NEUROMODULATION AND PAIN- THE ROLE OF SPINAL CORD STIMULATION

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Learning Objectives

- Define what is neuromodulation and its effects
- Define pain types effectively treated with spinal cord stimulation.
- Identify patient selection criteria for spinal cord stimulation
- Describe physician techniques
- List outcomes.
- Describe complications
What is neuromodulation?
Neuromodulation

- The first use of electricity for pain control was reported in *Compositiones Medicae* by Largus in 46 AD
- “Headache even if it is chronic and unbearable is taken away and remedied forever by a live torpedo (electric fish) on the spot which is in pain, until the pain ceases”
That was then

- 1831 Faraday induces a current in a coil which inhibited nerve conduction
- 1960’s Melzack and Wall published “gate control theory”
  - Stimulation of large fibers would close “the gate” to input from small fibers.
- 1970’s Holsheimer develops a series of 3D volume conductor computer models
  - Replicates electrical behavior of nerve fibers
  - Maps geometry of nerve fibers in dorsal columns
  - Determines fiber recruitment
Holsheimer’s computer model
How does neuromodulation effect us?

- Electrical stimulation of the dorsal column produces orthodromic and antidromic activation

- Neuropathic pain
  - Spinal level
    - Activation of DC stimulates substantia gelatinosa
    - Inhibition of lamina IV & V occurs
    - Reduction in hyper excitability of WDR neurons
    - Reduced glutamate and aspartate release
  - Supraspinal
  - Activation of descending pain controlling pathways
  - Increased release of GABA

- Ischemic pain
  - Spinal level
    - Increased peripheral blood flow
    - Decrease prostacyclin, substance P or calcitonin gene-related peptide
    - Inhibition of nicotinic receptors
Indications for Neuromodulation of the Spinal Cord

- Failed back surgery syndrome
- Complex regional pain syndrome
- Plexopathies
- Phantom limb
- Diabetic peripheral neuropathy
- Occipital neuralgia (not FDA approved)
- Pelvic pain (not FDA approved)
- Peripheral vascular disease
- Intractable angina pectoris
- Chronic ulcers

Neuropathic conditions

Ischemic conditions
Patient Selection Criteria for Advanced Pain Therapies

- More conservative therapies have failed
- An observable pathology exists that is concordant with the pain complaint
- Further surgical intervention is not indicated
- No serious untreated drug habituation exists
- Psychological evaluation and clearance for implantation has been obtained
- No contraindications to implantation exist. These include sepsis, coagulopathy, etc.
- Trial screening has been successful
Patient Selection

- **Inclusion criteria**
  - Appendicular pain
  - Pain of at least 6 months
  - Leg pain greater than back pain?
  - Informed consent
  - Psychological clearance

- **Exclusion criteria**
  - Surgical procedure within 6 months
  - Active psychiatric disorder
  - Younger than 18 years of age
  - not received adequate non surgical care
  - Failed trial
Patient testing

- Trial period
  - Outpatient procedure
  - Epidural placement
  - Fluoroscopic guidance
  - No sedation
  - 1 to 3 electrodes
  - Trial period 5-7 days
  - Document level before pulling lead
  - Document active program

- Implant
  - Outpatient procedure
  - Paddle vs. perc lead
  - Need experienced fluoro team
  - Laminotomy vs epidural
  - Tunnel
  - Confirm placement
Trial Overview

- A percutaneous lead is positioned in the epidural space on the dorsal aspect of the spinal cord at the appropriate nerve root level(s)
- Electrical current from the lead generates paresthesias that can be adjusted in intensity and location to achieve the best pain coverage.
- Leads are attached to an external {or internal} neurostimulator which supplies the current.
- Patients use a patient programmer to adjust stimulation to meet pain management needs.
- Trial is evaluated.
Spinal cord stimulator placement

- **Lumbar region**
  - Needle insertion at L3-4 to T12-L1 depending on extent of coverage
    - If you need feet insert L3-4 so that electrode will be completely epidural at L1-2 and you can troll.
  - Angle of needle should be 25 degrees
  - Starting point 1 ½ vertebral bodies distal to entry point
  - Ipsilateral paramedian approach

- **Cervical region**
  - Needle insertion generally T2-3
  - Angle about 55-60 deg if not using curved tip
  - Starting point is 1 ½ vertebral bodies distal to entry point.
  - Contralateral paramedian approach
Electrode Positioning Suggestions for Percutaneous Leads  
(Barolat 1993, Medtronic 1999)

<table>
<thead>
<tr>
<th>Pain Location (Dermatome)</th>
<th>Highest Probability 1-, 2+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior shoulder</td>
<td>C4 fibers</td>
</tr>
<tr>
<td>C3 Range C3-C5</td>
<td></td>
</tr>
<tr>
<td>External arm</td>
<td>C5 fibers</td>
</tr>
<tr>
<td>C4 Range C2-T3</td>
<td></td>
</tr>
<tr>
<td>Radial forearm</td>
<td>C6 fibers</td>
</tr>
<tr>
<td>C5 Range C2-T3</td>
<td></td>
</tr>
<tr>
<td>Median hand</td>
<td>C6-C7 fibers</td>
</tr>
<tr>
<td>C6 Range C2-T3</td>
<td></td>
</tr>
<tr>
<td>Ulnar hand</td>
<td>C8 fibers</td>
</tr>
<tr>
<td>C7 Range C2-T2</td>
<td></td>
</tr>
<tr>
<td>Ulnar forearm</td>
<td>T1 fibers</td>
</tr>
<tr>
<td>C7 Range C4-T3</td>
<td></td>
</tr>
<tr>
<td>Internal arm</td>
<td>T2 fibers</td>
</tr>
<tr>
<td>T1 Range C5-T3</td>
<td></td>
</tr>
<tr>
<td>Chest</td>
<td>T2-T6 fibers</td>
</tr>
<tr>
<td>T2 Range T1-T7</td>
<td></td>
</tr>
<tr>
<td>Low back</td>
<td>T9-L1 fibers</td>
</tr>
<tr>
<td>T9 Range T8-T11</td>
<td></td>
</tr>
<tr>
<td>Abdomen</td>
<td>T9-L1 fibers</td>
</tr>
<tr>
<td>T8 Range T6-T11</td>
<td></td>
</tr>
<tr>
<td>Anterior thigh</td>
<td>L2-L3 fibers</td>
</tr>
<tr>
<td>T11 Range T11-T12</td>
<td></td>
</tr>
<tr>
<td>Anterior leg</td>
<td>L4-L5 fibers</td>
</tr>
<tr>
<td>T12 Range T12-L1</td>
<td></td>
</tr>
<tr>
<td>Foot only</td>
<td>L5-S1 fibers</td>
</tr>
<tr>
<td>L1 Range T11-L1</td>
<td></td>
</tr>
<tr>
<td>Posterior leg</td>
<td>S1-S2 fibers</td>
</tr>
<tr>
<td>L1 Range T11-L1</td>
<td></td>
</tr>
<tr>
<td>Posterior thigh</td>
<td>S1-S2 fibers</td>
</tr>
<tr>
<td>L1 Range T11-L1</td>
<td></td>
</tr>
<tr>
<td>Buttock and lower extremity</td>
<td>T9-T10 T11-L1</td>
</tr>
</tbody>
</table>
Percutaneous Placement: Needle Angle & Placement
Lumbar spinal cord stimulator
Secure a Percutaneous Lead
Cervical spinal cord stimulator
Patient Outcomes

- **Prospective studies**

  - **Kumar 2007** 6-12 month follow-up
    - 48% achieved > 50% pain relief compared to 18% w CMM
    - Lower use of opioids
  
  - **North 2005** 6 month to 2 year follow-up
    - 47% achieved > 50% pain relief compared to 12% w redo op
    - 87% lower use of opioids compared to 15% w redo op
  
  - **Dario 2001** 24-84 month follow-up
    - 91% had good results
    - 33% returned to work
    - 50% resumed normal

*Sixty percent of FBSS patients reported > 50% pain relief in a retrospective study with a mean follow-up of 8.1 years.*
Improved Quality of Life

Quality of life improved significantly for failed back surgery patients (n=123) treated with neurostimulation.

Long-Term Pain Relief

**Key Findings:** 61.3% of failed back surgery syndrome patients with bilateral limb pain and 59.3% of patients with unilateral limb pain reported > 50% leg pain relief.

n=410

More Effective than Repeat Surgery

Key Findings: Among patients available for long-term follow-up, SCS was significantly more successful than reoperation: 9 (47%) of 19 patients randomized to SCS and 3 (12%) of 26 patients randomized to reoperation achieved at least 50% pain relief and were satisfied with treatment.

More effective if considered early

- The rate of success of neurostimulation is inversely correlated to the time between the start of chronic pain and the time of implantation.\(^8\)

The success rate of neurostimulation decreases from 85% with a delay of < 2 years to approximately 9% with a delay of > 15 years.\(^8\)
**SCS vs CMM**

*Quality of Life (QoL, as measured by the SF-36®)*

- Significant improvements in QoL in favor of SCS (P < 0.02 to 0.001) when comparing the 2 groups in 7 out of 8 domains on the SF-36 (role-physical was not statistically significant).

![Bar chart showing QoL comparisons between SCS and CMM](chart.png)

- Mental health: SCS 50.5, CMM 55.1
- Role-emotional: SCS 37.2, CMM 29.5
- Social functioning: SCS 34.1, CMM 36.4
- Vitality: SCS 41.3*, CMM 32.6
- General health: SCS 52.8*, CMM 48.1
- Bodily pain: SCS 33*, CMM 17.4
- Role-physical: SCS 17.5*, CMM 19.5
- Physical functioning: SCS 38.1*, CMM 21.8

*Statistically significant from baseline (P < 0.01, n = 50). Role-emotional was not statistically significant.

**General health statistically significant from baseline (P < 0.01, n = 44)
No other domains were statistically significant.
34 (47%) patients who received SCS+CMM achieved the primary outcome versus 1 (7%) who received CMM alone (p = 0.02).

17 (37%) randomized to SCS+CMM and 1 (2%) randomized to CMM alone achieved the primary outcome of ≥ 50% leg pain relief (p = 0.003).
At 24 months, compared to baseline, the 42 patients continuing SCS+CMM experienced statistically significant improvement in functional capacity ($p = 0.0002$).
At 24 months, 93% of the 42 patients continuing SCS+CMM declared that “based on their experiences so far, they would have agreed to treatment.”
PROCESS Study: 24 Month Results
Adverse Events of 42 Patients Continuing SCS+CMM

23 patients (55%) did not experience any SCS-related complications and 19 patients experienced a total of 34 SCS-related complications. For 13 patients, a surgical revision was required to resolve the event.

n=100

<table>
<thead>
<tr>
<th>SCS-related adverse event at 24 months</th>
<th>Number of events</th>
<th>Patients with ≥ 1 event Number (%)</th>
<th>Patients requiring surgery Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>34</td>
<td>19 (45)</td>
<td>13 (31)</td>
</tr>
<tr>
<td>Hardware-related</td>
<td>14</td>
<td>10 (24)</td>
<td>8 (19)</td>
</tr>
<tr>
<td>Lead migration</td>
<td>9</td>
<td>6 (14)</td>
<td>6 (14)</td>
</tr>
<tr>
<td>Lead/extension fracture/torqued contacts</td>
<td>4</td>
<td>3 (7)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Implantable pulse generator (IPG) migration</td>
<td>1</td>
<td>1 (2)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Loss of therapeutic effect, lost or unpleasant paresthesia</td>
<td>5</td>
<td>5 (12)</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Technique'</td>
<td>3</td>
<td>2 (5)</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Biological</td>
<td>12</td>
<td>9 (21)</td>
<td>3 (7)</td>
</tr>
<tr>
<td>Infection/wound breakdown</td>
<td>4</td>
<td>4 (10)</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Pain at IPG incision site/ pocket inflammation</td>
<td>5</td>
<td>5 (12)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>IPG pocket fluid collection</td>
<td>3</td>
<td>2 (5)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
Cost effectiveness
## Cost effectiveness

Kumar 2002

<table>
<thead>
<tr>
<th>Year</th>
<th>SCS cost ($)</th>
<th>CPT cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>9028.00</td>
<td>8865.00</td>
</tr>
<tr>
<td>2</td>
<td>4147.99</td>
<td>7664.81</td>
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<td>3</td>
<td>4206.88</td>
<td>8057.80</td>
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<td>4</td>
<td>9134.94</td>
<td>8470.93</td>
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<td>5</td>
<td>4333.77</td>
<td>8905.24</td>
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<tr>
<td>Total</td>
<td>30851.58</td>
<td>41963.78</td>
</tr>
<tr>
<td>Average</td>
<td>6170.32</td>
<td>8393.00</td>
</tr>
</tbody>
</table>
Cost Effectiveness - North 2007

- $31,530 w intention to treat
- $48,357 for 50% patients who achieved long term success
- $117,901 for patients with long term success after crossing over

Spinal cord stimulation

- $38,160 w intention to treat
- $105,928 for 37.5% who achieved long term success
- $260,584 for 0% patients with long term success after cross from SCS

Reoperation
Complications

- Infection 6%
- Generator problems 6%
- Leads 27%
- Extension cables 10%
- Complications higher in FBSS vs CRPS vs angina
Conclusions

- Neuromodulation involves generation of electrical impulses to provide antidromic and orthodromic stimulation of the dorsal columns to inhibit transmission of pain.
- In neuropathic pain relief is thought to be through modulation of Lamina IV and V, reduction of glutamate and aspartate production and reduction in hyper excitability of WDR neurons while Supraspinal increases in GABA and descending pathways stimulation occur.
- In ischemic pain relief is thought to be through increases prostacyclin, substance P or calcitonin gene-related peptide and inhibition of nicotinic receptors.
- Patient selection is key to a good outcome and a successful trial is a significant predictor of a successful therapy.
Conclusions

- Neuromodulation has been demonstrated in prospective studies to
  - Improve quality of life
  - Reduce pain medications
  - Reduce disability
  - Reduce cost of healthcare for CMM patients

- Complications occur but are not serious

- SCS is ranked level II-1 or level II-2 (moderately effective and should be considered) for clinical use on a long term basis
References