John J. Vargo, MD, MPH, MPH
Chairman, Department of Gastroenterology and Hepatology
Vice Chairman, Digestive Disease Institute
Cleveland Clinic

Disclosures

- Boston Scientific: Consultant
- Cook Medical: Consultant
- Olympus America, Inc.: Consultant
- Ethicon EndoSurgery: Consultant
- gEYE Cue Ltd.: Advisory Board
Outline

- Sedation landscape
- Capnography
- Computerized propofol sedation
- Pharmacoeconomics
- New challenges

The Landscape

Efficacy
- Procedure Completion
- Safety

Pharmacoeconomics
- Opioid
- Benzodiazepine
Why is it important to get this right?

Pay for Performance (P4P): AHRQ Resources

What Is Capnography?

- A non-invasive, continuous measurement of exhaled carbon dioxide concentration
- Expired CO$_2$ is sampled via a specialized nasal cannulae
- Measures ventilation, NOT oxygenation
What info does capnography provide?

ETCO₂ display

- Numerical value for ETCO₂
- Distinct waveform (tracing) for each respiratory cycle

Normal Waveform

- A-B: Baseline = no CO₂ in breath
- B-C: Rapid rise in CO₂
- C-D: Alveolar plateau
- D: End expiration (EtCO₂)
- D-E: Inhalation
### Capnography

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Sedation Regimen</th>
<th>Sedation Target</th>
<th>Hypoxemia</th>
<th>Apnea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric EGD / Colonoscopy</td>
<td>Benzo/Opioid</td>
<td>Moderate</td>
<td>↓</td>
<td>NE</td>
</tr>
<tr>
<td>ERCP / EUS</td>
<td>Benzo/Opioid</td>
<td>Deep</td>
<td>↓</td>
<td>↓</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>Propofol</td>
<td>Deep</td>
<td>↓</td>
<td>↓</td>
</tr>
</tbody>
</table>

### Capnography and the ASA

- “During moderate and deep sedation the adequacy of ventilation shall be monitored by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide...”
- **Standards for Basic Anesthetic Monitoring, Standard II, Section 3.2.4**

Accessed 9/30/12
Capnography Caveats

- Adult EGD: moderate sedation
- Adult Colonoscopy: moderate sedation
- Predictive outcomes
- Training
- Cost

Other Challenges

- Obstructive Sleep Apnea
- Obesity
- ASA III
OSA and Sedation-related Hypoxemia

- Hypoxic
- Non-hypoxic

<table>
<thead>
<tr>
<th>Low Risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>93</td>
<td>90</td>
</tr>
<tr>
<td>7</td>
<td>10</td>
</tr>
</tbody>
</table>

Low risk: n=143
High risk: n=90

Relative Risk Hypoxemia Berlin(+):
1.48: 95%:0.58-3.80

Is The Combination of a Benzodiazepine and Opioid Dead?

- Regionally, yes

- The only universally accepted combination available to GI’s who practice sedation

- Economic feasibility?
  - Patient perspective
  - Physician perspective
  - Third party payers
Propofol-Mediated Sedation

- NAPS
  - Propofol “monotherapy”
- Mixed NAPS
  - Opioid / Benzodiazepine / Propofol
- Anesthesiologist-directed sedation
- CAPS

NAPS and Mixed NAPS

- Throughput improved
- Patient satisfaction mixed
- NAPS = deep sedation / general anesthesia
- Mixed-NAPS = reliable targeting for moderate sedation
Computer Assisted Personalized Sedation (CAPS)

- Patient monitoring
  - Oximetry
  - Capnography
  - EKG
  - NIBP
  - Patient Responsiveness
- Oxygen delivery
- And propofol delivery
  - Computer controlled infusion pump

Study Endpoints

- Primary Endpoint
  - Hemoglobin desaturation [area-under-the-curve (AUC)]

- Secondary Endpoints
  - Clinician satisfaction
  - Patient satisfaction
  - Time to recovery
  - Duration of deep sedation / general anesthesia

\[
AUC = \text{Area}_1 + \text{Area}_2
\]
**Multicenter Controlled Trial of CAPS Versus Standard of Care: Primary Outcome**

- **AUC of $\text{SpO}_2 < 90\% \text{ - sec}$$^*$**
  - Colonoscopy:
    - n = 358
    - 17.8
  - Upper GI Endoscopy:
    - n = 138
    - 36.6
    - n = 141
    - 60.2

**Pambianco DJ et al. Gastrointest Endosc 2010**

**Safety and Effectiveness**

- **AUC_{Desat}**
  - Colonoscopy
    - EGD
      - MOAA/S Percent of Measures
        - Sedation Level
          - Minimal Sedation
            - Moderate Sedation
              - Deep Sedation
                - General Anesthesia

- **Level of Sedation**
  - Distribution Function
  - Time (mins)

- **Recovery Time**
  - MOAA/S Percent of Measures
  - Time (mins)
Computer Assisted Personalized Sedation (CAPS)

- Approved 5/13
- Initiation and maintenance of minimal to moderate sedation
- ASA Class I and II
- Age $\geq 18$
- Elective EGD and colonoscopy
- Immediate availability of anesthesia professional

CAPS Precautions

- Age $< 18$
- ASA III, IV, and V
- Use of fentanyl patch
- Abnormal airway or diagnosed sleep apnea
- Gastroparesis
- BMI $\geq 35$
- Undergoing both EGD / colonoscopy
- Emergent EGD and colonoscopy
CAPS Training

- Anesthesia development and oversight
- Web based training
  - Pharmacology of propofol
  - ID of high risk patients
  - Levels of sedation and rescue
  - Capnometry
- High Fidelity Simulation Centers of Excellence
  - Capnometry
  - Management of airway obstruction and hypoventilation
  - Sedasys hands-on training

Growth of Anesthesia Professional Delivered Sedation

- 5 billion dollars
- CPT Code 00810
  - $155/case CMS
  - $437/case private

Growth of Anesthesia Professional Delivered Sedation

Change in Business Model:
Independent Consultant Model → Employee Model

5 billion dollars

CPT Code 00810
$155/case CMS
$437/case private


EDP-Directed Propofol for Screening Colonoscopy in U.S.

$1.5 million / life year saved
How can ADP become cost effective?
31 fold increase in EDP mortality
17 fold decrease in ADP cost

34.8% non-EDP
2007 Medicare claims
Anesthetist Medicare: $95
Anesthetist non-Medicare: $450
Assuming stable model: $3.2 B over 10 yr
$1.5 million / life year saved

31 fold increase in EDP mortality
17 fold decrease in ADP cost
MAC Colonoscopy Outcomes

- CORI database
- Retrospective cohort study 104,868 average risk
- Moderate conscious sedation (MCS) vs Deep sedation (DS)
- Primary endpoint: ADR “surrogate” any polyp > 9 mm or and “suspected malignant tumor”
  - NO PATHOLOGY
- DS associated with a 25% increase in the detection of “advanced neoplasia” (OR 1.25, 95% CI: 1.10-1.43).
  - NNT: 141


Metwally et al. W J Gastroenterol 2011;17:3912-15

Is MAC Assisted Colonoscopy Safe?

- Patient unable to provide feedback
  - Perforation?
  - Splenic injury
- Patient unable to change position
- Risk of aspiration
- Anesthesia provider variability
Anesthesiologist vs. Gastroenterologist Directed Sedation for ERCP

![Bar chart showing deep cannulation rates for GDS and ADS with p=0.47](image)

OIG Advisory Opinion No. 12-06

- **Arrangement A: “management fee model”** A would pay center per-patient fee for “management services” for AEC space and use of AEC personnel to PE.

- **Arrangement B: “company model”** Physician-owner (PE) would establish an anesthesiologist company and pay anesthesiologist as an independent contractor a negotiated rate.
OIG Advisory Opinion No. 12-06

- Proposed arrangements could generate prohibited remuneration the anti-kickback statute
- No formal case brought to OIG

New Medications, New Challenges

- Telaprevir and Bocepravir
- Antiviral agents for Hepatitis C
- NS3/4A Protease inhibitors
- Interaction with benzodiazepines
- Propofol
Sleep Magnetic?

- Propofol induces slow waves by EEG similar to NREM sleep 1
- Slow waves triggered intracranially during NREM sleep in the rat model 2
- Slow waves triggered with TMS 3

1. Murphy M et al., Sleep 2011;34:283-91A.
Summary

- Propofol mediated sedation: paradigm shift underway
- Sedation with opioid and benzodiazepine is not dead yet!
- Capnography for deep sedation