Sedation for Interventional Spine Procedures: is it Necessary?

Tim Maus, MD
Assoc Prof of Radiology, Mayo Clinic
Board of Directors, International Spine Intervention Society

No Conflict of Interest to Disclose
Epidural steroids are off-label

Sedation for Interventional Spine Procedures: Why?

• Benefit – from anxiolytic, analgesic agents
  • Greater patient comfort
  • Greater safety? - less movement
  • Lesser likelihood of vasovagal reaction
• Risks
  • Lesser safety? – mask pain, neurologic change
  • Inherent risk – hypoventilation, allergy, idiosyncratic response
  • Cost
  • Confound diagnostic blocks
Wide variability in practice patterns
- Uniform use (cervical interlaminar) Botwin APMR 2003
- Never / rare (epidural injections) Johnson AJNR 1999

- Survey of 61 pain practices
  - Anesthesia 79%, PMR 5.3%, Anes & PMR 3.5%
  - Academic 63%; private 19.3%; mixed 17.5%
- NPO status: 74%
- PO sedation: 7%
- IV sedation; 64% overall
  - Discography, stimulator trials > 90%
  - Epidurals lumbar: 46%; cervical: 53%
  - RF: 80%
  - Intra-articular facet injections: 65%

<table>
<thead>
<tr>
<th>Procedure</th>
<th>NPO Status</th>
<th>SRP</th>
<th>Pain Centers</th>
<th>ERE</th>
<th>IV Use</th>
<th>IV Sedation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical Interlaminar</td>
<td>74%</td>
<td>87%</td>
<td>90%</td>
<td>63%</td>
<td>58%</td>
<td>92%</td>
</tr>
<tr>
<td>Lumbosacral interlaminar</td>
<td>87%</td>
<td>87%</td>
<td>90%</td>
<td>63%</td>
<td>58%</td>
<td>92%</td>
</tr>
<tr>
<td>Intradiscal dehydration</td>
<td>89%</td>
<td>88%</td>
<td>88%</td>
<td>63%</td>
<td>58%</td>
<td>92%</td>
</tr>
<tr>
<td>Disc block</td>
<td>89%</td>
<td>88%</td>
<td>88%</td>
<td>63%</td>
<td>58%</td>
<td>92%</td>
</tr>
<tr>
<td>Epi block</td>
<td>89%</td>
<td>88%</td>
<td>88%</td>
<td>63%</td>
<td>58%</td>
<td>92%</td>
</tr>
<tr>
<td>Cervical EK</td>
<td>89%</td>
<td>88%</td>
<td>88%</td>
<td>63%</td>
<td>58%</td>
<td>92%</td>
</tr>
<tr>
<td>Lumbosacral EK</td>
<td>89%</td>
<td>88%</td>
<td>88%</td>
<td>63%</td>
<td>58%</td>
<td>92%</td>
</tr>
<tr>
<td>Intrathecal injection</td>
<td>89%</td>
<td>88%</td>
<td>88%</td>
<td>63%</td>
<td>58%</td>
<td>92%</td>
</tr>
<tr>
<td>Spinal taps</td>
<td>89%</td>
<td>88%</td>
<td>88%</td>
<td>63%</td>
<td>58%</td>
<td>92%</td>
</tr>
<tr>
<td>Spinal needle</td>
<td>89%</td>
<td>88%</td>
<td>88%</td>
<td>63%</td>
<td>58%</td>
<td>92%</td>
</tr>
<tr>
<td>Peridural nerve block</td>
<td>89%</td>
<td>88%</td>
<td>88%</td>
<td>63%</td>
<td>58%</td>
<td>92%</td>
</tr>
<tr>
<td>Perineural nerve block</td>
<td>89%</td>
<td>88%</td>
<td>88%</td>
<td>63%</td>
<td>58%</td>
<td>92%</td>
</tr>
<tr>
<td>Interlaminar block</td>
<td>89%</td>
<td>88%</td>
<td>88%</td>
<td>63%</td>
<td>58%</td>
<td>92%</td>
</tr>
<tr>
<td>Adjacent nerve block</td>
<td>89%</td>
<td>88%</td>
<td>88%</td>
<td>63%</td>
<td>58%</td>
<td>92%</td>
</tr>
<tr>
<td>Adjacent interlaminar</td>
<td>89%</td>
<td>88%</td>
<td>88%</td>
<td>63%</td>
<td>58%</td>
<td>92%</td>
</tr>
</tbody>
</table>
Sedation in Interventional Pain Procedures

Is there real or perceived benefit?

A survey: conscious sedation with epidural and zygapophyseal injections: Is it necessary?
Cucuzzella et al Spine J 2006

- Case series of 500 consecutive patients receiving facet or epidural injections
- 17% requested sedation (not discussed or offered unless requested) 2-5 mg diazepam IV
- 28% would ask for sedation at a subsequent injection
  - Those requesting sedation for a second injection had higher pain rating during procedure
  - Conclusion: Routine sedation before diagnostic and therapeutic spinal injections is not necessary

Is Sedation Indicated Before Spinal Injections?

- Prospective consecutive series, N=301
- Patients allowed to choose no, oral or IV sedation
  - 5-10 mg oral diazepam; 5mg IV diazepam
  - Lumbar (74%) & cervical (22%); facet (7%), interlaminar or transforminal epidural (93%) injections
- 58% chose sedation, 96% IV
- Non-sedated patients: 93% satisfied, 1.5% wished they had chosen sedation
  - Conclusion: Routine sedation does not seem to be necessary for patients receiving spinal injections
Does Sedation Reduce the Rate of Vasovagal Reactions?

Incidence of Vasovagal Reactions

- Johnson AJNR 1999: No sedation, N=5333 epidurals; 0.03%, 2 cases of vasovagal reaction requiring intervention
- Botwin APMR 2003: Routine sedation, cervical interlaminar epidural injections. Vasovagal reactions: 1.7%
- Karamen Spine 2011: No routine sedation, transforaminal epidurals. Vasovagal reactions in 8.7%; 0.9% required medication administration

An audit of transforaminal epidural steroid injections without sedation: low patient dissatisfaction and low vasovagal rates.

6,878 transforaminal epidural injections in all spine segments
- 6,871 (99.9%) without sedation
- 7 (.0001%) with moderate sedation
- 0.3% vasovagal reactions

Retrospective case series of prospective data
8,010 consecutive procedures in 4,183 patients
97% No Sedation
Vasovagal rate: 2.6%
0.8% requiring procedure termination
4,512 TFESI 3.5% vasovagal reactions (lumbar > cervical)
Entire cohort, Vasovagal Rx associated with:
Male gender
Younger age (< 65)
Lesser pre-procedural pain (< 5/10)
Larger needle gauge

Is There a Role for Sedation in Patients who have Experienced a Vasovagal Reaction During a Prior Procedure?

The Use of Conscious Sedation for the Secondary Prevention of Adverse Vasovagal Reactions
Schneider, Plastaras, Kennedy ISIS ASM 2013

6364 Consecutive spine procedures
97% without sedation
0.3% vasovagal reaction
134 repeat injections with history of vasovagal rx
90 with sedation:
23% repeat vasovagal reaction
44 with moderate sedation:
0% repeat vasovagal reaction
Moderate sedation may be beneficial when there is a history of prior vasovagal reaction
Sedation in Interventional Pain Procedures

What data exists concerning risks / harms of sedation?

• Procedural risk due to diminished patient responsiveness
• Risk intrinsic to the sedation process
• Cost
• Confounding diagnostic blocks

Cervical Epidural Steroid Injection With Intrinsic Spinal Cord Damage: Two Case Reports

• Case report, Cervical interlaminar epidurals
• Versed & Diprivan IV sedation
• Probable direct cord penetrations without patient response due to sedation
• Permanent neurologic injuries with cord signal abnormality on MRI
• Recommend against IV sedation during epidural injections

Injury and Liability Associated with Cervical Procedures for Chronic Pain
Rathmell, et al Anesthesiology 2011

• ASA closed claims 1/2005- 12/2008
• Cervical procedures: 22% of chronic pain claims
  • 67% epidural, 11% stellate, 9% trigger, 3% facet
• Injury mechanism:
  • Direct needle injury to cord / nerve 31%
  • Cord infarction/ stroke 14%
Injury and Liability Associated with Cervical Procedures for Chronic Pain
Rathmell, et al Anesthesiology 2011

- Cord Injuries: 91% during epidural injection: 2/3 interlaminar, 1/3 transforaminal
- Sedation or general anesthesia used in 67% of procedures associated with cord injuries, but in only 19% of procedures without cord injuries
- Patient was not responsive in 25% of cases of spinal cord injuries, but in only 5% of procedures without cord injuries

Adverse events of conscious sedation in ambulatory spine procedures Schaufele et al, Spine J 2011

- Retrospective cohort chart review:
  - 1,228 case local anesthesia + conscious sedation
  - 1,266 local anesthesia alone
  - Epidural injections, MMB, RF, facet selective nerve blocks
- Immediate adverse events
  - 5.12% conscious sedation; 4.82% local only
  - 3 day follow up
    - 4.77% conscious sedation; 4.0% local only
  - No catastrophic complications

Sedation Related Complications

- Documented complications: death, airway compromise, arrhythmia, hypotension, venous thrombosis, pulmonary embolism, protracted nausea/vomiting
- GI interventions with conscious sedation: Arrowsmith Gastro Endosc 1991
  - Serious cardiorespiratory complications: 5.4 per 1000
  - Mortality 0.3 per 1000 procedures
**Sedation Related Complications**
- Interventional Radiology Arepally *CVIR* 2001
  - Moderate sedation
  - Respiratory complications 4.7%
  - Sedation related events 4.2%
  - Major Adverse events 2%
- Electrophysiology Geiger *Pacing Clin Electrophysiol* 1997
  - Deep sedation
  - Hypoxia requiring naloxone 5%
  - Respiratory obstruction: head/neck manipulation 4%
  - Hypotension as response to fentanyl 5%

**Cost**
Modest reimbursement, but any added cost without added value is non-trivial

**Confounding Effect of Diagnostic Blocks**
The effect of sedation on the accuracy and treatment outcomes for diagnostic injections: a randomized, controlled, crossover study.

Randomized crossover study (N=73) in patients receiving SI joint injections or sympathetic blocks
When sedated, subjects reported greater immediate & short term pain relief, in both continuous & categorical outcomes
There was no difference between sedated & non-sedated subjects in long term outcomes

The effect of sedation on the accuracy and treatment outcomes for diagnostic injections: a randomized, controlled, crossover study.

Sedation may increase false positive blocks
Use of sedation in diagnostic procedures may lead to inappropriate downstream interventions
Sedation did not increase overall satisfaction with the procedure

Can Spine Interventions be performed without sedation while preserving a positive patient experience?
An audit of transforaminal epidural steroid injections without sedation: low patient dissatisfaction and low vasovagal rates.

- 6,878 transforaminal epidural injections in all spine segments
  - 6,871 (99.9%) without sedation
  - 7 (.0001%) with moderate sedation
  - 0.3% vasovagal reactions

- Patient follow up at 2 weeks by telephone interview
  - Rate medical care experience
  - Would you refer family/friends for a similar procedure

An audit of transforaminal epidural steroid injections without sedation: low patient dissatisfaction and low vasovagal rates.

- Non-sedated: 4,980 responses to interview
  - 4,787 (96%) rated overall care experience as good to excellent
  - 81% would definitely or probably refer a friend or family member for a like procedure

ISIS Position Statement: Sedation

It is the position of the International Spine Intervention Society (ISIS) that routine use of sedation is not necessary for interventional spine procedures.

There are no features of any interventional spine procedures that warrant pre-emptive or routine use of sedation.

For those procedures where the patient and interventionalist decide that sedation will be provided, patients should ideally remain conversant to be able to warn of adverse events.
Don’t use intravenous sedation for diagnostic and therapeutic nerve blocks, or joint injections as a default practice. Intravenous sedation, such as with propofol, midazolam or ultrashort-acting opioid infusions for diagnostic and therapeutic nerve blocks, or joint injections, should not be used as the default practice. Ideally, diagnostic procedures should be performed with local anesthetic alone. Intravenous sedation can be used after evaluation and discussion of risks, including interference with assessing the acute pain relieving effects of the procedure and the potential for false positive responses.

The perceived goals of sedation
• Quiet, still patient
• Positive patient experience
• Minimal if any discomfort

Can be achieved by other means
• Skilful use of small gauge needles
• Adequate time spent in explanation & preparation
• Empathetic interaction by physician & procedural assistant
• Distraction

A good procedural assistant is better, and safer, than fentanyl, midazolam or propofol.
Mayo Radiology Experience

Compassion, distraction, and physical comforting are an essential component of the procedure.

Sedation for Interventional Spine Procedures: is it Necessary?

- Common, but widely variable utilization of sedation
- No convincing evidence of benefit for procedural safety or patient comfort
  - Potential benefit with prior vasovagal rx
  - Anecdotal and indirect evidence that excessive sedation increases procedural risk

Sedation for Interventional Spine Procedures: is it Necessary?

- Sedation has small but real intrinsic risks
- Sedation incurs cost
- Sedation may confound diagnostic blocks
- There is evidence that the purported benefits of sedation can be achieved by technical expertise and empathetic interaction and distraction by the procedural team
Sedation for interventional spine procedures is *NOT* necessary in the overwhelming majority of cases and should *NOT* be used routinely.