Capnography reduces the risk of adverse outcomes during gastrointestinal endoscopic procedures with sedation administration.

Role of procedural sedation

- Patients often need to undergo painful, distressing, or unpleasant diagnostic and therapeutic procedures as part of their care.
- Beyond analgesia, sedation may be required to complete the procedure successfully and/or with minimal distress.
- Sedatives are used to induce a state on the patient that enables operative procedures without interfering with cardiorespiratory function.
- The use of sedative/analgesia has been described in numerous guidelines.

Growth of procedural sedation

- An analysis in the US identified that gastroenterology procedures using anesthesia increased from 14% in 2003 to over 30% in 2009.1
  - Although the number of procedures remained constant in Medicare patients, procedures using anesthesia increased from 13.5% to 30.2%.
  - In privately insured patients, procedures increased by 51% and the use of anesthesia increased from 33.6% to 34.5%.
  - In Switzerland, the use of sedation in GI endoscopy increased from 60% in 1990 to 78% in 2003.2
  - In Canada, >90% of patients receive sedation during colonoscopy.3
  - Use of sedation is now standard practice in Italy during gastrointestinal endoscopy.4


Value of Capnography (etCO₂)

- etCO₂ monitors adequacy of ventilation, SpO₂ monitors oxygenation.
- Capnography is the earliest and only real-time measure of evolving respiratory compromise.
- waveform provides immediate indication of:
  - Hypoventilation
  - Airway obstruction
  - No breath
- 'Physiologic' respiration rate.

Important but Different Measurements

- Measures etCO₂.
- Reflected ventilation.
- Hypoventilation & apnea are detected immediately.
- During PAV, respiratory depression was 17.6 times more likely to be detected if monitored by capnography.

Capnography:

- Measures etCO₂
- Reflects ventilation
- Hypoventilation & apnea are detected immediately
- During PAV, respiratory depression was 17.6 times more likely to be detected if monitored by capnography.

Pulse Oximetry:

- Measures SpO₂
- Reflects oxygenation level in the blood
- Values lag with hypoventilation & apnea
- Researchers found significant lag time (avg. 3.7 minutes, up to 10 min) between etCO₂ abnormalities & SpO₂ desaturation.


Why is Capnography needed in Moderate – Deep Procedural Sedation?

Sedation is a continuum and patient response is unpredictable.

- Minimally sedation (Analgesia) - Normal response to verbal or tactile stimulation.
- Moderate sedation (Conscious Sedation) - Purposeful response to verbal or tactile stimulation.
- Deep sedation / Analgesia - Purposeful response following repeated or painful stimulation.
- General Anaesthesia - Unarousable, even with painful stimulation.

Responsiveness:

- Unaroused
- Unresponsive to verbal stimulation
- Unresponsive to painful or tactile stimulation.

Arterial:

- Uninjured
- No interventions required.
- Interventions may be required.
- Interventions often required.

Spontaneous ventilation:

- Uninjured
- Adequate
- May be inadequate
- May be inadequate.

Cardiovascular function:

- Uninjured
- Usual maintained
- May be inadequate.
**Dangers of Moderate Sedation**

- 100% of patients using propofol for colonoscopy dropped to general anesthesia levels by brain monitoring. (Brown et al. ASA 1965)

- 70% of the patients required airway intervention during propofol sedation for colonoscopy. (Brown et al. ASA 1965)

- The proportion of claims for death was increased in claims outside the OR. Respiratory events were more common in remote location claims with inadequate oxygenation/ventilation the most common. 62% of claims due to oversedation were judged to be preventable by better monitoring. (Mitchell et al. Journal of Clinical Anesthesia 1995)

- After overdose of sedative drug, respiratory depression was the most common specific damaging mechanism in MAC claims. Nearly half of these claims were judged as preventable by better monitoring, including capnography. (Kovac et al. Anesthesiology 2008; 108: 1193-95)

**Improving Outcomes in Procedural Sedation**

- The intention-to-treat analysis revealed a significant reduction of the incidence of oxygen desaturation in the capnography arm in comparison with the standard arm. (Beitz et al. American J of Gastroenterology 2012)

- The results of this controlled effectiveness trial support routine use of [...] capnography to detect alveolar hypoventilation and reduce hypoxemia during procedural sedation in children. (Lightdale et al. Pediatrics 2006)

- During Procedural Sedation and Analgesia, cases of respiratory depression were 17.6 times more likely to be detected if monitored by capnography than cases not monitored by capnography. (Meta-analysis, Waugh et al., J of Clinical Anesthesia 2011)

**Procedural Sedation**

**Standards for Moderate or Deep Sedation Procedural Sedation Practices-ASA Standards for Basic Anesthetic Monitoring (July, 2011)**

Excerpt from 3.2.4: “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 expired carbon dioxide unless precluded or invalidating by the nature of the patient, procedure, or equipment.”

ASA definition of “Standard” - “Standards provide rules or minimum requirements for clinical practice. They are regarded as generally accepted principles of patient management. Standards may be modified only under unusual circumstances, e.g., extreme emergencies or unavailability of equipment.”

Similar recommendations have also been passed by anesthesia societies in Canada, UK, and the European Society of Anesthesiology

**Routine use of capnography for procedural sedation**

- American Society of Anesthesiologists (ASA)
  - ASA Closed Claims project: 20 yrs of data revealed that over 60% of adverse events could have been prevented with improved monitoring
  - Standards for Basic Anesthetic Monitoring effective date of 7/1/2011
3.2.4 ... 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 unless precluded or invalidated by the nature of the patient, procedure, or equipment.

Routine use of capnography not yet recommended

- American Society for Gastrointestinal Endoscopy (ASGE) 2/2012 Statement:
  Universal adoption of capnography for moderate sedation in adults undergoing upper endoscopy and colonoscopy has not been shown to improve patient safety or clinical outcomes and significantly increases costs for moderate sedation.

Evaluating the Cost-Effectiveness of Capnography Monitoring in Procedural Sedation: A Gastroenterology (GI) Suite Cost-Avoidance Model

- Michael W Jopling, MD
- Timothy Keofo, BSE, MBA
- Lisa Heard, MSN

- Anesthesiology, Mount Carmel Health System, Columbus OH
- SLM Health, LLC, Boston MA
- Patient Safety, Risk Management Foundation for Hospitals and Affiliates, Boston MA

Monte Carlo Analysis

- 10,000 simulations
- Inputs
  - Reference hospital
  - Rates of adverse events
  - Costs of adverse events
  - Direct capnography cost assumptions
  - Capnography success rate
Conclusion

- The model demonstrates cost-effectiveness of routine capnography monitoring for GI procedural sedation
- Capnography represents an opportunity to improve patient safety and simultaneously decreasing overall facility costs

Capnography reduces the risk of adverse outcomes during gastrointestinal endoscopic procedures with sedation administration

Michael W. Jopling MD, NorthStar Anesthesia, Springfield Regional Medical Center, Springfield, OH, USA
JieJing Ou, MS, Health Economics and Outcome Research, MITG, Medtronic, Mansfield, MA, USA
Disclaimer

- Following a rejection from an APSF grant application, I found that Covidien (now Medtronic) has access to the Premier Database and statisticians familiar with this type of research.
- Therefore this research was performed as a consultant with assistance from Medtronic.

Methods

Premier Database:

- ~600 hospitals routinely submit data to Premier
- Complete hospital census (all patients, therapeutic classes, products / services used)
- HIPAA Compliant and undergoes rigorous quality checks
- Used by participating hospitals to benchmark clinical / financial performance
- FDA uses the Premier data for sentinel hospital surveillance
- 5.2+ million inpatient discharges per year
- 1 in 5 inpatient hospitalizations in the U.S.
Premier Database

- All hospital patients between 2008 and 2013
- Inpatients and outpatients
- Procedures:
  - esophagogastroduodenoscopy (EGD)
  - endoscopic retrograde cholangiopancreatography (ERCP)
  - colonoscopy
- Inclusion:
  - Sedative medication
- Exclusion:
  - Inhalation anesthetics (on procedure day)

Database results grouped:

- Pulse oximetry (SpO₂) only
- Capnography only
- SpO₂ and capnography
- Neither SpO₂ nor capnography

Multivariate logistic regression analysis

- Age
- Gender
- Race
- Comorbid conditions
- Hospital characteristics
Propensity-score matching

- Propensity Score methodology was used to match patients (1:1 ratio) in Capnography sensor use to only a SpO2 sensor used using age, gender, race, Comorbid conditions and Hospital characteristics
- Standard differences were calculated to measure how well the matched groups balanced

Key outcome measures

- Incidence of rescue events
  - Administration of naloxone and/or
  - Administration of flumazenil
- Incidence of death

Limitations

- Premier is a retrospective, administrative (billing) database
- Potential errors/biases
  - Coding error from the hospital end
  - Limited numbers of codes
- Retrospective review provides associations, not cause-and-effect

Results
**N= 4,065,413**
- Inpatients: 258,262
- Outpatients: 3,807,151

### Premier Hospital Database 2008 - 2013

**Inclusion Criteria:**
- Inpatient or outpatient
- Undergoing diagnostic or procedural codes for CAPS, SIRS, or other conditions
  - Diagnostic codes including pneumonia, sepsis, shock, organ failure, and hemorrhage

**Exclusion Criteria:**
- Be present on selected admission day
- Discharge, death, or transfer prior to procedure day

#### Eligible Inpatients
- **SpO2 Only**
- **Cotraproopy Only**
- **Both SpO2 and Cotraproopy**
- **Neither**

#### Eligible Outpatients
- **SpO2 Only**
- **Cotraproopy Only**
- **Both SpO2 and Cotraproopy**
- **Neither**

#### PS Matching:
- 8/1

<table>
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<th>Characteristic</th>
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<th>Outpatient (n=1,037,151)</th>
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### Table Data

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PS Matching – Inpatient Population

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### Table: Inpatient Outcomes Before and After Match

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<tr>
<th>Characteristic</th>
<th>Before Match</th>
<th>SpO2 Sensor Only</th>
<th>After Match</th>
<th>p-value</th>
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<tr>
<td>Death</td>
<td>510 (1.98%)</td>
<td>392 (1.41%)</td>
<td>357 (1.60%)</td>
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<td>Rescue event</td>
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<td>Death</td>
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<td>Rescue event</td>
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<td>34 (0.68%)</td>
<td>34 (0.68%)</td>
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### Table: Outpatient Outcomes Before and After Match

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<th>p-value</th>
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<td>Rescue event</td>
<td>12 (0.29%)</td>
<td>467 (0.35%)</td>
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<td>Death</td>
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<td>6 (0.12%)</td>
<td>25 (0.12%)</td>
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<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
Conclusions

Routine use of capnography not yet recommended

• American Society for Gastrointestinal Endoscopy (ASGE) 2/2012
  Statement:
  Universal adoption of capnography for moderate sedation in adults undergoing upper endoscopy and colonoscopy has not been shown to improve patient safety or clinical outcomes and significantly increases costs for moderate sedation.

• In hospital inpatients and outpatients undergoing gastrointestinal endoscopic procedures performed with sedation administration, capnography sensor use was associated with a reduced likelihood of rescue events and death.
• The use of capnography in these procedures is warranted.
Questions