Complex Pain Management

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Disclosures

NONE

Objectives

- Discuss the role of injection and neuromodulation therapy
- Discuss literature review and studies for efficacy of SCS
- Review of updated Ohio state regulatory laws for opioid prescribing
- Identification of appropriate patients for referral for interventional treatment

How can we treat pain?

- **Multi-modality treatment**
  - **Physical therapy**
  - **Aqua therapy**
  - **Pain psychology**
  - **Medications**
  - **Smoking cessation**
  - **Weight loss**
  - **Interventional procedures**
  - **Surgery**

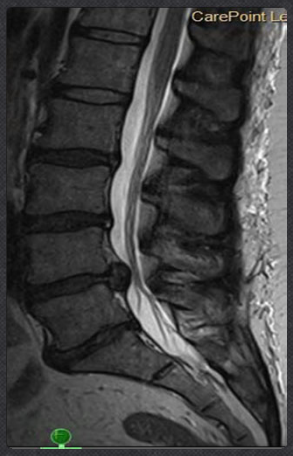
Interventional Pain Management

- For Chronic Pain
- Complementary to Medications
- As an adjunct, or as an alternative, to opioid therapy
- Multimodal Comprehensive Pain Program
- Improve Physical and Psychosocial Function

Interventional procedures

- Caudal epidural steroid injections
- Interlaminar epidural steroid injections
- Transforaminal epidural steroid injections
- Facet steroid injections
- Medial branch radiofrequency ablation
- Sympathetic blocks
- Peripheral nerve stimulator
- Spinal cord stimulator
- Intrathecal pain pump

Lumbosacral radiculopathy – most common at L4/L5 and L5/S1



Injections as part of multimodal plan

- Cochrane review notes strong evidence for interlaminar lumbar ESI for short-term relief but is limited for long-term relief
- Moderate evidence for cervical ESI for cervical radiculopathy
- Strong evidence for short-term relief and moderate evidence for long-term relief with TFESI

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Electrical Stimulation for Pain Control

- First used in ancient Rome in the first century; reported by Scribonius Largus that gout pain was relieved by standing on an electrical Torpedo fish at the seashore1
- In the 16th through the 18th century various electrostatic devices were used for headache and other pains
- Benjamin Franklin was a proponent of this method for pain relief

1Kane K; Taub, A; *Pain*. 1(2):125-138, Jun 1975. doi: 10.1016/0304-3959(75)90097-4.

19th century device called the Electreat

- Pain control, improve health and cancer cures
- Only the electreat survived into the 20th century, but was not portable, and had limited control of the stimulus
- FDA reports Misbranding of device; that its treatment claims are false, 1947

https://fdanj.nlm.nih.gov/catalog/ddnj02236

TENS (Transcutaneous Electrical Nerve Stimulator)

- Use of electric current produced by a device to stimulate the nerves for therapeutic purposes

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Head-mounted TENS device called Cefaly approved by FDA in 2014

- The Cefaly device was found effective in preventing migraine attacks in a randomized sham-controlled trial[1]
  - First TENS device the FDA approved for pain prevention, as opposed to pain suppression

1. Schoenen J, Vandersmissen B, Jeangette S, Herroelen L, Vandenheede M, Gérard P, Magis D (Feb 2013). "Migraine prevention with a supraorbital transcutaneous stimulator: a randomized controlled trial". Neurology. 80 (8): 697–704.
2. FDA allows marketing of first medical device to prevent migraine headaches". fda.gov

(Interventional = Invasive) Peripheral Nerve Stimulation

- Neuralgia – nerve pain along a named nerve distribution
- Therapeutic Targets
  - post-amputation pain
  - post-stroke pain
  - shoulder pain
  - lower back pain
  - post-operative pain following joint replacement
  - complex regional pain syndrome (CRPS)
  - post-traumatic pain

Implantable PNS (Permanent)

- First Diagnostic Block with Excellent Relief
- Primary Safety Endpoint defined by the FDA as a 30% decrease in pain[1]
- Thin Lead is Percutaneously Implanted Next to Target Peripheral Nerve
- Minimally Invasive, long-term treatment option
- External Battery sends stimulation to the lead
- MRI Conditional/Limitations

[1]Deer T, et al. 2016. Neuromodulation. 19:91-100.

Reversible PNS for Acute and Chronic Pain

- FDA cleared percutaneous peripheral nerve stimulation system designed for use in the periphery
- Used in acute post-surgical pain as well as chronic intractable pain
- Implanted for 60 days, zero cases of infection[1,2]

[1]Chae, J., David, T.Y., Walker, M.E., Kirsteins, A., Elovic, E.P., Flanagan, S.R., & Fang, Z.P. (2005) Intramuscular electrical stimulation for hemiplegic shoulder pain: a 12-month follow-up of a multiple-center, randomized clinical trial. *American journal of physical medicine & rehabilitation, 84(11), 832-842.*
[2]Gilmore C.A., Ilfeld B.M., Rosenow J.M., Li S., Desai M.J., Hunter C.W., Nader A., Mak J., Rauck R.L., Kapural L., Crosby N.D., Boggs J.W. (2018). Percutaneous peripheral nerve stimulation (PNS) for the treatment of chronic neuropathic post-amputation pain: Initial results from a multicenter, randomized, placebo-controlled study. *Napa Pain Conference.*

Indications

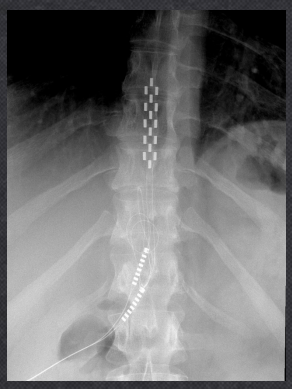
- Chronic shoulder pain
- Chronic back pain
- Chronic post-amputation pain/phantom limb pain
- Acute post-operative pain

Contraindications for PNS

- Need for MRI
- Pacemaker
- DBS
- Allergy to tape or adhesive

First Spinal Cord Stimulator in 1967

- Inventor Clyde Norman Shealy, M.D. , Ph.D is a Neurosurgeon and a Pain Pioneer



[1]*Shealy, C. N.; Mortimer, J. T.; Reswick, J. B. (July 1967). "Electrical inhibition of pain by stimulation of the dorsal columns: preliminary clinical report". Anesthesia and Analgesia. 46 (4): 489–491.*
Image By Mconnell - Own work, CC BY 3.0, https://commons.wikimedia.org/w/index.php?curid=9398692

Spinal Cord Stimulation

- Minimally invasive surgery
- MRI compatible up to 1.5 Teslas
- Stimulator leads can be placed in many different regions
  - Most commonly in the epidural space to modulate the dorsal column of the spinal cord
  - Peripheral nerves
  - Facial nerves

Gate Control Theory

- Hypothesized SCS stimulation of the dorsal columns inhibits the activity of the dorsal horn neurons
- Sends electrical activity to neurons in the spinal cord, thalamus and somatosensory cortices (SI/SII) per the Pain Matrix
- Modulates pain by decreasing sympathetic outflow and tone, activates descending inhibitory pathways
- Modulates many different chemicals that work on pain
  - Increases GABA (helps to inhibit pain signals in the spinal cord)
  - Increases glycine
  - Decreases substance P

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Indications

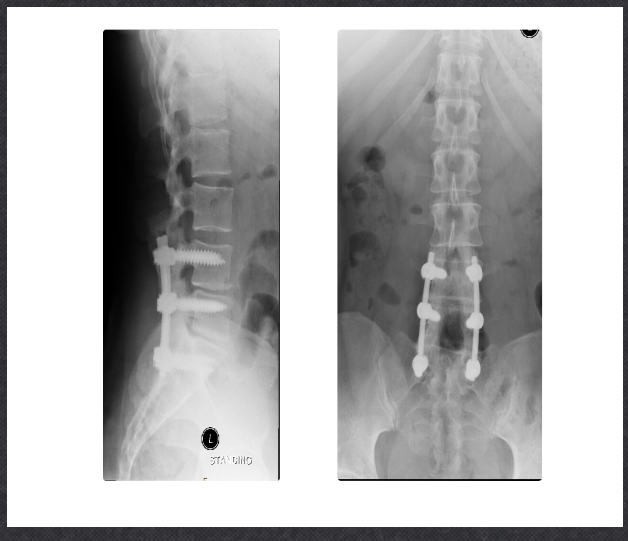
- Post-laminectomy syndrome
- Lumbar radiculopathy
- Neuropathic pain
- CRPS type 1 and 2
- Plexopathy
- Peripheral neuropathy
- Phantom limb pain
- Post-herpetic neuralgia
- Refractory angina

Literature Review

- Most prevalent indication studied is failed back surgery
- SCS can be preferred to repeat surgery (North, Kidd, Shipley, & Taylor, 2007)
- Larger percentage re-operative patients crossed over into SCS group
- SCS compared to conventional medication management showed almost 50% with primary outcome of 50% or mare pain relief compared to 9% of medication patients (Kumar, Taylor, Jacques et al, 2007)
- Neuromodulation Appropriateness Consensus Committee (NACC)
  - Randomized trials support efficacy of use in failed back surgery syndrome and CRPS

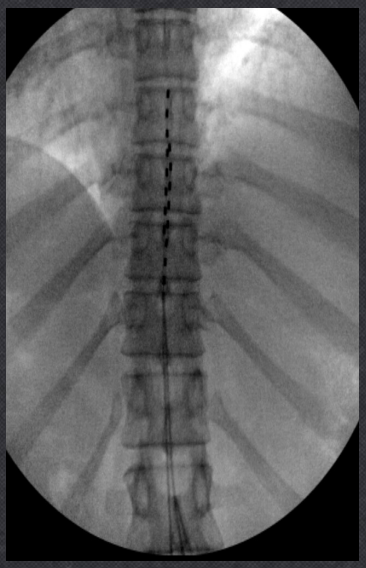
Patient #1

- Patient presents with lumbar surgeries x 3. She continues to have left > right radicular leg pain in an S1 distribution.
- There are associated muscle cramps of the calf worse at nighttime
- She has been working full time at a local hospital (she is a veteran with prior experience as a firefighter and EMT)



- Multiple left S1 TFESI with short term pain relief
- She has been trialed on multiple medications including gabapentin, Lyrica, and Cymbalta
- She follows regularly with a therapist, works with a trainer 3 days per week, and exercises as much as possible
- She is now on short term disability due to pain

- Stimulator trial provided more than 85% pain relief of the radicular leg pain. Calf cramping resolved almost 100% when the trial lead was in place
- Implant was performed and continues to have >75% pain relief ongoing

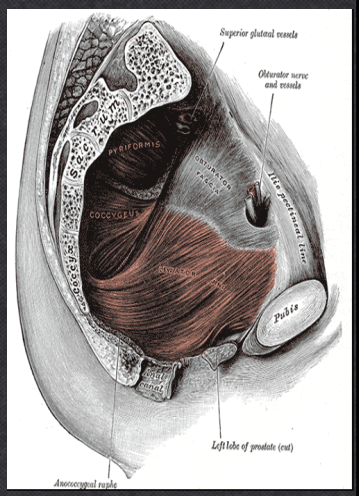


Patient #2

- 33 year old male diagnosed with rectal adenocarcinoma in 2015 s/p surgical resection and chemoradiation
- After his ileostomy takedown and re-anastomosis, he developed severe rectal pain that was burning and sharp in nature
- This pain was constant and worse with sitting and with bowel movements

Ganglion Impar Block/Neurolysis

- Anatomy – Fused terminal retroperitoneal solitary sympathetic ganglion
- Lies anterior to sacrococcygeal joint
- Innervations:
  - To provide innervations to
    - Perineum, distal rectum/anus, distal vagina, distal urethra



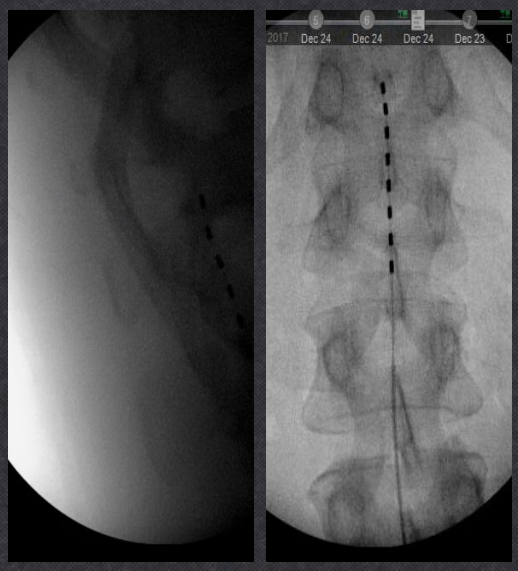
Indications

- Perineal malignant pain
- Rectal pain
- Perineal pain
- Genitalia pain

- Due to severe radiation fibrosis, ganglion impar block with only very short term pain relief
- In the interim, patient has been repeatedly hospitalized for uncontrolled pain and opiates escalated with minimal improvement in pain
- More imaging has been performed and no evidence of return of disease seen
- Pain is interfering with ADLs, ambulation, personal life
- He is not able to work
- Coping is poor

- Due to his severe depression, poor coping, and non-compliance with therapy sessions, multiple interdisciplinary meetings of providers took place
- Recommend he increase his therapy sessions to help with coping and controlling his mood/depression symptoms
- Recommend prescribing team begin slow opiate wean

Stim images



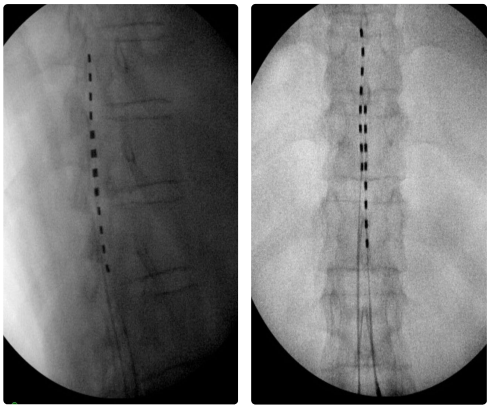
During the stimulation trial, pain was decreased by about 70%

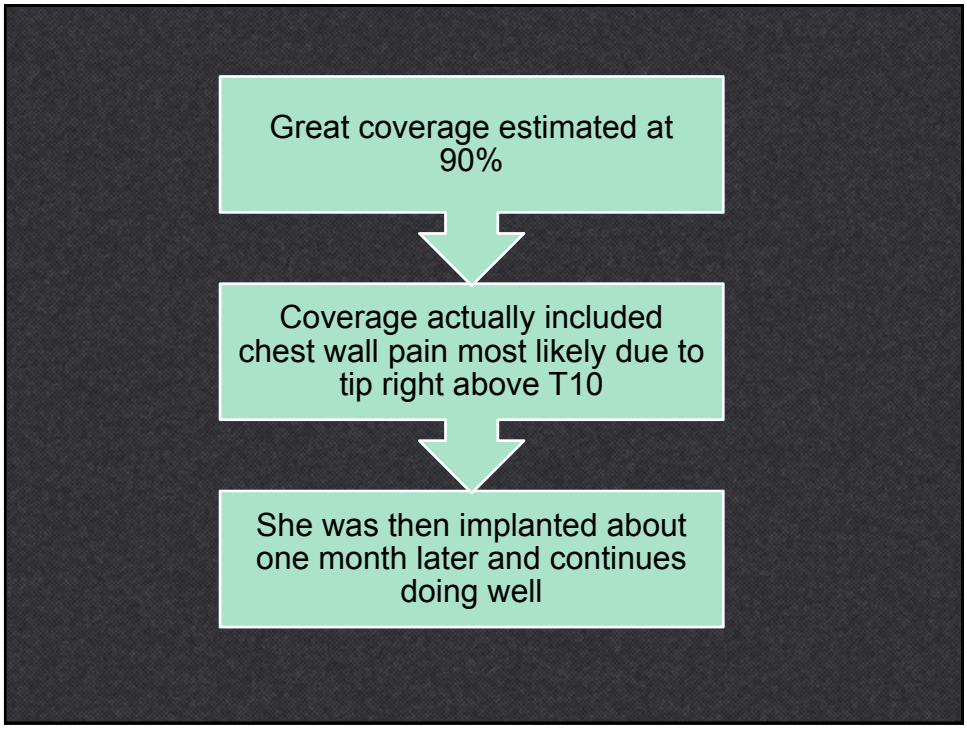
He decreased his breakthrough opiate use by at least half and was able to spread out the dosing frequency from q3 hours PRN to q4-6 hours PRN

Referral made to Neurosurgery for implantation

Patient #3

- 48 year-old with known stage III breast cancer with left chest wall pain from probable rib metastases at T9 as well as chemotherapy-induced neuropathy of the lower limbs present for possible interventional options
- Has confounding severe depression and anxiety – is separating from her husband





Opioid pain relievers

- **Prescription pain medication overdoses killed nearly 15,000 people in the US in 2008**
- **This is 3 times more than in 1999**
- **12 million Americans reported non-medical use of prescription pain medications in 2010**
- **Non-medical use of prescription medications cost health insurers up to $72.5 billion annually in direct health care costs**
- **Groups more likely to abuse: men, middle-aged adults, people in rural counties, whites and American Indians**

Acute Pain Prescribing Guidelines

- Defined as pain that normally fades with healing, related to tissue damage, significantly alters a patient's function, and is expected to be time limited
- No more than seven days of opioids with no refills
- Total morphine equivalent dosing (MED) shall not exceed an average of 30 MED per day
- Total may exceed 30 MED per day if pain cannot be managed with the average limit
  - Major orthopedic surgery
  - Severe burns
  - Traumatic crushing of tissue

Prescribing Opioids for Chronic Pain

- Chronic pain is defined as pain that has persisted after reasonable medical efforts have been made to relieve it and continues either episodically or continuously for twelve or more weeks following the initial onset of pain
- Does not include pain associated with a terminal condition or a progressive disease that may reasonably be expected to result in a terminal condition

- >50 MED
  - Re-evaluate status of underlying condition
  - Assess functioning
  - Look for signs of prescription misuse
    - Check state opioid monitoring system (OARRS)
  - Obtain written informed consent
  - Consider consultation with a specialist
  - Consider offering a prescription for naloxone
- >80 MED
  - Look for signs of prescription misuse
    - Check state opioid monitoring system (OARRS)
  - Required to consult with a specialist
  - Required to obtain a written pain management contract
  - Required to offer a prescription for naloxone

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- >120 MED
  - Required to obtain a recommendation from a board-certified pain medicine physician or board certified hospital and palliative care physician that is based on a face-to-face visit

Intrathecal Pain Pump for Intractable Pain

- A medication reservoir is connected intrathecal catheter, to deliver medications directly into the intrathecal space
- Bypass the blood brain barrier

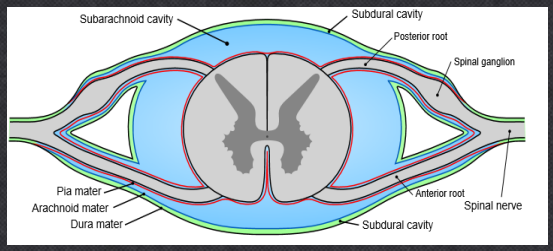


Photo By Mysid - Made by Mysid Inkscape, based on plate 770 from Gray's Anatomy (1918, public domain)., Public Domain, https://commons.wikimedia.org/w/index.php?curid=10496507

Intrathecal Therapy Useful for Cancer

- Significant pain is present in up to 25% of patients with cancer who are in active treatment and in up to 80% of patients with advanced cancer[1]
- oral or transdermal opioids are ineffective at reasonable doses or cause unacceptable side effects

https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf

Indications for Intrathecal Therapy

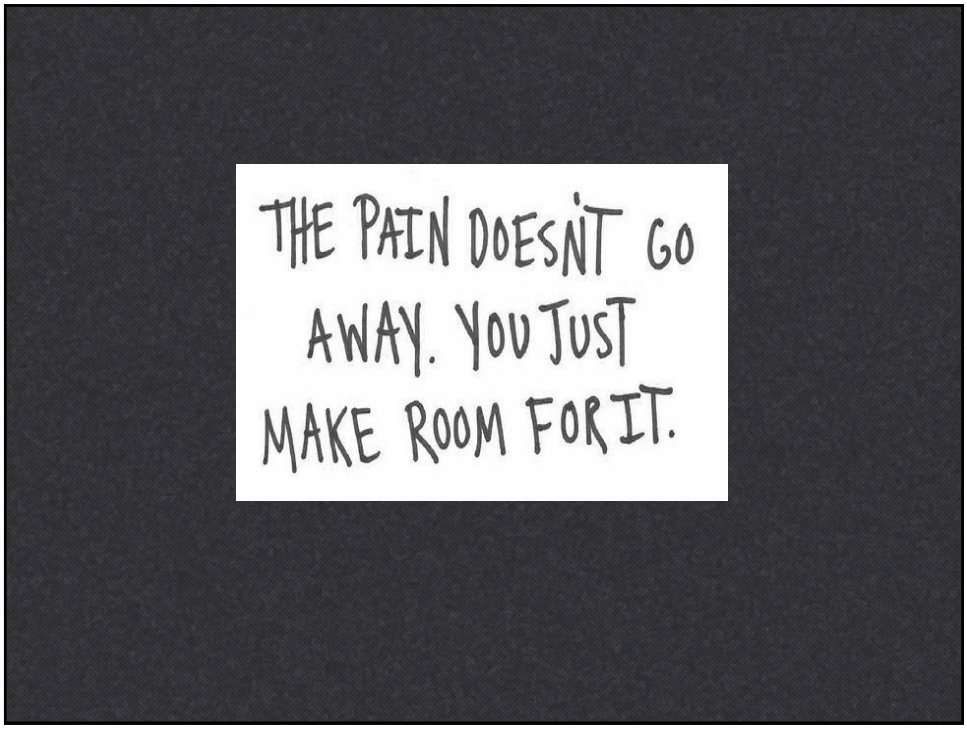
- Cancer pain and pain of spinal origin, with the majority of pumps placed in the United States for failed back surgery syndrome
- Baclofen has been administered in patients who have had a significant spinal cord injury or significant spasticity with very good success
- FDA approved drugs: ziconotide, baclofen, and morphine

Overall Contraindications

- Unable to take off blood thinners
- Platelet count under 75
- Does not want any procedure
- Skin issues, infection or getting radiation in the area of procedure
- Neutropenic

Neurological Red Flags - Spinal Cord Compression

- **New bowel/bladder dysfunction**
- **Acute loss of motor function in the limbs**
- **Hyperreflexia**
- **Imaging – MRI if possible**
- **If previous spinal hardware – consider MRI with contrast**


THE PAIN DOESN'T GO
AWAY. YOU JUST
MAKE ROOM FOR IT.