Stimulation of the Peripheral Nervous System

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Disclosures

Equity Owner:

• Ripple
• Microleads
• Mudjala
1968
WILLIAM SWEET MD
CHIEF OF NEUROSURGERY
MASSACHUSETTS GENERAL HOSPITAL
BOSTON

FIRST PERIPHERAL NERVE STIMULATOR

Sciatic Nerve
Cuff electrodes resulted in severe compression of the nerve.

PNS Abandoned
PNS retried in the 80s with paddle leads over the nerves

- Results were good but short lasting.
- Undesirable stimulation of the motor fibers almost always prevented stimulation of the sensory fibers within a useful range.
- At the time smallest voltage increments were in the 0.5 V, which did not allow enough “fine tuning” of the stimulation to prevent motor contractions.
- PW adjustments allowed some additional “tweaking”, but not enough to be useful.
PNS retried in the 80s with paddle leads over the nerves

- Three indications for stimulation of the PNS circumvented these issues:
  - Tibial nerve stimulation for foot drop. Stimulation of the motor fibers was the desirable outcome
  - Vagus nerve stimulator for epilepsy
    - Expandable lead coil
    - Stimulation could be kept sub-threshold for paresthesiae so undesirable motor contractions could be kept to a minimum
  - Interstim by Medtronic. Stimulation of the S3 nerve root. Some degree of motor contractions were acceptable and, in some instances, even desirable.
Today

- The current stimulation systems allow stimulation increments of at least 0.1 V with minute increments in the pulse width.

- Much easier to find the “Therapeutic Window” between sensory and motor stimulation.
Stimulation of the Peripheral Nervous System (PNS)

- True PNS
- Large Named Peripheral Nerves

- Peripheral “Field” Stimulation
- Network of Small Un-Named Branches of Peripheral Nerves
- Excellent alternative to Intra-Spinal Stimulation
- Many times a preferable alternative
- Sometimes as a supplement to Intra-Spinal Stimulation
Advantages of PNS over NTRASPINAL STIMULATION

<table>
<thead>
<tr>
<th>Advantage</th>
<th>Advantage Over:</th>
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<tbody>
<tr>
<td>No need to enter the spinal canal</td>
<td>SCS</td>
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<td></td>
<td>DRG</td>
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<td>Yes</td>
<td>Yes</td>
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<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Less risk of extensive neurological damage</td>
<td>Yes</td>
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<td></td>
<td>Yes</td>
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<td>Much more precise distribution of the stimulation</td>
<td>Yes</td>
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<td>Much greater acceptance by patients</td>
<td>Yes</td>
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<td>Yes</td>
<td>Yes</td>
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<td>More effective in CRPS cases</td>
<td>Yes</td>
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</table>
- Ulnar nerve: Mixed
- Median Nerve: Mixed
- Musculocutaneous Nerve: Mixed
- Superficial Radial Nerve: Sensory
- Axillary Nerve: Mixed
- Femoral Nerve: Mixed
- Sciatic Nerve: Mixed
- Saphenous Nerve: Sensory
- Posterior Tibial Nerve: Mixed
Stimulation of the Peripheral Nervous System (PNS)

**Equipment**

**Cylindrical leads**
- Specifically designed for PNS and inserted through a needle
- Many with “Tines” to prevent migration
- Most often associated with an external power source

**Surgical leads**
- Paddle leads
- Cuff leads
- Utilized either with fully implantable IPG or RF system
Stimulation of the Peripheral Nervous System (PNS)
Cylindrical leads
Cylindrical leads
Cylindrical leads
Cylindrical leads
Surgically placed leads: Cuff leads
Surgically placed leads: *Paddle leads*
<table>
<thead>
<tr>
<th>Advantage</th>
<th>Cylindrical leads</th>
<th>Surgical leads</th>
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<tr>
<td>Invasiveness</td>
<td>Advantage</td>
<td></td>
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<tr>
<td>Physical stability</td>
<td>Advantage</td>
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<tr>
<td>Better physical and electrical contact with the nerve</td>
<td>Advantage</td>
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<tr>
<td>More stable stimulation</td>
<td>Advantage</td>
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<tr>
<td>Implant Specialists</td>
<td>Pain Doctors</td>
<td>Surgeons</td>
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<td>Surgeons</td>
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A Systematic Literature Review of Peripheral Nerve Stimulation Therapies for the Treatment of Pain

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Pain Medicine, 21(8), 2020, 1590–1603
USPSTF : US Preventive Services Task Force

IPM-QRB: Interventional Pain Management Techniques–Quality Appraisal of Reliability and Risk of Bias Assessment. Scoring tool developed by the American Society of Interventional Pain Physicians (ASIPP) to assess RCTs
USPSTF: Level I evidence based upon 14 RCTs for PNS in the treatment of
- migraine headache
- cluster headache
- shoulder pain
- low back pain
- pelvic pain
- neuropathic pain of other origin.
USPSTF criteria suggest that all 14 studies evaluated meet Level I status as RCTs.

Using the mIPMQR procedure 12 of the 14 were deemed high quality based on study design and clinically meaningful outcomes.

Two were deemed moderate quality.

Of the 14 RCTs selected, two were deemed moderate risk of bias and 12 were scored as low risk of bias using the Cochrane scoring method.
• mIMP-QRB: Level is based upon specific indications.

➤ Level I for occipital nerve stimulation (ONS) for the treatment of migraine headache based on four high-quality RCTs and one moderate-quality RCT.

➤ Level I for PNS for the treatment of chronic low back pain (targeting the cluneal nerve and its branches) based on three high-quality RCTs.

➤ Level II for sphenopalatine ganglion (SPG) stimulation for the treatment of cluster headache based on one high-quality RCT.

➤ Level II for PNS for the treatment of poststroke shoulder pain (targeting the axillary and suprascapular nerves) based on one high-quality RCT.

➤ Level II for PNS for the treatment of neuropathic pain of the extremities and trunk based on one high-quality RCT. Common nerves targeted for trunk pain include the ilioinguinal/iliohypogastric, intercostal, and cluneal nerves. Common nerves targeted for the extremity include the median, ulnar, sural, and superficial peroneal nerves and the lateral femoral cutaneous nerves.

➤ Level III for peripheral tibial nerve stimulation (PTNS) for the treatment of chronic pelvic pain based on two low quality RCTs and one moderate-quality RCT.
Taken together, these 14 RCTs suggest several key points:

1. Multiple studies showing ONS can be beneficial for chronic migraine (CM), medication overuse headache (MOH), and intractable chronic migraine (ICM)
2. Moderate evidence (Level II) that implanted SPG stimulation is effective for cluster headaches
3. Strong evidence (Level I) that PNfS is beneficial for patients with continued low back pain following surgery medications, and/or interventional pain procedures
4. Moderate evidence (Level II) that implanted PNS can be expected to provide at least modest improvements in mononeuropathic pain and hemiplegic shoulder pain
5. PTNS may be helpful for overall pain, dyspareunia, and QoL in chronic pelvic pain (Level III)
Ulnar Nerve
Median Nerve
Combined Stimulation of Median and Ulnar nerve
Electrode on Median Nerve

Ulnar Nerve
Superficial Radial Nerve
❖ 29 Y/O white female with severe CRPS 1 of the Right Upper Extremity
❖ Failed all treatments
❖ Excellent candidate for neurostimulation
❖ Does NOT want to have cervical epidural leads !!!!!!
Radial nerve
Median nerve
Radial nerve
Pain in Musculo-Cutaneous Nerve Distribution
Pain in Musculo-Cutaneous Nerve Distribution

Nerve stimulation was missing this area
Posterior Tibial Nerve
- Saphenous nerve (L3, 4)
- Medial calcaneal branches (S1, 2)
- Medial planter nerve (L4, 5)
- Lateral planter nerve (S1, 2)
- Sural nerve (S1, 2) via lateral calcaneal and lateral dorsal cutaneous branches
Sciatic Nerve

Pain in L5 S1
Distribution
Below the Knee
Exposure between the Biceps Femoris and the Semitendinosus.
Sciatic Nerve
Pain in Musculo-Cutaneous Nerve Distribution

Nerve stimulation was missing this area
Combined SCS and PNfS

- 22 y/o
- Multi-level thoracic and lumbar spine degenerative disease
- Intractable pain in the lower/mid/upper lumbar area and both lower extremities
FACIAL PAIN SECONDARY TO MANY SINUS SURGERIES
TESTICULAR PAIN
INTRACTABLE NECK PAIN FOLLOWING RADICAL NECK DISSECTION FOR THYROID CANCER
SEVERE POST FRONTAL CRANIOTOMY PAIN
Severe Post- Frontal Craniotomy Pain
Severe Post-Frontal Craniotomy Pain
Severe Post- Frontal Craniotomy Pain
What is the Biggest Challenge with PNS?
THANK YOU

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