PRONE SEDATION FOR SPINAL CORD STIMULATOR IMPLANTS
IS IT SAFE?

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NEUROMODULATION

- Technology based treatment to enhance/suppress activity of the nervous system for treatment of diseases

- It is the convergence of bio-medical engineering, biotechnology, neuro computing, developing systems for neural interfaces
NEUROMODULATION

- Modulating the electrochemical nature of the central, peripheral, autonomous nervous systems

- Inhibition, stimulation, modification, regulation, alteration of neuronal function & performance

- Modulating the functionality of the nervous system reversibly by means of electrical, chemical, mechanical, optical, magnetic or other interventions
NEUROMODULATION
MECHANISMS OF SCS
SCS:
• 1.5 billion people suffer from chronic pain worldwide
• 100 million chronic pain sufferers in the US; 30 million from chronic back pain (US)
• Addresses opioid epidemic in US: 100 people die every day from opioid overdose

DBS - Parkinson’s disease: 10 million worldwide; 1.1 million (US)
• Essential tremor: 7-10 million (US)
• Dystonia: <300,000 (US)

VNS: epilepsy:
• 50-65 million worldwide; 3.4 million (US)
• Drug-refractory epilepsy: 1 million (US)
NEUROMODULATION DEVICES MARKET

<table>
<thead>
<tr>
<th>Neuromodulation Segment</th>
<th>Total Sales ($m; %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCS</td>
<td>$2,534 (59%)</td>
</tr>
<tr>
<td>SNS</td>
<td>675 (16%)</td>
</tr>
<tr>
<td>DBS</td>
<td>620 (15%)</td>
</tr>
<tr>
<td>VNS</td>
<td>450 (11%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$4,279m</strong></td>
</tr>
</tbody>
</table>

- All 4 segments = $4.3bn
- SCS/DBS/VNS = $3.6bn, or 85% of total sales
- SCS = $2.5bn, or 60% of total sales

Source: Meddevicetracker; company financials
**SEGMENT VALUATIONS & GROWTH EXPECTATIONS**

Growth: upper single-digit or double-digits

Highest growth segment = SCS

- SCS: 13.2%
- DBS: 11.8%
- VNS: 8.9%
- Nearly doubling in size by 2022

<table>
<thead>
<tr>
<th>Neuromodulation Segment</th>
<th>Estimated Revenues/Expected Growth (%)</th>
</tr>
</thead>
</table>
| SCS                     | $2,534m (2017)  
                          | $4,713m (2022)  
                          | CAGR: 13.2% |
| DBS                     | $620m (2017)  
                          | $1,081m (2022)  
                          | CAGR: 11.8% |
| VNS                     | $450m (2017)  
                          | $688m (2022)  
                          | CAGR: 8.9% |
| **Total**               | $3.6bn (2017) 
                          | $6.5bn (2022)  
                          | CAGR: 12.5% |
FUTURE TRENDS AND ADVANCES

- Miniaturization (of IPGs)
- Improved lead technology
- Improved precision/targeting of nerves
- Less invasive/avoiding implantation of IPGs or batteries
- MRI compatibility (all competitors)
- Longer-life batteries, recharge-free systems
- Customizing therapy, patient tracking, wireless communication
- New indications/targets
- Improving trial process
- Future goal: significantly improving pain relief (80% or higher)
- Combining SCS & PNS
- Next gen, closed-loop, “responsive” systems; eliminating patient use of remote control
- Non-invasive peripheral & brain stimulation technologies
SEDATION PRACTICE GUIDELINES


SEDATION PRACTICE GUIDELINES

ACADEMY OF MEDICAL ROYAL COLLEGES

Safe Sedation Practice for Healthcare Procedures
Standards and Guidance
October 2013
# Levels of Sedation and Analgesia

<table>
<thead>
<tr>
<th></th>
<th>Minimal Sedation/Anxiolysis</th>
<th>Moderate Sedation/Analgesia ('Conscious Sedation')</th>
<th>Deep Sedation/Analgesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsiveness</td>
<td>Normal response to verbal stimulation</td>
<td>Purposeful* response to verbal or tactile stimulation</td>
<td>Purposeful* response following repeated or painful stimulation</td>
</tr>
<tr>
<td>Airway</td>
<td>Unaffected</td>
<td>No intervention required</td>
<td>Intervention may be required</td>
</tr>
<tr>
<td>Spontaneous Ventilation</td>
<td>Unaffected</td>
<td>Adequate</td>
<td>May be inadequate</td>
</tr>
<tr>
<td>Cardiovascular function</td>
<td>Unaffected</td>
<td>Usually maintained</td>
<td>Usually maintained</td>
</tr>
<tr>
<td>Escalation of required competencies</td>
<td></td>
<td></td>
<td></td>
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</table>

* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response. Excerpted from Continuum of Depth of Sedation. Definition of General Anesthesia and Levels of Sedation/Analgesia of the American Society of Anesthesiology. From the ASA, 520N, Northwest Highway, Park Ridge, Illinois, 60068-2573, USA.
DEEP SEDATION

- Screening GI Endoscopy
- Colonoscopy
- Transvenous pacing lead removal
- Catheter Ablation for arrhythmias
- Percutaneous mitral valve repair
- Laser disc surgery
- Minimally invasive spine surgery
- Full thickness skin grafts
- Neurosurgical procedures
**REScue During Sedation**

- Individuals administering ‘Conscious Sedation’ should be able to rescue patients who enter a state of Deep Sedation or General Anaesthesia.

- Rescue of a patient from a deeper level of sedation than intended is by a practitioner proficient in airway management and advanced life support.

- The practitioner corrects adverse physiologic consequences of the deeper-than-intended sedation and returns the patient to the intended level of sedation.
In sum, anaesthesia-related mortality in patients without relevant systemic disease is low, at 0.4/100 000.

Increase in death rates was observed in patients with relevant comorbidities (ASA III: 27/100 000 and ASA IV: 55/100 000).

Anaesthesia-related mortality was 0.69/100 000.

*Dtsch Arztebl Int. 2011 Jul; 108(27): 469–474, Review Article*
P.14.9

PRONE POSITION FOR ERCP UNDER DEEP SEDATION WITH PROPOFOL: OUTCOMES AND RISK FACTORS FOR SEDATION-RELATED ADVERSE EVENTS OVER A 10-YR EXPERIENCE

G. Rossi *, L. Fanti, M. Agostoni, M. Gemma, N. Pasculli, L. Beretta, P.A. Testoni
Ospedale San Raffaele, Milan, Italy

Background and aim: Endoscopic retrograde cholangiopancreatography (ERCP) is a procedure usually performed, in patients presenting biliary-pancreatic diseases, under deep sedation. Prone position is preferred by endoscopists for better endoscopic view of the ampulla, for better x-ray imagines and lower risk of pulmonary aspiration. However this condition can create many concerns in the anaesthetist regarding the possibility of airway management or for resuscitation manoeuvres when necessary. The purpose of the study was to provide data on adverse events during sedation for ERCP.

Material and methods: The design of the study was a retrospective analysis of a total of 3964 ERCP performed over 10 years in an endoscopy unit of an university hospital. Following data were recorded: sex, age, body mass index, smoking habits, American Society of Anesthesiologists and Mallampati score, duration of the procedure, type of sedative drug administered. We registered also the cases of failure of prone position and failed sedation, meaning in the first case the decision to turn the patient supine and in the latter the need to convert sedation to general anesthesia or to stop the procedure if systemic complications occur.

Results: 3913 patients underwent deep sedation, 28 of them (0.72%) were turned supine because of severe systemic complications. All these episodes were considered as failed sedation. The occurrence of failed sedation was predicted by 3 of the variables that we screened for: BMI, ASA score and length of the procedure. Only one death occurred.

Conclusions: ERCP can be safely performed in prone position under deep sedation.
3913 patients underwent deep sedation

28 patients were turned supine because of severe systemic complications

The occurrence of failed sedation was predicted by 3 variables - BMI, ASA score and length of the procedure

Only one death occurred

Conclusions: ERCP can be safely performed in prone position under deep sedation
A prospective assessment of sedation-related adverse events and patient and endoscopist satisfaction in ERCP with anesthesiologist-administered sedation

Tyler M. Berzin, MD, Sirish Sanaka, MD, Sheila R. Barnett, MD, Eswar Sundar, MD, Paul S. Sepe, MD, Moshe Jakubowski, PhD, Douglas K. Pleskow, MD, Ram Chuttani, MD, Mandeep S. Sawhney, MD

Boston, Massachusetts, USA

**Background:** Despite the increasing use of anesthesiologist-administered sedation for monitored anesthesia care (MAC) or general anesthesia in patients undergoing ERCP, limited prospective data exist on the effectiveness, safety, and cost of this approach.

**Objective:** To prospectively assess sedation-related adverse events (SRAEs), patient- and procedure-related risk factors associated with SRAEs, and endoscopist and patient satisfaction with anesthesiologist-administered sedation.

**Design:** Single-center, prospective cohort study.

**Setting:** Tertiary-care referral center.

**Patients:** A total of 528 consecutive patients undergoing ERCP.

**Interventions:** Anesthesiologist-administered MAC or general anesthesia.

**Main Outcome Measurements:** SRAEs, endoscopist and patient satisfaction.
INTRA/POST PROCEDURE COMPLICATIONS

A total of 528 consecutive patients undergoing ERCP.

- O2 desaturation to less than 85% (66 events),
- unplanned intubation (16 events),
- procedure termination (1 event).
- Post procedure endotracheal intubation (2 events)
Clinical Study

Adverse events of conscious sedation in ambulatory spine procedures

Michael K. Schaufele MD, Daniel R. Marín MD, Jordan L. Tate MD, MPH, Adam C. Simmons MPH, CCRC

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cervical</th>
<th></th>
<th>Thoracic</th>
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<th>Lumbar</th>
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<tr>
<td></td>
<td>CS</td>
<td>Local Only</td>
<td>CS</td>
<td>Local Only</td>
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<td>Local Only</td>
</tr>
<tr>
<td></td>
<td>Total Cases</td>
<td>AE's</td>
<td>Total Cases</td>
<td>AE's</td>
<td>Total Cases</td>
<td>AE's</td>
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<tr>
<td>Discogram</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
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<tr>
<td>Facet Injection</td>
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<td>5</td>
<td>30</td>
<td>4</td>
<td>12</td>
<td>1</td>
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<tr>
<td>Intertinemar Epidural</td>
<td>16</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>1</td>
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<tr>
<td>Medial Branch Injection</td>
<td>7</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>3</td>
<td>0</td>
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<tr>
<td>Nerve Root Injection</td>
<td>43</td>
<td>5</td>
<td>24</td>
<td>2</td>
<td>1</td>
<td>0</td>
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<tr>
<td>Radiofrequency Neurotomy</td>
<td>5</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
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<tr>
<td>Transforaminal Epidural</td>
<td>93</td>
<td>9</td>
<td>23</td>
<td>1</td>
<td>5</td>
<td>0</td>
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<tr>
<td>Epidural Adhesiolysis</td>
<td>1</td>
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<td>0</td>
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<td>0</td>
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<td>Intradiscal Procedure</td>
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<td>0</td>
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<td>0</td>
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<td>Other</td>
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<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>218</td>
<td>20</td>
<td>84</td>
<td>7</td>
<td>27</td>
<td>1</td>
</tr>
<tr>
<td>Average AE %</td>
<td>9.2%</td>
<td>8.3%</td>
<td>3.7%</td>
<td>8.3%</td>
<td>6.0%</td>
<td>4.6%</td>
</tr>
</tbody>
</table>
KEY POINTS — SCS IN PRONE POSITION

▪ Patient cohort
▪ Polypharmacy
▪ Variable depth of anaesthesia
▪ Use of Target controlled infusions
▪ Sedation in prone position
▪ Monitoring of depth of anesthesia
▪ Airway access and support
60yr old male
- Height of 6’2
- Weight – 90kgs
- Had SCS trial which was uneventful
- Sedation for SCS trial procedure with propofol and remifentanil over 55mins
- Presented for SCS implant
- Post lead positioning loss of airway
- Procedure abandoned as drop in saturations to <80%
- Intubated and ventilated
- Equipment removed – planned for further date
CASE 2

- 40 yr old lady
- Lean 50 kg
- Had SCS trial which was uneventful
- Sedation for SCS trial procedure with propofol and remifentanil over 70mins
- Present for SCS implant
- Post lead positioning loss of airway
- Procedure abandoned as drop in saturations to <80%
- Intubated and ventilated
- Equipment removed – planned for further date
Desaturation occurred in 4 out of 30 patients allocated to the high-flow nasal oxygen group, compared with 10 out of 30 in the standard oxygenation group.

Oxygen saturation after pre-oxygenation and the lowest oxygen saturation during procedure were significantly higher in the high-flow nasal oxygen group.
Higher nasopharyngeal pressures with HFNO (Park et al 2009)
Increase in positive end-expiratory pressure prevents alveolar collapse
Improving ventilation-perfusion matching and PaO2 (Chikhani et al 2016)
Increased end-expiratory lung volume and compliance (Mauri et al 2017)
Reduction in re-breathing and physiological dead space (Möller et al 2017)
## Oxygen Delivery

<table>
<thead>
<tr>
<th>Delivery device</th>
<th>Flow rates</th>
<th>FiO₂</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal cannula</td>
<td>1 – 4 L/min</td>
<td>24 – 35%</td>
</tr>
<tr>
<td>Face mask</td>
<td>&gt;5 L/min</td>
<td>40 – 60%</td>
</tr>
<tr>
<td>Venturi mask</td>
<td>Variable</td>
<td>24 – 60%</td>
</tr>
<tr>
<td>Non-rebreath reservoir mask</td>
<td>15 L/min</td>
<td>&gt;60%</td>
</tr>
<tr>
<td>HFNO</td>
<td>Up to 60 L/min</td>
<td>21 – 80%</td>
</tr>
</tbody>
</table>
Summary

We describe the use of high-flow nasal oxygen for an obese patient with obstructive sleep apnoea presenting for revision of a spinal cord stimulator. The use of high-flow nasal oxygen allowed the delivery of a high inspired oxygen concentration with humidification and improved patient comfort compared with our usual choice of device, the Hudson mask. It also provided continuous positive airways pressure which is likely to have reduced pharyngeal collapse and atelectasis. The use of high-flow nasal oxygen enabled the delivery and careful titration of deep sedation with propofol and remifentanil, to allow a successful revision procedure to take place without airway complications or significant oxygen desaturation in a high-risk patient in the prone position.
FUTURE AND RESEARCH

- Effective Pre-Assessment – STOP BANG, polypharmacy, etc..
- Use of adjuncts
- Clear management pathways for airway compromise
- Monitoring guidelines
- Sedation options: dexmedetomidine, opioid free analgesia
- HFNO delivery devices
- HOOPS