Propofol and Sedation for the Endoscopy Patient

Speaker Disclosure

- I have received no research grants, honoraria or money of any kind which might influence my talk
- My group provides anesthesia services for Syracuse Endoscopy Associates
- I will try to reference peer reviewed journals when possible
- I am a member of the ASA house of delegates which gives approval of ASA guidelines

Learning Objectives

- Understand current guidelines and regulations for the administration of safe procedural sedation
- Compare the efficacy and safety of various agents used for procedural sedation
- Review Propofol Guidelines and Standards
- Review potential new systems
38 million procedures requiring IV sedation in the USA in 2009

- GI: 15,500,000
- Urology: 6,700,000
- Surgery: 4,000,000
- OB/GYN: 3,600,000
- Plastic/derm: 2,200,000
- Cardiology: 2,100,000
- ENT: 2,000,000
- IR: 1,900,000

Data courtesy of John Devlin PharmD, Northeastern University, 2011

In the old days

- Low-risk colonoscopy got lighter sedation, though most patients didn't remember anything afterward.
- These drugs were ordered by the doctor doing the exam.
- A nurse administered the sedation and was responsible for monitoring the patient.
- High-risk patients; old, sick or previously had complications were reserved for anesthesia.

Sedation Continuum

- Moderate sedation: Purposeful response to verbal or tactile stimulation, airway, ventilation and CV requires no intervention.
- Deep sedation: Purposeful response after repeated or painful stimulation, airway and ventilation maybe inadequate.
- General anesthesia: Unarousable even with painful stimulus, airway often inadequate, ventilation often impaired, CV may be impaired.

MOAA/S

Responsiveness: Score
• Responds readily to spoken name  5
• Lethargic response to name        4
• Responds loud/repeated name       3
• Responds to mild shaking          2
• Responds painful trapezium poke   1
• No response to trapezium poke     0

Procedural Safety

• Often a dark room, patient turned away, and many times uncooperative
• Should each patient get supplemental Oxygen?
• How do we rescue a failed airway?
• ACLS or airway course required?
• Equipment and monitors nearby?
• Standards met?

Rescue from a deeper plane of sedation

• Airway skills: jaw lift to intubation
• ACLS becomes a basic skill set
• Standardization of practice
• QI documentation:
  – Airway intervention
  – Use of reversal agents
  – Hypoxia
  – Transfer to higher level of care
H&P

• A history and physical examination, with particular emphasis on sedation-oriented issues, should be performed at the time of endoscopy.

The history:
• (1) abnormalities of major organ systems;
• (2) snoring, stridor, or sleep apnea;
• (3) drug allergies, current medications, and potential for drug interactions;
• (4) prior adverse reactions to sedatives or anesthetics;
• (5) time and type of last oral intake
• (6) tobacco, alcohol, or substance use.

The physical examination
• should include the following: measurement of vital signs, determination of baseline level of consciousness, and examination of the heart and lungs and airway anatomy.

Standard Monitoring

• Moderate or deep sedation must have continuous monitoring before, during and after the administration of sedatives
• ECG
• BP at least every 5 minutes
• Sedation scale
• Pulse oximeter
• Capnography (ET CO2 monitoring)

Airway Obstruction

• Ventilation is not oxygenation
• Airway collapse and/or apnea slower to diagnosis with supplemental oxygen use
• Oxygen administration may prevent hypoxemia and its deleterious effects it will not detect the development of hypercapnea. Deleterious consequences of alveolar hypoventilation include myocardial depression, acidosis, intracranial hypertension, narcosis, and arterial hypertension or hypotension
Capnography

- Effective July 1, 2011, ASA’s New Standard For Basic Anesthesia Monitoring Reads:
  - 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.

UNSEDATED ENDOSCOPY

- Selected patients may be able to undergo endoscopic procedures without sedation. Small-diameter endoscopes (less than 6 mm) can improve tolerability.
- Topical anesthesia is used during unsedated endoscopy.
- Successful colonoscopy may be performed in selected patients who receive no sedation or sedation only if needed.
- Older patients, patients who are not anxious, or patients without a history of abdominal pain may have better tolerance of upper endoscopy or colonoscopy with little or no sedation.
- For procedures performed without medications, the types of and levels of monitoring should be individualized. However, preparation should be the same as described for sedation in the event that sedation is administered.
- “Position statement: Nonanesthesiologists administration of propofol for GI endoscopy” Gastrointest Endosc 2009: 70: 1053-9

TOPICAL ANESTHESIA

Topical pharyngeal sprays with lidocaine, tetracaine, and benzocaine are often used for anesthetic purposes during upper endoscopy, particularly when unsedated endoscopy is performed.
Glycopyrrolate to dry the mucosa prior to local anesthesia use in conjunction with intravenous or intramuscular sedative greatly improves success.
Ideal Sedative

- Rapid onset of action
- Effective at providing desired sedation
- Rapid recovery
- Easy to administer
- Excellent patient safety
- Few side effects
- Minimal interaction with other drugs
- Low Cost
  - Jacobi et al, Crit Care Med, 2002;30:119-41

Benzodiazepines
Riker SEDCOM Study JAMA 2009:301 489-99

- Sedation, anxiolysis and amnesia
- Rapid onset of action
- Clinical experience
- Low acquisition cost
- Reversal agent available
- Longer time to recovery
- Respiratory depression
- Hypotension with CV instability
- Paradoxical agitation

Propofol

- Intravenous sedative / hypnotic/anxiolytic
- Onset within one circulation time
  - Onset 30 seconds in a 20 year old
  - Onset 4 minutes in a 90 year old
- Half life 2-4 minutes
- Average sedative dose varies
- Some antiemetic properties
Propofol Adverse effects

- Pain on injection
- No real analgesia
- Respiratory depression
- Hypotension
- Myocardial depression
- Potential for infection
- Hypersalivation
- Addiction


Propofol for sedation

Pro:
- Higher satisfaction for gastroenterologist as patient in deeper sedation
- Faster throughput with quick wake up
- Patient satisfaction higher and more likely to return for future procedures
- Transfer of sedation liability to anesthesia provider

Con:
- Anesthesia Provider costs and availability
- Primarily screening
- Not all procedures nor all patients require the skill set of an anesthesia provider

Statement on Safe Use of Propofol

- The Warnings section of the Propofol package insert (Diprivan®, AstraZeneca) states that 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.”

- ASA statement on Safe Use of Propofol; October 2009
FDA upholds Safe use of Propofol

- In 2005 the American College of Gastroenterology (ACG) asked that FDA remove the language
- On August 16, 2010 FDA denied the ACG petition in its entirety.
- FDA summarized its reasoning as follows "After considering ACG claims and the literature, ... we conclude that you have not shown that the warning is no longer warranted or appropriate. In fact, we conclude that the warning is warranted and appropriate in light of the significant risks associated with propofol, and we further conclude that the warning should help ensure that propofol is used safely. Accordingly, we will not seek to have the warning removed, reduced, or otherwise amended."
- The letter also references ASA, saying that the warning is consistent with recommendations of ASA.
- FDA also dispelled ACG's cost contention, saying that added costs associated with having an anesthesia provider administer the drug was warranted in light of the risks.
- Finally, FDA concluded that the warning did not unduly restrict the practice of gastroenterology, mentioning that hospitals typically set their own procedures, but that in any event the warning was "appropriate and warranted in light of the significant risks associated with propofol."

Center for Medicare and Medicaid Services Interpretative Guidelines

- December 2009 & May 2010
- for the hospital setting only
- All anesthesia services must be directed by a physician and consistently implemented in every department and setting which provides anesthesia services
- Deep sedation can only be given by anesthesiologist, CRNA, AA or otherwise qualified anesthesia provider

The JC Standards for Procedural Sedation

- Hospitals can set their own policies re: procedural sedation
- Qualified personnel must be available to administer, monitor and evaluate patient receiving sedation
  - TJC specifically references deep sedation in the GI suite with propofol as an anesthesia providers level skill set
- Defined monitoring standards and assessment tools are ID in institutional policies
- Documentation available in med record for all patients receiving sedation
- Appropriate monitoring equipment
- Rescue equipment immediately available

JCS on Accreditation of HealthCare Organizations
www.jacho.org/standards April 2011
Fospropofol

- Water soluble
- Prodrug: metabolized in the liver to propofol
- Onset in 4 minutes
- Dose more unpredictable
- Manufacture hope was that it would avoid the Black box warning of propofol
- FDA didn’t buy it and now the drug has disappeared

Dexmedetomidine (preceax)

- A2 agonist
- Sedative/Anxiolytic
- Good Analgesic
- Less respiratory depression than Propofol
- Significant Bradycardia
- Hypotension if bolus
- Much slower onset and recovery

Remifentanil

Ultra short acting narcotic
Broken down by blood esterases
Good analgesic
Some sedative properties
No amnesia
Very significant respiratory depression
AnaConDa Vaporizer

- New miniature vaporizer developed by Sedana Medical for ICU patients for sedation
- Old concept of self-administration of anesthesia gases
- Used worldwide for painful contractions in labor
- Entonox (50% nitrous oxide premixed in oxygen)
- AnaConDa now added volatile anesthesia gases
- General anesthesia often results


Computer Assisted Personalized Sedation System (SEDASYS®)

- Investigation device, not approved by FDA
- The first computer-assisted personalized sedation (CAPS) system designed to allow physician/nurse teams to provide minimal-to-moderate sedation with propofol during routine upper and lower gastrointestinal procedures in healthy adults
- Monitors heart rate, respiratory rate, O2sat, EtCO2, and has a feedback loop (basically a speaker in the ear, "squeeze your hand" and automatically reduces dose if no response)
- Several small studies in healthy patients
- Most had much or complete recall as propofol doses averaged 8ml for colonoscopies, 5ml for endoscopies
- Very little "hang over"
- "The SEDASYS® System has the potential to benefit patients, physicians and nurses. If approved, it may help reduce sedation-related risks associated with endoscopic procedures, may improve the overall patient experience, and may encourage more individuals to be screened for colon cancer."

UNSEDATED ENDOSCOPY

- Capsule endoscopy
- "pill" sized camera and transmitter or pH monitor
- Swallowed by patient
- Current indications:
  - Obscure GI bleeding
  - Evaluation of Celiac Ds.
  - Evaluation of IBS
  - Measure GERD
Hot off the press

- Use of anesthesiologists to monitor sedation has doubled in last 5 years
- Mostly low risk patients
- "these services are not harming patients ..., basically giving them a luxury that is not strictly necessary"
- "That matters when policymakers are trying to rein in rising medical costs"
- Regional variation, 13% in the West to 59% in the Northeast
- JAMA March 21, 2010 Vol 307, No. 11

“For some must watch, while some must sleep” Hamlet Act III sc.ii

- Sedation for procedures is rising rapidly
- Propofol is an excellent drug for this use because it produces rapid deep sedation but wears off rapidly
- Throughput and patient satisfaction are significantly improved
- Propofol has a “narrow window” between producing sedation and stop breathing
- Careful monitoring is necessary and no reversal drug is available
- Rescue training and equipment must be available
- Standards and measures for use must be met
Sedation Scale

• Ramsey Sedation Scale:
  • 1 Anxious or restless
  • 2 Cooperative, oriented and tranquil
  • 3 Responds when asked
  • 4 Asleep, brisk respond to light glabellar touch
  • 5 Asleep, slow response
  • 6 Asleep, no response to touch

• Richmond Agitation-sedation Scale
  • +4 combative, 0 alert and calm, -4 deep sedation