SPINAL CORD STIMULATION FOR FAILED BACK SURGERY SYNDROME

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Overview

- Background/Scope of the Problem
- Indications
- Mechanism of Action
- Workup and Preoperative Evaluation
- Trial and Permanent Implant
- Outcomes
How bad is it out there?

Current World Population
7,413,100,530

<table>
<thead>
<tr>
<th>TODAY</th>
<th>THIS YEAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Births today</td>
<td>323,602</td>
</tr>
<tr>
<td>Deaths today</td>
<td>135,516</td>
</tr>
<tr>
<td>Population Growth today</td>
<td>188,086</td>
</tr>
<tr>
<td>Births this year</td>
<td>36,775,019</td>
</tr>
<tr>
<td>Deaths this year</td>
<td>15,400,375</td>
</tr>
<tr>
<td>Population Growth this year</td>
<td>21,374,644</td>
</tr>
</tbody>
</table>

Trends in Lumbar Fusion in the United States:

Cage Rage
Intervertebral cages approved by FDA

Operations per 100,000 adults
Thousands of Operations

Deyo, 2005
A problem of our own making?

**Table 2. Frequency of FBSS in the general population.**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Lower estimate</th>
<th>Upper estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low back pain</td>
<td>12%</td>
<td>40%</td>
</tr>
<tr>
<td>CLBP (5-10%)</td>
<td>0.6%</td>
<td>4%</td>
</tr>
<tr>
<td>FBSS (4-50%)</td>
<td>0.02%</td>
<td>2%</td>
</tr>
<tr>
<td>FBSS (4-50%)</td>
<td>20/100,000</td>
<td>2000/100,000</td>
</tr>
</tbody>
</table>

CLBP: chronic low back pain; FBSS, failed back surgery syndrome.

Taylor, 2012
Spinal Cord Stimulation: It’s the best we have

TABLE 1. Estimated 2007 US SCS Implants

<table>
<thead>
<tr>
<th></th>
<th>Inpatient</th>
<th>Outpatient</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare</td>
<td>3309</td>
<td>8,509</td>
<td>11,818</td>
</tr>
<tr>
<td>Non-Medicare</td>
<td>4387</td>
<td>11,279</td>
<td>15,666</td>
</tr>
<tr>
<td>US total</td>
<td>7696</td>
<td>19,788</td>
<td>27,484</td>
</tr>
</tbody>
</table>

SCS, spinal cord stimulation.

Prager, 2010

INDICATIONS
What exactly is Failed Back Surgery Syndrome?

- Did not achieve the desired relief following a spinal operation (traditional definition)
  - Approved by the FDA to treat chronic pain of the back or legs
  - Most common indication in the United States for SCS is FBSS
- OR...Developed recurrent pain following a spinal operation and are not responding to non-operative treatments
- OR...as an alternative when the proposed spine surgery is considered high risk
- OR...as another therapy to complement non-operative treatment for end stage spinal disease

SCS indications – type of pain

- Nociceptive pain
  - Deep ache
  - Discrete (bone, muscle, organ)
- Neuropathic pain
  - Burning pain
  - Localized or diffuse
- Mixed pain
  - Most common
- IF STILL HAVING RADICULAR PAIN THAT IS RESPONDING TO INJECTIONS → Consider repeat decompression
Who to refer for spinal cord stimulation

- No obvious anatomic explanation for pain
- Prior surgery >1 typically
- Leg pain >> back pain
  - A reasonable pt with predominant back pain would consider a trial
  - Newer paddle leads and programming software may improve back pain
- Smokers +/-
  - Incorporate cessation into the overall management
- Approved by neuropsychology
- Old age/high risk patients ok
- Implant/hardware ok

Goals for SCS therapy

- Decrease pain by 50%
  - Reduction of pain medications
- Increase function
- Return to work
- Improved quality of life
Who NOT to consider for SCS

- Isolated back pain
- Severe scoliosis
- Active drug abuse
- Active infections
- Personality disorders

Spinal cord stimulation

- Delivers current to dorsal columns of spinal cord
- Blocks pain signals in A-delta and C-fibers
- Produces paresthesias in distribution of pain
  - Except for Nevro
- Reversible
- Adjustable
- General indications – neuropathic pain
  - Leg pain
  - Arm pain
  - Back pain
- First implant 1967 – Norman Shealy CWRU
PREOPERATIVE EVALUATION

Is there a structural cause for pain?

If no updated imaging-Order it!
Thoracic imaging

- Elective procedure - non-invasive options may better even if less likely to control pain
- Bleeding disorders
- Coagulation studies
- Platelet count
  - Safe to hold medications that inhibit platelet function or reduce clotting
- Sleep apnea - prone position?
- General anesthesia/conscious sedation
- MAC

Medical comorbidities

- Weight
  - Nutritional status - hypoalbuminemia associated with increased infection risk
  - Obesity
- Skin conditions - pre-existing surgical scars or other devices - increased risk of infection
- Spinal hardware
  - May limit head turning/positioning
How long should I wait before Spinal Cord Stimulation?

• Do not wait!
  – patients in the PROCESS study waited 4.7 years before implant

• 15,000 overdose deaths per year-if on high dose opioids send for SCS evaluation
  – From 2004 to 2013 there were 75 deaths with SCS (none related to device itself) in one manufacturers event summary

Psychiatric/psychological evaluation

- **A technical success is not necessarily a clinical success** as psychological factors are often a reason for failure following pain surgery (North and Shipley, 2007)
  - Acute major psychiatric co-morbidity
  - Unresolved possibility of secondary gain
  - **inconsistency** among the patient’s history, pain description, physical examination, and diagnostic studies;
  - abnormal or inconsistent pain ratings;
  - and/or a predominance of nonorganic signs (e.g., Waddell signs)

When are psychological factors more or less likely to influence outcomes?

<table>
<thead>
<tr>
<th></th>
<th>Probably Less</th>
<th>Probably More</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>Specific, well localized</td>
<td>Generalized; multifactorial</td>
</tr>
<tr>
<td>Etiology</td>
<td>Well defined</td>
<td>Multifactorial</td>
</tr>
<tr>
<td>Patient</td>
<td>Psychologically intact; concordant symptoms; acceptance high</td>
<td>Axis I/II Diagnosis, psychological symptoms disproportionate, dependent; deferring</td>
</tr>
<tr>
<td>Procedure</td>
<td>Free from medical system; non-interactive, no sensation</td>
<td>Dependent on medical system, patient interactive, detectable sensation</td>
</tr>
<tr>
<td>Practice</td>
<td>Multidisciplinary/modality; psychological support; physician attitude</td>
<td>Single discipline/interventional; disease/pain generator oriented</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Functional; objective; QoL; functionally related (dose/response)</td>
<td>Perceptual; experiential</td>
</tr>
</tbody>
</table>


PATIENT BELIEFS THAT CORRELATE WITH A POSITIVE OUTCOME
(a) pain is multidimensional and multifactorial,
(b) attitudes and behaviors can affect treatment outcomes,
(c) coping skill (e.g., relaxation, distraction, goal setting) can be helpful,
(d) an active participant in therapeutic decision,
(e) support systems that reinforce positive behavioral change are useful
(f) proper expectations influence outcomes

PATIENT BELIEFS THAT CORRELATE WITH A NEGATIVE OUTCOME
(a) pain is a purely physical phenomenon
(b) psychosocial factors play little role in pain and treatment outcome
(c) chronic pain means loss of productive life
(d) pain can only be relieved if the medical cause (e.g., arthritis, scar tissue) is eliminated
(e) medical technology holds the solution

Patient education

• Introduce the concept early in a patient not improved after surgery (6 months, sometimes sooner)
• Implantable devices are available to help control pain
• They get to ‘try it out’
• If implanted and not working, is reversible
• Will usually block pain signals and provide a “tingling” sensation in the area of the pain

Patient education and selection

• Capable of using/understanding neuromodulation equipment
  - influence treatment choice
  - may be a contraindication
• Willing/able to return for frequent follow up if needed-monthly tapered to yearly
• Understand unique risks of devices such as MRI safety, US, diathermy
• Will they engage in lifestyle modification post procedure
  - Tobacco cessation
  - Return to work
  - Wean off meds
  - Diet/exercise
  - Pain surgery should not be overemphasized as the source of improvement
PROCEDURE

Spinal cord stimulation trial

• Pain diary for one week prior to trial
  – 0-10 scale three times a day – separate back and leg pain

• Implant cylindrical lead(s)
  – Awake
  – ASC
  – Imaging XR for placement

• Programming
  – Product rep

• Pain diary during one week trial
  – 0-10 scale three times a day – back & leg pain

• Removal of trial leads
  – Office
Spinal cord stimulation trial assessment

- Relief of 50% of pain during trial
- Assessment for migration of leads
- Analysis of best program to determine permanent lead placement

Spinal cord stimulation permanent implant

- Percutaneous or paddle leads
  - Awake
  - Asleep with neural monitoring
  - Some MRI compatible
- Placement of implanted pulse generator
  - Gluteal area
  - Some MRI compatible
- Programming
  - Product rep
- Confirmation of lead placement with imaging
Percutaneous or laminectomy leads

SURGICAL COMPLICATIONS
SCS complications – Infection / erosion

- Immunosuppressed/On immunosuppressants (HIV)
  - Infectious disease consult
- Diabetes
  - Keep glucose <200mg/dL
- Malignancy
- Chronic steroid use
- History of prior hardware related infections
- Recent operative procedure
- History of poor wound healing
- Tobacco use
- CBC, UA and Cx
- Wait until conditions optimal

Infection risk assessment and prevention

- Preoperative and postoperative antibiotics
- How long after a trial?
Lead migration

Laminectomy lead – fewer migrations

Complications
Loss of efficacy

- Rule out lead fracture, migration, or infection
- Reprogramming
- Switch to High Density or High Frequency stimulation
- Consider switching from percutaneous to paddle lead

Complications

OUTCOMES
Outcomes

NORTH study, 2005
At mean follow up of 2.9yrs, 47% randomized to SCS and 12% randomized to reoperation achieved 50% pain relief

KUMAR 2007
The Prospective Randomised Controlled Multicentre Trial of the Effectiveness of Spinal Cord Stimulation (PROCESS) tested the hypothesis that SCS plus CMM is more effective than CMM alone
Primary endpoint 50% pain relief in leg
48% in the SCS+CMM vs 9% in CMM alone

Neurostimulation vs Re-operation:
A Single Center Study.

<table>
<thead>
<tr>
<th>TABLE 5. Long-term outcomes of reoperation and spinal cord stimulation as randomized and as treated</th>
<th>Randomized</th>
<th>Crossover</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reoperation</td>
<td>12% (3/26)</td>
<td>0% (0/4)</td>
</tr>
<tr>
<td>Spinal cord stimulation</td>
<td>47% (9/19)</td>
<td>43% (6/14)</td>
</tr>
</tbody>
</table>

*Values are percentages and numbers of patients in each group.

6-month follow-up before cross over
2 year follow-up
Success = >50% pain alleviation and patient satisfaction (would undergo procedure again)
Neurostimulation vs Re-operation: A Single Center Study.

SCS better than re-operation
P< 0.001

1. North RB et al. Neurosurgery. 2005;56:98-107. Success was defined as ≥50% pain relief.

1 year prospective, multi-center of SCS for chronic back and extremity pain
Burchiel et al Spine 1996

Study included 219 pts, 64% with FBSS
182 internalized after trial
70 pts completed the follow-up (outcomes reported for these pts)

55% pts presented with >50% pain relief and would undergo the procedure again to gain the same results
104 pts with FBSS followed for 5 years

Canadian study, included professional fees, implants, studies, medication costs, hospitalizations, programming visits

After 5 years, SCS was less expensive than medical / conventional treatment
Long-Term Outcomes of Spinal Cord Stimulation With Paddle Leads in the Treatment of Complex Regional Pain Syndrome and Failed Back Surgery Syndrome
Cleveland Clinic Experience Neuromodulation 2011

Percent of patients that would undergo the procedure again for the same result

<table>
<thead>
<tr>
<th></th>
<th>Less than four-year follow-up</th>
<th>Greater than four-year follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRPS</td>
<td>56.7% (4/6)</td>
<td>80.0% (10/12)</td>
</tr>
<tr>
<td>FBSS</td>
<td>75.0% (6/8)</td>
<td>66.7% (6/9)</td>
</tr>
</tbody>
</table>

Visual analog scale poorly associated with the degree of satisfaction

→ Pain disability index data collection

Summary

Good candidates:

• No need for additional spine surgery
• With neuropathic pain
• Reasonable pain psychology profile
• Not a replacement for reoperation if there is gross mechanical failure

Outcomes:

• 50% have 50% relief of pain
• Side effects: paresthesias
• May lose coverage over time
  • Paddle lead conversion may be of benefit
  • Newer systems and programming software mitigate lost coverage
THANK YOU!