New Paradigms in Spinal Cord Stimulation

Steven Falowski MD
Objectives

- Background of SCS
- Mechanisms of Action
- Indications
- Equipment
- Placement
Introduction

- Spinal cord stimulation (SCS) delivers electrical current to the spinal cord
- Ideal for Neuropathic Pain
- Adjustable
- Non-Destructive
- Neuromodulatory
Indications

- **Most Common**
  - Post-laminectomy syndrome
  - Complex regional pain syndrome (CRPS)
  - Ischemic limb pain
  - Angina
- **Other**
  - Visceral/abdominal pain
  - Cervical neuritis pain
  - Spinal cord injury pain
  - Post-herpetic neuralgia
  - Neurogenic thoracic outlet syndrome
Background

Initially all unipolar electrodes

Set Programming

Only radio-frequency (RF) driven passive receivers were available.
Background

- **1970’s:** Pulse Generator
- **1980’s:** Percutaneous electrode
- **Waltz et al 1982:** First percutaneous quadripolar electrode
- **2004:** Rechargeable Battery
Mechanism of Action

1980-1990

- Holsheimer, Coburn, and Strujik: Distribution of the electrical fields within the spinal structures

1997 - Holsheimer et al: Effect of anode-cathode configuration on paresthesia coverage in spinal cord stimulation
Mechanism Of Action

- **Barolat 1993**: Mapping of sensory responses
- **Barolat 1998**: Anatomical and electrical properties of the intraspinal structures and clinical correlations
Mechanism of Action

- **Foreman et al. 1976** Primate Studies
- **Linderoth et al. 1992** Rat Studies

- At the chemical level, animal studies suggest that the SCS triggers the release of serotonin, substance P, and GABA within the dorsal horn.

- ?Descending Inhibition
Mechanism of Action - Electrodes

Fig. 3. Potential fields (isopotential lines) in the model of patient A: (a) monopolar stimulation and (b) transverse tripolar stimulation. Solid lines: negative potentials, dashed lines: positive potentials, dotted line: zero potential. Stimulus amplitude [difference between anodal and cathodal voltage in (b)] is 1.0 V. The voltage difference between adjacent isopotential lines is 5 mV.
Indications

- Post Laminectomy Syndrome
- CRPS
- Angina
- Abdominal/Visceral Pain

50% pain relief in 50-60% of the patients
Maintained over several years
Post- Laminectomy Syndrome

**Etiology:**
- Pain in Center Lower Lumbar Area
- Pain in Buttocks
- Radicular Pain

**Also included:**
- Arachnoiditis
- Epidural Fibrosis
- Radiculitis
- Microinstability
- Recurrents Disc Herniations
- Infections
Stimulation of the Low Back

Single vs Dual Electrode

- Law et al: Multiple Bipole Arrays
- North et al: Midline Quadripolar Electrode

Tripole Electrode

- Steer Current
- Sharan 2007: Lateral anodes increase discomfort threshold
Post- Laminectomy Syndrome

Marchand et al: Pain scores reduced with SCS
- Prospective RCT
- Acted as Own Control
- Small Study Group
Post- Laminectomy Syndrome

North et al-1991: 
SCS is superior to repeat surgery

- 50 patients
- Average 3 surgeries for FBSS prior to SCS
- 53% of patients had pain relief at 2.2 years
- Patient Satisfaction

North et al-1995: 
Better outcomes with SCS

- Prospective RCT
- Repeat back surgery vs SCS
- Allowed Crossover
Post- Laminectomy Syndrome

**Turner-1995: Systematic Review of Literature**
- 41 articles from 1966-1994
- 50-60% of patients had greater than 50% pain relief

**Burchiel et al-1996: 55% Successful Stimulation**
- Prospective Multi- Center one year trial
Post- Laminectomy Syndrome

Cameron 2004-JNS:

- 51 studies
- Total of 3,700 patients
- SCS had a positive, symptomatic, long-term effect in cases of:
  - refractory angina pain, severe ischemic limb pain secondary to peripheral vascular disease,
  - peripheral neuropathic pain, and chronic low-back pain
Complex Regional Pain Syndrome

Pain and swelling in a single body part

Pain may start after an injury

Pain will usually gradually worsen

Usually affects the hands, feet, elbows or knees

Two Types:

- Type I: May not have cause
- Type II: Always follows an injury
Complex Regional Pain Syndrome
Complex Regional Pain Syndrome

**Challenges:**
- Pain is not well defined
- Difficult to cover affected area with stimulation
- May aggravate original pain
CRPS-Early Work

- **Barolat et al - 1989**
  - Pain reduction in 10 of 13 patients
  - Short follow up

- **Kumar et al - 1997**
  - 41 month follow up of 12 patients
  - All patients with pain relief
CRPS-More Recent Data

Kemlar -1999: 78% pain relief
- 23 patients

Kemlar- 2000: SCS vs Physical Therapy
- 54 Patients randomized
- 67% pain relief at 6 months
- Improved VAS scores

Kemlar- 2006: Diminished effectiveness over 5 year follow up
CRPS-Limitations

- Difficult to cover affected area with stimulation
- Long-term efficacy is yet to be determined
- Improvement in pain scores, but not necessarily improvement in functional impairment
Angina

Factors Involved
- EKG changes
- Time to Angina
- Exercise Capacity
- Recovery Time
- Use of Nitrates
- Anginal Attacks

End Results
- Ischemia
- Myocardial Flow
- MI
- Arrhythmias
Angina-Use of SCS

- Lower cervical and upper thoracic region
- Continuous vs cyclical use
  - Often use a low intensity stimulation for several hours per day for prophylactic purposes
  - *Eddicks S et al (2007)*: Continuous sub threshold stimulation
    - RCT demonstrating improved functional status and symptoms
    - “Blinded”
Angina-Efficacy of SCS

DeJongste et al 1994: decrease in anginal attacks and nitrate consumption
- Treatment group as Control

DiPede 2003: Immediate and long-term clinical outcome with SCS
- Prospective
- 104 pts with SCS for refractory angina
- Decrease anginal episodes at rest and with activity
Angina-Efficacy of SCS

Vulink et al -1998: Improved pain and quality of life

Hauvast et al-1998:
- Increased exercise duration and time to Angina
- Decreased Anginal Attacks
- Decreased use of Nitrates
- Decreased Ischemic episodes on EKG
Angina-ESBY Study

Mannheimer et al 1998-2002:

- RCT: CABG vs SCS
- Prospective Non-Blinded Trial
- SCS/CABG: Both with 30% Improvement
  NHP scores
- 5 year Mortality: 27% in both groups
  - No difference in the percentage of cardiac deaths
Angina-ESBY Study

Mannheimer et al 1998-2002:

- Cardiac Events were similar across the groups
- More Cerebrovascular events observed in CABG group*
  - Eight in CABG group/Two in SCS group
- Both groups had decrease in anginal attacks and decreased nitrate use
  - No significant inter-group difference
Angina- ESBY Study

**Study Limitations:**

- Limited number of patients
- Limited follow-up time
- Not Blinded
Conclusion of ESBY Study

- CABG and SCS appear to be equivalent methods in terms of symptom relief.
- SCS may be a therapeutic alternative for patients with an increased risk of surgical complications.
Angina-Mechanism of SCS

- Homogenization of myocardial blood perfusion with SCS
- **Augustinsson et al.**-1995: SCS patients have improved heart muscle lactate metabolism, oxygen demand, and blood flow in the coronary sinus
- **Hautvast et al.**: No change in HR variability after 6 weeks
  - i.e. autonomic modulation may not be the explanatory mechanism of action
Angina-Mechanism of SCS

Foreman/Linderoth: Pain Relief from direct inhibition of signal or decrease in ischemia?
- Decreased activity in Spinothalamic/Sympathetic Tracts in Rat Model

Hautvast et al-1996: Positron emission tomography study
- Redistribution of myocardial flow in favor of ischemic parts of the myocardium
- Both at rest and after pharmacologic stress induction
- Demonstrated as a long-term effect of SCS
The role of SCS in the management of refractory angina pectoris seems to be very promising. Uniformly good results in the relief of Anginal pain shown in the literature. Results maintained in long-term follow up. Effects go beyond pain relief.
Abdominal/Visceral Pain

- 20% of the population in United States has abdominal pain
- Many etiologies
  - gastrointestinal
  - genitourinary
  - musculoskeletal
  - nervous system

Treatment modalities
- Cognitive-behavioral
- Physical
- Pharmacological therapies

More Invasive:
- Celiac plexus blocks
- Celiac ganglia destruction
Abdominal/Visceral Pain-Initial Interest

Some studies have demonstrated some localization in the spinal cord for visceral pain secondary to malignancy.

Hirschberg-1996: Increased Dorsal Column Activity

Midline Myelotomy
Abdominal/Visceral Pain-Initial Interest

Case Reports:

Ceballos et al-2000: Mesenteric Ischemia
- Reduction in pain scores
- Decrease Narcotic Use

Krames et al-2004: Irritable Bowel Syndrome
- Reduction in diarrhea
- Initial reduction in pain
**Abdominal/Visceral Pain**

*Khan et al-2005: Refractory Abdominal Pain*

- Non-alcoholic pancreatitis, abdominal wall neuromas, post splenectomy pain
- All patients (9) had a significant improvement in VAS scores
- Decreased narcotic use
- Placement of the leads at the T5-7 level
- 8 month follow up
**Abdominal/Visceral Pain**

- **Tiede et al:** Multiple abdominal surgeries
  - 2 patients
  - Placed at T2
  - Relieved postprandial pain
  - Decrease Narcotic Use
  - Patients returned to work

- **Kapural et al:** Chronic visceral pelvic pain
  - 6 females
  - Endometriosis/Multiple Surgical Explorations
  - >50% Pain relief
  - Decrease opiate use
  - Decrease VAS score
  - 30 month follow up
Abdominal/Visceral Pain-Mechanism

- Viscerotomes

- Sympathetic and Parasympathetic Pathways
  - The sympathetic afferents in the lower thoracic/upper lumbar spinal segments have been shown to transmit painful impulses from the viscera
Equipment
Equipment

- Rapidly Changing
- Multiple Stimulation Parameters
- Multiple Types of Electrodes and Combinations
- Increased Uses
Pulse Generators

Two basic types
- Internal Pulse Generator
- Radiofrequency coupled pulse generator

Rechargeable Pulse Generator
- Power Requirement Issues
Pulse Generators

IPG:
- Lithium Battery
- Activation/Control occur through an external transcutaneous telemetry device
- Control by patient and physician
- Battery life: 2.5 to 4.5 years
  - Outpatient surgery to replace
Pulse Generators

Rechargeable Systems
SCS Model

- Large fibers activated near the cathode

Fig. 3. Potential fields (isopotential lines) in the model of patient A: (a) monopolar stimulation and (b) transverse tripolar stimulation. Solid lines: negative potentials, dashed lines: positive potentials, dotted line: zero potential. 
Stimulus amplitude [difference between anodal and cathodal voltage in (b)] is 1.0 V. The voltage difference between adjacent isopotential lines is 5 mV.
- Transverse tripolar stimulation (4 pts)
- Central cathode and two lateral anodes
- Anodes increase the discomfort threshold over the roots compared to the paresthesia threshold (thus increasing the therapeutic range)
- Lateral/medial steering advantage by setting different voltages of the flanking anodes
- Closer spacing = More effective fiber activation

FIGURE 1. Schematic drawing of the transverse tripolar electrode.
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- **UB**: 2 anodes
- **GC**: 4 anodes
- **LTS-2A**: 2 anodes
- **LTS-4A**: 4 anodes
- **LTS-6A**: 6 anodes
Tripole Paddle-Summary

- Similar activation ratios were obtained as with trialed percutaneous leads.
- Lower paresthesia thresholds and energy per pulse were seen with the paddle than with the percutaneous array.
- Trialing with one or more percutaneous arrays can aid in determining the effectiveness of paddle arrays.
Awake versus non-Awake Surgery for Placement of Spinal Cord Stimulators
Study Design

A retrospective review of 291 internalization operations to determine whether first time awake surgery for placement of spinal cord stimulators is preferable to non-awake placement.

Electrode implantation can be performed either under monitored (local anesthetic and intravenous sedation) or under general anesthesia.
Surgeries Performed

- 61% New Implantation
- 16% Failure
- 10% Repositioning of the battery or stimulator
- 7% EOL of the battery
- 6% are due to infection
Placement of Stimulator

![Graph showing the number of cases and # No Wakeup and # Wakeup over years 2002 to 2006. The graph has a y-axis labeled # cases with values ranging from -5 to 35. The x-axis is labeled Year with years 2002 to 2006. The graph includes two lines, one in red labeled # No Wakeup and one in blue labeled # Wakeup. The number of cases increases from 2002 to 2004, then decreases to 2005, and increases again in 2006. The number of # No Wakeup cases is higher than the number of # Wakeup cases in 2002 and 2006, while the number of # Wakeup cases is higher in 2004 and 2005.](image-url)
Monitoring
Failure Rate

- Non Awake Surgical Failure Rate: 16%
- Awake Surgical Failure Rate: 31%

* = p < 0.05
Repositioning

- Non Awake Surgical Repositioning Rate: 16%
- Awake Surgical Repositioning Rate: 17%
Infection

- Non Awake Surgical Infection Rate 7%
- Awake Surgical Infection Rate 7%
Summary

**Important Points:**

- Radiographical position and motor stimulation responses to assure proper electrode positioning under general anesthesia
- Performed after a percutaneous trial

**Conclusion:**

- Non-awake surgery is associated with fewer failure rates and therefore fewer re-operations, making it a viable alternative
SCS-Conclusions

- SCS Technology is improving
  - Equipment and stimulation parameters
- Reliable and safe modality
- Goal of neurostimulation is to reduce pain rather than to eliminate pain
  - 50% improvement in pain relief
  - Reduce use of pain medications
- Increasing amount of uses
  - Importance of selection criteria
Thank You


References


References


References
