PainWeek®

Best Practices for Identifying Chronic Pain Patients for Interventional Procedures

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Disclosure

- Consultant/Independent Contractor: Abbott, Biotronik, Boston Scientific, Nalu, Nevro, Saluda, SI-Bone, Vertos
- Grant/Research Support: Avanos, Biotronik, Nevro, Saluda, SPR Therpeutics, Boston Scientific
- Advisory Board: BiotrasStock
- Shareholder: Nalu

Learning Objectives

- Review the history of pain medicine
- Discuss the impact of chronic pain
- Describe the evolution of opioid therapy
- Describe the role of interventional pain medicine
- Explain when to refer patients for interventions

Outline

- Evolution of pain medicine
- Chronic pain in America
- Evolution of opioids
- Emerging concepts
- What is IPM
- Selecting IPM physician
- When to refer for IPM
- IPM consultation workflow examples
- Case studies

Pain

- “An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage...”

Raja, S. el al. IASP Task Force on Taxonomy; Pain, 2020

“Like a rope ringing a bell”

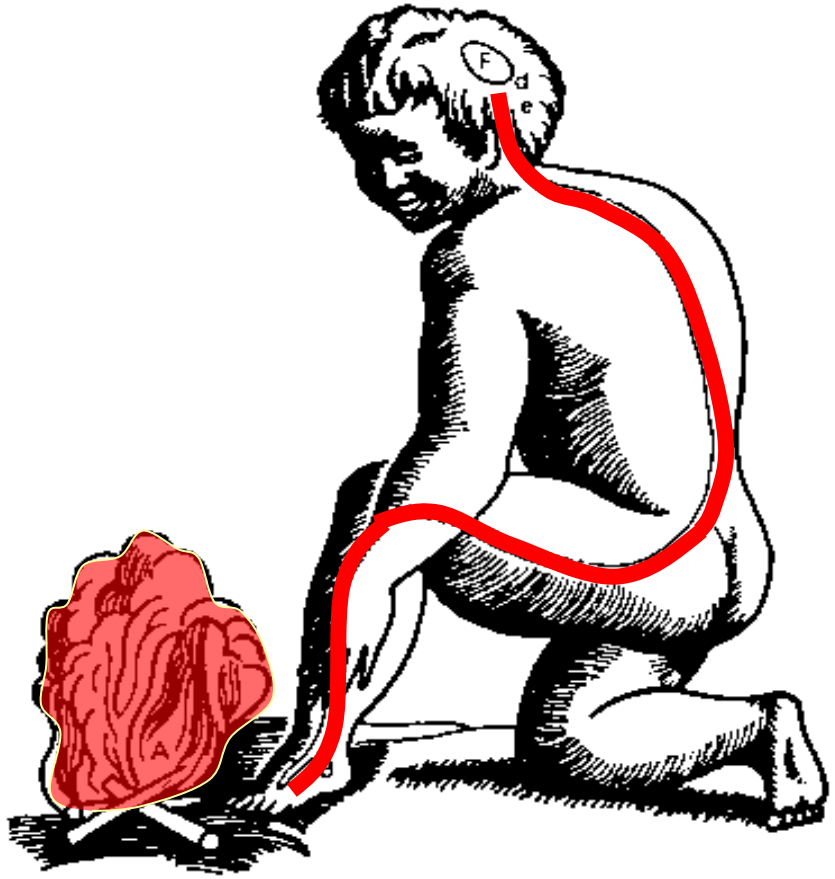
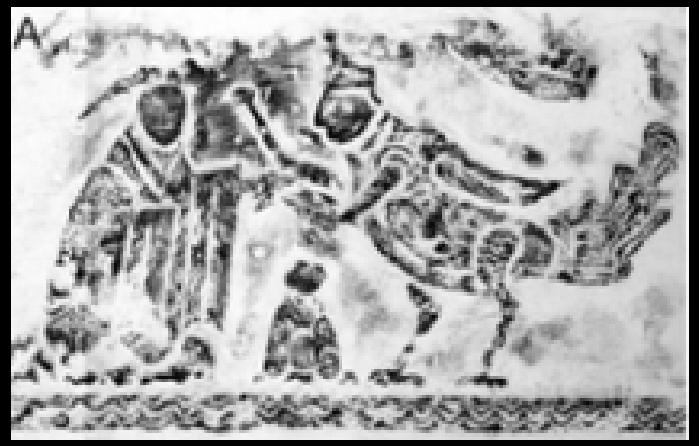


FIG. 1-1. Descartes' (1664) concept of the pain pathway. He writes: "If for example fire (A) comes near the foot (B), the minute particles of this fire, which as you know move with great velocity, have the power to set in motion the spot of the skin of the foot which they touch, and by this means pulling upon the delicate thread (cc) which is attached to the spot of the skin, they open up at the same instant the pore (d.e.) against which the delicate thread ends, just as by pulling at one end of a rope makes to strike at the same instant a bell which hangs at the other end." From Melzack, R., and Wall, P.D.: Pain mechanisms: A new theory. Science, *150*:971, 1965.

Analgesia

- Sumerians, 3000 B.C. who first cultivated the poppy plant for its opium
- Homer in 300 B.C. Helen of Troy to treat her grief over the absence of Odysseus

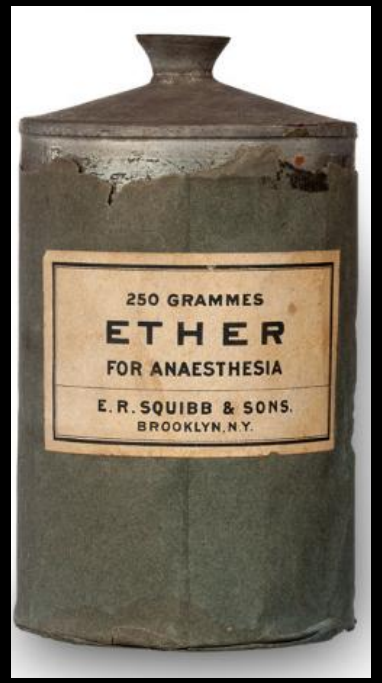
Ancient Pain Management



Auricular acupuncture depicted during Han dynasty, 200 BC

Cauterizing the external ear to treat migraine, 12th century Persian surgery text

Contemporary Anesthesia



- Oct. 16, 1846, William Morton demonstrates the use of ether for dental extraction at Massachusetts General Hospital
- Surgeon, John Warren, “Gentleman , this is no humbug.”

Chronic Pain in the US

- Major health issue: 1 in 10 Americans suffer from chronic pain
- Large economic impact: ~$600 billion/year
- Loss of productivity: ~$300 billion/year
- Opioid epidemic: #1 health crisis in America
- National health survey by NIH 2012
  - 25.3 million adults (11.2%) pain every day
  - Pain→ worse overall health status
  - Female, elderly, non-Hispanics (Asians less likely)

A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients.
http://jama.ama-assn.org/cgi/content/abstract/274/20/1591

ASIPP: Advocating Pain Treatment

- 21 million Americans suffer from substance/drug use disorder
- 80% heroin users report prior misuse of Rx opioids
- #1 Health crisis in America
- 116/day, opioid related deaths
- 63,632 opioid related deaths in 2016
- Only 1 in 10 receive treatment
- Opioid Task Force
- IPM offer alternative to opioids

American Society of Interventional Pain Physicians
The Voice of Interventional Pain Management

https://www.surgeongeneral.gov/priorities/index.html

https://www.cdc.gov/media/releases/2018/p0329-drug-overdose-deaths.html

HHS 5-POINT STRATEGY TO COMBAT THE OPIOIDS CRISIS

1. **Better** addiction prevention, treatment, and recovery services
2. **Better** data
3. **Better** pain management
4. **Better** targeting of overdose reversing drugs
5. **Better** research

ASIPP Member, Vanila Singh, MD, Named Chief Medical Officer for the Office of the Assistant Secretary for Health at HHS

We are pleased to announce the appointment of Vanila M. Singh, M.D., MACM, as Chief Medical Officer for the Office of the Assistant Secretary for Health at ..

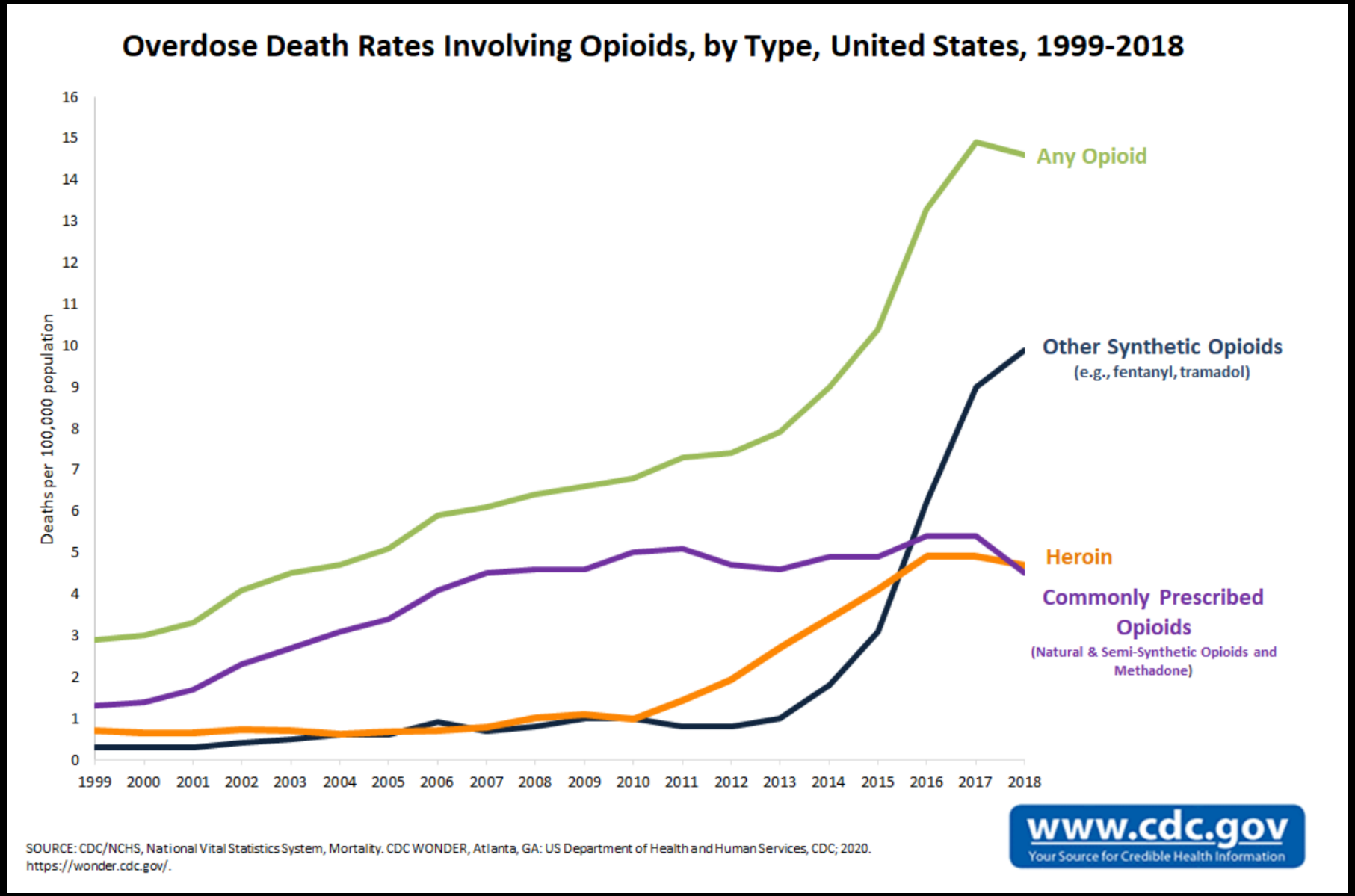
https://www.hhs.gov/opioids

ABOUT PAINWeek

A Single Point of Access

PAINWeek is more than an annual or regional conference. **It is now the Pain Education Resource for Frontline Practitioners.**

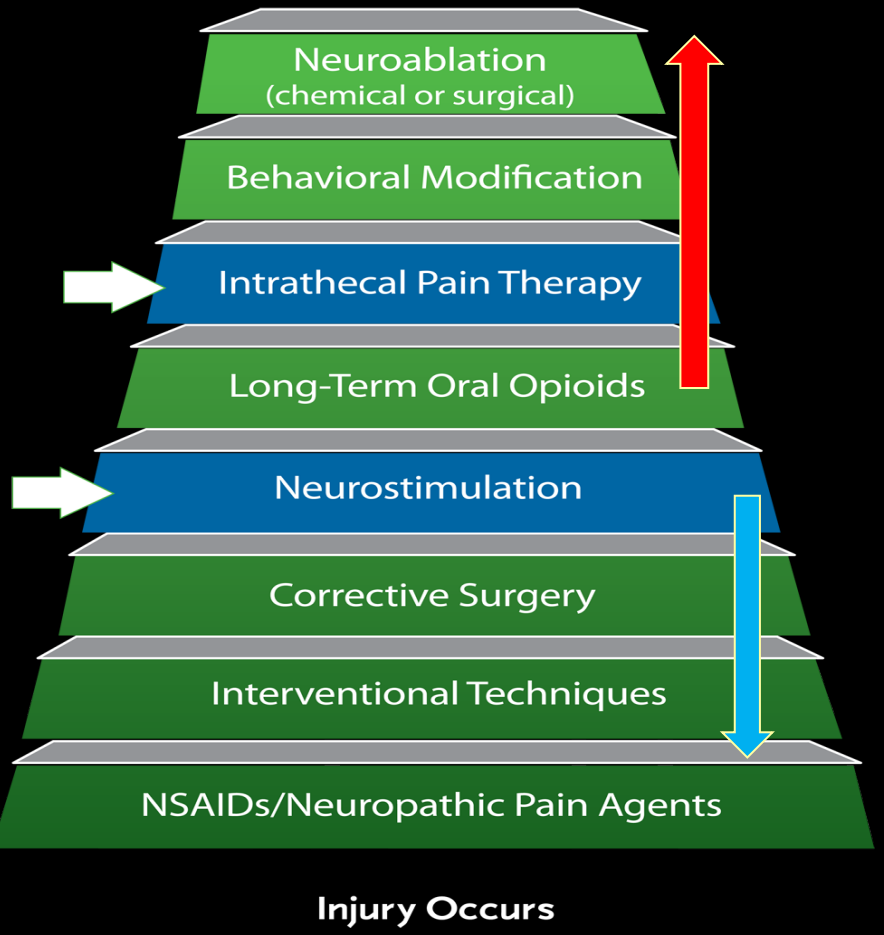
The PAINWeek communications platform represents a single point of access for busy practitioners spanning live, digital, and print communications that will extend the energy and experience of our national and regional conferences throughout the year, and to a wider audience of frontline practitioners with an interest in pain management.



Center for Disease Control (CDC): http://www.cdc.gov

Evolution of Pain Medicine

In contrast to earlier thinking on the order of treatments in the pain treatment continuum,[1] it has been proposed that device therapies be considered at an earlier stage.[2]



[1]Krames ES. Intraspinal Opioid Therapy for Nonmalignant Pain: Current Practices and Clinical Guidelines. *J Pain Symptom Manage* 1996;11:333-352.
[2]Stamatos JM, et al. *Live Your Life Pain Free*, October 2005. Based on the interventional pain management experience of Dr. John Stamatos.

Evolution of Opioid therapy

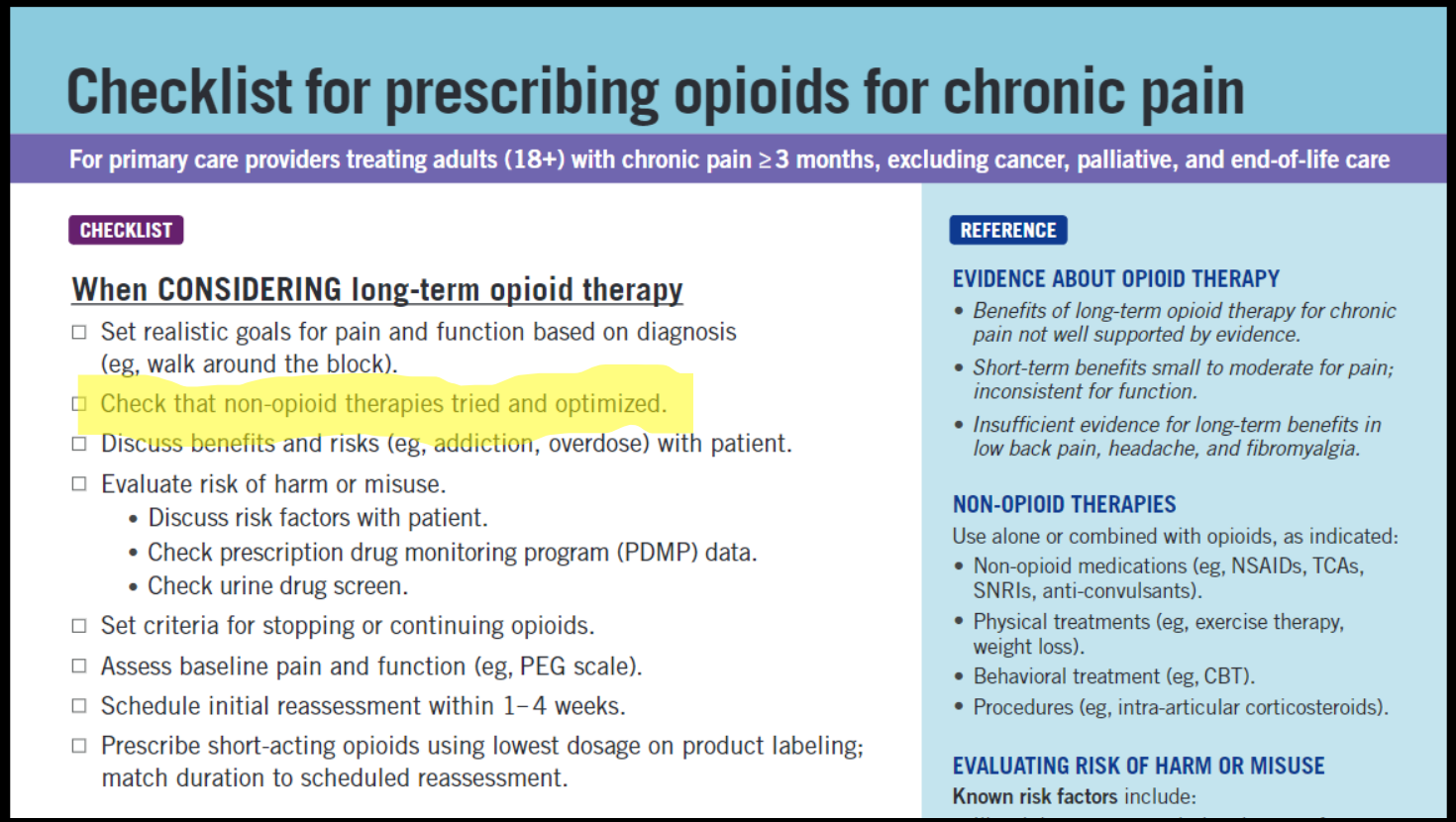
- Lack of long term efficacy for treating chronic pain
- Risk for tolerance, dependency, and abuse
- National opioid crisis
- New CDC opioid prescribing guidelines

Common Chronic Pain Conditions

- Low back pain, 27%
- Migraine headache, 15%
- Neck pain, 15%
- Facial pain, 4%

National Centers for Health Statistics, Chartbook on Trends in the Health of Americans 2006, Special Feature: Pain. http://www.cdc.gov/nchs/data/hus/hus06.pdf.

Before Starting Opioid Medications



Checklist for prescribing opioids for chronic pain

For primary care providers treating adults (18+) with chronic pain ≥ 3 months, excluding cancer, palliative, and end-of-life care

CHECKLIST

When CONSIDERING long-term opioid therapy

- ☐ Set realistic goals for pain and function based on diagnosis (eg, walk around the block).
- ☐ Check that non-opioid therapies tried and optimized.
- ☐ Discuss benefits and risks (eg, addiction, overdose) with patient.
- ☐ Evaluate risk of harm or misuse.
  - Discuss risk factors with patient.
  - Check prescription drug monitoring program (PDMP) data.
  - Check urine drug screen.
- ☐ Set criteria for stopping or continuing opioids.
- ☐ Assess baseline pain and function (eg, PEG scale).
- ☐ Schedule initial reassessment within 1–4 weeks.
- ☐ Prescribe short-acting opioids using lowest dosage on product labeling; match duration to scheduled reassessment.

REFERENCE

EVIDENCE ABOUT OPIOID THERAPY

- *Benefits of long-term opioid therapy for chronic pain not well supported by evidence.*
- *Short-term benefits small to moderate for pain; inconsistent for function.*
- *Insufficient evidence for long-term benefits in low back pain, headache, and fibromyalgia.*

NON-OPIOID THERAPIES

Use alone or combined with opioids, as indicated:

- Non-opioid medications (eg, NSAIDs, TCAs, SNRIs, anti-convulsants).
- Physical treatments (eg, exercise therapy, weight loss).
- Behavioral treatment (eg, CBT).
- Procedures (eg, intra-articular corticosteroids).

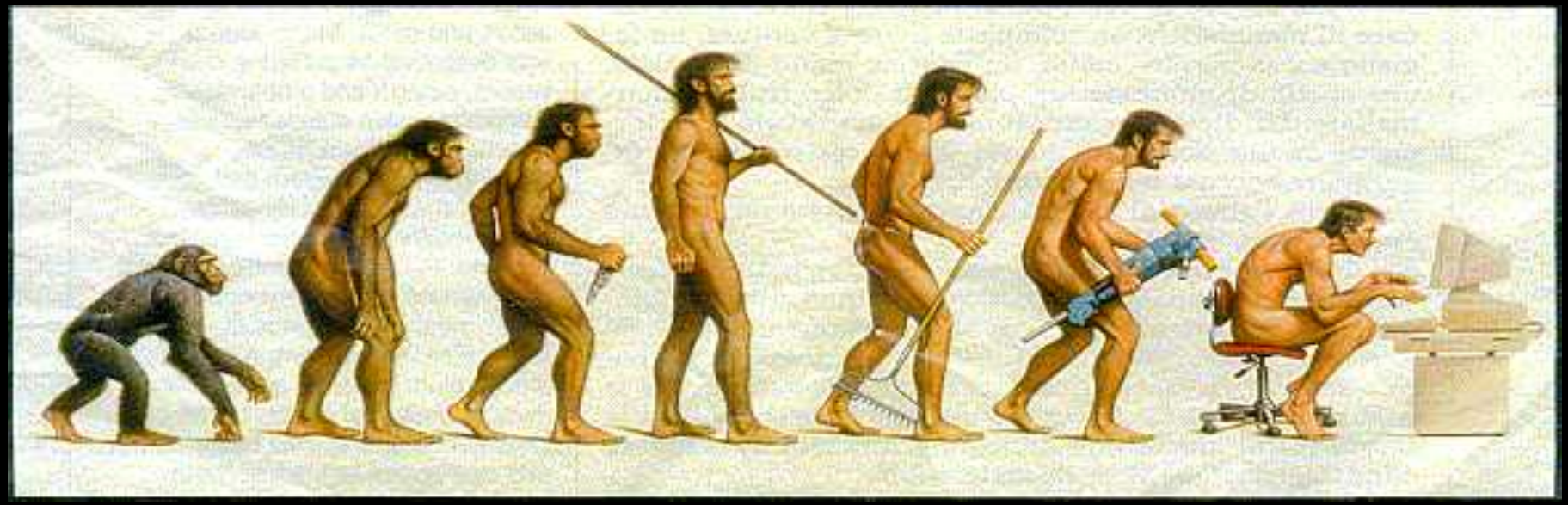
EVALUATING RISK OF HARM OR MISUSE

Known risk factors include:

PAINWEEK®

https://stacks.cdc.gov/view/cdc/38025

Evolution of Neuromodulation



Innovations in Neuromodulation

- Adaptive stimulation
- MRI compatibility
- Novel wave forms
- Novel targets of stimulation
- Closed loop technology (not FDA approved)
- Peripheral nerve stimulation
- Vagal nerve stimulation
- Micro-dose intrathecal drug delivery

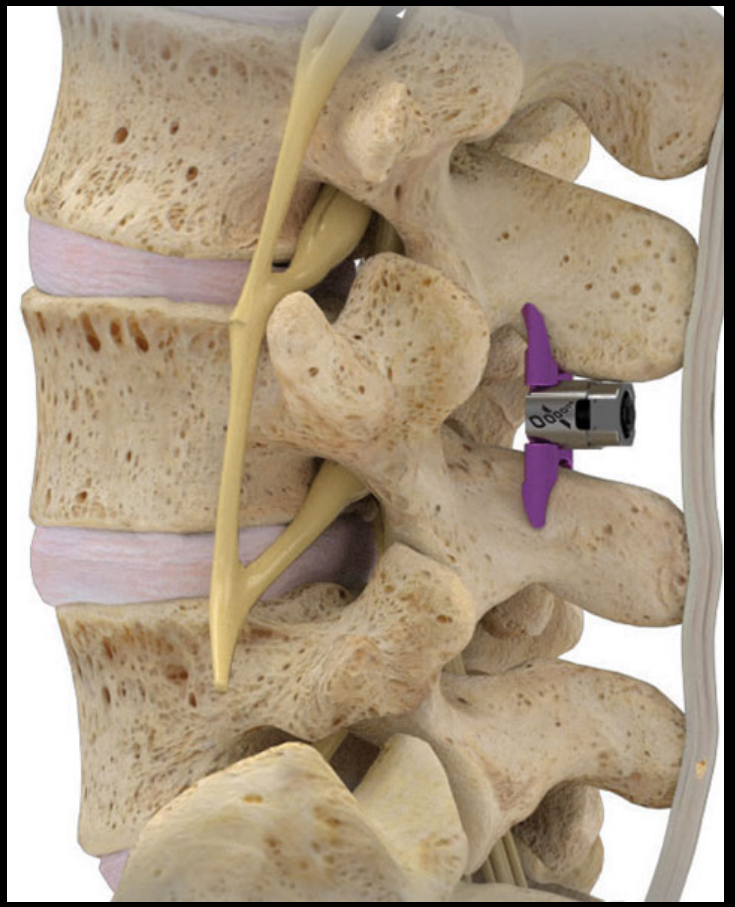
Indications for Neuromodulation Therapy

- SCS: Chronic refractory neuropathic pain of the trunk and limb
- PNS: Focal refractory neuropathic pain

- Examples:
  - FBSS
  - CRPS
  - Peripheral mononeuropathy
  - Post-amputation pain
  - DPN
  - Non-surgical back pain

Emerging Concepts in IPM

- Novel targets: genicular nerves
- Non-invasive vagal nerve stimulation
- Minimally invasive lumbar decompression
- Interspinous decompression
- Endoscopic discectomy
- Closed loop stimulation (not FDA approved)
- Peripheral nerve stimulation
- Basovertebral nerve ablation
- Regenerative medicine



Complimentary Pain Treatment

- Dietary supplements (nutraceuticals)
- Relaxation (deep breathing, guided imagery)
- Yoga
- Tai Chi
- Qi Gong
- Acupuncture
- Chiropractic care
- Meditation
- Massage therapy
- Special diets

Emerging Non-Opioid Medications

- CGRP (calcitonin gene-related peptide receptor protein) antagonist (Erenumab, Fremanezumab)
- NGF (nerve growth factor) antagonist (Tanazumab)
- Cannabinoids (medical marijuana)
- Ketamine infusion
- Low dose naltrexone
- Bisphosphonate (neridronic acid)

What is Interventional Pain Management (IPM)?

The application of site specific drugs, the use of nerve blocks or destruction of nerves, minimally invasive surgical procedures, the infusion of drugs to modify the nervous system or the use of electrical stimulation to modify disease.

Role of IPM Physician

- Primary “pain” physician
- Recognize, diagnosis, treat, and delegate
- Patient advocacy and education
- Coordinate various specialties
- Application of minimally invasive therapeutic modalities to treat various chronic pain conditions
- 2nd opinion on medication management

Scope of Practice

- Spinal fusion surgery
- 1 room surgery center
- Without hospital privileges
- Lack formal training
- Convicted of manslaughter in UK
- Spine surgery courses in Korea

State suspends license of N.J. doctor for performing spinal surgery without proper training

Updated Jun 14, 2012; Posted Jun 14, 2012

0 62 shares

By **Susan K. Livio**, slivio@njadvancemedia.com,
NJ Advance Media for NJ.com

YouTubeRichard Kaul, shown on a News 12 New Jersey program about spinal surgery, had his license suspended by the state Board of Medical Examiners because of accusations that he performed spinal surgeries without proper training.

TRENTON — The state Board of Medical Examiners voted tonight to

https://www.nj.com/news/index.ssf/2012/06/state_suspends_license_of_nj_s.html

IASP: Pain Clinic Guidelines

International Association for the Study of Pain
IASP
Working together for pain relief

- Task force to outline desirable qualities of a pain clinic
  - Multidisciplinary
  - Integrative
  - Comprehensive
  - Research

- Pain treatment facility:
  - Modality oriented clinic
  - Pain clinic
  - Multidisciplinary pain clinic
  - Multidisciplinary pain center

http://www.iasp-pain.org/Education/Content.aspx?ItemNumber=1471

When to Refer for Intervention?

- Referral ≠ failure of healthcare provider
- Unable to make clear diagnosis
- Failure of conservative treatment
- Immediate surgical indication
- Improve patient access
- Incorporate multidisciplinary care
- Complimentary pain treatment

Chronic Pain Consultation

- Pain assessment
- Combination therapy
- Multidisciplinary approach: behavioral health, physical medicine, surgeon
- Consider interventional options
- Risk assessment
- Informed consent and opioid agreement
- Goal directed therapy
- Monitoring: PMP, UDS
- Consult pain specialist early in the treatment continuum

Chronic Pain Consultation Workflow

- Evaluation (what, where, when, why, how)
- Focused exam (Neuro, Musculoskeletal, etc.)
- Diagnostic workup (studies, imagine, nerve block)
- Conservative options
- Complimentary options
- Medication options
- Interventional options
- Surgical options
- Treatment should be goal directed

Avoid Last-Minute Referrals

- Dose escalation: >90 MME
- Polypharmacy: benzodiazepines, muscle relaxants, anticonvulsant
- Chronic opioid use disorder: verbal requests, early refills, refuses non-opioid option, emergency room visits
- Non-compliance: illegal drugs, non-prescribed drugs in urine
- Abuse behavior: abuses or misuses medical regimen, sedation, non-functional

Chou, R., CDC guideline for prescribing opioids for chronic pain—United States, JAMA 2016

Challenges and Unmet Needs For PPN/PDN Patients

- Current treatment options often provide insufficient pain relief
- Medications for neuropathic pain can have significant side effects
- Chronic opioid therapy (oral, transdermal, and intrathecal)
- Low frequency spinal cord stimulation presents challenges for patients
  - Suboptimal pain relief
  - Need to adjust stimulation based on posture/movement
  - Inability to target feet without uncomfortable stimulation
  - Inability to report changes in dysesthesias due to the confounding presence of paresthesias

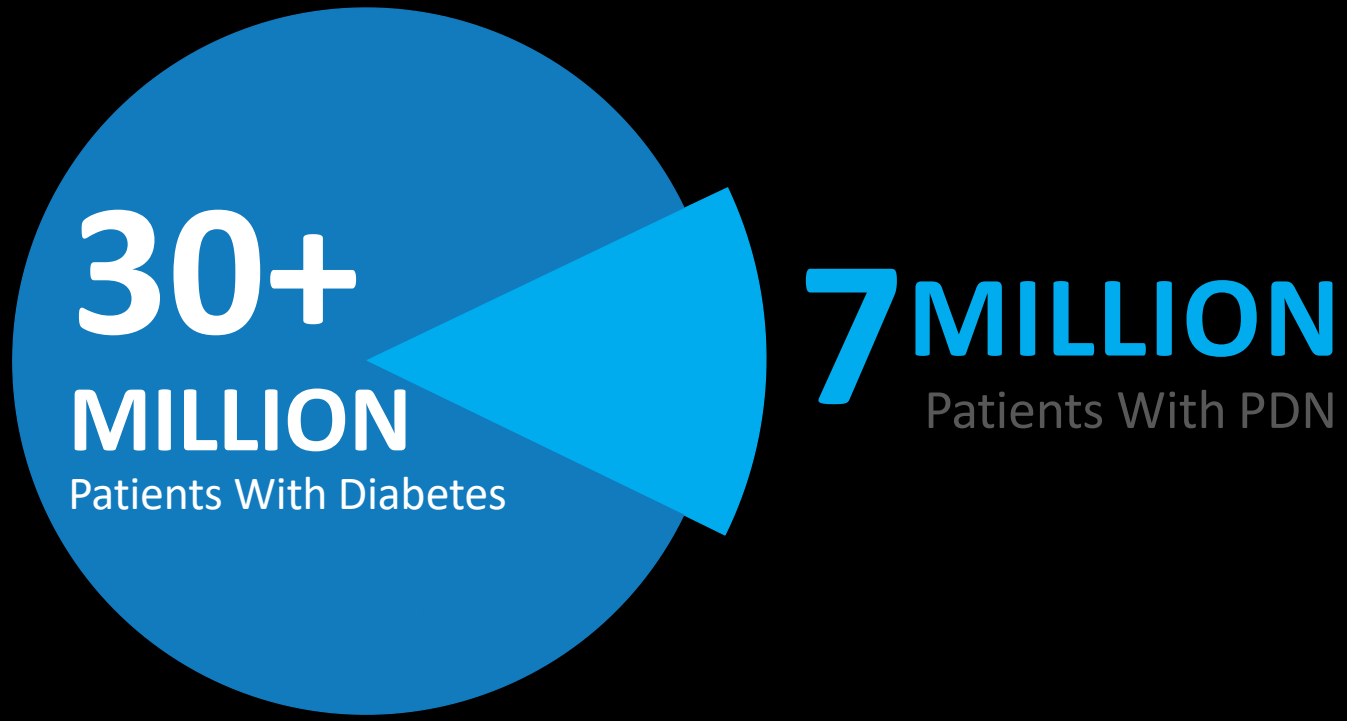
Disease Prevalence and Cost

Diabetes is a National Epidemic

- 30.2 million people with diabetes = 9.3% of the population
- Another 86 million people are pre-diabetic (more than 1 in 3 people)
- Costs: $245 billion
  - Direct medical costs = $176 billion
  - Indirect costs = $69 billion

Painful Diabetic Neuropathy is Common

- 20% to 26% of those with diabetes have PDN



CDC National Diabetes Statistics Report, 2014; Davies M et al. Diabetes Care 2006; Schmader KE. Clin J Pain 2002

DRIVING INNOVATION THROUGH
SCIENCE & EVIDENCE

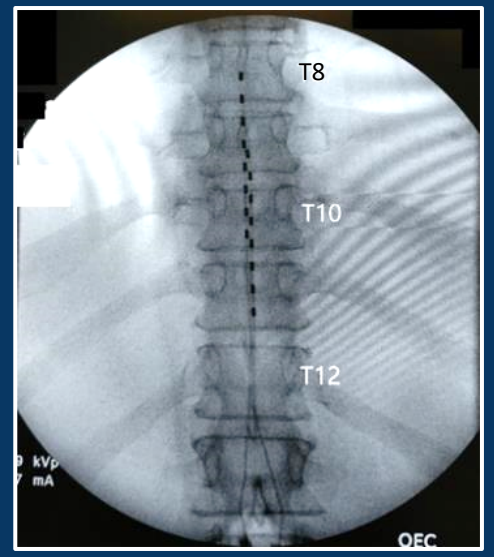
10 kHz Spinal Cord Stimulation for Treatment of Painful Diabetic Neuropathy: A Multicenter, Randomized, Controlled Trial

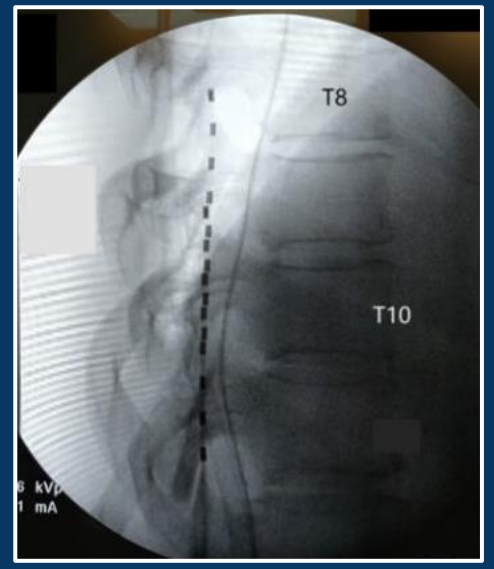
Erika Petersen, MD, FAANS, FACS

Associate Professor
Residency Program Director
University of Arkansas for Medical Sciences
Department of Neurosurgery

Methods

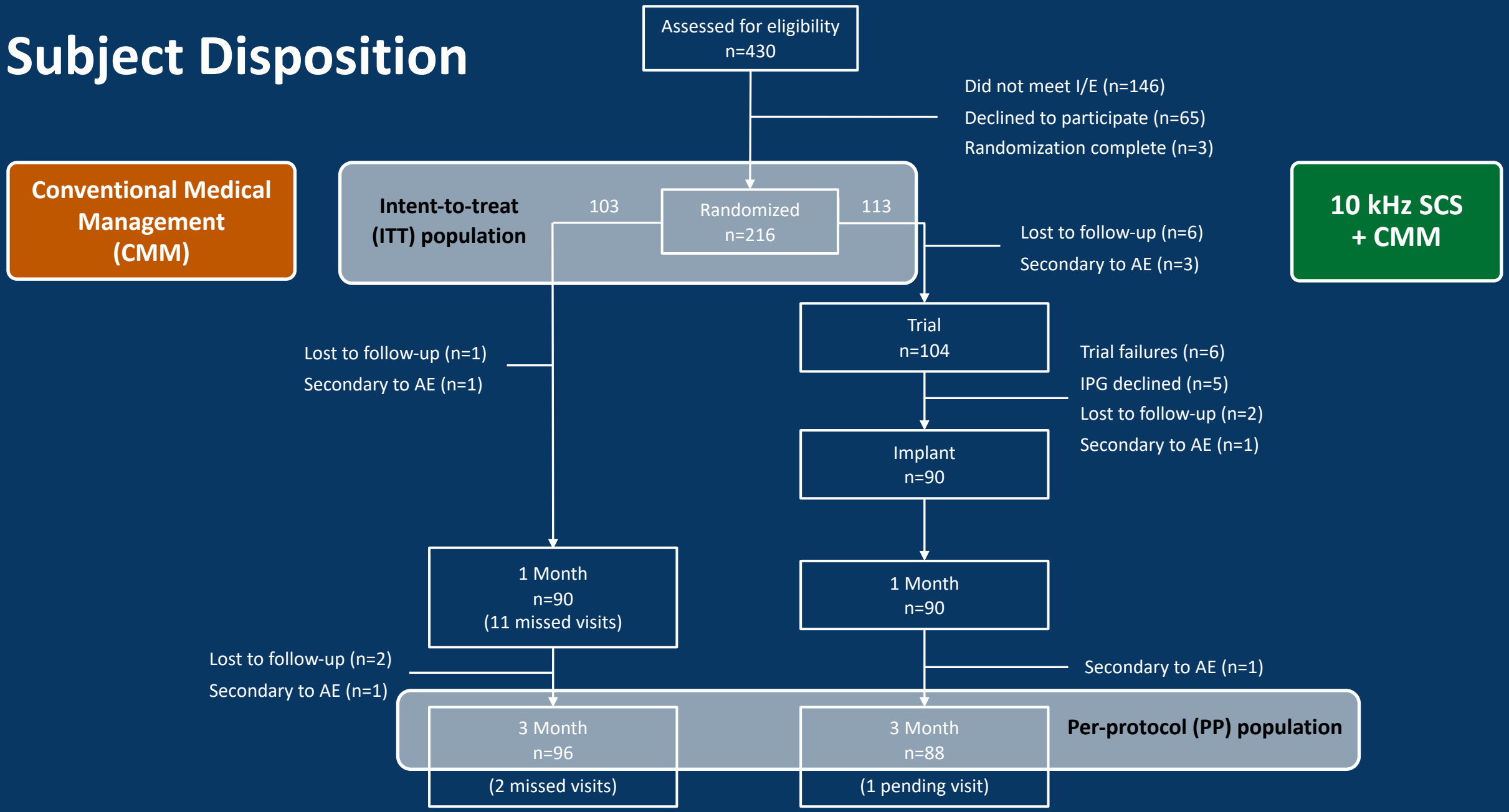
- Painful diabetic neuropathy (PDN) of the lower limbs in patients refractory to conservative treatments
- ≥ 5 of 10 cm on pain VAS, HbA1c < 10%, BMI < 45
- 18 US centers
- Independent Medical Monitors reviewed all subjects
- 216 subjects randomized 1:1 to CMM alone vs. CMM + 10 kHz SCS (Nevro Corp.)
- SCS subjects: At least 50% pain relief during trial stimulation required for implant
- 3-month follow-up assessing
  - Pain
  - Quality of life
  - Neurological function
    - Including diabetic foot exam w/ Semmes-Weinstein 10g monofilament and 40g pinprick tests





Mekhail et al. *Trials* 2020

Subject Disposition



Baseline Characteristics

	CMM n = 103	10 kHz SCS + CMM n = 113	Standardized Difference*
Age in years, mean (SD)	60.8 (9.9)	60.7 (11.4)	0.01
Male, n (%)	66 (64%)	70 (62%)	0.04
Race			
White, n (%)	85 (82.5%)	87 (77.0%)	0.14
Black or African American, n (%)	13 (12.6%)	18 (15.9%)	
Native Hawaiian or other Pacific Islander, n (%)	1 (1.0%)	3 (2.7%)	
American Indian or Alaska Native, n (%)	0 (0.0%)	2 (1.8%)	
Asian, n (%)	1 (1.0%)	1 (0.9%)	
Other, n (%)	3 (2.9%)	2 (1.8%)	
Diabetes			
Type 1, n (%)	3 (3%)	8 (7%)	0.19
Type 2, n (%)	100 (97%)	105 (93%)	
Duration in years			
Diabetes, mean (SD)	12.2 (8.5)	12.9 (8.5)	0.09
Peripheral neuropathy, mean (SD)	7.1 (5.1)	7.4 (5.7)	0.06
Lower limb pain VAS in cm, mean (SD)	7.1 (1.6)	7.5 (1.6)	0.22
< 7.5 cm, n (%)	57 (55%)	54 (48%)	0.15
≥ 7.5 cm, n (%)	46 (45%)	59 (52%)	
HbA1c, mean (SD)	7.4% (1.2%)	7.3% (1.1%)	0.11
< 7.0%, n (%)	40 (39%)	46 (41%)	0.04
≥ 7.0%, n (%)	63 (61%)	67 (59%)	
BMI, mean (SD)	33.9 (5.2)	33.6 (5.4)	0.06

*Effect size index (Cohen's d):
≥ 0.20 = small
≥ 0.50 = medium
≥ 0.80 = large

Safety: Study-Related Adverse Events

	CMM n = 103	10 kHz SCS + CMM n = 113
Total study-related AEs, n (# of subjects, %)	None reported	19 (15, 13.3%)
Rated as Serious AEs	-	2 (2, 1.8%)
Study-related AEs by type		
Lead migration	-	4 (2, 1.8%)
Wound dehiscence	-	3 (3, 2.7%)
Infection	-	2 (2, 1.8%)
Incision or IPG discomfort	-	2 (2, 1.8%)
Irritation from surgical dressings	-	2 (2, 1.8%)
Impaired healing	-	1 (1, 0.9%)
Radiculopathy	-	1 (1, 0.9%)
Uncomfortable stimulation	-	1 (1, 0.9%)
Gastroesophageal reflux	-	1 (1, 0.9%)
Arthralgia	-	1 (1, 0.9%)
Hyporeflexia	-	1 (1, 0.9%)

Outcomes of the SAEs:

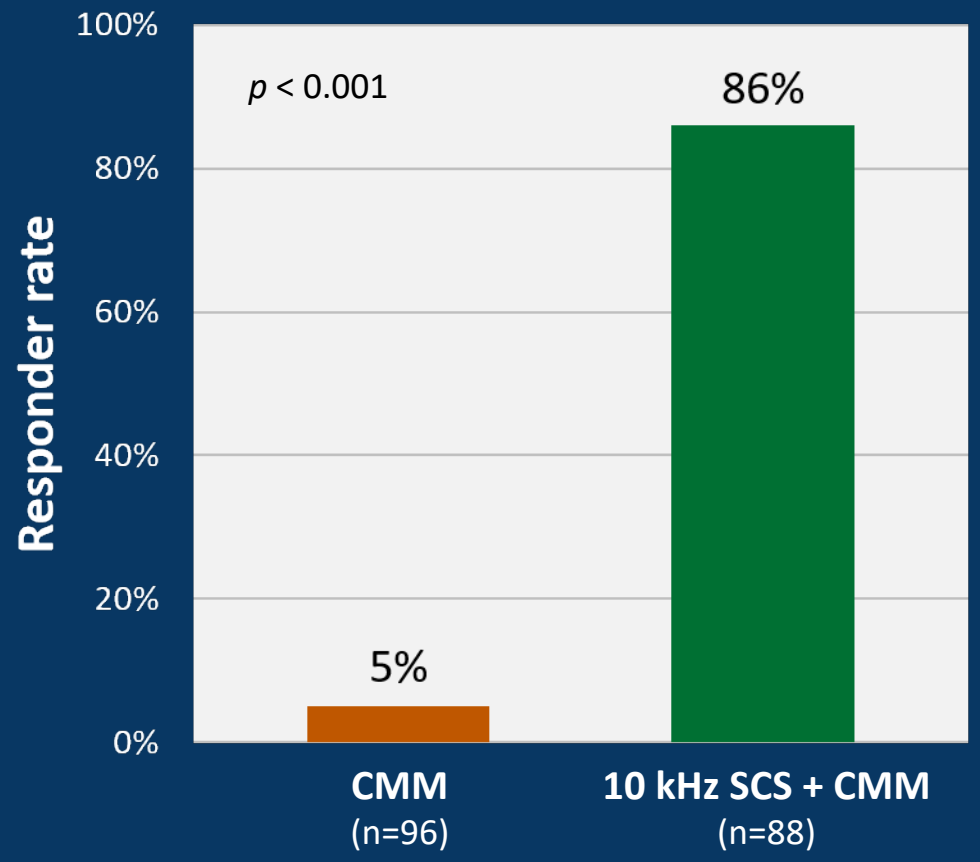
- Infection resolved with I&D, antibiotics, subject continues in the study
- Wound dehiscence resulted in device explant, subject will exit study

Reported SCS infection rates:

- 2.45% (Hoelzer et al. 2017)
- 3.4% (Kumar et al. 2006)
- 4.5% (Mekhail et al. 2011)
- 8.9% (Diabetes cohort, Mekhail et al. 2011)

Primary Endpoint Analysis: Per-Protocol Population

- Primary Endpoint is a composite of safety & effectiveness at 3 months
  - compare responders (≥ 50% pain relief) without a worsening neurological deficit from baseline
- ITT analysis consistent with PP analysis, significant difference between groups



Conclusions

- **Study primary endpoint met** - A large proportion of subjects benefited from 10 kHz SCS
- 10 kHz SCS is a safe and effective treatment for PDN patients refractory to CMM
- Study follow-up will continue for 24 months total with evaluation of health economics and pain medication usage

SENZA-PDN Investigators


Kas Amirdelfan


Matthew Bennett


Rick Bundschu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Paul Chang


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David DiBenedetto


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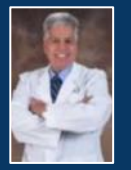
Vincent Galan


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EDUCATION
TREATMENT
ADVOCACY
PUBLISHED BY ELSEVIER

The Journal of Pain, Vol 18, No 1 (January), 2017: pp 42-53
Available online at www.jpain.org and www.sciencedirect.com

Capsaicin 8% Patch in Painful Diabetic Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Study

David M. Simpson,[*] Jessica Robinson-Papp,[*] Joanna Van,[†] Malcolm Stoker,[‡] Hélène Jacobs,[‡] Robert J. Snijder,[‡] Diederik S. Schregardus,[‡,§] Stephen K. Long,[‡,¶] Bruno Lambourg,[‖] and Nathaniel Katz[**,††]

Topical Capsaicin 8% Patch for Diabetic Neuropathy

- FDA approved 2020 for diabetic peripheral neuropathy
- Capsaicin (1816), chili pepper extract
- Binds to TRPV1 receptor, Na+, Ca++ influx: depolarization
- TRPV1 found on A delta, C nociceptive nerve fibers
- Capsaicin binding leads to loss of mitochondrial function
- Desensitization of sensory afferent axons
- Chemoneurolysis of peripheral nerves

Zuo et al. Anesthesiology. 2019

Complex Regional Pain Syndrome (CRPS)

- Weir Mitchell during Civil War
- Causalgia
- Sudeck's dystrophy
- James Evans (RSD)
- Philip Foisie (vasospasms)
- IASP: CRPS I and CRPS II

Complex Regional Pain Syndrome CRPS

- Array of painful conditions
- Continuing pain (spontaneous or evoked)
- Disproportionate in time or severity
- Regional distribution (not in specific nerve pattern)
- Variable progression
- Sensory, motor, sudomotor, vasomotor, trophic changes

CRPS: Epidemiology

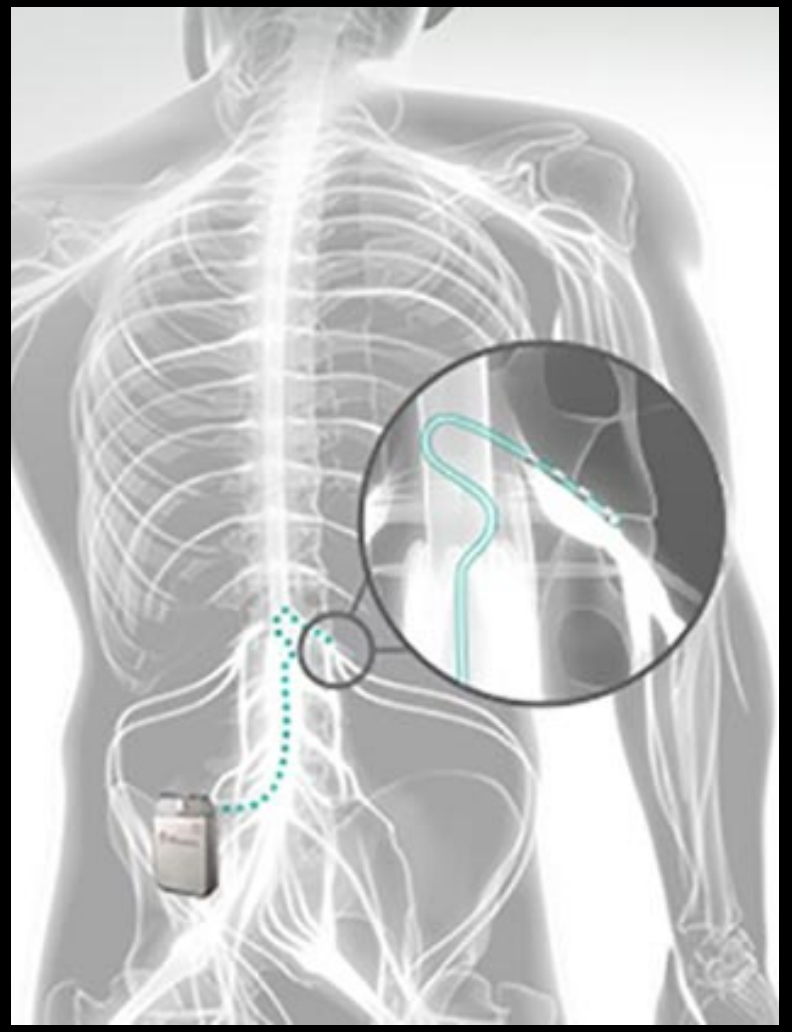
- Incidence is unknown
- 5.5-26.6/100,000 person-years at risk
- Female>male, 3:1
- 17% pending lawsuits
- 54% workman's compensation

CRPS: Diagnosis

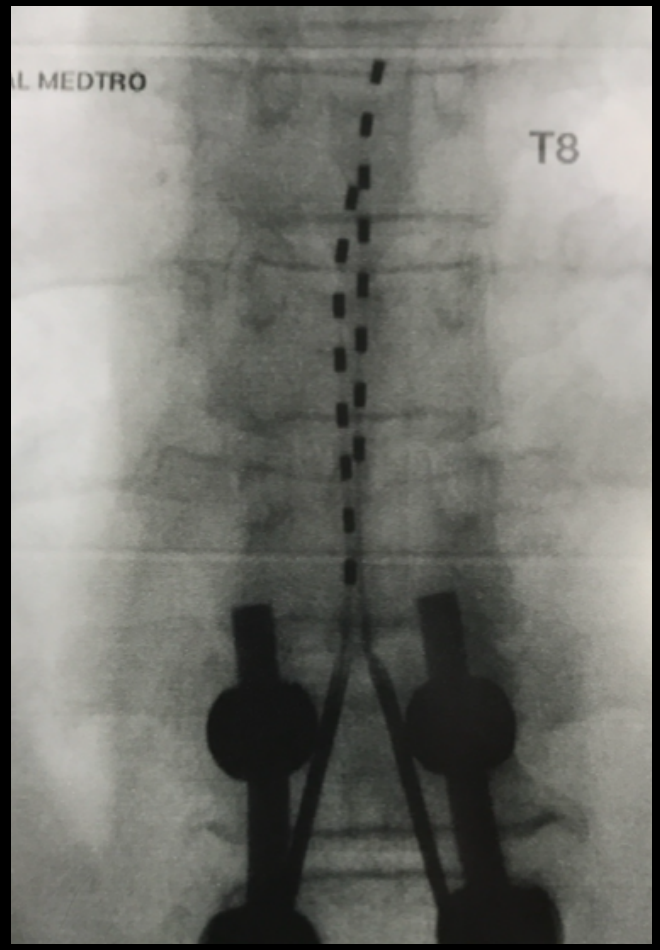
- Diagnosis of exclusion
- Clinical history
- Quantitative sensory testing
- Autonomic function tests (infrared thermometry)
- Vascular abnormalities (peripheral perfusion)
- Trophic changes (bone density)
- Sympathetic nerve block

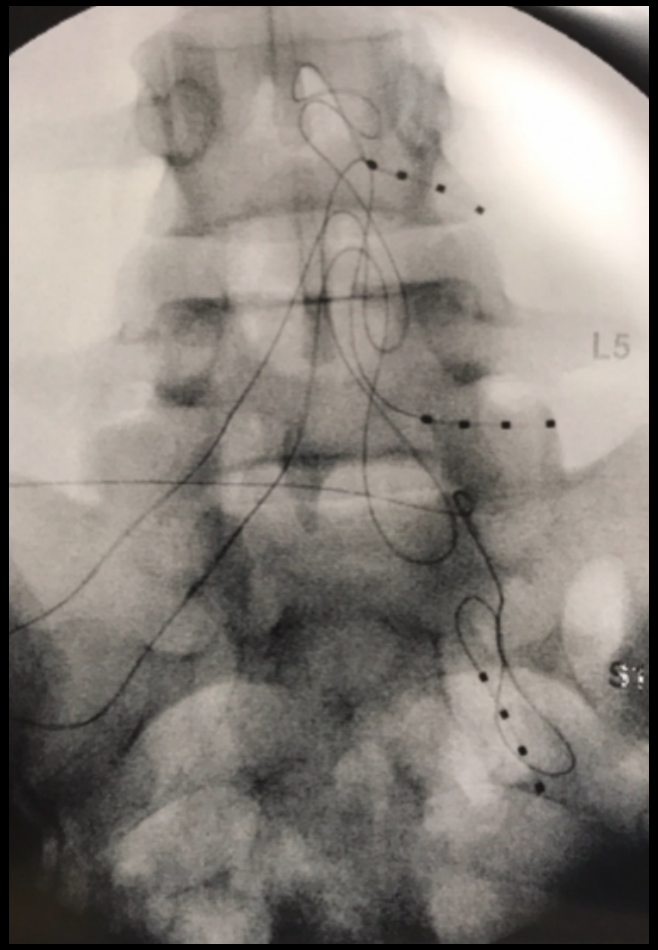
Approved Indication: DRG Stimulation

- FDA approval February 2016
- Severe chronic intractable pain of the lower limbs with CRPS I and II
- Spinal column stimulation via epidural and intra-spinal lead access to the dorsal root ganglion
- From T10 down



Traditional SCS Versus DRG Stimulation





Research Paper

PAIN

OPEN

Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial

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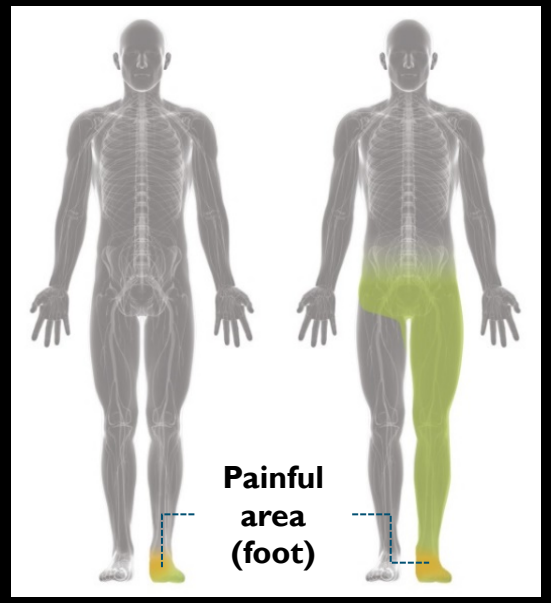
- U.S. pivotal trial, comparing DRG and traditional stimulation
- Multi-center, randomized controlled trial
- 152 subjects with CRPS, causalgia of the lower extremity
- At 3 months DRG group 81.2% and SCS group 55.7% efficacy

Deer T, Levy R, et al. Pain. 2017;158(4):669-681.

TARGETED STIMULATION



Subjects receiving targeted stimulation in the area of pain without extraneous paresthesia

DRG	CONTROL
95%	61%

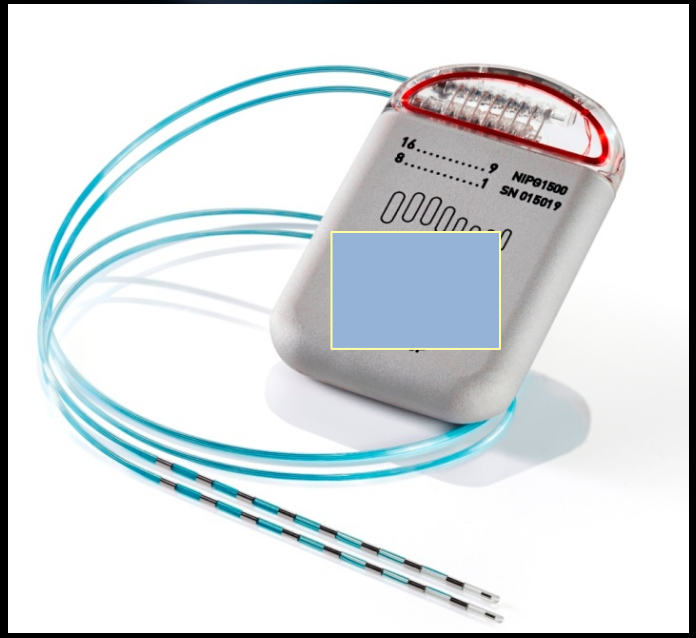
Programming guidelines suggest sub-paresthesia

Case Study 1

- 58M, 3 months status post lumbar fusion surgery. Oxycodone 15 mg TID prescribed by surgeon who no longer wants to prescribe. Patient instructed to follow up with PCP. Now 12 months post-surgery, he continues to request increased doses, shows up early for renewals.

- Opioid agreement?
- Risk assessment?
- Monitoring?
- Referral to pain specialist or continue to prescribe pain medications?
- Pain psychologist?

Neuromodulation?



PainWeek

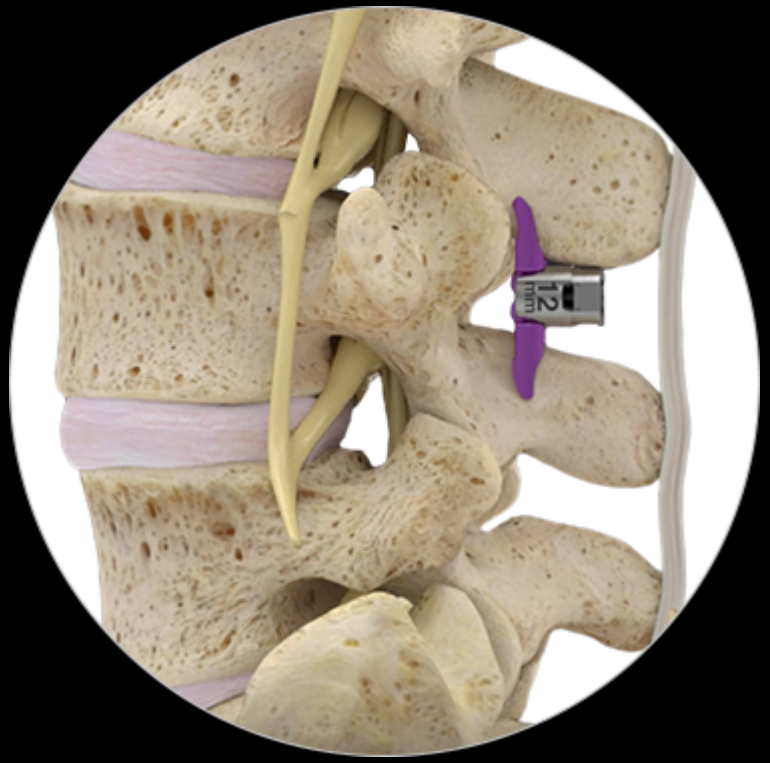
Case Study 2

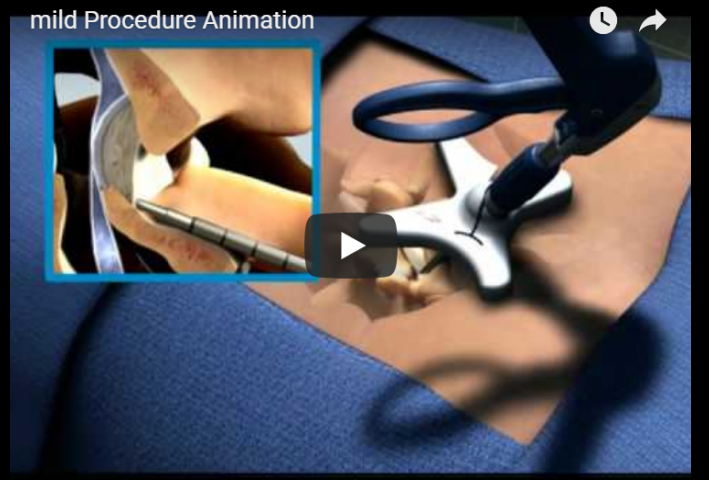
- 76F, with spinal stenosis. Low back pain radiating into the lower extremities with standing and walking. Alleviated with sitting and leaning on shopping cart. Tramadol is becoming less effective. No prior surgery. Normal exam findings.

- Increase opioids?
- Obtain new imaging?
- Referral for interventional pain management?
- Referral for surgical decompression?

Case Study 2

Indirect Interspinous Decompression





Minimally Invasive Lumbar Decompression (MILD)

Case Study 3

- 42F, chronic diffuse pain. H/o anxiety, depression, migraine HA, fibromyalgia, RA, and low back pain. Alprazolam (psychiatrist), Fentanyl patch (rheumatologist), Carisoprodol (PCP). Rheumatologist no longer feels comfortable prescribing opioids.

- Takeover opioid prescriptions?
- Referral for interventional pain management?
- Behavioral health specialists?
- Addiction specialist?

Case Study 3

---- (0 = no pain 10 = unbearable pain) ----

Pain level today

0 1 2 3 4 5 6 7 8 9 10

Over the last 4 weeks, please identify your pain levels below:

Severe pain level (on a bad day)

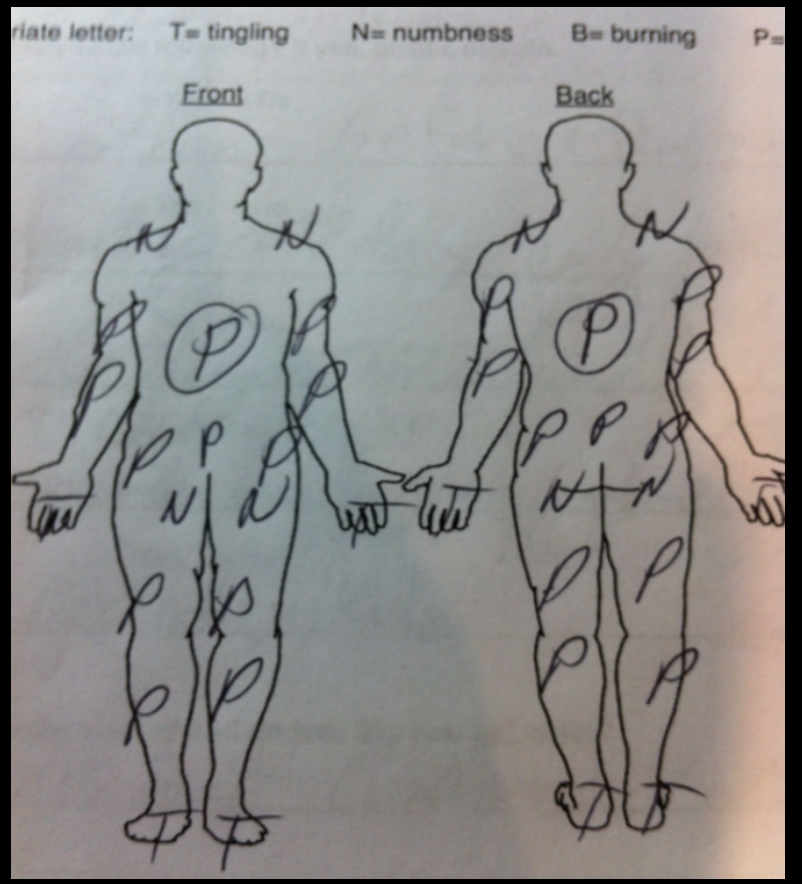
0 1 2 3 4 5 6 7 8 9 10

Average pain level (on an average day)

0 1 2 3 4 5 6 7 8 9 10

Percentage of Relief _____

Allergies Poverty



Summary

- Chronic pain: >100 million Americans, >1.5 billion worldwide
- #1 cause of disability in America
- Prescription opioid epidemic
- MUST address underlying problem of pain
- Evidence based patient-centric care
- Multidisciplinary approach
- Consider intervention early in treatment algorithm

Thank You