PRONE SEDATION FOR SPINAL CORD STIMULATOR IMPLANTS IS IT SAFE?

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NEUROMODULATION

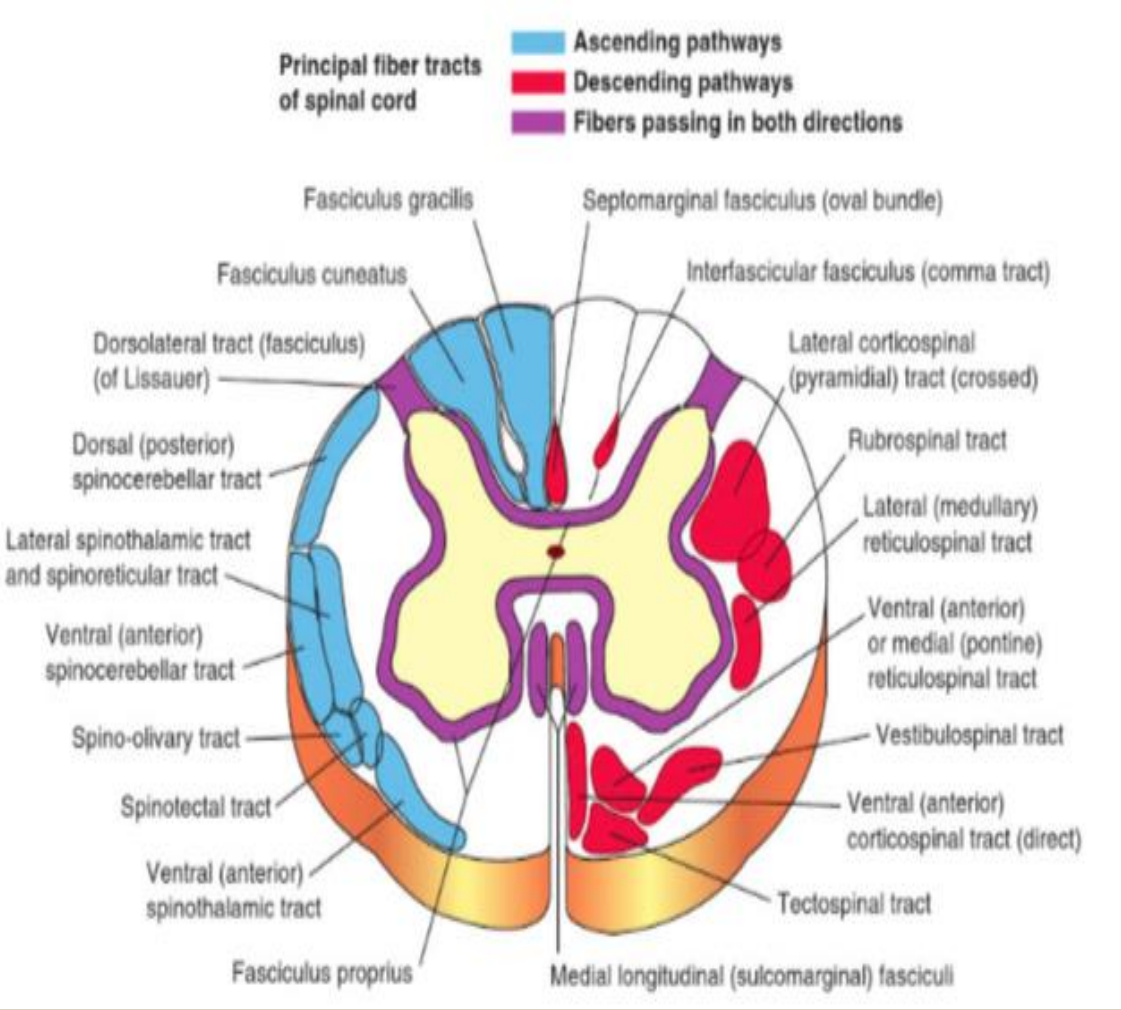
- Technology based treatment to enhance/suppress activity of the nervous system for treatment of diseases

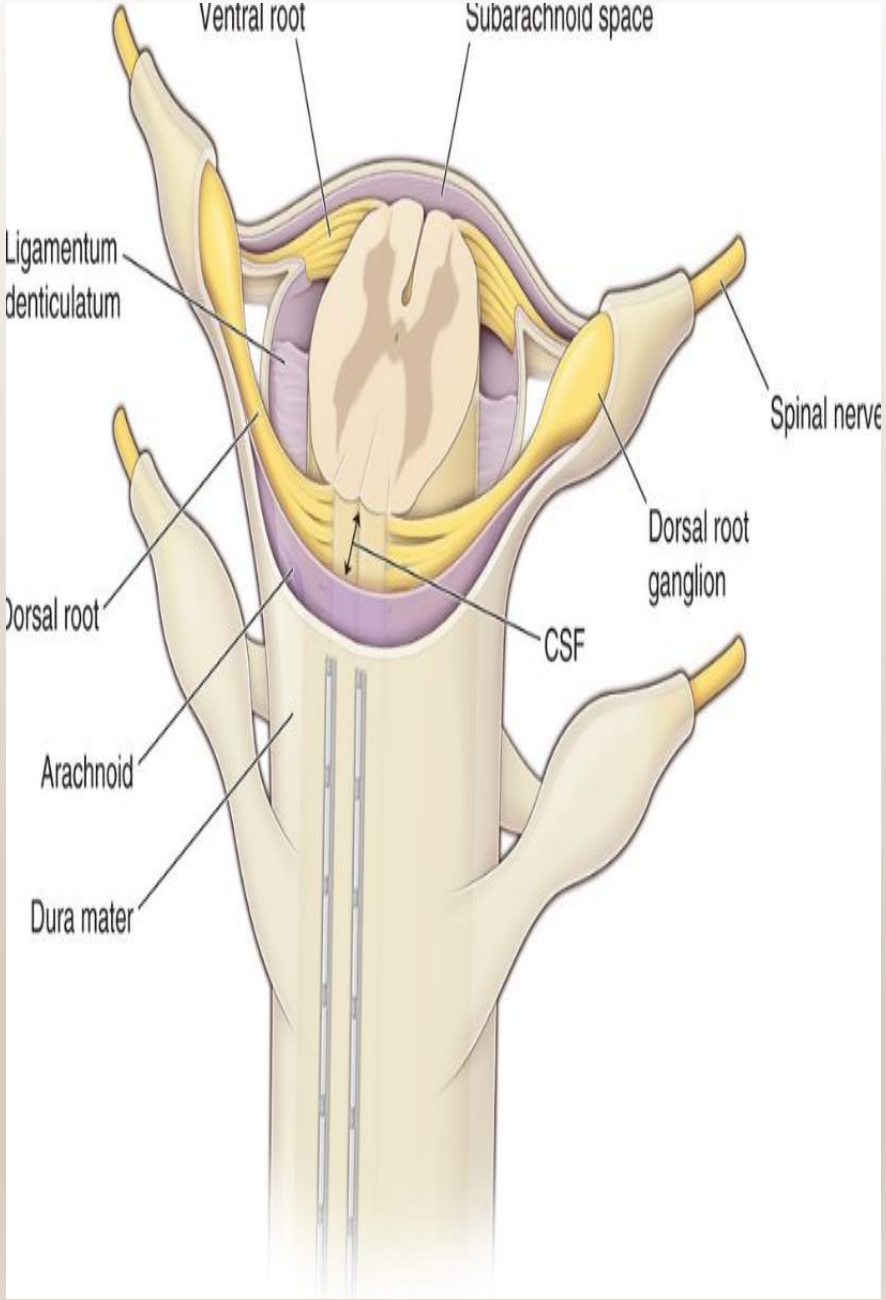
- It is the convergence of bio-medical engineering, biotechnology, neuro computing, developing systems for neural interfaces

NEUROMODULATION

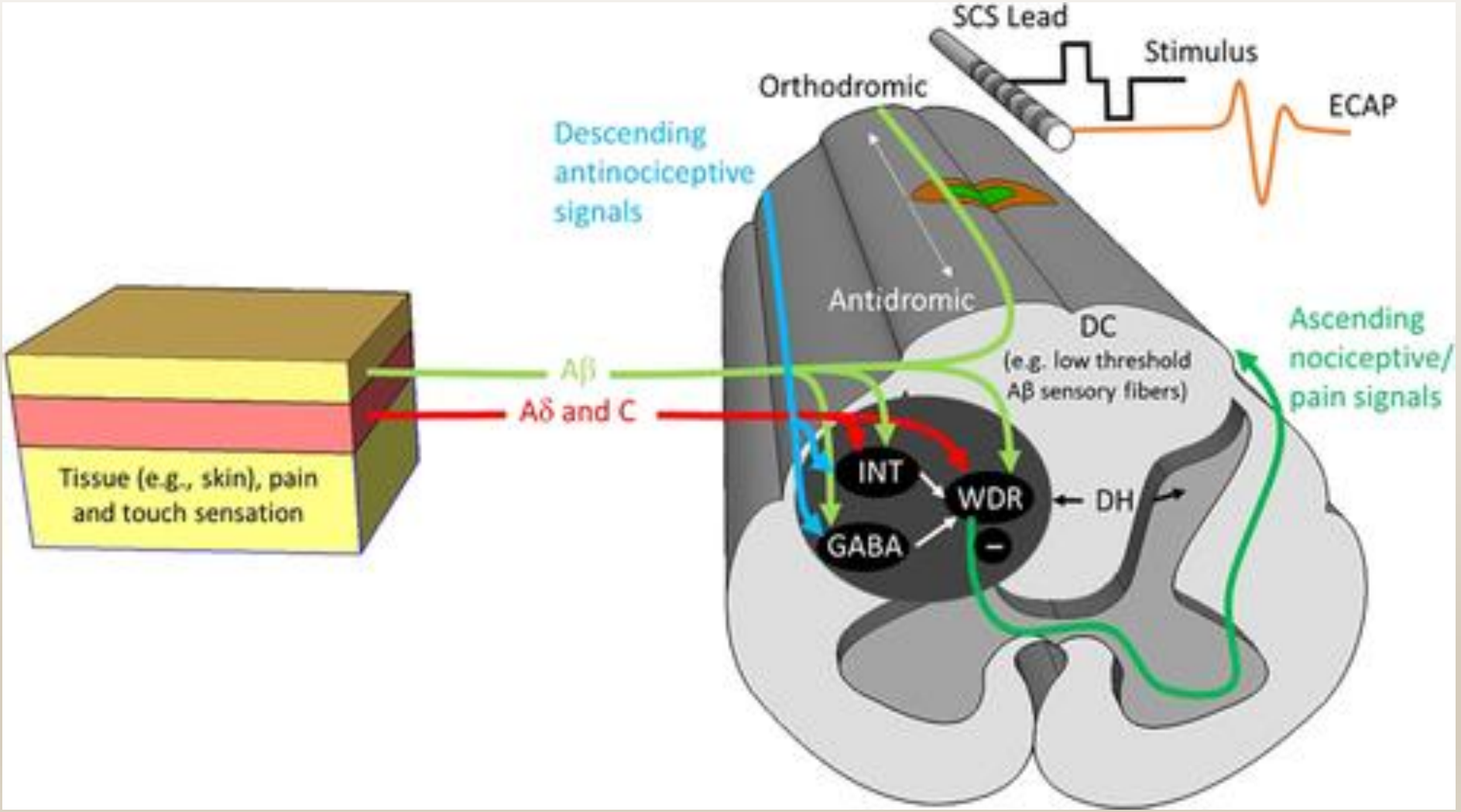
- Modulating the electrochemical nature of the central, peripheral, autonomous nervous systems
- Inhibition, stimulation, modification, regulation, alteration of neuronal function & performance
- Modulating the functionality of the nervous system reversibly by means of electrical, chemical, mechanical, optical, magnetic or other interventions

NEUROMODULATION





MECHANISMS OF SCS



Neuromodulation: Technology at the Neural Interface, Evoke study, Volume: 22, Issue: 3, Pages: 317-326,

NEUROMODULATION DEVICES MARKET CONSUMPTION GROWTH RATE, MARKET DRIVERS AND OPPORTUNITIES

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

Neuromodulation Segment	Total Sales ($m; %)
SCS	$2,534 (59%)
SNS	675 (16%)
DBS	620 (15%)
VNS	450 (11%)
Total	**$4,279m**

Source: Meddevicetracker; company financials

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

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

Neuromodulation Segment	Estimated Revenues/ Expected Growth (%)
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

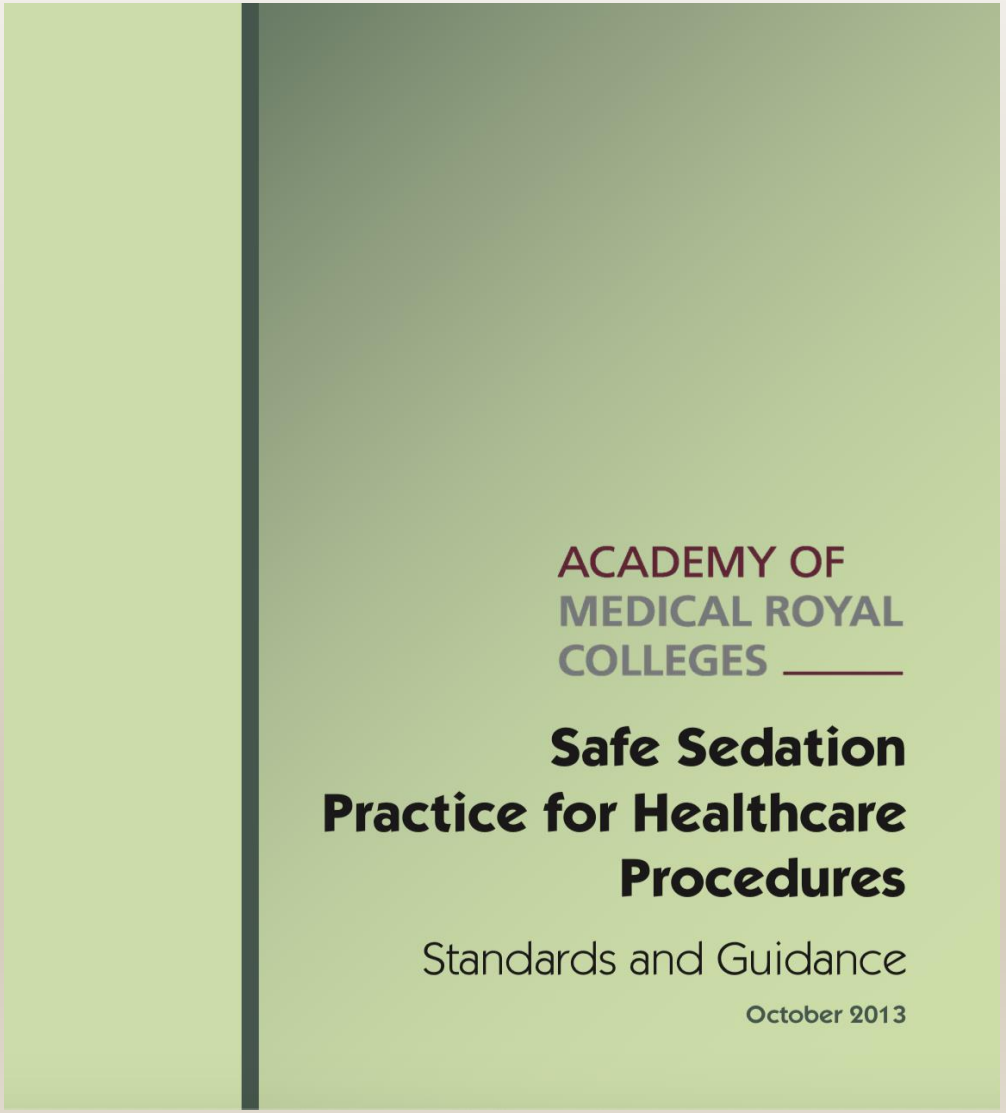
- Miniaturization (of IPGs)
- Improved lead technology
- Improved precision/targeting of nerves
- Less invasive/avoiding implantation of IPGs or batteries
- MRI compatibility (all competitors)
- Longer-life batteries, recharge-free systems
- Customizing therapy, patient tracking, wireless communication
- 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

- Use of Anesthesia Providers in the Administration of Office-based Deep Sedation/General Anesthesia to the Pediatric Dental Patient, Latest Revision 2019, AAPD: American Academy of Pediatric Dentistry.

- Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018:A Report by the American Society of Anesthesiologists Task Force, the American Association of Oral and Maxillofacial Surgeons, American College of Radiology, American Dental Association, American Society of Dentist Anesthesiologists, and Society of Interventional Radiology

SEDATION PRACTICE GUIDELINES



LEVELS OF SEDATION AND ANALGESIA

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

* 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.*

IS ANAESTHESIA DANGEROUS?

- 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

ABSTRACTS OF THE 19TH NATIONAL CONGRESS OF DIGESTIVE DISEASES

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 bilio-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 anaesthesist regarding the possibility of airway management or for resuscitation maneuvers 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.

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INTRA PROCEDURE COMPLICATIONS

ORIGINAL ARTICLE: Clinical Endoscopy

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)

ELSEVIER

The Spine Journal

Volume 11, Issue 12, December 2011, Pages 1093-1100

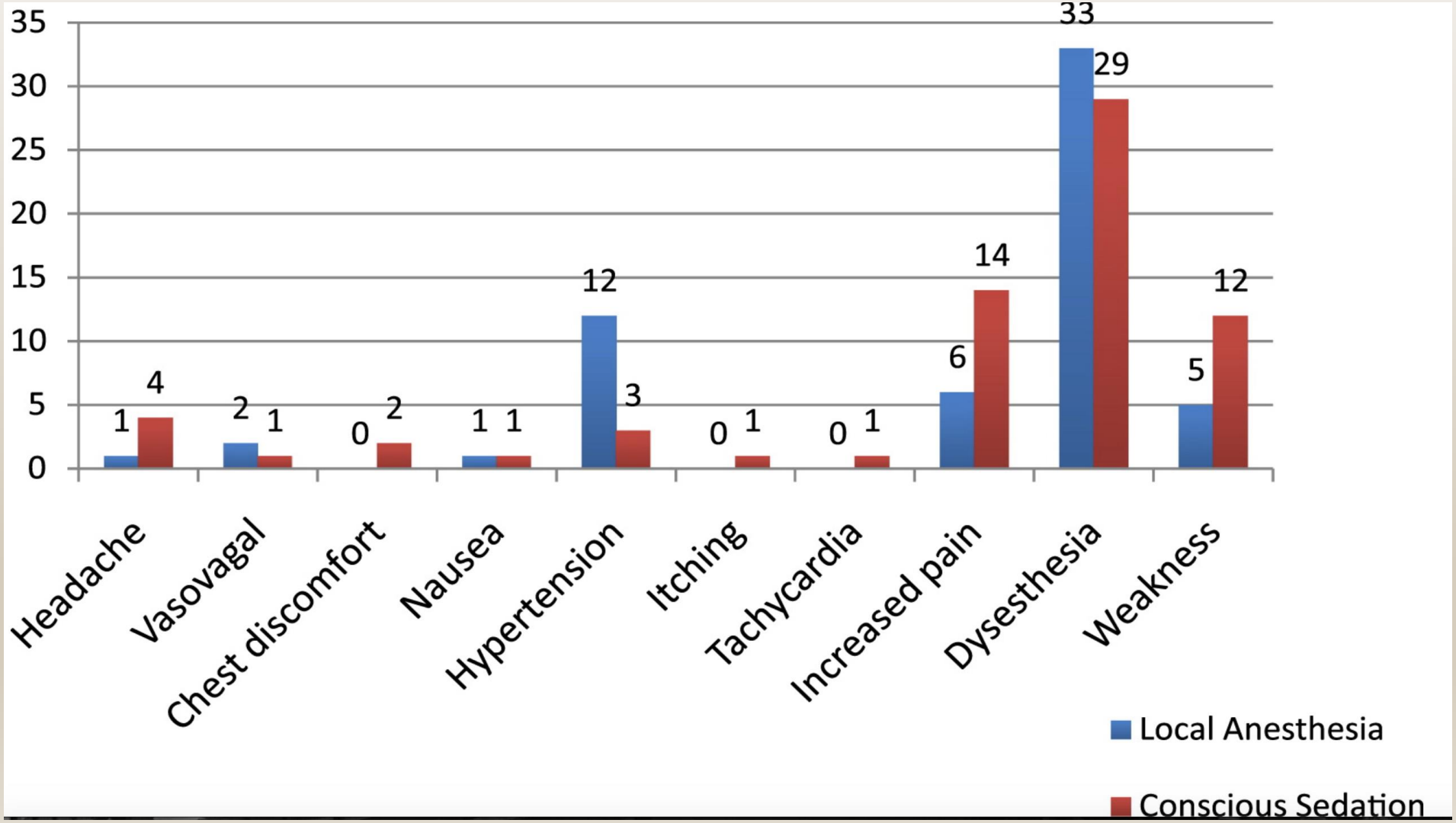
Clinical Study

Adverse events of conscious sedation in ambulatory spine procedures

Michael K. Schaufele MD [a], Daniel R. Marín MD [b], Jordan L. Tate MD, MPH [c], Adam C. Simmons MPH, CCRC [d]

Procedure	Cervical				Thoracic				Lumbar			
	CS		Local Only		CS		Local Only		CS		Local Only	
	Total Cases	AE's	Total Cases	AE's	Total Cases	AE's	Total Cases	AE's	Total Cases	AE's	Total Cases	AE's
Discogram	5	0	0	0	2	0	1	1	67	4	1	0
Facet Injection	44	5	30	4	12	1	4	0	187	8	303	9
Interlaminar Epidural	16	1	3	0	2	0	1	0	42	1	39	2
Medial Branch Injection	7	0	2	0	3	0	1	0	26	0	37	1
Nerve Root Injection	43	5	24	2	1	0	0	0	91	12	65	5
Radiofrequency Neurotomy	5	0	1	0	2	0	1	0	39	2	15	0
Transforaminal Epidural	93	9	23	1	5	0	4	0	427	28	607	33
Epidural Adhesiolysis	1	0	0	0	0	0	0	0	3	0	0	0
Intradiscal Procedure	0	0	0	0	0	0	0	0	13	0	0	0
Sacroiliac Injection	0	0	0	0	0	0	0	0	14	0	10	0
Other	4	0	1	0	0	0	0	0	10	0	4	0
Total	**218**	**20**	**84**	**7**	**27**	**1**	**12**	**1**	**919**	**55**	**1081**	**50**
Average AE %		**9.2%**		**8.3%**		**3.7%**		**8.3%**		**6.0%**		**4.6%**

ADVERSE EVENTS



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

CASE DISCUSSION

- 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
- 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

Anaesthesia
Peri-operative medicine, critical care and pain
Association of Anaesthetists

Original Article | Free Access

A randomised controlled trial comparing high-flow nasal oxygen with standard management for conscious sedation during bronchoscopy

N. Douglas, I. Ng, F. Nazeem, K. Lee, P. Mezzavia, R. Krieser, D. Steinfort, L. Irving, R. Segal

- 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

HIGH FLOW NASAL OXYGEN

- 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

Delivery device	Flow rates	FiO_2
Nasal cannula	1 – 4 L/min	24 – 35%
Face mask	>5 L/min	40 – 60%
Venturi mask	Variable	24 – 60%
Non-rebreath reservoir mask	15 L/min	>60%
HFNO	Up to 60 L/min	21 – 80%

Anaesthesia Reports
Cases in clinical practice

Association of Anaesthetists

Case Report

High-flow nasal oxygen for a high-risk patient undergoing sedation in the prone position

S. Sodha ✉, T. Fernandez

First published: 08 May 2019 | https://doi.org/10.1002/anr3.12011 | Cited by: 1

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