The Case Manager Is the Key…

- To educating patients on best therapy options
- To ensuring proper care coordination for patient success
- To helping place patients on the path to improved functionality and return to work
- To assisting adjustors in case closure

What is Pain?

“Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.”

(IASP)

PAIN

- Most common reason individuals seek health care. 9 in 10 American regularly suffer from pain
- Chronic pain is the most common cause of long-term disability and almost 1/3 of American will experience chronic pain.
- As population ages the number of people who will need treatment for chronic pain will increase tremendously
Physiological Pain

- High threshold
- Well-localized and transient
- Stimulus-response relationship
- Warning/protective system
- Carried by A δ and C fibers

Acute Pain is a **Warning Symptom** of an Underlying Problem
What Is Chronic Pain?

- Chronic pain is pain that
  - Lasts past the expected time of healing
  - Has no physiological value or warning function for the body
  - May spread and increase in intensity
  - May become stronger than the initial pain from the injury


Acute Tissue Injury May Lead to Chronic Pain

<table>
<thead>
<tr>
<th>Time in Seconds (logarithmic scale)</th>
<th>Time in Minutes</th>
<th>Time in Hours</th>
<th>Time in Days</th>
<th>Time in Months</th>
<th>Time in Years</th>
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Stimulus (acute tissue injury)

CLINICAL PAIN

Low Intensity Stimulus

Sensitized Neocortex A delta & C

PHS CNS

PAIN

Anesth Analg 1993; 77:362-79

Central Sensitization

C-Noceptive primary afferent

Glutamate

NMDA

Hyperalgesia – heightened sense of pain to noxious stimuli

Allodynia – pain resulting from normally painless stimuli

Inflammatory or Neuropathic

Hyperalgesia

Allodynia

Spontaneous

Pain does not have any protective function
Adverse Consequences

- **Physical:**
  - Impair ability to carry out ADL, decrease QOL and cause significant suffering
- **Psychological:**
  - Anxiety, fear, anger or depression
- **Financial:**
  - Individuals absenteeism, underemployment and unemployment
  - Health care cost and disability compensation

Chronic Pain is Very Expensive

Chronic Pain is the most expensive health care problem in the US today at $240 billion annually.

- 40 Million physician visits per year
- 515 Million lost work days per year

The Average Chronic Pain Patient:
- Suffered seven years
- Undergone three major surgeries
- Incurred medical bills of $50,000 - $100,000

Back Pain

- Costs Americans billions a year (Boyle)
  - Third most expensive disorder, after heart disease and cancer (University of Wisconsin)
  - Accounts for 2.5% of the nation’s total health-care bill (Boyle)
- Second most common reason for visits to the doctor’s office, outnumbered by upper-respiratory infections (In Project Briefs)
- One of the most common reasons for missed work (In Project Briefs)
  - Accounts for more than 6 million cases annually (University of Wisconsin)
  - One-half of all working Americans admit to having back pain symptoms each year (Vallfors)

Failed Back Surgery Syndrome

- Also known as post-laminectomy syndrome
- General term to describe condition of patients who have not had a successful result with spine surgery
  - Surgery fails to remove the pain
  - Pain is diffuse, dull, and achy in the back and sharp, burning, and stabbing in the legs
Complexities in Managing FBSS

- Between 20 and 40 percent of patients were diagnosed with FBSS resulting from lumbar spine surgeries in 2005.

Costs to Disability and Workers Compensation

- "Back pain is the most common reason for filing workers’ compensation claims."3
- From an economic perspective, the average cost of a workers’ compensation claim for low back pain was $8,300, which was more than twice the average cost ($4,075) for all compensable claims combined.4

Complexities in Managing FBSS

- After receiving treatment for low back pain, patients are less likely to return to work the longer they have been out.

Unmanaged Pain: Economic Costs

- Emergency Room Visits
- Diagnostic Merry-Go-Round
- Hospitalizations, Multiple Surgeries
- Rehabilitation Therapies
- Pharmaceuticals
- Loss of Productivity

Chronic Pain Patients

- Multifaceted problem
  - Loss of employment or income, depression, fear, anxiety, sleep disorders, marital and family dysfunction
  - Physicians are often as dissatisfied as the patients
  - Search for the "pain generator" is frequently unsuccessful
  - Unrealistic expectations
  - Secondary gain issues
  - An approach is needed

Philosophy of Care

Acute Pain - Chronic Pain

Medical Management
Behavioral Modification
Interventional Management
Pain

- An unpleasant sensory or emotional experience
- Two types of pain
  - Acute Pain
    - Short term
    - Associated with actual or potential tissue damage
  - Chronic Pain
    - Nociceptive
    - Neuropathic

Nociceptive Pain

- Somatic pain arises from
  - Bones and joints
  - Muscles
  - Skin
  - Connective tissue
    - Aching or throbbing
    - Localized
  - Visceral pain arises from
    - Visceral organs, such as the GI tract and pancreas
    - Tumor involvement
    - Obstructive

Neuropathic Pain

- Abnormal processing of sensory input by the peripheral nervous system (PNS) or CNS
- Centrally generated pain
- Peripherally generated pain

Mixed Pain

- Many patients have a combination of both nociceptive and neuropathic pain
- Disease or trauma has damaged nerve cells and other tissues

Causality of Neuropathic Pain

- When nerves become damaged or injured, they stop working properly.
- They may send the wrong signal to the brain.
- Injured nerves might tell the brain that your foot is experiencing burning pain even when you aren’t stepping on something hot.

Character and Quality of Neuropathic Pain

- Burning
- Tingling
- Sharp, shooting
- Throbbing
- Numbness
- Painful to light touch
- Itching
Types of Neuropathic Pain

- Neuropathic chronic pain patterns (may be mixed with aching pain)
  - Failed Back Surgery Syndrome (FBSS)
  - Complex Regional Pain Syndrome I (CRPS I)
  - Complex Regional Pain Syndrome II (CRPS II)
  - Postherpetic Neuralgia
  - Phantom Limb Pain

Multimodal Approach


Old Chronic Pain Treatment Continuum

Treatment Considerations

- Rest
- Physical medicine
- Non-opioid analgesics
- Injections
- Opioid analgesics
- Psychological evaluation
- Surgery or implantable devices
- Neuroablation

Is Opioid Therapy Effective?9

- Short-term efficacy
  - RCTs and observational studies demonstrate improvement in pain
  - No evidence to support dosing >180 mg morphine equivalent per day
- Long-term efficacy
  - No RCTs for longer than 8 months
  - Overall evidence is weak
  - Most studies look at VAS; no evidence of improved function

Are Opioids Safe Therapy?

- Side effects
  - Dysphoria, constipation, urinary retention, somnolence, cognitive changes
- Immune and hormonal function
  - Testosterone, estrogen, cortisol suppression, decreased libido, infertility
- Addiction
  - Social, psychological, physical, and financial consequences
Opioid Summary

- The literature suggests that chronic opioids do not provide a functional benefit or even adequate reductions in VAS for most patients.
- High dose opioids have little value in chronic long-term use.

Who Should We Refer to Interventional Pain?

- Injury to the spine or specific body part
- Pain persisting past expected time
- Treating doctor stalled in progress and treatment ideas
- Motivated and legitimate patient

Why Interventional?

- **Diagnostic**
  - Anatomical source of the pain
  - Placebo effect
  - Failed block
- **Therapeutic**
  - Immediate relief of pain
  - Break pain cycle
  - Long term relief

Interventional Therapy

- Trigger Points Injections
- Epidural Steroid Injection
- Selective Nerve or Nerve Root Block
- Discogram and IDET
- Facet Block and RFA

Definition of Neuromodulation

- Neuromodulation is the electrical or chemical modulation of the central nervous system (CNS) to reduce chronic pain or improve neurologic function.

Neuromodulation Devices

- Electrical stimulators and drug pumps
- Allow the delivery of very small, precise doses of electricity or drugs directly to targeted nerve sites
CNS Pain Management

- Gate Control Theory (Melzack)

Gate Control Theory (Melzack)

- Sensory impulses are greater than pain impulses
- A “gate” in the spinal cord closes, preventing the pain signal from reaching the brain

Gate Control Theory and SCS

An SCS system implanted near the dorsal columns stimulates pain-inhibiting nerve fibers, which masks painful sensations with tingling sensations (paresthesia)

Indicated Use Statement for SCS

- Indicated as an ”aid in the management of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with: failed back surgery syndrome, and intractable low back and leg pain”

Spinal Cord Stimulation (SCS)

- Use of an implanted medical device to deliver electrical pulses to the dorsal spinal cord.

SCS Is Not TENS

- SCS should not be confused with TENS.
- TENS is an external device that reduces pain by applying low-voltage energy through electrode pads over the skin.
SCS and Pain

- SCS devices are FDA-approved/cleared as an aid in the management of chronic, intractable pain of the arms, legs, and trunk of the body
- Used for over 40 years for chronic pain conditions
- Intractable neuropathic pain

Patient Selection Criteria

- Pain is neuropathic in origin
- Patient has undergone a successful trial and has demonstrated a willingness to participate in the treatment protocol
- Pain is in the arms, legs, and trunk of the body
- Conservative therapies have not provided long-term pain relief
- Patient is willing, motivated, and able to operate the device
- Patient is a suitable candidate for surgery and free of active general infections
- No contraindications present (demand-type cardiac pacemakers)
- Multidisciplinary screening

Components of SCS Devices

- Leads
- Power source
- Programmer
- Charging system, if applicable

Leads

- Leads come in a variety of lengths
- Spacing between the contacts varies and will influence the shape of the electrical field
- Leads are placed in the epidural space
- Placed either percutaneous through a needle or surgically

Lead Family
Percutaneous Leads
- Catheter style
- Placed via special needle
- Less invasive
- Have cylindrical electrodes
- Provide circumferential stimulation

Surgical Leads
- Paddle style
- Placed via incision (laminectomy)
- More invasive implantation
- Very stable
- Have plate electrodes
- Provide unidirectional stimulation

Primary Cell Power Source
- Finite battery life
- Replacement depends on usage
- Ideal for patients that require or prefer the simplicity of a non-rechargeable battery

Rechargeable Power Source
- Functions like the primary cell battery, but it has more battery power
- Frequency of recharging depends on how often the stimulator is used and at what settings
- Ideal for patients with moderate to high power requirements who can manage a recharge schedule

Programming Options
- Rapid Programmer™ system with MultiSteering™ technology—simplifies the programming of multifocal pain to help deliver optimal therapy.
- Patient Programmer—a handheld, portable device that lets patients adjust how the therapy feels.

Recharging System
- Transfers energy from external charging unit to the battery
- System plugs into standard electrical outlet
- Frequency of recharging depends on amount of time stimulation is used and power required
Matching Device to Patient

- Matching the device to patient
  - What is the cause of the patient's pain?
  - Where is the patient's pain pattern?
  - Does the patient have any unusual anatomy?
  - What are the power requirements?
  - One of the purposes of the trial

Procedure

- Usually performed in two stages
  - Temporary evaluation period
  - Permanent implant

Temporary Evaluation Period

- A temporary evaluation period provides an opportunity to measure the effectiveness of SCS without making a long-term commitment
  - Gauge patient response
  - Provide an adjustment period
  - Fine-tune therapy parameters
  - Improve therapy cost-effectiveness

Temporary Evaluation Period

- The goal is at least a 50% reduction in pain without intolerable side effects
  - Patient-specific goals may include less pain reduction but improved quality of life

Purpose of Psychological Assessment

- Exposes psychological factors that can influence the outcome of surgery
- Used to determine how well a presurgical assessment could predict a surgical outcome
- Facilitates patient selection for specific pain therapies
- Provides clues to evaluate the patient's response to a temporary evaluation or treatment

Temporary Evaluation Period

- Patient and family receive extensive pre-trial education
- Outpatient/office procedure to place leads
- Leads are connected to a trial stimulator with settings created to cover painful areas
- Allows the patient and the physician to determine if SCS will provide pain relief
Nerve Fibers

Dorsal Root
Ventral Root
Nerve Root

How Are Device Factors Evaluated?

- Temporary SCS trial

Neurostimulation Temporary Evaluation Assessment Criteria

- Pain control—Did the trial relieve the patient’s pain and by what percentage?
- Activities—Did the trial improve the patient’s ability to participate in normal activities and to what degree?
- Sleep—Was the patient able to sleep comfortably during the trial?
- Medication—Did the need for pain medications change during the trial?
- Patients who experience a positive response to the temporary evaluation may be candidates for long-term neurostimulation therapy.

Temporary Evaluation Outcomes

- Determine the number of leads and contacts for permanent implant—match the device to the patient
- Determine device type
  - Primary cell IPG
  - Rechargeable IPG
- Monitor patient expectations
**After Temporary Evaluation Period**

- Patient, family, and physician discuss the temporary evaluation and determine if the patient should move forward with the permanent implant.
- The physician and patient will decide what is the best type of system for the patient’s pain pattern.

**Permanent Implant**

- The leads and IPG will be implanted during a minor surgical procedure.

**Implantation Procedure**

- Implantation procedure performed by a physician in a hospital or ambulatory surgery center.
- On average, the procedure takes 1-2 hours from start to finish.
- May be an outpatient procedure or, in some cases, may require a stay in the hospital.

**Getting Their Lives Back**

- Patients should gradually return to activities of daily living.
- Some changes in stimulation are common as activity increases.
- Adjustments can be made through the programming system.
- Patients and physicians have a life-long relationship.

**Rethinking the Chronic Pain Treatment Continuum**

The objective is moving device therapy earlier in the continuum of care.

**Cost-Effectiveness Analysis of Neurostimulation Therapy For Chronic Pain**

- Evaluated 104 patients with FBSS.
- 60 implanted after successful trial; 44 control patients.
- Actual mean cumulative costs.
- 5-year follow-up.
- SCS group: $29,123, 15% RTW.
- Control group: $38,029, 0% RTW.

* Canadian dollars

RTW = return to work.
Cost-Effectiveness of Neurostimulation

- SCS is cost-effective, as several experts have shown:
  - Bell et al.\textsuperscript{21} showed that SCS pays for itself within 2.1 years with patients who have clinically effective SCS for failed back surgery syndrome.

Neurostimulation vs. Repeat Surgery

- Based on a study by North\textsuperscript{14}, neurostimulation is more effective than repeat surgery as a treatment for persistent radicular pain after lumbosacral spine surgery.

Importance of Timing With SCS in the Treatment of FBSS

- The sooner an SCS system is implanted after a failed back surgery, the more effective SCS may be.

SCS Studies

Reduction in pain

<table>
<thead>
<tr>
<th>Author</th>
<th>No. Patients</th>
<th>Follow-Up</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kumar</td>
<td>410</td>
<td>8 years</td>
<td>74% had (\geq 50)% relief</td>
</tr>
<tr>
<td>North</td>
<td>19</td>
<td>3 years</td>
<td>47% had (\geq 50)% relief</td>
</tr>
<tr>
<td>Barolat</td>
<td>41</td>
<td>1 year</td>
<td>50%-65% had good/excellent relief</td>
</tr>
<tr>
<td>Van Buyten</td>
<td>123</td>
<td>2 years</td>
<td>60% had good/excellent relief</td>
</tr>
<tr>
<td>Alò</td>
<td>80</td>
<td>30 months (2.5 years)</td>
<td>Mean pain scores declined from 8.2 to 4.8</td>
</tr>
<tr>
<td>Cameron</td>
<td>747</td>
<td>up to 59 mos.</td>
<td>62% had (\geq 50)% relief or significant reduction in pain scores</td>
</tr>
</tbody>
</table>

Reduction in medication

<table>
<thead>
<tr>
<th>Author</th>
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</tr>
</thead>
<tbody>
<tr>
<td>North</td>
<td>19</td>
<td>3 years</td>
<td>60% reduced their med use</td>
</tr>
<tr>
<td>Van Buyten</td>
<td>123</td>
<td>3 years</td>
<td>As a group reduced the medication use by 74%</td>
</tr>
<tr>
<td>Cameron</td>
<td>747</td>
<td>up to 84 mos.</td>
<td>45% reduced their med use</td>
</tr>
<tr>
<td>Taylor</td>
<td>481</td>
<td>n/a</td>
<td>55% no longer needed Analgesics</td>
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</table>

Improvement in daily activities

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<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barolat</td>
<td>41</td>
<td>1 year</td>
<td>As a group, significant improvements in function and mobility</td>
</tr>
<tr>
<td>North</td>
<td>19</td>
<td>3 years</td>
<td>As a group, improvements in range of activities</td>
</tr>
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The success rate of neurostimulation decreased from 85\% at <2 years to about 9\% if delayed by >15 years.
**SCS Studies**

**Return to work**

<table>
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<th>Follow-Up</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Van Buyten</td>
<td>123</td>
<td>3 years</td>
<td>31% returned to work</td>
</tr>
<tr>
<td>Taylor</td>
<td>1133</td>
<td>n/a</td>
<td>40% returned to work</td>
</tr>
<tr>
<td>Harris</td>
<td>23</td>
<td>3 years</td>
<td>35% returned to work</td>
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**The Take-Home**

- You are the key to educating patients about therapy options.
- You are the key to helping place patients on the path to improved functionality and return to work.
- You are the key to providing the best opportunities for case closure.

**The Take-Home**

- A team approach using the case manager, physicians, and other medical personnel can be very successful.
- In selected patients, implantable devices provide the best outcomes when compared to other options.
- You are the quarterback for ensuring optimal communication among all parties.

**Questions?**

Thank you for your time!

**References**

References