

**Procedural Sedation by Anesthesiologists or Non-Anesthesiologists: An Institutional Perspective**

Ronald Pearl, MD, PhD  
Professor and Chair  
Department of Anesthesia  
Stanford University  
Rpearl@stanford.edu



**No Financial Disclosures**



**Chair of Moderate Sedation Committee**

- Responsible for sedation throughout the health care system, even when anesthesiologists are not involved
- Complex regulations (TJC, CMS, state)
- Create policies and procedures
- Collect process and outcomes data
- Report data



---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

**Chair of Moderate Sedation Committee**



---

---

---

---

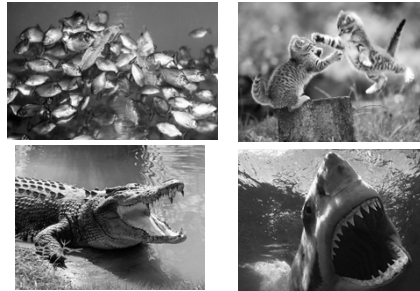
---

---

---

---

**Chair of Moderate Sedation Committee**



---

---

---

---

---

---

---

---

**Sedation Issues**

- Compliance with simple requirements
- Challenge of procedural sedation
- Sedation by non-anesthesiologists
- Computer-Assisted Personalized Sedation (CAPS)

---

---

---

---

---

---

---

---

### Capnography During Moderate Sedation

- ASA 2010 Standards for Basic Anesthetic Monitoring: "During moderate or deep sedation the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide"
  - Pulse oximetry does not monitor ventilation
  - Airway obstruction is common during moderate sedation and often not recognized by the provider
  - Capnography routinely detects respiratory changes prior to the onset of hypoxia
  - Closed claims data indicate increased risk of respiratory events and respiratory deaths with sedation outside the operating room, and the majority of these events could have been prevented with better monitoring

---

---

---

---

---

---

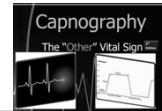
---

---

---

### Capnography During Moderate Sedation

- American Society for Gastrointestinal Endoscopy, the American Gastroenterological Association, and the American College of Gastroenterology
  - The adoption of the revised ASA Standard will unnecessarily add cost, inefficiency and waste to a healthcare system already overrun with excess costs and waste...a costly technology that has no proven value in healthcare delivery.



---

---

---

---

---

---

---

---

---

### The Capnography Journey



- Discussions began in 2011
- "I am not sure that capnography is available everywhere moderate sedation is provided but recognize this is the wave of the future. I need to find out if placing it, or recommending it in the moderate sedation policy would put the hospital in a liability position until we are better prepared"
- Creation of a revised moderate sedation committee in 2012 with the charge of implementing capnography for all moderate sedation
  - 39 members
  - Moderate sedation administered in over a dozen distinct settings, each with different moderate sedation procedures, preferred drugs, monitors, and documentation

---

---

---

---

---

---

---

---

---

### The Capnography Journey



- Four subcommittees with at least monthly meetings
  - Equipment
  - Education
  - Documentation/IT
  - Audits/Reporting
- Progress delayed with departure of quality manager
- Capital budget request for over \$1 million in 2014
  - 220 capnography modules
  - 60 portable capnography monitors
  - 2 complete monitoring systems
  - Extensive supply of disposables
- Pilot programs in 2014
- Full implementation with electronic data capture in 2015
- Plans for capnography for PCA patients in the future
- Moral: Changes in sedation practice are never simple!

---

---

---

---

---

---

---

---

---

---

### Continuum Of Depth Of Sedation

- Moderate Sedation is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate.
- Deep Sedation is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired.
- General Anesthesia is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation.




---

---

---

---

---

---

---

---

---

---

### What Is Procedural Sedation?

- Frank, "Procedural sedation in adults", Up-to-Date
- The practice of acute care medicine often requires the performance of procedures that can cause pain and anxiety. Procedural sedation reduces the discomfort, apprehension, and potential unpleasant memories associated with such procedures and facilitates performance of the procedure...The practice of providing sedation, once primarily the domain of anesthesia practitioners, is now routinely performed by other specialists, such as emergency clinicians, critical care specialists, and various nurse specialists...PSA may be used for any procedure...Common procedures in which PSA may be beneficial include electrical cardioversion, closed joint reduction, complicated laceration repair...
- Propofol, etomidate, midazolam, fentanyl, ketamine

---

---

---

---

---

---

---

---

---

---

### Procedural Sedation

- **Clinical Policy: Procedural Sedation and Analgesia in the Emergency Department.** Ann Emerg Med 2014; 63:247
- **Fasting: Level B recommendation:** Do not delay procedural sedation in adults or pediatrics in the ED based on fasting time. Preprocedural fasting for any duration has not demonstrated a reduction in the risk of emesis or aspiration when administering procedural sedation and analgesia.
- **Capnography: Level B recommendation:** Capnography may be used as an adjunct to pulse oximetry and clinical assessment to detect hypoventilation and apnea earlier than pulse oximetry and/or clinical assessment alone in patients undergoing procedural sedation and analgesia in the ED.
- **Personnel: Level C recommendations.** During procedural sedation and analgesia, a nurse or other qualified individual should be present for continuous monitoring of the patient, in addition to the provider performing the procedure.
- **Medications: Level A recommendation:** Propofol can be safely administered to children and adults for procedural sedation and analgesia in the ED.

---

---

---

---

---

---

---

---

---

---

### Procedural Sedation in the ED

- **Multiple studies demonstrate safety (but may not be adequately powered for rare adverse events and may not have captured all adverse events)**
- **Safety requires appropriately trained personnel, appropriate patient selection, limited doses of high-risk drugs, understanding of drug interactions, and appropriate monitoring**
- **Risks are often not appreciated by ED physicians**
  - **Proposal to use propofol in the ED did not include any training, did not have dedicated physician for sedation, did not limit depth of sedation, did not have quality review, etc.**

---

---

---

---

---

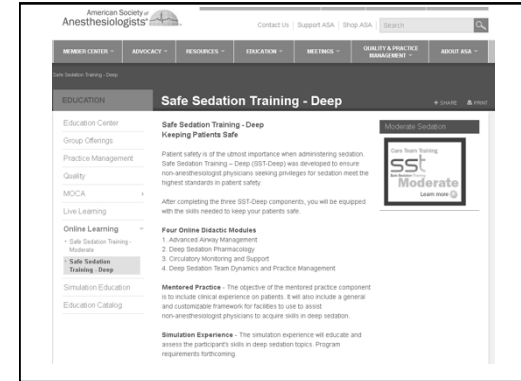
---

---

---

---

---




---

---

---

---

---

---

---

---

---

---

### Sedation for Endoscopy

- 40% of endoscopies performed with propofol

GASTROENTEROLOGY 2009;137:2161-2167

#### AGA

##### Position Statement: Nonanesthesiologist Administration of Propofol for GI Endoscopy

*This statement on the use of nonanesthesiologist administered propofol (NAAP) for GI endoscopy is issued jointly by The American Association for the Study of Liver Diseases, American College of Gastroenterology, American Gastroenterological Association, and American Society for Gastrointestinal Endoscopy. A 4-member committee, composed of a representative from each society, prepared the first draft of this document, which was then reviewed and approved by the governing board of each organization. This document is designed to provide an evidence-based assessment of propofol-mediated sedation by properly trained gastroenterologists and other nonanesthesiologists. The safety, efficacy, cost-effectiveness, and training issues involved with nonanesthesiologist administration of propofol for GI endoscopy are reviewed, and a series of concluding statements and recommendations are provided. Whenever possible, these summary conclusions are graded based upon the strength of the supporting evidence (Table 1).*

### New Acronyms

- Nurse-administered propofol sedation (NAPS)
- Non-anesthesiologist administered propofol (NAAP) sedation



### AGA Conclusions

- For ERCP and EUS (endoscopic ultrasound), NAAP is more cost-effective than standard sedation (grade 1B).
- Nonanesthesiologist-administered propofol sedation improves practice efficiency when compared to standard sedation (grade 2C).
- The use of anesthesiologist-administered sedation for healthy, low-risk patients undergoing routine GI endoscopy results in higher costs with no proven benefit with respect to patient safety or procedural efficacy (grade 2C).

---

---

---

---

---

---

---

---

---

---



---

---

---

---

---

---

---

---

---

---



---

---

---

---

---

---

---

---

---

---

### Propofol and OSA

- Lo, J Clin Sleep Med 2015;11:1011
- 90 patients with OSA underwent polysomnography and drug-induced sleep endoscopy (DISE) under BIS-guided propofol infusion at BIS 65-75 (light sedation) and 50-60 (deep sedation)
- Sedation depth was associated with the severity of velopharynx and oropharynx obstruction, oropharynx obstruction pattern, tongue base obstruction, epiglottis anteroposterior prolapse and folding, and arytenoid prolapse

---

---

---

---

---

---

---

---

---

---

### Propofol and Endoscopy

- Goudra, Saudi J Gastroenterol 2015 Sep 8. [Epub ahead of print]
- Cardiac Arrests in Patients Undergoing Gastrointestinal Endoscopy: A Retrospective Analysis of 73,029 Procedures
- Incidence of cardiac arrest during and immediately after endoscopy was 3.92 per 10,000 with propofol sedation and zero with midazolam-fentanyl sedation
- 89% of these periprocedural cardiac arrests were airway management related
- The incidence of cardiac arrest and death throughout admission was 10 times higher in patients receiving propofol-based sedation compared with midazolam-fentanyl sedation (6.07 vs. 0.67; 4.28 vs. 0.44)

---

---

---

---

---

---

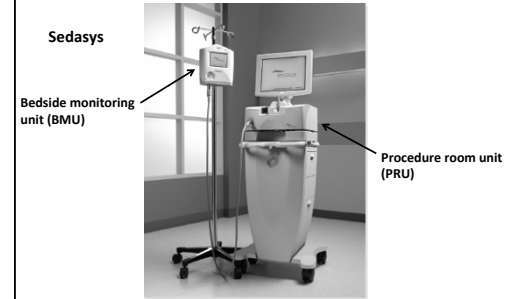
---

---

---

---

### Computer-Assisted Personalized Sedation (CAPS)



---

---

---

---

---

---

---

---

---

---

**Sedasys System**

- **Bedside monitoring unit (BMU)**
  - Portable unit attached to the patient throughout the perioperative process
  - Monitors heart rate, NIBP, and SpO<sub>2</sub>
  - Oxygen delivery by oronasal cannula
  - Automated responsiveness monitor (ARM)
    - Auditory request to squeeze a handset, combined with mild vibration of the handset
    - Increased volume and vibration if no response

---

---

---

---

---

---

---

---

**Sedasys System**

- Procedure room unit (PRU)
  - Display Monitor
    - ECG, NIBP, SpO<sub>2</sub>, capnography, patient response time
  - Control Unit
    - Intravenous infusion pump with proprietary propofol drug delivery/dosing algorithm to target serum propofol concentration
    - Fentanyl bolus (25-75 mcg), 3 minute wait, 0.4 mg/kg propofol bolus over the following 3 minutes
    - Maintenance rate decreased if responsiveness absent
    - Propofol delivery (0.25 mg/kg bolus and infusion rate) can be adjusted by the provider
    - Oxygen delivery increased up to 12 L/min if desaturation, bradypnea, or apnea occurs

---

---

---

---

---

---

---

---

**Sedasys System**

- **Sedasys rejected by the FDA in 2010 but approved in 2013 following modifications**
  - Mild to moderate sedation for simple endoscopy procedures in ASA 1 and 2 patients
  - Extensive training of the provider physician
  - Immediate availability of anesthesia provider

---

---

---

---

---

---

---

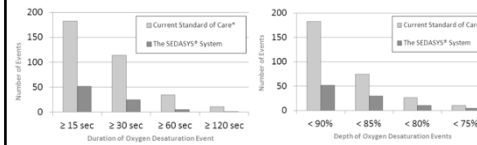
---



### Sedasys System

- Pambianco, *Gastrointestinal Endoscopy*, 2011; 73:773
  - 1,000 ASA I and II patients undergoing routine endoscopy
  - Randomized to Sedasys or to standard of care (opioid/midazolam)
  - Sedasys group had decreased oxygen desaturation, decreased apnea duration, increased patient and clinician satisfaction, and decreased recovery time

	Sedasys	Standard of Care
Desaturation (AUC sec*%)	23.6	88.0
Clinician satisfaction	92.2%	76.3%
Patient satisfaction	92.3%	89.7%



- Comparison was to non-propofol regimen administered by the endoscopist and often included meperidine
- EGD time was under 4 minutes
- Doses were low (74 mcg fentanyl and 106 mg propofol for colonoscopy)
- Hypoxia differences (primary outcome) were specific to two study sites which did not increase oxygen delivery in the standard care group
- Study was not blinded
- Study funded by the sponsor and all authors had consulting agreements or were employees of the company

---

---

---

---

---

---

---

---

---

---



---

---

---

---

---

---

---

---

---

---



---

---

---

---

---

---

---

---

---

---

### Limitations of Sedasys

- Safety only demonstrated within the significant constraints of the study
- Need for extensive training of the gastroenterologist (4 hours of online training and 6 hours of simulation-based training)
- Cost of the device (\$150 per patient)
  - Drug delivery cassette, oral/nasal cannula, and bite block are proprietary
- Cost of a dedicated nurse
- Need for a rescue anesthesiologist to be immediately available

---

---

---

---

---

---

---

---

---

---

### ASA Ad Hoc Committee on Sedays

- Use of CAPS limited to:
  - ASA I and II patients ≥ 18 years old
  - Colonoscopy and EGD procedures
  - Minimal-to-moderate sedation
  - Anesthesia provider immediately available for assistance or consultation
  - Training of the physician responsible for the sedation
  - Nurse assigned to monitor the administration of sedation
  - Fentanyl limited to a single premedication dose 3 minutes before the start of the propofol infusion
  - Procedure stopped during any alarm state if doing so does not compromise patient safety; if procedure cannot be stopped, infusion stopped and physician should immediately call for help

---

---

---

---

---

---

---

---

---

---

### Final Thoughts



- We are the experts in sedation
- Moderate sedation can be safely provided by other physicians, nurses, and advanced practice providers
- Deep sedation and propofol can be dangerous
- New technologies may add value in decreasing risk
- Our responsibility is to regulate rather than prohibit these advances
- Modify the APSF mission statement to “That no patient shall be harmed by sedation”

---

---

---

---

---

---

---

---

---

---



---

---

---

---

---

---

---

---