Utilization of Implantable Devices for Chronic Pain

LISA STEARNS
CENTER FOR PAIN AND SUPPORTIVE CARE
PHOENIX, ARIZONA
Objectives

- Neurostimulation
  - Indications/Contraindications
  - Trialing and Maintenance
  - Risks

- Intrathecal Drug Delivery
  - Indications/Contraindications
  - Trialing and Maintenance
  - Risks

- Intrathecal Drug Delivery PACC Guidelines
Neurostimulation

- Spinal, peripheral nerve, field and brain stimulation
  - A generator (about the size of a pocket watch) sends electrical signals through small implanted wires/leads
  - Leads are either placed percutaneously or surgically
    - percutaneous lead via needle
    - paddle lead via laminectomy or burr hole
  - Signals travel faster than pain fibers and replace the pain signal with a tingling sensation
  - signals can vary in amplitude, voltage and frequency of wave signals which can be programmed for pain optimization and patient comfort
Neurostimulation

- Companies:
  - Medtronic
  - St. Jude
  - Boston Scientific
  - Spinal Modulation (clinical trials)
  - Nevro (at FDA)
Neurostimulation

Potential Benefits
- Improved pain relief
- Decreased medications
- Able to perform trial first to test therapy
- Programmable to each patient
- Patient can control frequency and intensity
- If necessary, can explant
Indications

The decision to offer a patient surgery should be based on consideration of their clinical symptoms, and their potential for functional benefits.

Implantation of a spinal cord stimulation device in adults with chronic, intractable, neuropathic pain is justified and appropriate in the following situations:

- failure of an improvement in symptoms following at least six months of conservative management
- successful completion of a physical and psychological assessment
- successful outcome from a trial of stimulation as part of the assessment by a multidisciplinary team experienced in chronic pain management and the management and ongoing support of those with spinal cord stimulation devices AND
- clinical symptoms and diagnostic imaging compatible with failed back surgery syndrome OR
- clinical symptoms and diagnostic imaging compatible with complex regional pain syndrome Type 1.

A patient should not be referred for spinal cord stimulation if:

- The patient’s quality of life or ability to function is not compromised.
Neurostimulation for Pain

- Deep brain stimulation
- Spinal cord stimulation
  - Dorsal column stimulation
  - Spinal stimulation
  - Dorsal root ganglion stimulation
- Peripheral nerve stimulation
- Gastric stimulation
- Sacral stimulation
Deep Brain Stimulation

- Lead placement
- Indications (not FDA approved)
  - Complex facial pain
  - Central pain syndromes
  - Complex peripheral pain
Dorsal Column Stimulation

Indications:
- Intractable pain of the trunk and/or limbs
  - Failed back syndrome
  - Post-laminectomy syndrome
  - Radicular pain
  - Complex regional pain syndrome
  - Peripheral vascular disease/non healing wounds
  - Angina (not FDA approved)
Peripheral Nerve Stimulation

Indications:

- Patient cannot tolerate DCS or adequate pain relief was not obtained with DCS trial
- Pain is localized to a small region in the distribution of a single nerve
- Complex regional pain syndrome
- Post-herpetic neuralgia
- C2 headaches (occipital neuralgia)
- Ilioinguinal neuritis
Gastric Stimulation

- Gastric
  - Lead placement
- Indications
  - Gastric and small bowel dysmotility
    - Pain lessens secondary to decreased gut distention
Sacral Stimulation

- Sacral
  - Lead placement
  - Indications
    - Interstitial cystitis
    - Pain with micturition and/or defecation (+FDA)
    - Pudendal neuralgia
    - Complex pelvic pain syndromes
Neurostimulation

- **Absolute Contraindications**
  - Untreated depression/anxiety disorder or major psychosis/personality disorder

- **Relative Contraindications**
  - Chronic infections not resulting in sepsis
  - Coagulopathies
  - History of psychological disorders
  - Anatomical aberrations which would prevent percutaneous lead placement
Neurostimulation

- Trialing neurostimulation
- Able to test the therapy prior to implant
  - Behavioral Health Evaluation prior to trial to identify any contraindications.
  - Temporary system with implanted leads and an external generator
  - Patient can return to the clinic for reprogramming
  - Duration of trial is variable, usually 2-10 days
- Outcome: Greater than 50% pain relief for implant
Neurostimulation Maintenance

- Little maintenance required
- Patient’s return to clinic for reprogramming, as needed
- Document usage in chart for revisions or replacements
- Loss of pain relief
  - Lead tip migration
  - Scar tissue
  - Pain remodeling
Neurostimulation

Risks

- Surgical risks
- System failure
  - Lead complications
    - Lead migration or fracture
  - Generator complications
    - Inversion, battery failure, pocket necrosis
- Stimulation side effects
  - Over or under stimulation, change in stimulation effect
Implantable Drug Delivery Device

- An implanted pump delivers medication through a catheter.
  - Intrathecal
  - Epidural
  - Peripheral
    - Plexus or neural delivery
    - Sympathetic ganglia
    - Other potential targets

- Programmable or non-programmable
Intrathecal Drug Delivery

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

Oral
Systemic delivery through the circulatory system.
Intrathecal Drug Delivery

- Companies: Medtronic, Flowonics, Codman (non-programmable)

- Potential Benefits
  - Lower doses of medication required
  - Decreased side effects
  - Clinician programmed - does not rely on patient compliance
  - Patients can self-administer a bolus dose within clinician set parameters
Intrathecal Drug Delivery

- **Candidates**
  - Chronic cancer or non-cancer related pain
  - Patient that have not responded to conservative treatments: medication management, physical therapy, injections therapy
  - Patients with intolerable side effects with conservative treatment
  - Patients unable to comply with treatment plan secondary to cognitive dysfunction or family/caregiver interference
  - Patients with reasonable expectations
Contraindications

Absolute Contraindications

- Untreated depression/anxiety disorder or major psychosis/personality disorder
- Sepsis
- Anticoagulation cannot be interrupted
- Unable to meet maintenance requirements

Relative Contraindications

- Chronic infections not resulting in sepsis
- Coagulopathies
- History of psychological disorders
- Anatomical aberrations which would prevent percutaneous lead placement
Intrathecal Drug Delivery

- **Trialing the Therapy**
  - Behavioral Health Evaluation prior to trial to identify any contraindications.
  - Single-shot intrathecal or epidural injection
  - Continuous infusion through epidural or intrathecal catheter
    - Usually last 2-7 days
  - Can adjust the medication/dose during the trial
  - Greater than 50% pain relief to implant
Intrathecal Drug Delivery

- **Maintenance**
  - Pump requires refill every 1-6 months
  - Documentation of Use of Patient bolus device
  - Monitoring for inflammatory mass formation
    - Recommended physical exam by provider every 3 months
  - Monitoring battery life
  - Monitoring for system failure
    - Electronic logs
    - System review for signs of under or over infusion
Intrathecal Drug Delivery

- Risks
  - Surgical risks
  - Medication side effects
  - Catheter complications
    - Catheter kink or leak
    - Catheter dislodgement
  - Pump complications
    - Motor stall
    - Pump inversion
Safety Concerns

- Immunosuppression
- Respiratory Depression
- Peripherals Edema
- Granulomas/Inflammatory Masses
- Tolerance
- Tissue necrosis around device
PACC Guidelines

- Pump Medications for Neuropathic Pain
- Pump Medications for Nociceptive Pain
- Recommended Starting Doses
- Maximum Concentrations
- Maximum Dose Per Day
- Complication Management
- Trialing recommendations
New guidelines to be published late 2015

Historical PACC Guidelines:


- Portenoy, Russell K et al. (2000) Journal of Pain and Symptom Management, Volume 20, Issue 2, S3