Microdose Intrathecal Pumps: Redefining Chronic Pain Treatment

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Twin Cities Pain Clinic

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Clinical Interests

- Interventional pain management
- Spinal cord stimulation
- Treating spine pain

Board Certifications

- American Association of Nurse Practitioners
- American Society for Pain Management Nursing
- Associate Certification in Controlled Substance Management
- Credentialed Fellow - American Academy of Pain Management

Education

- BS in Nursing – Minnesota State University, Mankato
- MS in Family Nurse Practitioner studies – University of Minnesota

Hobbies

- Spending time with family, volleyball, boating, biking, & reading

Chronic Pain vs. Acute Pain

Pain: An unpleasant sensory and emotional experience association with, or resembling that associated with, actual or potential tissue damage.

Acute Pain	• Represents the actual or the potential for tissue damage • Resolves with healing
Chronic Pain	• Lasts at least three months • Does not resolve over time

Pain Experience: Affected by stress, environmental and affective factors

"It is not the duration of pain that distinguishes acute from chronic pain, but more importantly, the inability of the body to restore its physiological functions to normal homeostatic levels."

Risk Factors for Chronic Pain

Biologic

- Severity and extent of surgery/trauma/disease
- Genetic factors (i.e. Sickle cell disease)
- Metabolic disorders (i.e. Diabetes)

Psychological

- Pre-existing mental health issues

Substance use/abuse

Repeated surgeries

Social

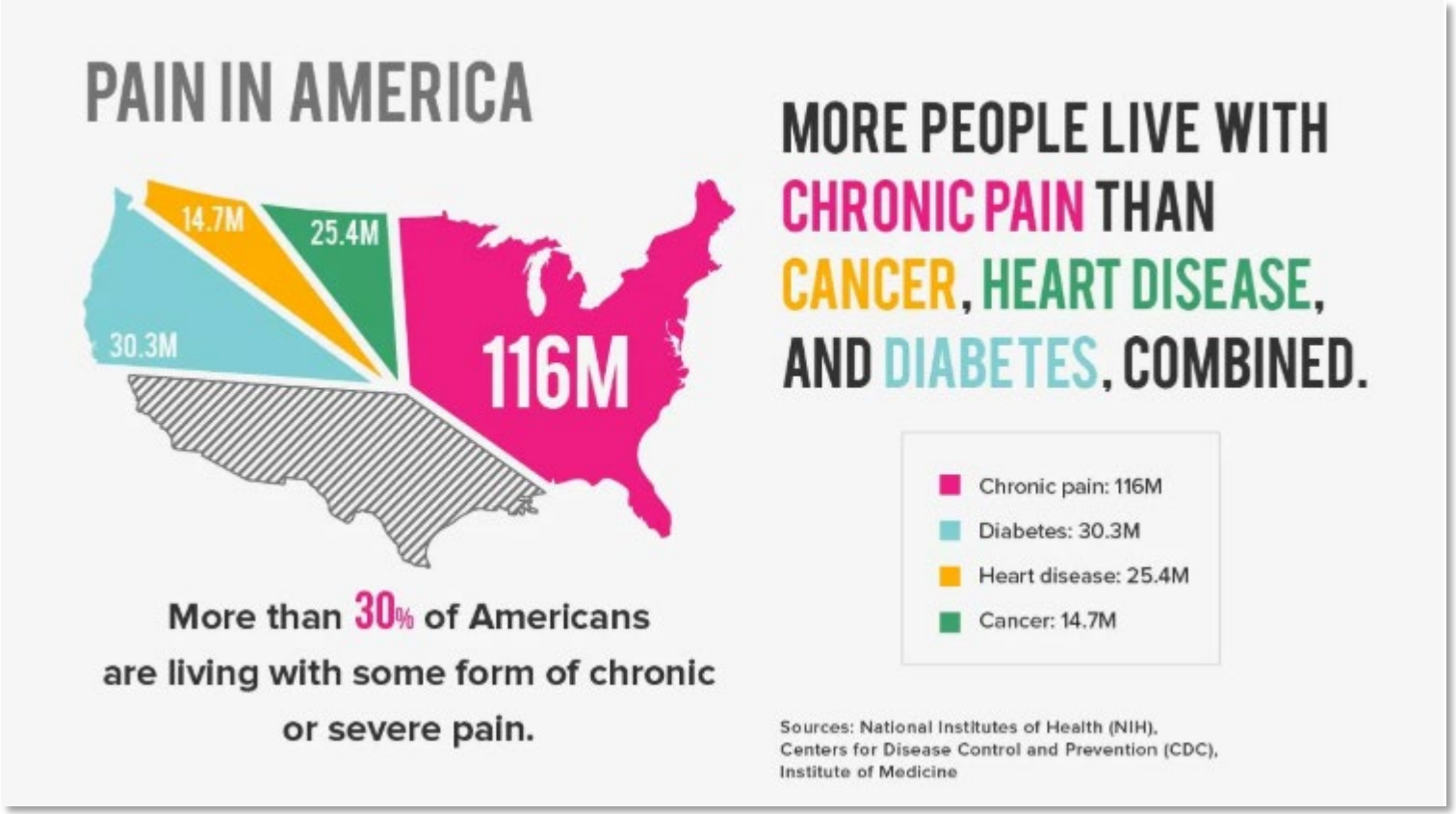
- Disabled
- Loneliness
- Unstable housing
- Poverty
- Low health literacy
- Poor access to healthcare

Prolonged exposure to systemic opioids

Pre-existing widespread pain *(i.e. Fibromyalgia)*

Prevalence of Chronic Pain

- >100 million suffer from chronic pain *(2011)*
- Impacts 1 in 5 adults in the U.S.
- 29.1 million suffer from low back pain *(2016)*
- One of the most common reasons patients seek care



https://www.healthline.com/health-news/america-is-losing-the-war-on-chronic-pain

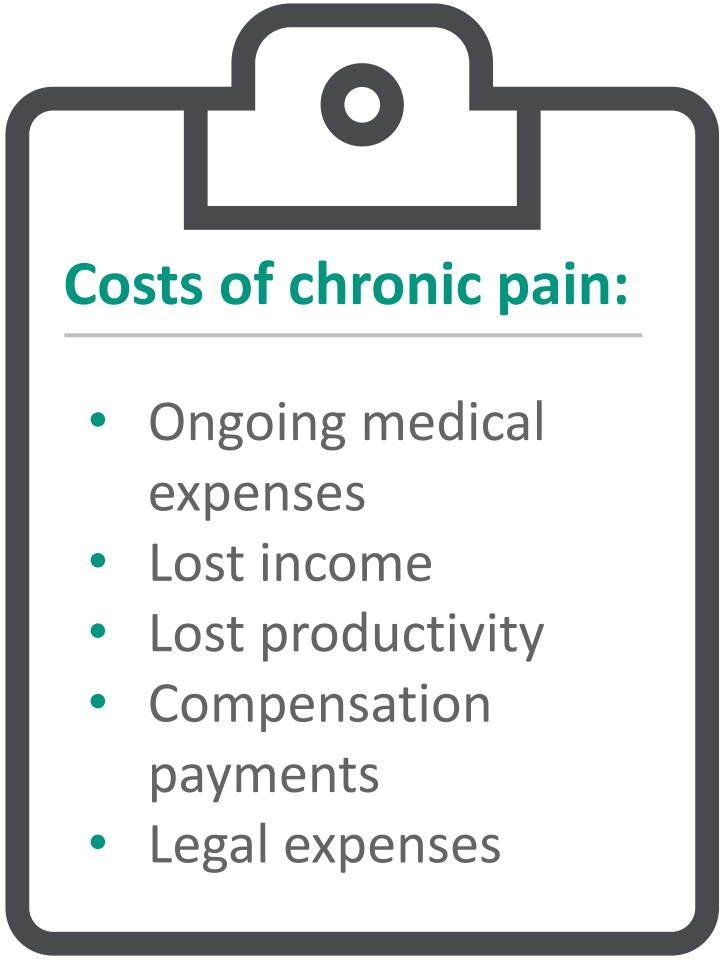
Cost of Chronic Pain

$ 635 billion annually

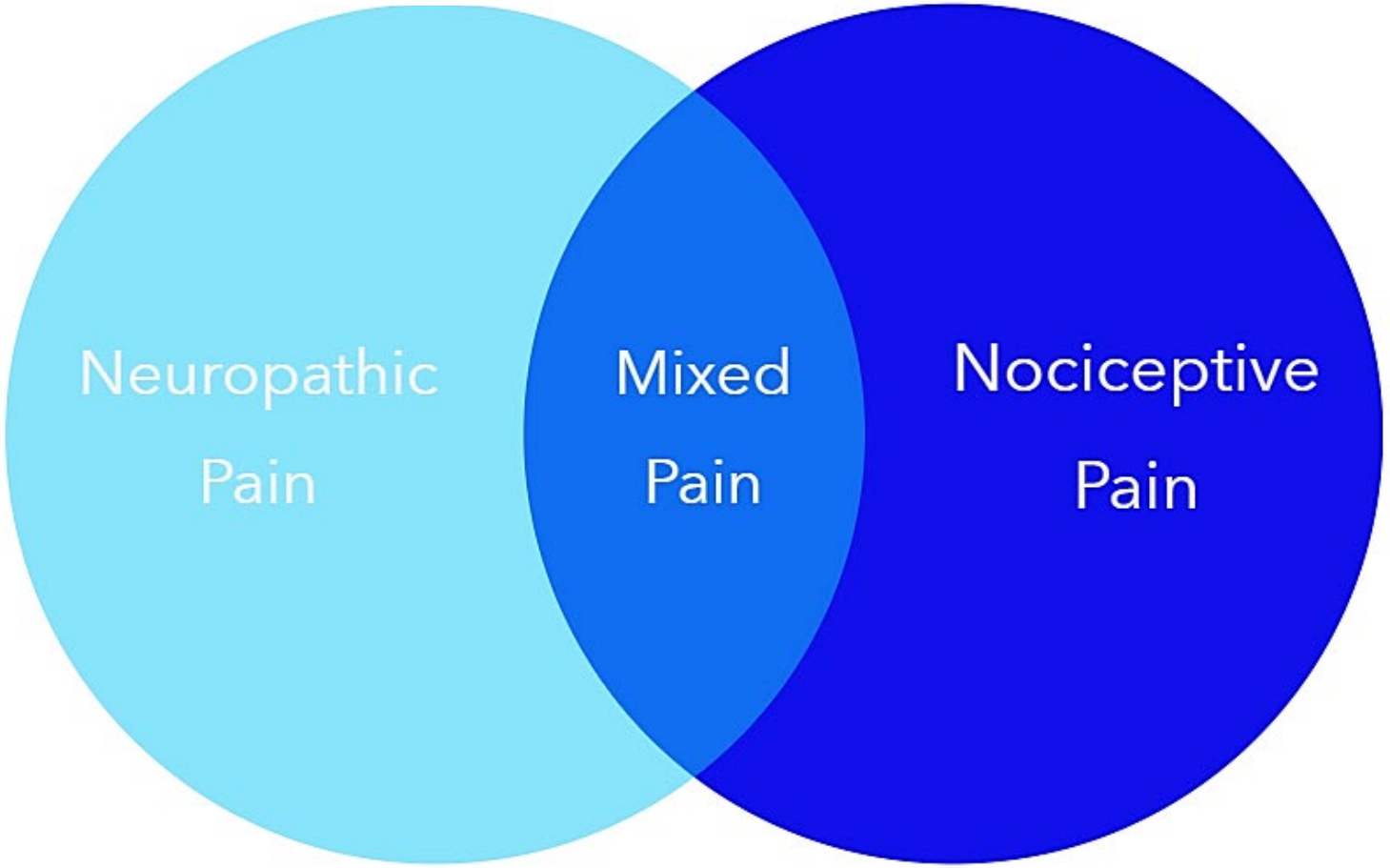
$ 299-335 billion annually due to lost productivity alone

- Job loss and sick days

Americans with chronic pain miss an average of **10.3 workdays** per year, compared to **2.8 workdays** for those without chronic pain.



Types of Pain



Nociceptive Pain

Nociceptive Pain: Actual or potential tissue damage

↳ Associated with injury or inflammation

Examples:

- Sprains, strains, burns, cuts
- Post surgical/trauma
- Arthritis
- Compression fractures
- Mechanical low back pain

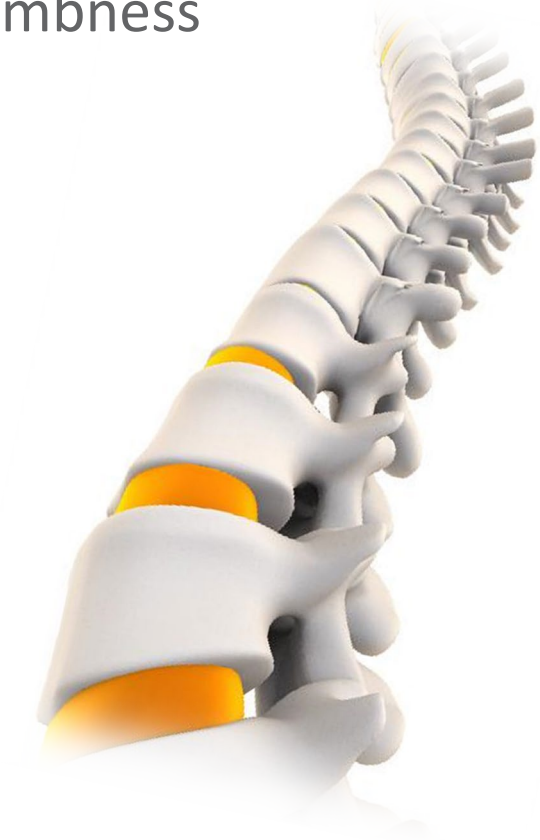
Neuropathic Pain

Neuropathic Pain: Injury to the peripheral nervous system or spinal cord

Shooting • Burning • Aching • Tingling • Numbness

Examples:

- Complex Regional Pain Syndrome
- Radicular leg pain/sciatica
- Phantom limb pain
- Diabetic neuropathy
- Postherpetic neuralgia



Other Types of Pain

Mixed Pain: Complex condition with neuropathic and nociceptive characteristics

Examples:

- Failed back surgery syndrome (FBSS)

Nociplastic Pain: Altered nociception without actual tissue damage, disease, or lesion

- **Newer concept**
- Altered pain processing
- “Central sensitization”

Treatment of Chronic Pain

Therapy

- Physical therapy
- Pool therapy
- TENS Unit *(optional)*

Alternative *(optional)*

- Chiropractic
- Acupuncture
- Biofeedback
- Yoga
- Other

Injections/Procedures

- ESI
- Facet procedures
- SI joint procedures
- Nerve blocks
- Ultrasound-guided injections
- TPI
- Other

Implantable Devices

- SCS
- DRG
- PNS
- IT pump

Psychology

- Coping skills
- Pain management skills
- CBT
- Chronic pain program

Medications

- OTC Meds
- Opioid analgesics

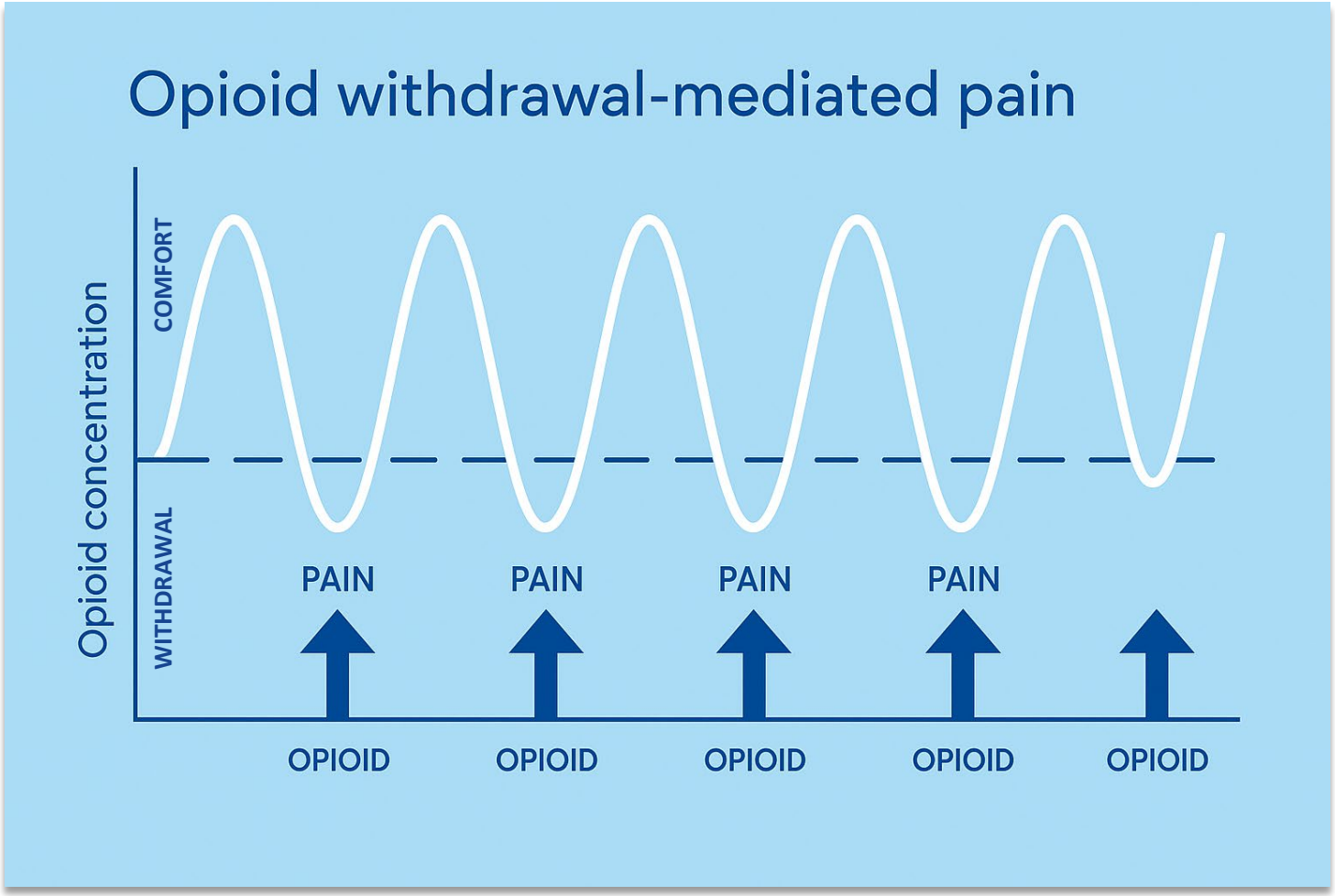
ADJUNCT MEDS

- NSAIDs
- Topicals
- Muscle relaxers
- Anticonvulsants
- SNRIs
- TCAs

Treatment options typically move from conservative to interventional.

Chronic pain and systemic opioids

Safety and efficacy of long-term systemic opioids?



Intrathecal pump

How does a pump work?

- Implanted pump delivers precise doses of pain medication directly into the CSF
- Small fraction of medication because it’s delivering the medication *directly* where it needs to go

Advantages & Disadvantages of a Pump

ADVANTAGES

- Physician-controlled dosing; does not rely on patient compliance
- Continuous around-the-clock drug delivery
- Bypasses the blood-brain barrier, which means:
  - Lower dosing for analgesia
  - Reduced side effects
- Reduce/eliminate the need for systemic opioids
- Reduced lifetime costs

DISADVANTAGES

- More invasive than systemic medications
- Potential for surgical complications
- Potential for device-related complications
- Higher initial costs
- Diminished outcomes if patient remains on high doses of systemic opioids.

Potential Adverse Events With a Pump

- Drug adverse events/reactions
- Allergic or sensitivity reaction to drug
- Local and systemic drug toxicity and related side effects
  - Including inflammatory mass
- System or catheter complications
- Surgical complications
- Refill error

Patient Selection

Selection Criteria

- When patients aren't getting adequate benefit from more conservative therapies
- When long-term opioids will be necessary
- Patients who have had spine surgery
- Chronic compression fractures
- Degenerative disc disease
- Spinal stenosis
- Primary nociceptive pain
- Abdominal pain

GOAL:

1. Choose patients most likely to experience therapeutic success
2. Minimize likelihood of risks, complications, and adverse events

Patient Success

A successful pump patient will have:

- Sufficient pain relief
- Increased function
- Improvement in ADL's
- Decreased/**elimination** of systemic opioids
- Reduced/minimal side effects

Microdose vs. Macrodose

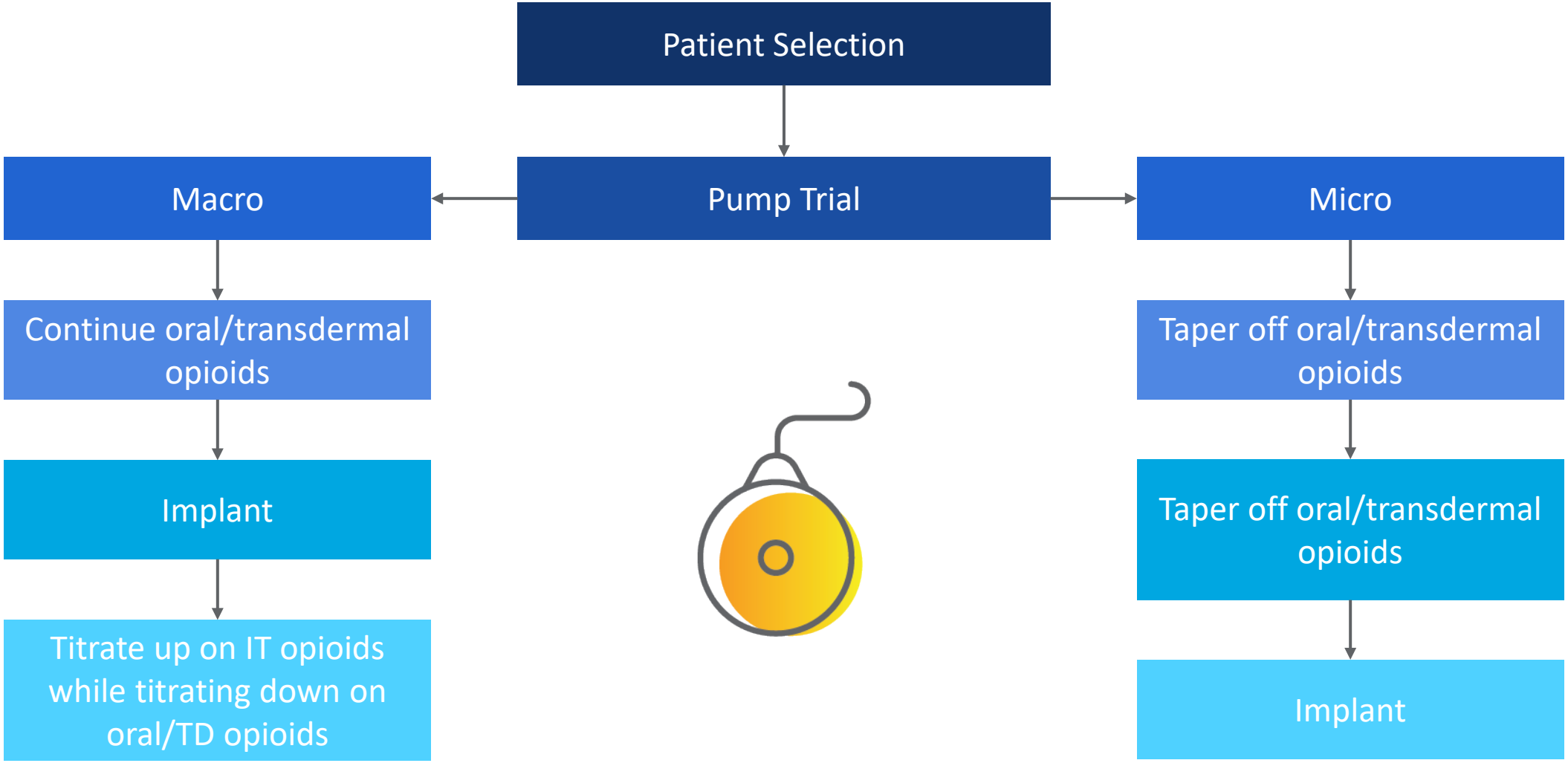
MACROdose (High-dose)

- Dosing of 1-15 mg per day (or higher)
- Can continue oral opioids before therapy and during therapy
- Catheter tip location always the same no matter the pain location
- Variable dosing over time

MICROdose (Low-dose)

- Dosing of less than 1mg per day of morphine (or it's equivalent)
- Patient must be opioid-free before starting therapy and during therapy
- Pump catheter tip location is important – based on pain location
- Less side effects
- Stable dosing

Pump Process



Study 1: Low-dose IT Opioids

Objective: long-term follow-up of intrathecal low-dose opioids for treatment of intractable, severe chronic nonmalignant pain

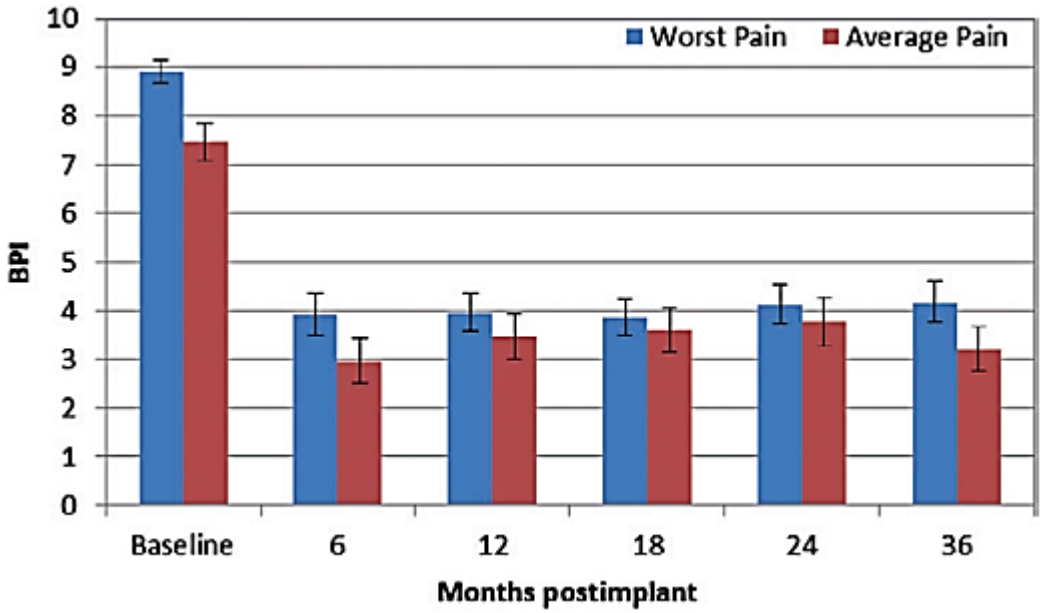
Design:

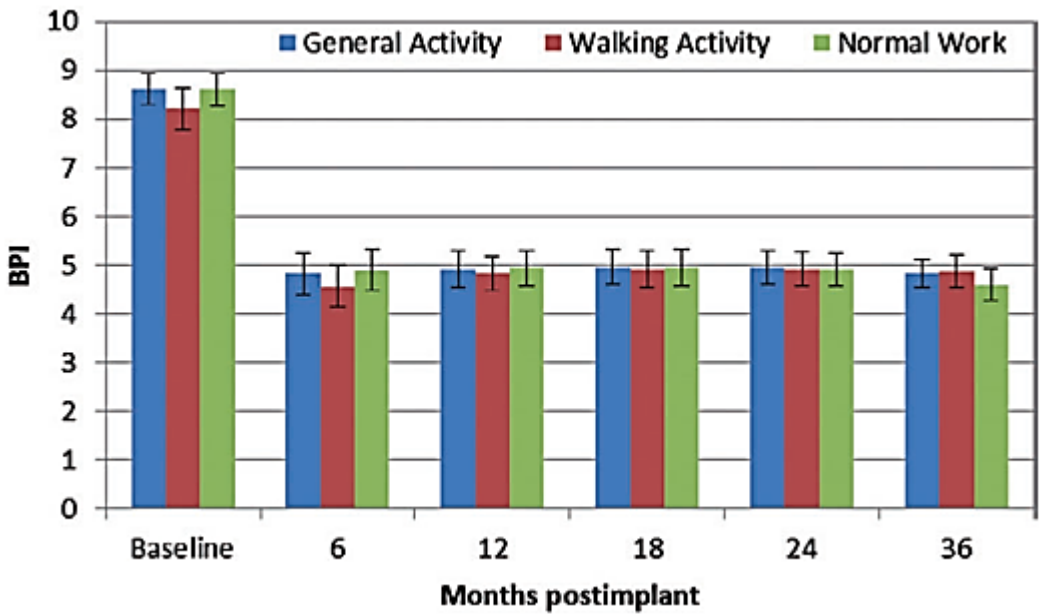
- Prospective, cohort long-term outcome study
- n = 58 patients implanted
- FBSS (35), low back pain (16), CRPS (3), abdominal pain (2), pelvic pain (2)
- Opioid free 7-10 days before implant
- Follow up at 6, 12, 18, 24, and **36 months**
- Brief Pain Inventory

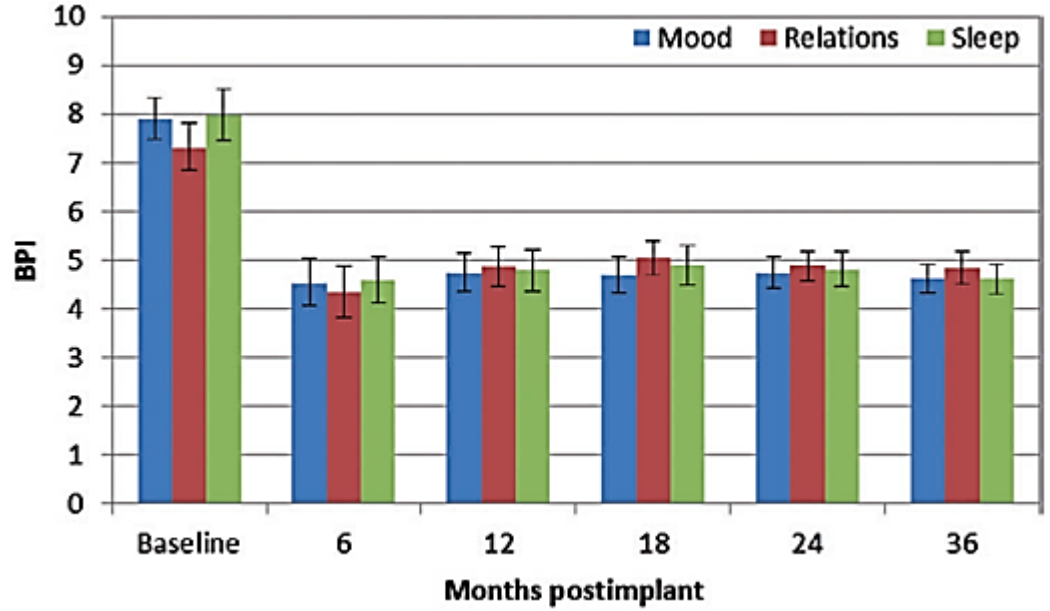
Results:

- Reduction in both worst and average pain from baseline throughout the duration
- Improvement in physical and behavioral function
- Significant reduction in oral opioids
- Stable IT dose

Hamza et al. 2012. Prospective Study of 3-Year Follow-up of Low-Dose Intrathecal Opioids in the Management of Chronic Nonmalignant Pain. Pain Medicine 13: 1304-1313.

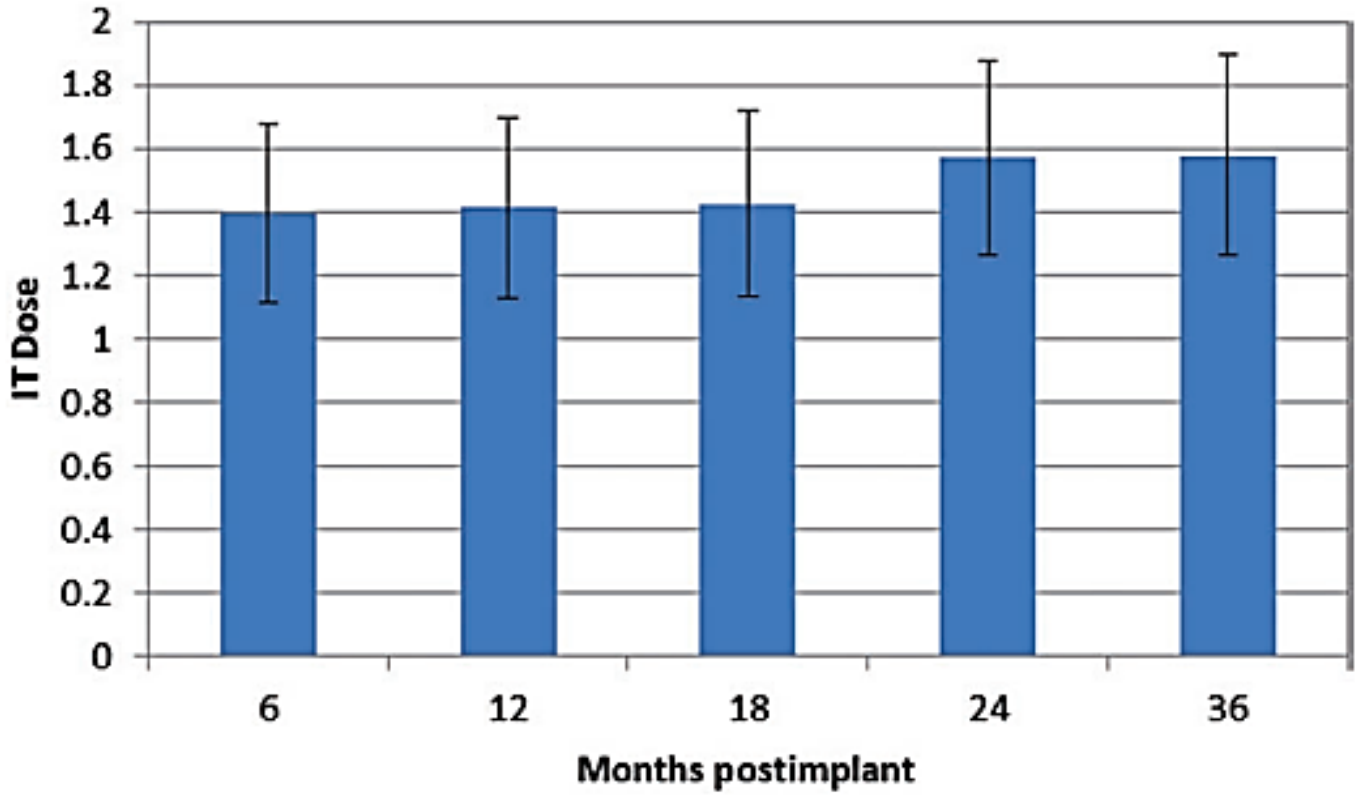






Hamza et al. 2012. Prospective Study of 3-Year Follow-up of Low-Dose Intrathecal Opioids in the Management of Chronic Nonmalignant Pain. Pain Medicine 13: 1304-1313.

- **Mean IT morphine dose ranged from 1.4 mg/day to 1.58 mg/day**
- **Mean systemic morphine equivalents decreased significantly from 126.71 mg/day prior to 3.8 mg/day at 3 months post implant.**



Hamza et al. 2012. Prospective Study of 3-Year Follow-up of Low-Dose Intrathecal Opioids in the Management of Chronic Nonmalignant Pain. Pain Medicine 13: 1304-1313.

Study 2: Low-Dose IT Opioids

Objective: Compare trialing techniques prior to implantation for treatment of severe intractable chronic nonmalignant pain

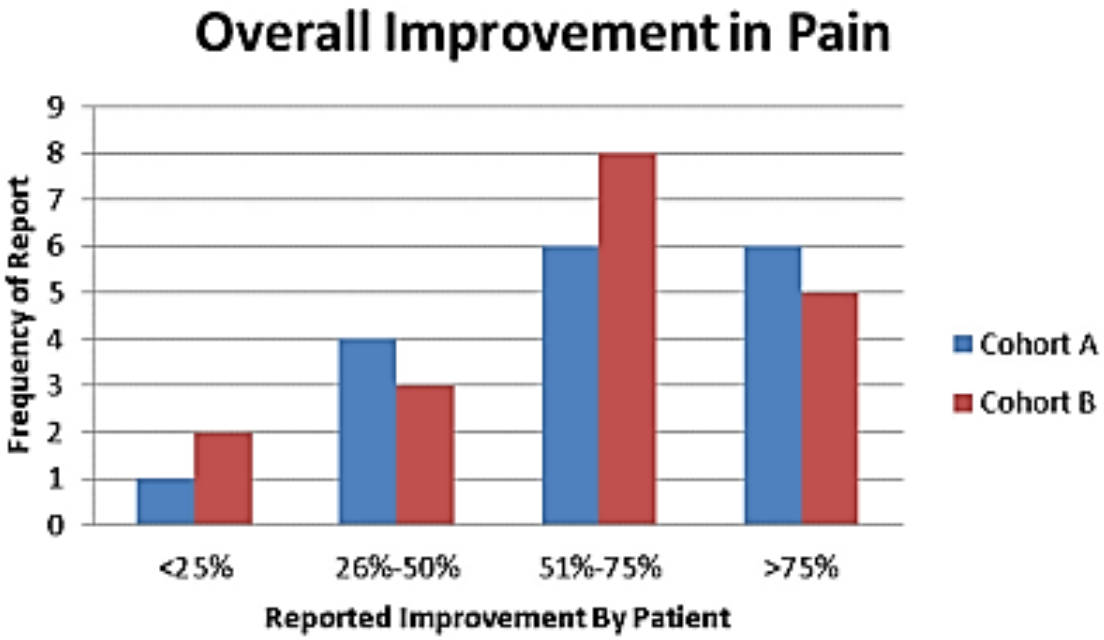
Design:

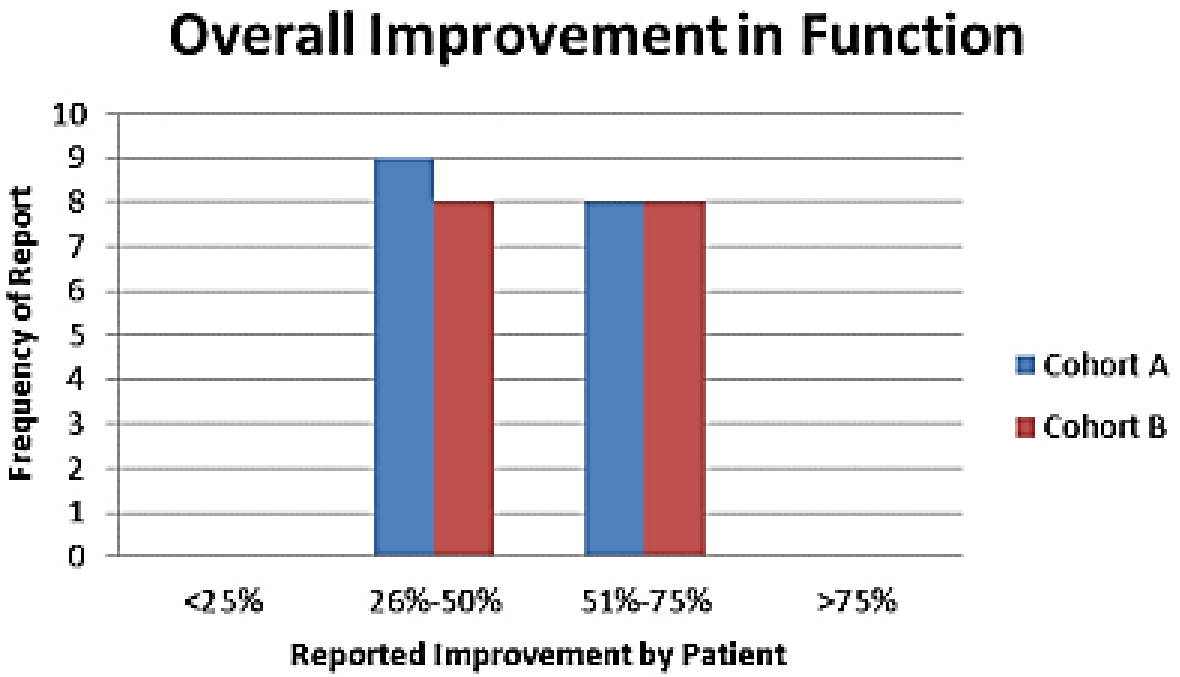
- Prospective, randomized, head-to-head long-term outcome study
- n=40
- Randomly assigned to two cohorts: intermittent boluses vs continuous infusion
- Opioid free 7-10 days before implant
- 36 patients implanted
- Follow up at 6, 12, 18, 24, and 36 months
- Brief Pain Inventory

Results:

- Significant reduction in pain and improvement in function in both cohorts after implant
- Oral opioid dose significantly reduced
- Stable IT dose

Hamza et al. 2015. A Prospective, Randomized, Single-Blinded, Head-to-Head Long-Term Outcome Study, Comparing Intrathecal (IT) Boluses With Continuous Infusion Trialing Techniques Prior to Implantation of Drug Delivery Systems for the Treatment of Severe Intractable Chronic Nonmalignant Pain. Neuromodulation: Technology at the Neural Interface; 18: 636-649.





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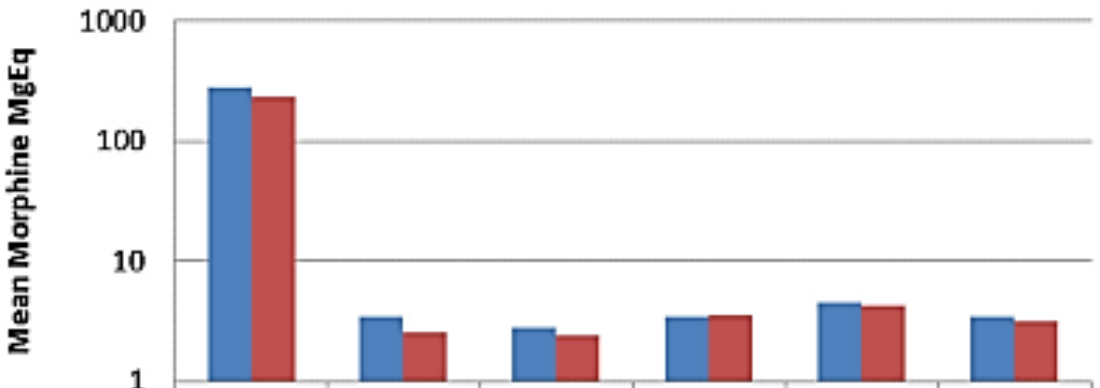
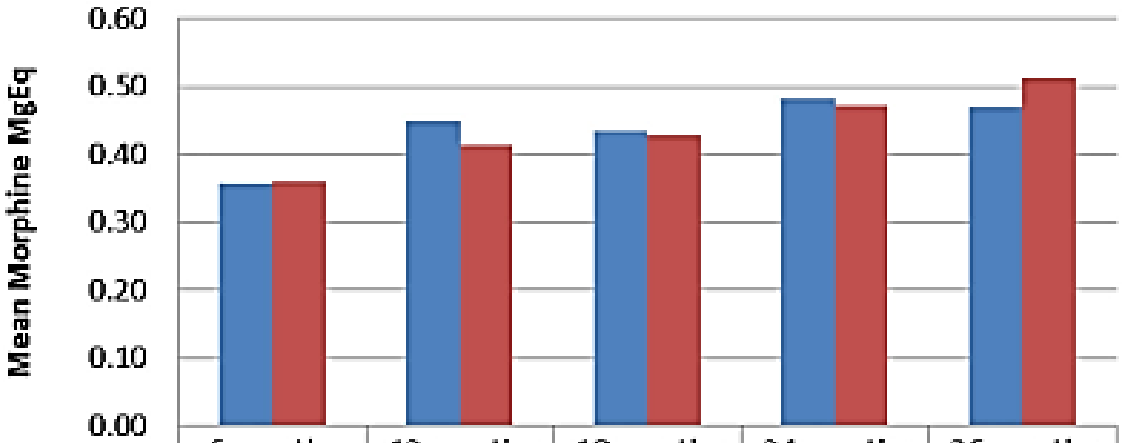
Oral Opioid Usage



	baseline	6 months	12 months	18 months	24 months	36 months
Cohort A	278.06	3.41	2.76	3.47	4.47	3.47
Cohort B	230.44	2.56	2.44	3.56	4.22	3.11

IT Dose



	6 months	12 months	18 months	24 months	36 months
Cohort A	0.36	0.45	0.44	0.48	0.47
Cohort B	0.36	0.41	0.43	0.47	0.51

Mean IT morphine dose ranged from 0.36 mg/day to 0.51 mg/day

Hamza et al. 2015. A Prospective, Randomized, Single-Blinded, Head-to-Head Long-Term Outcome Study, Comparing Intrathecal (IT) Boluses With Continuous Infusion Trialing Techniques Prior to Implantation of Drug Delivery Systems for the Treatment of Severe Intractable Chronic Nonmalignant Pain. Neuromodulation: Technology at the Neural Interface; 18: 636-649.

Study 3: Low-dose IT Opioids

Objective: evaluate efficacy of low-dose IT opioids for chronic nonmalignant pain

Design:

- Prospective, observational cohort study
- n=58
- FBSS (20), lumbar degenerative disc disease with/without spondylosis (23), nonoperative lumbar spinal stenosis (11), CRPS type II (1), scoliosis (3)
- Opioid free prior to trial
- Follow up at 6, 12, 24, and 36 months
- Visual analog scale, Global Pain Scale (patient satisfaction), Multidimensional Pain Inventory (function)

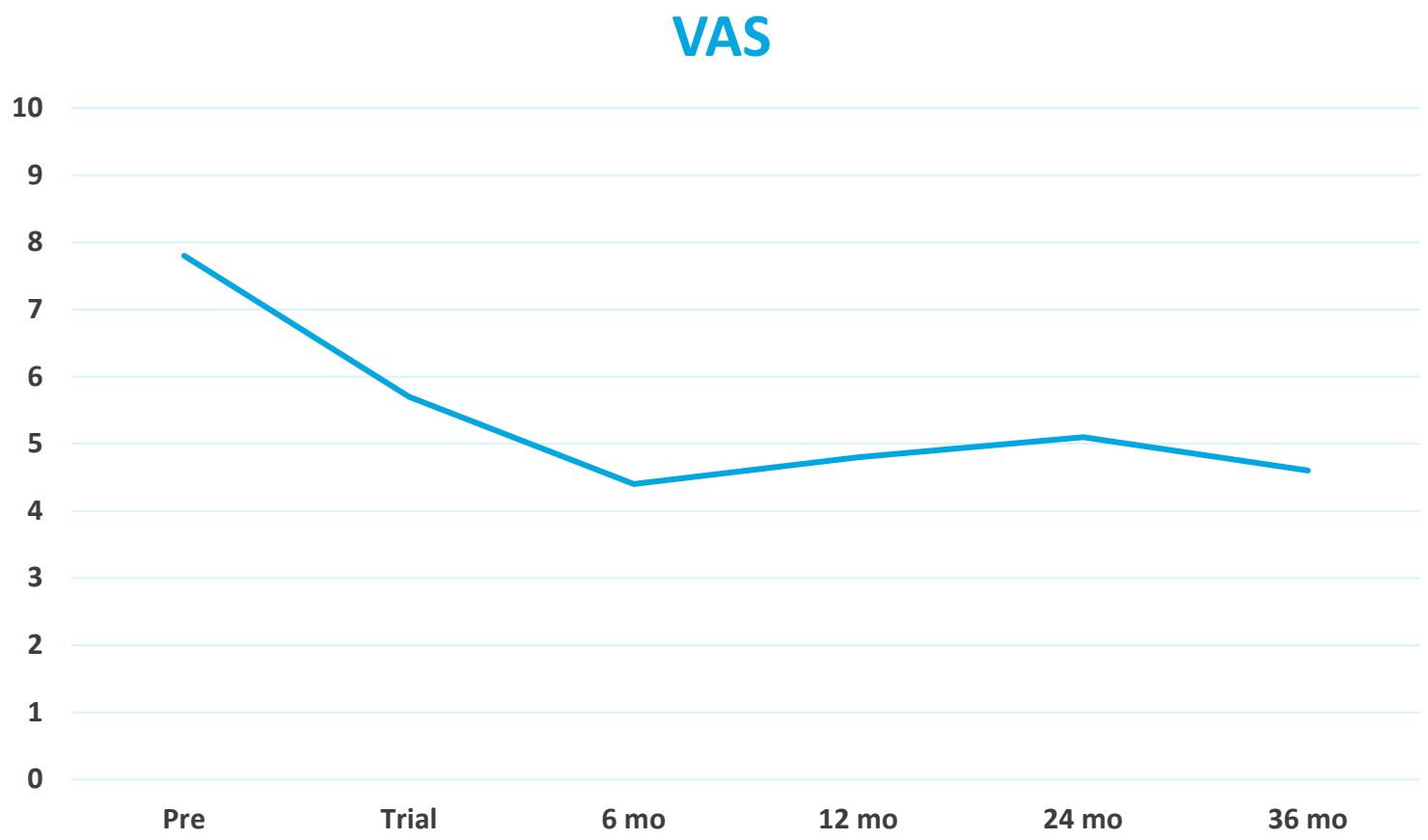
Results:

- Mean IT dose of less than 350 mcg per day of morphine
- Primary nociceptive pain conditions were associated with lower doses and improved scores

Grider et al. 2016. Trialing and Maintenance Dosing Using a Low-Dose Intrathecal Opioid Method for Chronic Nonmalignant Pain: A Prospective 36-Month Study. Neuromodulation, 19(2):206-219.

Study 3

- No significant correlation between pretrial oral opioids dose and IT dose needed at 36 months
- Prior to implant, mean systemic opioid dose was 64 mg of morphine equivalents per day. All but one patient remained opioid free post implant.



Grider et al. 2016. Trialing and Maintenance Dosing Using a Low-Dose Intrathecal Opioid Method for Chronic Nonmalignant Pain: A Prospective 36-Month Study. Neuromodulation, 19(2):206-219.

Study 1: Cost effectiveness

Objective: Compare cost-effectiveness of IT drug therapy with conventional pain therapy

Design:

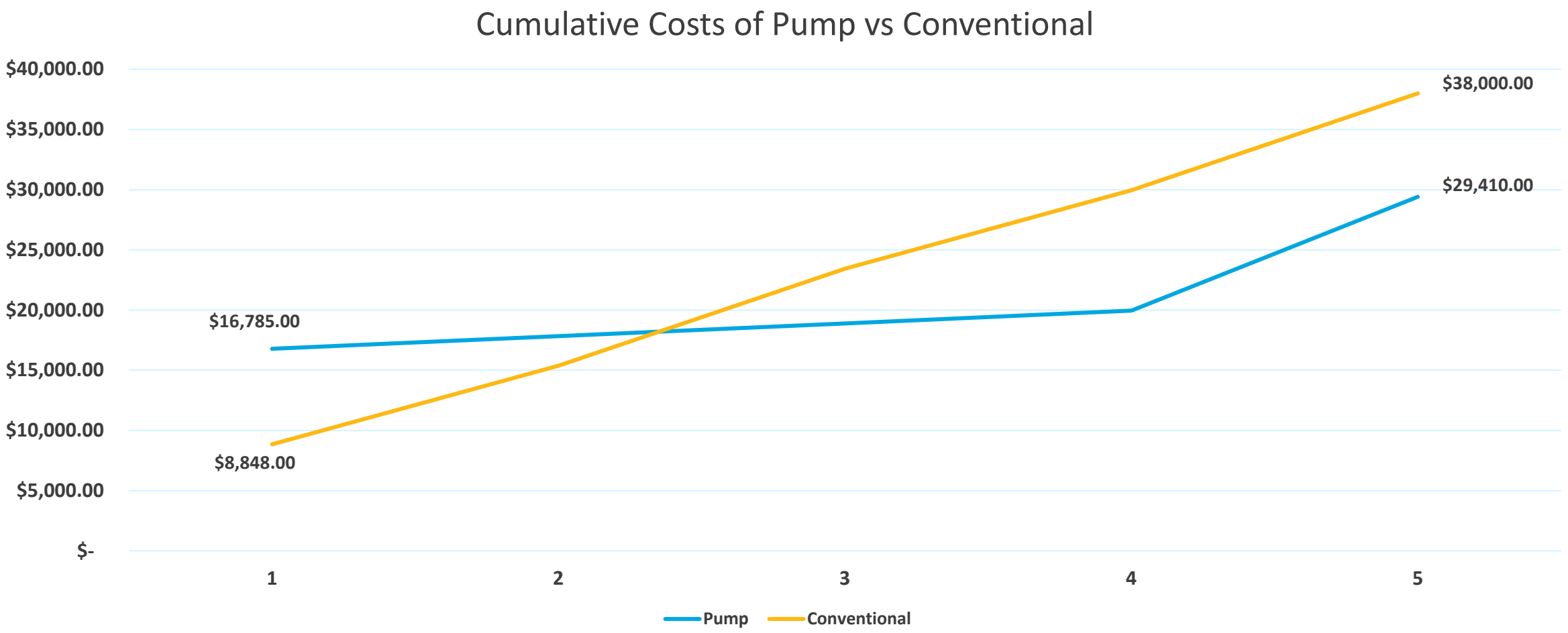
- Prospective, consecutive series
- Canada
- n=88 (only 23 went on to be implanted)
- FBSS who had failed SCS
- 5-year period

Results:

- Cumulative costs for IT drug therapy: $29,410
- Cumulative costs for conventional pain therapy: $38,000
- High initial costs of IT drug therapy was recovered by 28 months.

Kumar et al. 2002. Treatment of chronic pain by using intrathecal drug therapy compared with conventional pain therapies: a cost effectiveness analysis. Neurosurg 97(4): 803-810.

Study 1



Kumar et al. 2002. Treatment of chronic pain by using intrathecal drug therapy compared with conventional pain therapies: a cost effectiveness analysis. Neurosurg 97(4): 803-810.

Study 2: Cost effectiveness

Objective: Evaluate cost-effectiveness of IT drug therapy with conventional medical management

Design:

- Probabilistic Markov model
- Canada
- n=169
- FBSS, degenerative disc disease, small fiber neuropathy, pelvic pain, chronic pancreatitis
- 10-year period

Results:

- ICER ($11,326) was below the WTP threshold ($23,400 CAD) for patients with chronic nonmalignant pain

Kumar et al. 2013. Cost Effectiveness of Intrathecal Drug Therapy in Management of Chronic Nonmalignant Pain. Clinical Journal of Pain 29(2): 138-145.

Study 2

TABLE 3. ICER of IDT (Per Patient; 10 y Time Horizon)

Strategy	IDT	CMM
Cost per patient*	$61,442	$48,408
Effectiveness per patient*	2.3838	1.233
ICER (cost/QALY)	$11,326	—

Costs included:

- Initial eval
- Physician visits
- Diagnostic procedures
- Adjunctive therapies
- Medications
- Hospital stays
- Pharmacotherapy
- Hardware
- Complications r/t procedure
- Hospital/surgical fees for implantation

Kumar et al. 2013. Cost Effectiveness of Intrathecal Drug Therapy in Management of Chronic Nonmalignant Pain. Clinical Journal of Pain 29(2): 138-145.

Study 3: Cost effectiveness

Objective: compare health expenditures over 12 months for chronic pain patients with implanted intrathecal drug delivery systems who eliminated or continued systemic opioids postimplant

Design:

- Claims data
- n=389
- Postimplant: 30 days, 120 days, 150 days, 210 days

Results:

- 51% completely eliminated opioids
- Associated with 10%-17% reduction (4,689 - $5,571) in inpatient, outpatient, and drug expenditures

Hatheway et al. 2015. Systemic Opioid Elimination After Implantation of an Intrathecal Drug Delivery System Significantly Reduced Health-Care Expenditures. Neuromodulation; 18: 207-2013.

Study 4: Cost effectiveness

Objective: Evaluate systemic opioid utilization before and after IT therapy in patients with chronic noncancer pain, as well as the effect on opioid elimination on payer costs

Design:

- Retrospective cohort analysis of administrative claims data from 2011-2016
- n=631
- Radiculopathy, general chronic pain conditions, post laminectomy, LE peripheral neuropathy, CRPS I

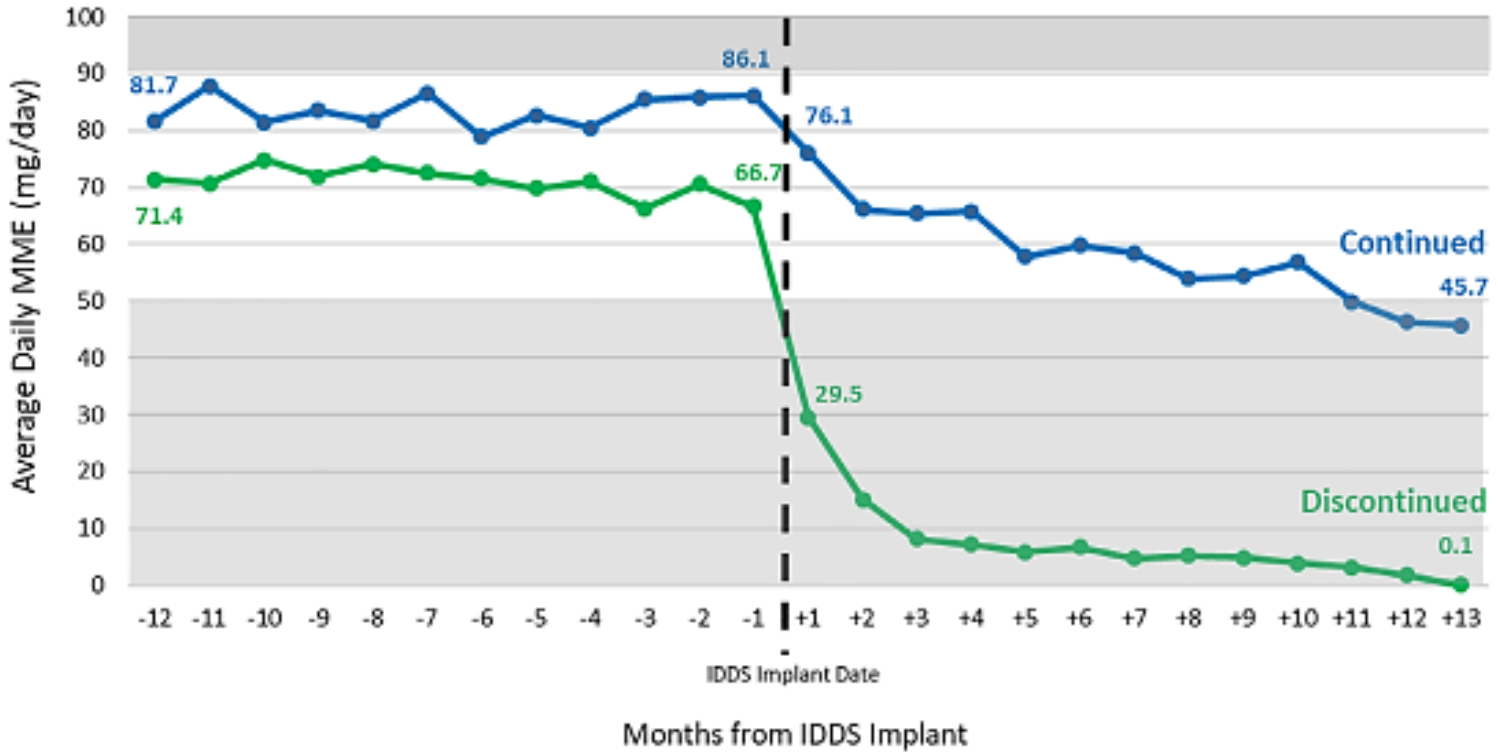
Results:

- Avg daily MME decreased in 81.5%
- Mean annual payer costs were reduced 29% for patients who discontinued vs continued systemic opioids

Hatheway et al. 2020. Systemic Opioid Reduction and Discontinuation Following Implantation of Intrathecal Drug-Delivery Systems for Chronic Pain: A Retrospective Cohort Analysis. Neuromodulation; 23:961-969.

Study 4

- 43.3% discontinued systemic opioids completely
- Of those patients who continued on systemic opioids, avg daily MME decreased in 74.9%
- MME <50 prior to implant was associated with a two times odds of discontinuation vs. >90 MME



Hatheway et al. 2020. Systemic Opioid Reduction and Discontinuation Following Implantation of Intrathecal Drug-Delivery Systems for Chronic Pain: A Retrospective Cohort Analysis. Neuromodulation; 23:961-969.

Case Study 1 – Foot Pain

- 50-year-old female
- Low back and left foot pain
- **Prior treatments:**
  - 3 back surgeries
  - 4 left foot surgeries – leading to CRPS
  - L2,L3 sympathetic nerve blocks x7
  - Peroneal nerve blocks x3
  - SPRINT PNS
  - Medtronic SCS
  - Meds: Cyclobenzaprine, Ibuprofen, Naproxen, Prednisone, Tramadol, Codeine, Hydrocodone, Oxycodone, Morphine, Baclofen, gabapentin, Topamax, amitriptyline, cannabis, Butrans patches
  - **MME prior to pump = 67-75 (Percocet)**

Case Study 1 – Foot Pain

- Pump trial – 90% relief; felt “amazing”
  - Itching and sweating – manageable
- Pump implant – Morphine 0.15 mg/day (150 mcg/day)
  - Itching after implant – resolved within a few days
- 3 weeks after implant reporting 60% relief
- Currently stable at 0.15 mg/day
- **NO ORAL OPIOIDS**

Case Study 2 – Neck Pain

- 59-year-old male
- Widespread pain – neck, right shoulder, low back, BLE, headaches
- Prior treatments:
  - Multiple cervical and lumbar surgeries
    - Fused from C4-7
    - Fused from L5-S1
    - Left SIJ fusion
  - Boston Scientific SCS for low back pain
  - Cervical ESI's
  - TPI's
  - Cervical RFA's
  - Meds: *Topamax, Cymbalta, amitriptyline, nortriptyline, cyclobenzaprine, tizanidine, ibuprofen, and prednisone, gabapentin, cannabis, Norco*
- Avoiding Norco use and cervical SCS d/t PMH vertigo

Case Study 2 – Neck Pain

- Pump trial with >50% relief
- Pump implanted with Morphine 0.15 mg/day
- 2 weeks later reporting 75% relief
- Currently stable at 0.15 mg/day (150 mcg/day) plus occasional PTM’s
- He has been able to be more active, go to the gym, attend the state fair, improved mobility.

Case Study 3 – Low Back Pain

- 35-year-old female
- Low back pain with radiation into BLE
- Prior treatments:
  - Physical therapy
  - Chiropractic care
  - Facet joint injections
  - GTB injections
  - SIJ injections
  - Unable to have ESI d/t limited access into the epidural space
  - Meds: oxycodone, gabapentin, Lyrica, Flexeril, Robaxin, CBD creams, lidocaine patches, low dose naltrexone, Cymbalta, amitriptyline, and paroxetine.
    - ❖ Gabapentin and Lyrica both caused suicidal ideation.
  - **MME prior to the pump = 60 (tramadol and Norco)**

Case Study 3 – Low Back Pain

- Pump trial with >50% relief
  - Temporary itching and urinary retention after the trial
- Pump implanted with Morphine 0.15 mg/day
- Currently at Morphine 0.3758 mg/day (376 mcg/day) with >50% pain relief
- **NO ORAL OPIOIDS**

Questions

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