Implantable Spinal Devices

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Lunch is on the way!
Disclosures

• No financial disclosures to report.
• No off label use of products will be discussed.
Presentation Will Review

• Neuromodulation
  – Spinal Cord Stimulators
  – Intrathecal Pumps
Pain Treatment Ladder

Behavioral Modification

Intrathecal Pain Therapy

Long-Term Oral Opioids

Neurostimulation

Corrective Surgery

Interventional Techniques

NSAIDs/Neuropathic Pain Agents

Device therapies are now considered earlier in the treatment continuum.
Case

- HPI: 52 y/o F p/w severe low back and leg pain for 4 years. The pain is constant and described as burning, sharp and stabbing in character.
  - Current VAS 5/10, increasing to 7/10 with activity
  - Meds: Opana ER, Oxycodone, Amitriptyline, Lyrica
- PSH: Lumbar Laminectomy L4-S1
- PE: +SLR b/l, b/l lumbar paravertebral tenderness, motor/sensory intact, reflexes intact
- Poor pain control and functional ability!
- Goals for pain control: Going for walks in the park, interact with 10 y/o granddaughter, reduce medications (feels sedated)
What is Spinal Cord Stimulation?

• Well-established, reversible therapy for certain types of chronic pain
• Electrical energy is applied to specific regions of the epidural space in spinal cord
• Interrupts pain messages transmitted from spine to brain
• May restore some of the abnormal chemical processing present in the CNS present in chronic pain conditions
Spinal Cord Stimulator

- Percutaneously placed electrodes in the epidural space, connected to a pulse generator

- Stimulation of electrodes interrupts pain sensation going from periphery to CNS

- Patient has to be involved and learn how to use it
Mechanism of Action

• 1965 by Ron Melzak and Patrick Wall “Gate Theory”
• Mechanism most likely differs based on type of pain being treated
  – **Neuropathic pain** - secondary to stimulation-induced suppression of central excitability
  – **Ischemic pain** - secondary to stimulation induced inhibition of sympathetic outflow (decrease in peripheral vasoconstriction) which increases blood flow to ischemic areas and decreases $O_2$ demand
Framework for the way in which SCS exerts its effect on pain.
Indications

• FDA has approved SCS as a tool in managing chronic, intractable pain of the trunk or limbs associated with
  – Failed back surgery syndrome (FBSS)
  – Intractable low back pain
  – Upper extremity or Lower Extremity Pain

• Higher probability of SCS success has been associated:
  – Postlaminectomy pain
  – Radiculopathy/Spinal Stenosis
  – Plexopathy
  – Arachnoiditis
  – Epidural Fibrosis
  – Painful peripheral neuropathy (Diabetic, Chemo/radiation)
  – CRPS
Favorable Patient Characteristics

• Success of SCS dependent on patient selection

• Basic selection criteria include:
  – Radicular, not central pain
  – Anatomically limited pain
  – Poor response to conservative treatment for at least 6 months
  – No untreated bleeding disorders
  – No active systemic infection or infection at the site of implant
  – No untreated drug addiction issues
  – Psychologically stability
  – Successful 3-8 day screening trial
Results

• Recent systemic review of 49 studies between 1981-2001 with success rate by diagnosis showed long term results of stimulation use with >6 month follow-up:
  – 57% improvement for back and leg pain
  – 83% improvement with CRPS
  – 67% FBSS/stump pain/peripheral neuropathy
  – 77% in patients with ischemic limb pain
  – 82% in patients with post-herpetic neuralgia
Evidence

• Reduction in pain by ranges of 40-80%
• Reduced use of opiates
• Increased ability to perform activities of daily living (61%)
• Return to work (25%)
• Potential cost effectiveness for batteries lasting over one year
• Stimulation devices may be trialed and permanent implants can be reversed. Practical component in the patient’s decision making process and assessment of efficacy.
Spinal Cord Stimulation Trial

- Under fluoroscopic guidance, an electrode is inserted through an epidural needle
- Electrode is then connected to an external generator controlled by the patient
- Purpose of Trial: Help clinician and patient determine whether permanent implant would be useful
- A successful 3-8 day screening trial of SCS
  - 50% reduction in pain scores
  - Improvement in functional quality
Lead Types

Type of leads used dependent upon the patient’s pain generators, physician preference and ability, and co-morbidities.
Transition to Permanent

• Trial period is 24 hours to 2 weeks based on patient response and physician preference

• Adequate assessment of efficacy and reduces risk of fibrosis which hinders placement of a permanent leads.

• Temporary leads are most often removed and replaced.

• Pulse generator is placed subcutaneously in a comfortable locations that is determined beforehand.
Neurostimulation Risks

The most frequently reported problems following the spinal cord stimulator implant surgery include:

- infection,
- lead movement,
- pain at the implant site,
- loss of therapy effect, and
- therapy which did not meet the patient's expectations.

Risks:
- epidural hemorrhage
- spinal fluid leakage
- paralysis.
SCS Newer Applications

- Occipital neuralgia
- Axial back pain
- Chronic abdominal pain secondary to multiple surgeries (not IBD)
- Chronic pancreatitis
- Vascular lower extremity pain and insufficiency
INTRATHECAL THERAPY
SYSTEMIC VS. SPINAL ANALGESIA

Intrathecal: Targeted delivery of the drug directly to the cerebral spinal fluid.

Oral: Systemic delivery through the circulatory system.
Intrathecal pain therapy

- Medication delivered to intrathecal fluid
- The device consists of a catheter and pump
- Battery powered (10 year)
- Smaller doses of medication are needed for effective pain relief because drug is delivered directly to the pain receptors
Smaller, Programmable Pumps
20 ml & 40 ml

Intrathecal Catheter

PTM (Patient Bolus Dose)
Physician Control of Opioids
Less dose needed, Less Side effects!

<table>
<thead>
<tr>
<th>Route of Administration</th>
<th>Relative Potency (mg)*</th>
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<tbody>
<tr>
<td>Oral</td>
<td>300</td>
</tr>
<tr>
<td>Intravenous</td>
<td>100</td>
</tr>
<tr>
<td>Epidural</td>
<td>20</td>
</tr>
<tr>
<td>Intrathecal</td>
<td>1</td>
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</tbody>
</table>
Patient Selection

- Not received adequate relief with conventional therapies
- Reduce adverse effects from oral opioids such as nausea, vomiting, sedation, and constipation
- Decrease or eliminate use of oral analgesics
- Increased ability to perform activities of daily living
- Patient control of medication within physician-set limits
- May be effective for patients who do not experience relief from neurostimulation therapy
Pre-Implantation Trial

• Medications delivered to spinal canal by injection or infusion

• Allows assessment of pain relief and evaluation of side effects

• 50% reduction in pain, side effects, functional ability positive result
Risks Associated with Targeted Drug Delivery

• surgical procedure
• drug-related adverse events
• pump or catheter problems

• can cause serious or fatal drug overdose or underdose, and may require corrective surgery

• Inflammatory masses can form at the catheter tip and result in serious neurological impairment, including paralysis
Which Therapy?

Neurostimulation
- Radiculopathy
- Post laminectomy pain
- Epidural fibrosis
- Degenerative disc disease
- Peripheral causalgia

Neurostimulation or Intrathecal Drug Delivery
- Failed back surgery syndrome
- Complex regional pain syndrome
- Arachnoiditis

Intrathecal Drug Delivery
- Intractable pain
- Chronic pain due to cancer
How to determine which therapy?

- Neuropathic pain with specific anatomic distribution usually respond best to neurostimulation (NS) therapy.
- Nociceptive pain respond best to intrathecal drug delivery (IDD).
- Patients who do not respond well to stimulation may be candidates for IDD therapy.
Summary for Implantable Devices

• Intractable pain
• Intolerable side effects from systemic analgesics
• Conservative therapies ineffective
• Patient’s functional status declines
• Surgery may provide little benefit (or residual pain from surgery)
• Patient wants to get better!
References

References continued


