

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Propofol

Limitations

MDs biased and give smaller doses to elderly anyway which influenced induction and total dosages

May have limited documentation in the medical chart

Table 2. Pain and Sedation Data (n = 170)

Variable	18–40 Years (n = 66) Median, IQR	41–64 Years (n = 59) Median, IQR	≥ 65 Years (n = 45) Median, IQR	*p* Value
Opioid before procedure (mg/kg)*	0.08 (0–0.12)	0.05 (0–0.12)	0.06 (0–0.1)	0.478
Opioid during procedure (mg/kg)*	0.02 (0–0.1)	0 (0–0.07)	0 (0–0.08)	0.616
Pain score before procedure (0–10 scale)	7 (4.5–9)	5 (0–8)	4 (0–6)	0.001, < 0.001
Procedure time (min)	15 (11–27)	15 (10–25)	15 (8–28)	0.914
Propofol doses (mg/kg)				
Induction dose	1.4 (1–2.1)	1 (0.7–1.8)	0.9 (0.7–1.2)	< 0.001†
Total dose	2 (1.3–2.7)	1.7 (1–2.5)	1.2 (0.8–1.6)	< 0.001‡, 0.002§

IQR = interquartile range.
* Morphine intravenous equivalents.
† *p* value indicates difference between 18–40 year and 41–64 year age groups.
‡ *p* value indicates difference between 18–40 year and ≥65 year age groups.
§ *p* value indicates difference between 41–64 year and ≥65 year age groups.

Propofol Safety Considerations

- Consider giving patients with concern for hypovolemia or who are dehydrated
- Use ETCO2 monitoring when using propofol
- Reduce dosage of propofol in elderly patients

Is propofol safe for use for procedural sedation in the ED?

ETCO2

Does End Tidal CO_2 Monitoring During Emergency Department Procedural Sedation and Analgesia With Propofol Decrease the Incidence of Hypoxic Events? A Randomized, Controlled Trial

Kenneth Deitch, DO
Jim Miner, MD
Carl R. Chudnofsky, MD
Paul Dominici, MD
Daniel Latta, BS

From the Department of Emergency Medicine, Albert Einstein Medical Center, Philadelphia, PA (Deitch, Chudnofsky, Dominici, Latta); Department of Emergency Medicine, Hennepin County Medical Center, Minneapolis, MN (Miner).

Study objective: We determine whether the use of capnography is associated with a decreased incidence of hypoxic events than standard monitoring alone during emergency department (ED) sedation with propofol.

Methods: Adults underwent ED propofol sedation with standard monitoring (pulse oximetry, cardiac and blood pressure) and capnography and were randomized into a group in which treating physicians had access to the capnography and a blinded group in which they did not. All patients received supplemental oxygen (3 L/minute) and opioids greater than 30 minutes before. Propofol was dosed at 1.0 mg/kg, followed by 0.5 mg/kg as needed. Capnographic and SpO_2 data were recorded electronically every 5 seconds. Hypoxia was defined as SpO_2 less than 93%; respiratory depression, as end tidal CO_2 ($ETCO_2$) greater than 50 mm Hg, $ETCO_2$ change from baseline of 10%, or loss of the waveform.

Results: One hundred thirty-two subjects were evaluated and included in the final analysis. We observed hypoxia in 17 of 68 (25%) subjects with capnography and 27 of 64 (42%) with blinded capnography ($P=.035$; difference 17%; 95% confidence interval 1.3% to 33%). Capnography identified all cases of hypoxia before onset (sensitivity 100%; specificity 64%), with the median time from capnographic evidence of respiratory depression to hypoxia 60 seconds (range 5 to 240 seconds).

Conclusion: In adults receiving ED propofol sedation, the addition of capnography to standard monitoring reduced hypoxia and provided advance warning for all hypoxic events. [Ann Emerg Med. 2010;55:258-264.]

Please see page 259 for the Editor's Capsule Summary of this article.

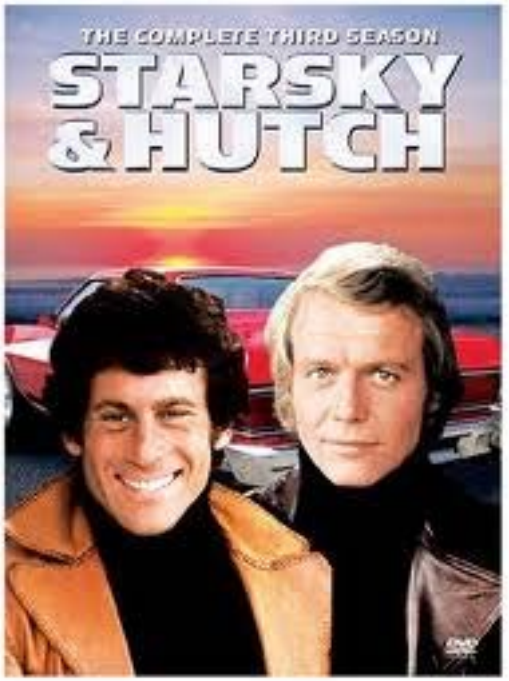
Provide feedback on this article at the journal's Web site, www.annemergmed.com.

0196-0644/$-see front matter

doi:10.1016/j.annemergmed.2009.07.030

WHAT'S BETTER THAN KETAMINE AND PROPOFOL?

KETOFOL!!!…..but, is it really better???



Ketofol ~ a balancing act

Propofol

- Sedative Hypnotic
- Antiemetic
- Respiratory Depression
- Hypotension
- Anxiolysis

Ketamine

- Analgesic and Amnestic
- Vomiting
- Sympathomimetic
  - Preserves respiratory drive
  - Hypertension
  - Tachycardia
- Emergence Reactions

Ketofol

N = 136
Prospective, blinded RCT ketofol vs. ketamine for orthopedic fracture reduction

Dosages:
Ketofol (0.5mg/kg ketamine + 0.5mg/kg propofol) vs.
Ketamine 1mkg/kg

Was sedation time shorter with ketofol than ketamine alone?

Was recovery time faster with ketofol than ketamine alone?

Median Sedation Time
Ketofol = 13 minutes
Ketamine = 16 minutes

Recovery Time
Ketofol = 10 minutes
Ketamine = 12 minutes

Less vomiting in ketofol group (2% vs. 12%)

Adverse events easily managed with oxygen and airway repositioning

A Blinded, Randomized Controlled Trial to Evaluate Ketamine/Propofol Versus Ketamine Alone for Procedural Sedation in Children

Amit Shah, MD, Gregory Mosdossy, MD, Shelley McLeod, MSc, Kris Lehnhardt, MD, Michael Peddle, MD, Michael Rieder, MD, PhD

From the Division of Emergency Medicine, Schulich School of Medicine and Dentistry (Shah, Mosdossy, McLeod, Lehnhardt, Peddle) and the Division of Clinical Pharmacology (Rieder), The University of Western Ontario, London, Ontario, Canada.

Study objective: The primary objective is to compare total sedation time when ketamine/propofol is used compared with ketamine alone for pediatric procedural sedation and analgesia. Secondary objectives include time to recovery, adverse events, efficacy, and satisfaction scores.

Methods: Children (aged 2 to 17 years) requiring procedural sedation and analgesia for management of an isolated orthopedic extremity injury were randomized to receive either ketamine/propofol or ketamine. Physicians, nurses, research assistants, and patients were blinded. Ketamine/propofol patients received an initial intravenous bolus dose of ketamine 0.5 mg/kg and propofol 0.5 mg/kg, followed by propofol 0.5 mg/kg and saline solution placebo every 2 minutes, titrated to deep sedation. Ketamine patients received an initial intravenous bolus dose of ketamine 1.0 mg/kg and Intralipid placebo, followed by ketamine 0.25 mg/kg and Intralipid placebo every 2 minutes, as required.

Results: One hundred thirty-six patients (67 ketamine/propofol, 69 ketamine) completed the trial. Median total sedation time was shorter (P=0.04) with ketamine/propofol (13 minutes) than with ketamine (16 minutes) alone (Δ –3 minutes; 95% confidence interval [CI] –5 to –2 minutes). Median recovery time was faster with ketamine/propofol (10 minutes) than with ketamine (12 minutes) alone (Δ –2 minutes; 95% CI –4 to –1 minute). There was less vomiting in the ketamine/propofol (2%) group compared with the ketamine (12%) group (Δ –10%; 95% CI –18% to –2%). All satisfaction scores were higher (P<0.05) with ketamine/propofol.

Conclusion: When compared with ketamine alone for pediatric orthopedic reductions, the combination of ketamine and propofol produced slightly faster recoveries while also demonstrating less vomiting, higher satisfaction scores, and similar efficacy and airway complications. [Ann Emerg Med. 2011;57:425-433.]

Please see page 426 for the Editor's Capsule Summary of this article.

Provide **feedback** on this article at the journal's Web site, www.annemergmed.com.
A **podcast** for this article is available at www.annemergmed.com.

0196-0644/$-see front matter

doi:10.1016/j.annemergmed.2010.08.032

Ketofol

Randomized, double blind, placebo controlled trial
n=193

Compare frequency of respiratory depression of ketofol vs. propofol alone

Ketamine 0.5mg/kg or placebo, then propofol 1mg/kg with repeated doses of 0.5mg/kg to maintain sedation

Difference in respiratory depression not statistically significant between groups

Respiratory Depression Defined as:
-ETCO2 increase 5mmHg lasting >10 seconds
-RR < 8 bpm for >10 seconds
-SaO2 < 90% for > 10 seconds
-Apnea >15 seconds
-Airway Manipulation (jaw thrush ot BVM)

Median propofol dose
Ketofol = 100mg
Propofol alone =175mg

A Randomized Controlled Trial of Ketamine/Propofol Versus Propofol Alone for Emergency Department Procedural Sedation

Henry David, MD, Joseph Shipp, PAC

From the Department of Emergency Medicine, University of Missouri–Columbia, Columbia, MO.

Study objective: We compare the frequency of respiratory depression during emergency department procedural sedation with ketamine plus propofol versus propofol alone. Secondary outcomes are provider satisfaction, sedation quality, and total propofol dose.

Methods: In this randomized, double-blind, placebo-controlled trial, healthy children and adults undergoing procedural sedation were pretreated with intravenous fentanyl and then randomized to receive either intravenous ketamine 0.5 mg/kg or placebo. In both groups, this procedure was immediately followed by intravenous propofol 1 mg/kg, with repeated doses of 0.5 mg/kg as needed to achieve and maintain sedation. Respiratory depression was defined according to any of 5 predefined markers. Provider satisfaction was scored on a 5-point scale, sedation quality with the Colorado Behavioral Numerical Pain Scale, and propofol dose according to the total number of milligrams of propofol administered.

Results: The incidence of respiratory depression was similar between the ketamine/propofol (21/97; 22%) and propofol-alone (27/96; 28%) groups, difference 6% (95% confidence interval −6% to 18%). With ketamine/propofol compared with propofol alone, treating physicians and nurses were more satisfied, less propofol was administered, and there was a trend toward better sedation quality.

Conclusion: Compared with procedural sedation with propofol alone, the combination of ketamine and propofol did not reduce the incidence of respiratory depression but resulted in greater provider satisfaction, less propofol administration, and perhaps better sedation quality. [Ann Emerg Med. 2011;57:435-441.]

Please see page 436 for the Editor's Capsule Summary of this article.

Provide **feedback** on this article at the journal's Web site, www.annemergmed.com.
A **podcast** for this article is available at www.annemergmed.com.

0196-0644/$-see front matter

doi:10.1016/j.annemergmed.2010.11.025

Ketofol

Ketofol had less frequent changes in depth of sedation

Resulted in more consistent sedation

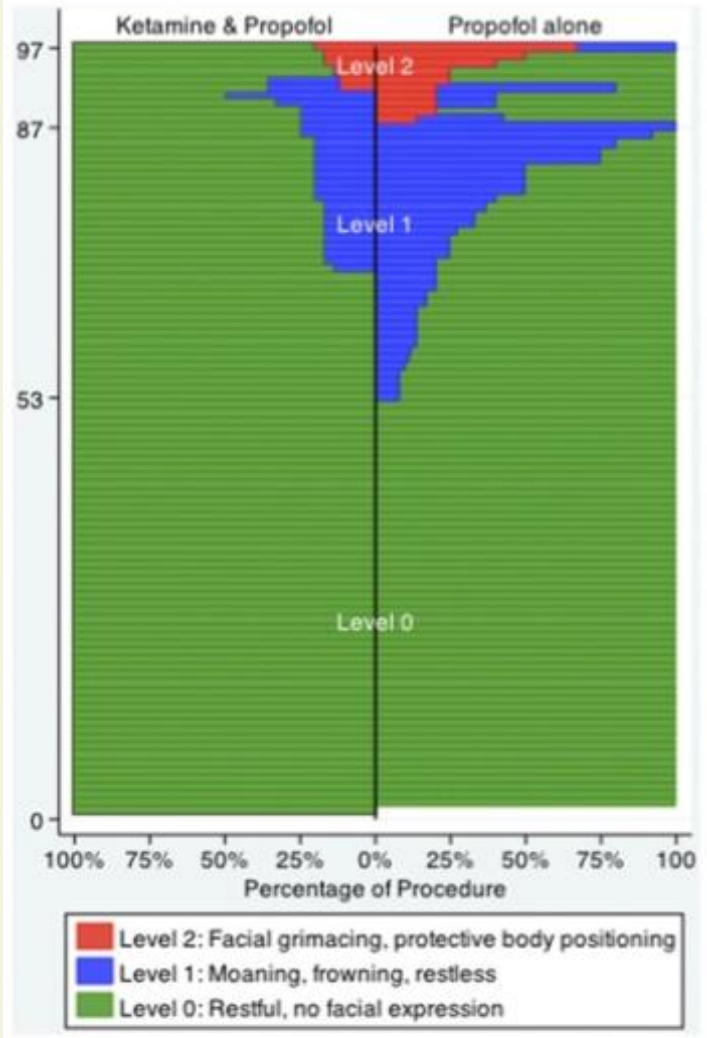


Figure 4. Percentage of the procedure spent at each sedation level.

Ketofol

n = 284
RDBT

Does ketofol have less adverse events than propofol alone?

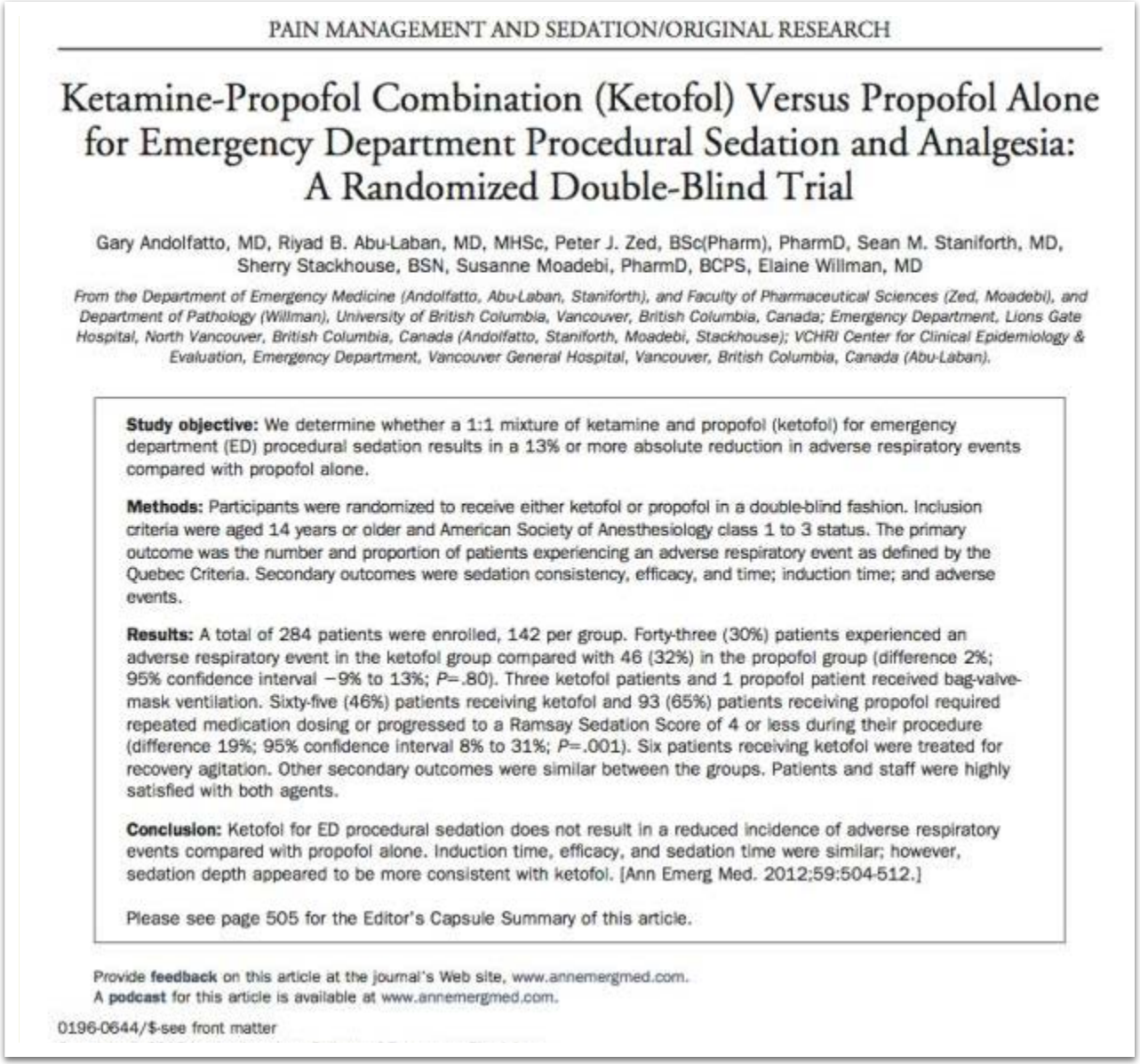
Dosages:

- **Ketofol** (single syringe) 0.375mg/kg each of ketamine and propofol (add'l doses of 0.188mg/kg of each)
- **Propofol** 0.75mg/kg initial bolus and then 0.375mg/kg)

- Similar number of repeat dosages

Respiratory adverse events were similar in both groups; all responded to either airway repositioning, oxygen, or BVM or combination of all three

More consistent sedation depth



PAIN MANAGEMENT AND SEDATION/ORIGINAL RESEARCH

Ketamine-Propofol Combination (Ketofol) Versus Propofol Alone for Emergency Department Procedural Sedation and Analgesia: A Randomized Double-Blind Trial

Gary Andolfatto, MD, Riyad B. Abu-Laban, MD, MHSc, Peter J. Zed, BSc(Pharm), PharmD, Sean M. Staniforth, MD, Sherry Stackhouse, BSN, Susanne Moadebi, PharmD, BCPS, Elaine Willman, MD

From the Department of Emergency Medicine (Andolfatto, Abu-Laban, Staniforth), and Faculty of Pharmaceutical Sciences (Zed, Moadebi), and Department of Pathology (Willman), University of British Columbia, Vancouver, British Columbia, Canada; Emergency Department, Lions Gate Hospital, North Vancouver, British Columbia, Canada (Andolfatto, Staniforth, Moadebi, Stackhouse); VCHRI Center for Clinical Epidemiology & Evaluation, Emergency Department, Vancouver General Hospital, Vancouver, British Columbia, Canada (Abu-Laban).

Study objective: We determine whether a 1:1 mixture of ketamine and propofol (ketofol) for emergency department (ED) procedural sedation results in a 13% or more absolute reduction in adverse respiratory events compared with propofol alone.

Methods: Participants were randomized to receive either ketofol or propofol in a double-blind fashion. Inclusion criteria were aged 14 years or older and American Society of Anesthesiology class 1 to 3 status. The primary outcome was the number and proportion of patients experiencing an adverse respiratory event as defined by the Quebec Criteria. Secondary outcomes were sedation consistency, efficacy, and time; induction time; and adverse events.

Results: A total of 284 patients were enrolled, 142 per group. Forty-three (30%) patients experienced an adverse respiratory event in the ketofol group compared with 46 (32%) in the propofol group (difference 2%; 95% confidence interval −9% to 13%; *P*=.80). Three ketofol patients and 1 propofol patient received bag-valve-mask ventilation. Sixty-five (46%) patients receiving ketofol and 93 (65%) patients receiving propofol required repeated medication dosing or progressed to a Ramsay Sedation Score of 4 or less during their procedure (difference 19%; 95% confidence interval 8% to 31%; *P*=.001). Six patients receiving ketofol were treated for recovery agitation. Other secondary outcomes were similar between the groups. Patients and staff were highly satisfied with both agents.

Conclusion: Ketofol for ED procedural sedation does not result in a reduced incidence of adverse respiratory events compared with propofol alone. Induction time, efficacy, and sedation time were similar; however, sedation depth appeared to be more consistent with ketofol. [Ann Emerg Med. 2012;59:504-512.]

Please see page 505 for the Editor's Capsule Summary of this article.

Provide **feedback** on this article at the journal's Web site, www.annemergmed.com.
A **podcast** for this article is available at www.annemergmed.com.

0196-0644/$-see front matter

Ketofol vs. Propofol

Ramsey Scale

1 = anxious and agitated or restless, or both

2 = co-operative, oriented, and calm

3 = responsive to commands only

4 = exhibiting brisk response to light glabellar tap or loud auditory stimulus

5 = exhibiting a sluggish response to light glabellar tap (tap on forehead) or loud auditory stimulus

6 = unresponsive

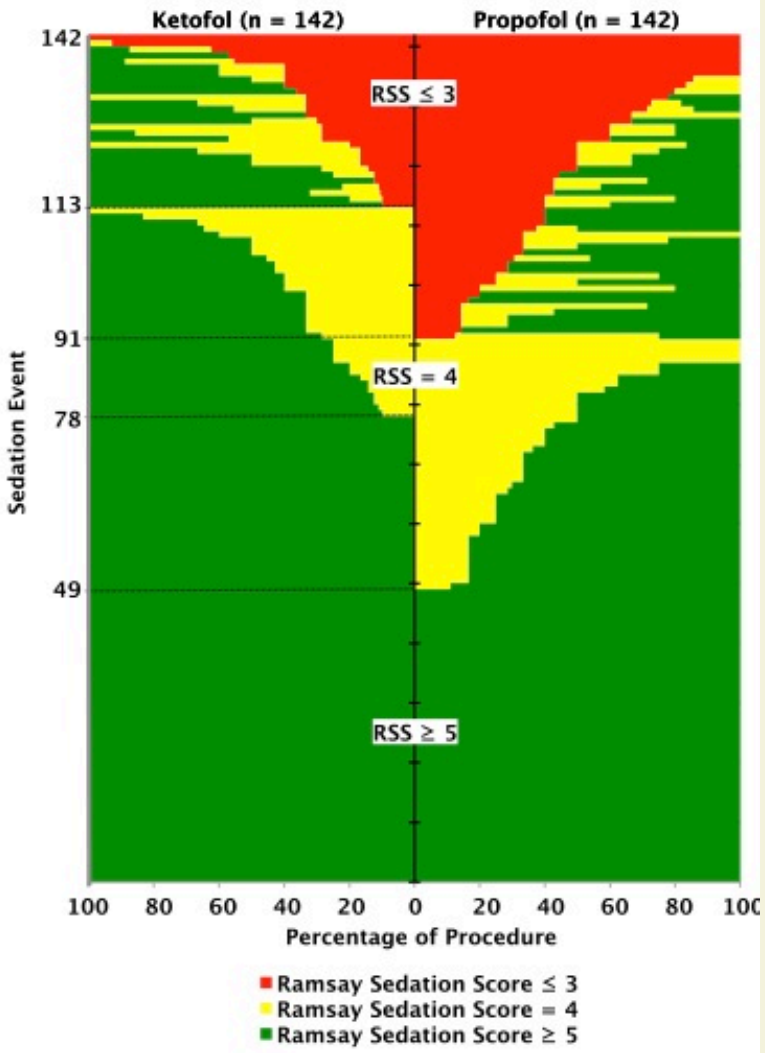


Figure 2. Sedation consistency: Percentage of procedure spent at each sedation level.

Thoughts on Ketofol

- Adverse events are similar between ketofol and propofol
- Using ketamine in sub-dissociative doses….perhaps seeing analgesic effects and not “dissociative effects”??
- Less vomiting in ketofol groups
- MD and RN satisfaction high in ketofol groups
- Ketamine may blunt the peaks and troughs seen with propofol monotherapy ie…more consistent

ROADBLOCKS TO PROPOFOL (AND KETAMINE) USE IN THE ED

The “BIG THREE”

- **Is it safe to use propofol in the ED for procedural sedation?**
- **Does there need to be 2 ED physicians in the room?**
  - One to monitor sedation
  - Second to perform procedure
- **Can nurse “push the plunger” for ketamine and propofol?**

Propofol

- Diprivan (Propofol) package insert (7/2004) …

- “propofol used for sedation or anesthesia should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.”

ADVISORY ON GRANTING PRIVILEGES FOR DEEP SEDATION TO NON-ANESTHESIOLOGIST SEDATION PRACTITIONERS
Committee of Origin: *Ad Hoc* on Non-Anesthesiologist Privileging
(Approved by the ASA House of Delegates on October 20, 2010)

- Note: The *Hospital Anesthesia Services Condition of Participation 42 CFR 482.52(a)* limits the administration of deep sedation to "qualified anesthesia professionals" within their scope of practice. ***CMS defines these personnel specifically as an anesthesiologist; non-anesthesiologist MD or DO; dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law; CRNA, and AA.***
- Any professional who administers and monitors deep sedation must be dedicated to that task. Therefore, the non-anesthesiologist sedation practitioner who administers and monitors deep sedation must be different from the individual performing the diagnostic or therapeutic procedure (see ASA Guidelines for Sedation and Analgesia by Non-anesthesiologists).

American Society of Anesthesiologists

MARK A. WARNER, M.D.
President

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January 20, 2011

Sandra Schneider, M.D.
President
American College of Emergency Physicians
1125 Executive Circle
Irving, TX 75038-2522

Re: Statement by American Society of Anesthesiologists on Granting Privileges for Deep Sedation to Non-Anesthesiologist Sedation Practitioners

Dear Dr. Schneider:

My colleagues and I are grateful to have had the chance to meet with your leadership in New York City last month. I hope our discussion addressed your questions about the American Society of Anesthesiologists' (ASA) recently issued "Statement on Granting Privileges for Deep Sedation to Non-Anesthesiologist Sedation Practitioners."

The purpose of the statement must be clearly understood. It states that it "is designed to *assist* health care facilities in developing a program for the delineation of clinical privileges" (emphasis mine). Our expectation is that facilities and medical staffs will use our statement as a starting point when they consider how to establish institution-specific criteria appropriate for deep sedation privileging. We understand that each setting has unique characteristics that should be reflected in the development of medical staff privileging criteria. We also recognize that some institutions may find it unnecessary to privilege non-anesthesiologists for this service at all.

The considerations appropriate for one specialty may not pertain to others. For example, institutions may require some or all staff members to maintain Advanced Cardiac Life Support (ACLS) certification. Some institutions recognize that the ACLS skill set is a core competency of specialties such as anesthesiology or emergency medicine and may treat these specialties differently with respect to their ACLS requirements. We would expect that a facility may address the deep sedation privileging standards with similar distinctions among medical specialties. Note, too, that the ASA statement makes reference to "advanced life support skills and current certificate *such as those* required for Advanced Cardiac Life Support (ACLS)." (again, emphasis mine). Our document does not suggest a requirement for ACLS certification *per se*, but instead calls for documented competency in those skills.

As physicians, we all understand that patient needs trump guidelines and standards. A critical function of the medical professional is to weigh the likelihood of patient harm, particularly in emergency situations, in comparison to the benefits of strict adherence to even the most compelling standards. For example, we all have cared for patients who have critical, urgent need for intravenous access and resuscitation; in these instances it may be necessary to put aside time-consuming techniques in their best interests. Central venous catheters inserted at the scene of major trauma provide another good illustration. We understand there may be rare circumstances in which practices suggested in our statement cannot reasonably be followed under extenuating circumstances.

We are hopeful that the ASA statement will be helpful to institutions that need to establish privileging criteria for deep sedation. Our goal is to contribute to thoughtful consideration of the ways in which this can be accomplished . . . with patient safety foremost.

Sincerely,

Mark A Warner

Mark A. Warner, M.D.
President
American Society of Anesthesiologists

cc: David Seaberg, M.D., ACEP President-Elect
Andrew Sama, M.D., ACEP Vice President
Dean Wilkerson, ACEP Executive Director
Jerry Cohen, ASA President Elect
John Zerwas, ASA First Vice President
John Thorner, ASA Executive Vice President
Beverly Philip, M.D., Chair, ASA'S Committee on Non-Anesthesiologist Privileging

February 10, 2011

Dear ACEP Member:

One of the core competencies of an emergency physician is procedural sedation. Our clinical policies have outlined the evidence that we are skilled in the area of analgesia, sedation, and emergency airway management. The Centers for Medicare & Medicaid Services (CMS) has revised its interpretive guidelines for anesthesia services. Hospitals are to use these guidelines in developing their individual credentialing policies. These guidelines and their FAQs note that "…emergency medicine-trained physicians have very specific skill sets to manage airways and ventilation that is necessary to provide patient rescue. Therefore, these practitioners are uniquely qualified to provide all levels of analgesia/sedation and anesthesia (moderate to deep to general)." This change in CMS' guidelines is the result of vigorous efforts by ACEP leadership and staff working with others to achieve this result.

The CMS document also suggests that hospitals should use specialty-specific guidelines in creating their credentialing policies and specifically cites ACEP's clinical policy on sedation, and quotes the Emergency Nurses Association (ENA) and ACEP to "support the delivery of medications used for procedural sedation and analgesia by credentialed emergency nurses working under the direct supervision of an emergency physician. These agents include but are not limited to etomidate, propofol, ketamine, fentanyl, and midazolam."

Recently, the American Society of Anesthesiologists (ASA) issued their "Statement on Granting Privileges for Deep Sedation to Non-Anesthesiologist Sedation Practitioners." After ACEP leaders met with the ASA, they wrote the attached letter of clarification. Of note, their statement and this letter preceded the CMS revision noted above.

We believe, based on the CMS interpretive guidelines and the ASA's letter of clarification, that physicians who are residency trained and/or board certified by ABEM/AOBEM in emergency medicine have the skills necessary to perform procedural sedation (including analgesia), as well as all levels of sedation. These skills surpass what is taught in Advanced Cardiac Life Support, Advanced Trauma Life Support, and Pediatric Advanced Life Support courses, so current certification in these courses should not be required. Many states and individual hospitals agree with this conclusion.

Further, as noted in the ASA's letter of clarification, our practice environment is unique. When two or more physicians are readily available to the emergency department, we feel it is prudent to have both present during the sedation. However, because our procedures are brief and we are able to address any airway issues, when two physicians are not available, sedation can be performed initially by an emergency physician, and once stable sedation and adequate monitoring are established, the emergency nurse can monitor the patient while the physician performs the procedure.

Emergency physicians provide care to more than 120 million people each year. We provide safe, quality care, including the comfort of our patients during painful procedures. These documents reaffirm our ability to safely care for our patients.

Sincerely,

Sandra M. Schneider, MD, FACEP
President, American College of Emergency Physicians

ACEP Recommendations

- **Sedation and Analgesia in the Emergency Department: Recommendations for Physician Credentialing, Privileging and Practice**

- O'Connor RE, Sama A, Burton JH, Callaham ML, House HR, Jaquis WP, Tibbles PM, Bromley M, Green SM

- This article was approved by the ACEP Board of Directors at its June 2011 Board meeting and reflects ACEP's position on procedural sedation and analgesia in the emergency department.

ACEP Recommendations for MD credentialing, privileging, and practice

- Practitioner administering sedation: …*Actual drug administration may be delegated to a RN or other qualified staff with established competency for sedative administration under direct- contemporaneous physician supervision……*

- Emergency Nursing:….*The capability of qualified ED nurses to administer propofol, ketamine and other sedatives under the direct supervision of a privileged emergency physician is strongly supported by ACEP*

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group, January 14, 2011

Anesthesia exists along a continuum. For some medications there is no bright line that distinguishes when their pharmacological properties bring about the physiologic transition from the analgesic to the anesthetic effects. Furthermore, each individual patient may respond differently to different types of medications

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group, January 14, 2011

- *Hospitals are free to develop their own specific organizational arrangements in order to deliver all anesthesia services in a well-organized manner. Although not required under the regulation to do so, a well-organized anesthesia service would develop the hospital's anesthesia policies and procedures in collaboration with several other hospital disciplines (e.g., surgery, pharmacy, nursing, safety experts, material management, etc.) that are involved in delivering these services to patients in the various areas in the hospital.*

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group, January 14, 2011

Under the "Surveyors" section:

- *Request a copy of and review the hospital's anesthesia services policies and procedures.*
- *Do they apply in all hospital locations where anesthesia services are provided?*
- *Do they indicate the necessary qualifications that each clinical practitioner must possess in order to administer anesthesia as well as moderate sedation or other forms of analgesia?*
- *Do they address what clinical applications are considered to involve analgesia, in particular moderate sedation, rather than anesthesia, based on identifiable national guidelines? What are the national guidelines that they are following and how is that documented?*

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group, January 14, 2011

- *CMS expects surveyors to verify that the hospital can identify appropriate guidelines that support its policies.* ***A hospital could use multiple guidelines, for example, ACEP for sedation in the emergency department*** *and ASA for anesthesia/sedation in surgical services, etc.*

The Joint Commission

- JCAHO *permits the use of propofol by emergency physicians,* ***depending on the policy of the individual hospital***
- *Individuals administering moderate or deep sedation are qualified and have credentials to manage and rescue patients at whatever level of anesthesia is achieved intentionally or unintentionally*
- *In addition to the individual performing the procedure, a sufficient number of qualified staff is present to evaluate the patient, to provide the sedation and/or anesthesia, to help with the procedure, and to monitor and recover the patient.*

Nursing Issues

- Can nurses “push the plunger” and administer propofol and ketamine?

BON Moderate Sedation Position Statement

North Carolina

- ***"Administration of such drugs as Propofol and Ketamine for procedural purposes, if ordered by a physician and allowed by agency policy, is not prohibited providing patient retains control of reflexes and can be aroused."***

- South Carolina ??

- Georgia ??

Resources

- Emergency Nurses Association
  - http://www.ena.org/government/Advocacy/Procedural/default.asp
- ACEP website
- Email: amywgriffin@gmail.com