Learn the latest treatment strategies and multidisciplinary management options for patients with acute and chronic pain.
Spinal Cord Stimulation, Pumps, and Your Patients

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Disclosures

• Financial

Dr. Lamer is involved in funded research from Medtronic and Boston Scientific (neuromodulation device companies). All $ paid to Mayo Clinic

• Off label discussions

Brief discussion of some off label neuraxial/intrathecal pain medications
Objectives

• Give examples of pain syndromes/indications that benefit from advanced interventional options such as spinal cord stimulation and intrathecal analgesia.

• List patient selection criteria for patients being considered for treatment with spinal cord stimulation or intrathecal analgesia.

• Recognize that medical therapy for chronic pain does not provide sufficient pain relief in a significant percentage of patients
Neuromodulation for Refractory Pain: Pumps & Stimulators

- Neurostimulation/Spinal Cord Stimulation (SCS)
- Intrathecal Drug Delivery Systems (IDDS)
Neuromodulation

- Parkinson’s
- Tremor
- Dystonia
- Spasticity
- Chronic Pain
- Liver Cancer
- Gastroparesis
- Urinary Incontinence
- OCD
- Depression
- Epilepsy
- Brain Infusion
- Occipital Neuralgia
- Nonopioid Pain
- Obesity
- Interstitial Cystitis
- Bowel Disorders
Neuromodulation

• Why Should we consider it?

• When should we consider it?

• Which Patients Benefit?
Why?
Pharmacologic Management of Chronic Pain

Pain 2007;132:237-251

Review and recommendations

Pharmacologic management of neuropathic pain: Evidence-based recommendations

Robert H. Dworkin a,*, Alec B. O’Connor a, Miroslav Backonja b, John T. Farrar c, Nanna B. Finnerup d, Troels S. Jensen d, Eija A. Kalso e, John D. Loeser f, Christine Miaskowski g, Turo J. Nurmikko h, Russell K. Portenoy i, Andrew S.C. Rice j, Brett R. Stacey k, Rolf-Detlef Treede l, Dennis C. Turk f, Mark S. Wallace m

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l Johannes Gutenberg Universitat, Mainz, Germany
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Typical Medications Prescribed for Pain

- SNRIs - duloxetine, venlafaxine
- Pregabalin
- Gabapentin
- Antiinflammatory medications (ibuprofen)
- Opioids (hydrocodone, oxycodone, etc)
- Lidocaine topical (patches and creams)
Conclusion: “Existing pharmacologic treatments for NP pain are limited, with no more than 40-60% of patients obtaining partial relief of their pain.”
Opioid Related Overdose Deaths
United States, 1999-2014

When Should a Patient Be Referred

• When it is clear that conservative pain care measures are not working/will not work

• **Before committing to long-term opioids**

**
When NOT to Consider Pumps or Stims

• Active substance abuse/misuse

• Untreated significant psychiatric disorder (especially depression)

• Significant chronic pain syndrome
Cases
Case 1: 67 y.o. male with refractory LBP (axial/non-radicular)

- Previous L4-L5 instrumented fusion
- Minimal relief with multiple injections
- Extensive PT/Rehab
- Full complement of medications: Preop pain meds: MS, hydrocodone, cyclobenzaprine and gabapentin
- Multiple medical comorbidities
  - morbid obesity
  - diabetes
  - hypertension
- no significant active psych dx
- Difficult to exercise, loose weight, or control diabetes due to pain
Surgical Consultation

Impression / Report / Plan

IMAGING STUDIES
His most recent imaging studies are limited to x-rays and a CT scan of the lumbar spine, which show an instrumented fusion of the L5-S1 segment. His CT does appear that these levels have gone on to fuse. He has retrolisthesis at the L4-5 and L3-4 segments that do result in some foraminal stenosis. His central canal, according to an MRI in 2010, does appear to be widely patent, although we have no updated central imaging of the canal with MRI secondary to concern over the bone growth stimulator, which was implanted for his fusion.

IMPRESSION
#1 Axial back pain in the setting of morbid obesity and poorly controlled diabetes
We had a lengthy discussion with Mr. At this point, I do not have any definitive ability to tell him that fusing these adjacent segments would help him with his pain, but I have given him some definitive goals. If he works on weight loss and is able to lose the majority of his belly and comes back to me approximately 50 to 60 pounds lighter, I would consider doing this as the safety profile would probably be more reasonable. I told him that there is approximately a 50% chance that this would help him at all with his symptoms. I have told him I will not consider any intervention until his abdomen girth has been significantly reduced. I have given him a target weight of approximately 200 to 210 pounds. If he is unable to do this, I would not consider this, and I have discussed this with him and been very frank about this. He is in agreement with this plan. He will continue to work with Dr. Lamer on further nonoperative treatment.
Plan: Intrathecal pump placement (IDDS)
Results

• Preimplant HbA1C       7.1
• Preimplant Wt             141 Kg

• 15 month post implant
• IT Morphine Dose: 0.3 mg per day!!
  HgA1C   5.8 (endocrinologist stopped insulin)
  Wt      108 kg
• Walking 3 miles/day 5 x per week
• Snowshoeing during the winter
Case 2: 75 y.o. female with refractory low back and left leg pain x 4 years

- Progressive pain and disability
- Extensive injection and radiofrequency history
- Extensive PT
- No active psych dx
- Multiple med trials with severe side effects
  - oxycodone 5 mg 0.5-1 tab q 4 hrs
- Previously very active-travel, hiking, etc
- “No surgical options”
Plan-Spinal Cord Stimulation
Two Year Follow Up

• Pain reduced greater than 50%
  Pre Rx NRS: 7-9   Post Rx NRS 2-4
• Oxycodone 2.5 mg qhs
• No further MD visits or pain procedures since post-op followup
• Significant increase in activity tolerance, travelling to see grandchildren…
SCS The Process: 2 stage procedure:
Part 1  Trial
Part 2  Implant
Spinal Cord Stimulation Outcomes
Mechanism of Pain Relief for Spinal Stimulation

SCS alters levels of multiple neurotransmitters (in animal models):

- GABA
- ACH
- 5 HT
- NE
- EAA (Glutamate)
Summary of Major SCS Trials

1. The PROCESS Trial 100 Pts. Medtronic. 2007 and 2008
2. The SENZA-RCT. 171 Pts. trial Nevro. 2015
5. Sunburst Trial. 100 Pts. St Jude Medical. Early 2017
6. De vos et al RCT SCS vs Medical for Diabetic Neuropathy 60 pts 2014
7. North et al RCT Surgery vs SCS for FBSS 50 pts 2005

>850 patients, f/u 1-3 years
SCS Outcomes

- 850 patients
- SCS more effective than surgery or medical rx for FBSS
- SCS more effective than medical rx for painful DPN
- SCS more effective than medical rx for CRPS
- SCS offers significant pain relief in greater than 75% of properly selected patients with neuropathic pain
Spinal cord stimulation in patients with painful diabetic neuropathy: A multicentre randomized clinical trial.

de Vos, Cecile; Meier, Kaare; Zaalberg, Paul; Nijhuis, Harold; Duyvendak, Wim; Vesper, Jan; Enggaard, Thomas; Lenders, Mathieu

DOI: 10.1016/j.pain.2014.08.031

Table 1. Baseline patient characteristics.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>SCS (n = 40)</th>
<th>Control (n = 20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, n</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>15</td>
<td>7</td>
</tr>
<tr>
<td>Male</td>
<td>25</td>
<td>13</td>
</tr>
<tr>
<td>Diabetes, n</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type I</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Type II</td>
<td>30</td>
<td>15</td>
</tr>
<tr>
<td>Age, y, average (SD)</td>
<td>58 (11)</td>
<td>61 (12)</td>
</tr>
<tr>
<td>Duration of diabetes, y, average (SD)</td>
<td>16 (11)</td>
<td>17 (12)</td>
</tr>
<tr>
<td>Duration of pain, y, average (SD)</td>
<td>7 (6)</td>
<td>7 (6)</td>
</tr>
<tr>
<td>Pain, VAS, average (SD)</td>
<td>73 (16)</td>
<td>67 (18)</td>
</tr>
<tr>
<td>Quality of life, MPQ score, average (SD)</td>
<td>16 (5)</td>
<td>15 (6)</td>
</tr>
<tr>
<td>Self-reported health, VAS, average (SD)</td>
<td>50 (19)</td>
<td>47 (17)</td>
</tr>
<tr>
<td>Pain medication, MQS, average (SD)</td>
<td>10.6 (9.7)</td>
<td>9.2 (7.8)</td>
</tr>
</tbody>
</table>

SCS, spinal cord stimulation; MPQ, McGill Pain Questionnaire; VAS, visual analog scale; MQS, Medication Quantification Scale III.
Spinal cord stimulation in patients with painful diabetic neuropathy: A multicentre randomized clinical trial.

de Vos, Cecile; Meier, Kaare; Zaalberg, Paul; Nijhuis, Harold; Duyvendak, Wim; Vesper, Jan; Enggaard, Thomas; Lenders, Mathieu


Fig. 1. (a) Average pain scores for the SCS treatment group (dark grey) and control group (light grey) at baseline and after 1, 3, and 6 months of treatment; high score corresponds with severe pain. (b) Average McGill Pain Questionnaire Quality of Life scores; high score corresponds with severely disturbed daily activities and sleep. Error bars represent standard deviation.
Intrathecal Analgesia Outcomes (Intrathecal Drug Delivery Device)
Intrathecal Medication Options

1. Opioids
   Morphine is FDA approved
   Hydromorphone, Fentanyl, Sufentanil-commonly used (off-label)

2. GABA agonist-Baclofen

3. Alpha 2 agonists-Clonidine (approved for epidural/intrathecal is off-label)

4. Local Anesthetics-Bupivacaine (off-label)

5. Calcium Channel Blockers-Ziconotide (Prialt)
Intrathecal Opioids

- Approximately 100 x more potent than p.o.
- This translates clinically to:
  - improved analgesia
  - significantly less GI & CNS A.E.s

**Example**

Patient on 100 mg/day oral morphine
- IT analgesia- 0.5-1mg/day
Intrathecal Drug Delivery (IDD) for Intractable Back Pain

- National Outcomes Registry for LBP
- Outcome data baseline, 6, and 12 months
- 166 patients/36 physicians/practices

RESULTS

-NRS Low Back Pain scores decreased by 47%
-65% had a significant decrease in ODI (disability score)
-87% of patients would choose this treatment again

Intrathecal Drug Delivery for Treatment of Chronic Low Back Pain: Report from the National Outcomes Registry for Low Back Pain

*Statistically significant reductions compared to baseline.*
Intrathecal Drug Delivery for Treatment of Chronic Low Back Pain: Report from the National Outcomes Registry for Low Back Pain
SCS has been shown in several studies to be cost-effective compared to conventional medical management for:

- Post-laminectomy chronic pain
- CRPS

Pain Medicine 2013:14;1631-1649 (FBSS, CRPS, Refractory Angina)
Clin J Pain 2010;26:463-469 (FBSS)
Value Health 2010;13:735-742 (CRPS)
Advanced Interventional Therapies Are Cost Effective

- The ICER or Cost per QALY gained for FBSS treated with SCS vs medical therapy is approximately 9000 CAN $.

Kumar K and Rizvi S. Cost-Effectiveness of SCS Therapy in Management of Chronic Pain. Pain Medicine 2013;14:1631-49
Patients that Can Most Benefit

- Failed spine surgery
- CRPS w refractory pain
- Painful neuropathy (diabetes, etc)
- Post trauma/surgery neuralgia
- Refractory chest pain
- Refractory pain in patients with cancer
Conclusions

1. Consider Referring a patient:
   - when it is clear that conservative pain care measures are not working/will not work
   - Before committing to long-term opioids
   - Refractory neuropathic pain (CRPS, surgery, DPN, etc)
   - Persistent pain after spine surgery
   - Refractory cancer pain

2. There are advanced interventional options that can be useful for refractory spine pain syndromes
Thank You
RCTs have demonstrated benefit...  

**SCS is the treatment of choice for:**

- Pain following failed back surgery
- Refractory pain from CRPS

Neuromodulation 2013;16:125-141 and 523-529 (CRPS)
Anesthesiology 2015;123:851-860 (FBSS)
Neurosurgery 2007;132:179-188 (FBSS)

**SCS (vs conventional management) benefits**

- Painful neuropathy (esp DPN)
- Refractory chest pain/angina-like syndromes

Pain 2014;155:2426-2431 (diabetic neuropathy)
Diabetes Care 2014;37:3016-3024 (diabetic neuropathy)
Pain 2008;140:501-508 (angina)
Spinal Stimulation (SCS) vs Conventional Medical Management (CMM) … in Patients with Failed Back Surgery Syndrome

- RCT-100 patients w FBSS (neuropathic radicular pain).
  - SCS+CMM vs CMM

- 50% of SCS and 5% of CMM achieved primary outcome of ≥ 50% pain relief (p > .01)

- SCS group also had
  - improved Q.O.L.
  - improved functional measures
  - greater treatment satisfaction

Questions & Discussion