Nerve Blocks, Injections, Pain Pumps, and Neural Stimulation

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Disclosures

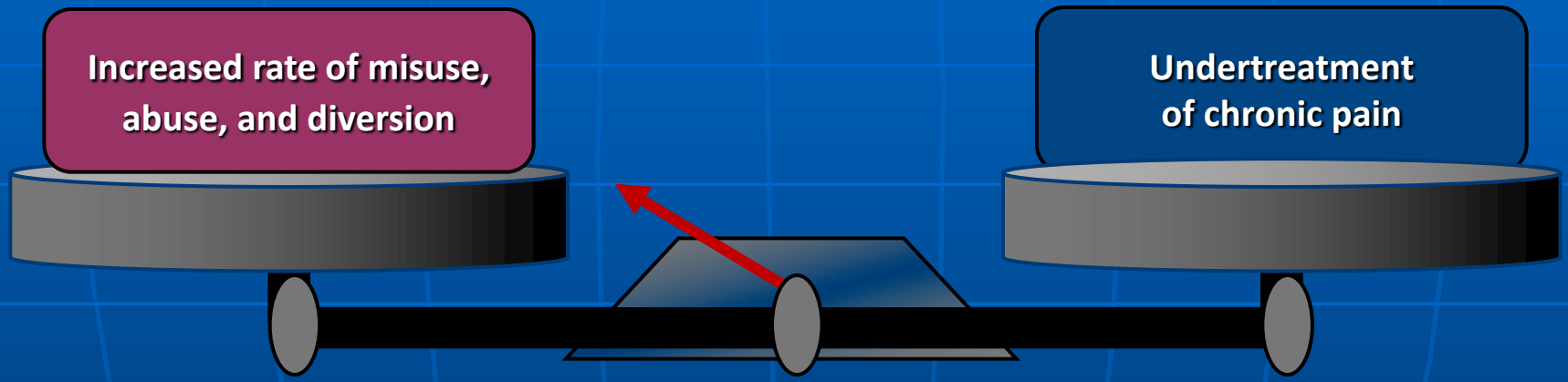
- Consultant/Advisory Board: GlaxoSmithKline Consumer Healthcare, Eli Lilly
- Media Work: Algiatry, LLC
- This presentation may contain references to off-label or investigational use of drugs or products

Learning Objectives

- Identify patients who may benefit from interventional procedures
- Recognize procedural interventions for spinal/ non-spinal pain
- Describe patients who may benefit from pain pumps and neural stimulation

Addressing Dual Public Health Concerns
Chronic Pain and Opioid Abuse

Risk management and new drug formulations may help balance the scale



CDC Guideline & Prescription Monitoring Programs

Kuehn BM. *JAMA*. 2007;297:249-250.
Potter M, et al. *J Fam Pract*. 2001;50:145-151

CDC Guideline

Nonpharmacologic Therapies

- **Procedures**
- Exercise
- Weight Loss
- Psychological Therapy
  - CBT
- Sleep Interventions

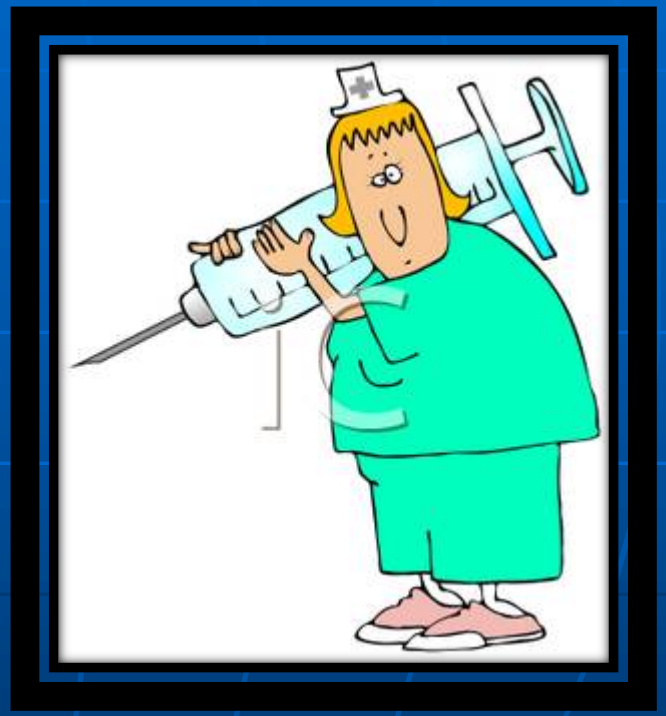
CDC Guideline for Prescribing Opioids for Chronic Pain – U.S., 2016. U.S. Department of Health & Human Services

Historical Perspective

- 20th Century:
  - Many analgesics developed
    - Acetaminophen, NSAIDS, opioids
      - Hydromorphone, meperidine, methadone
  - Spinal and epidural anesthesia, expansion of regional anesthesia
  - Techniques applied to acute and chronic pain management
  - Intrathecal use of medications (1980's)
  - Spinal Cord Stimulation (1967)
    - Expanded use in 1990's

Why Do We Do Injections?

- Therapeutic value
- Diagnostic value
  - Anesthetic blocks can help establish basis for pain when pain presents from several possible sources
- Prognostic value
- Expectations
  - Referring doctors, patients, colleagues



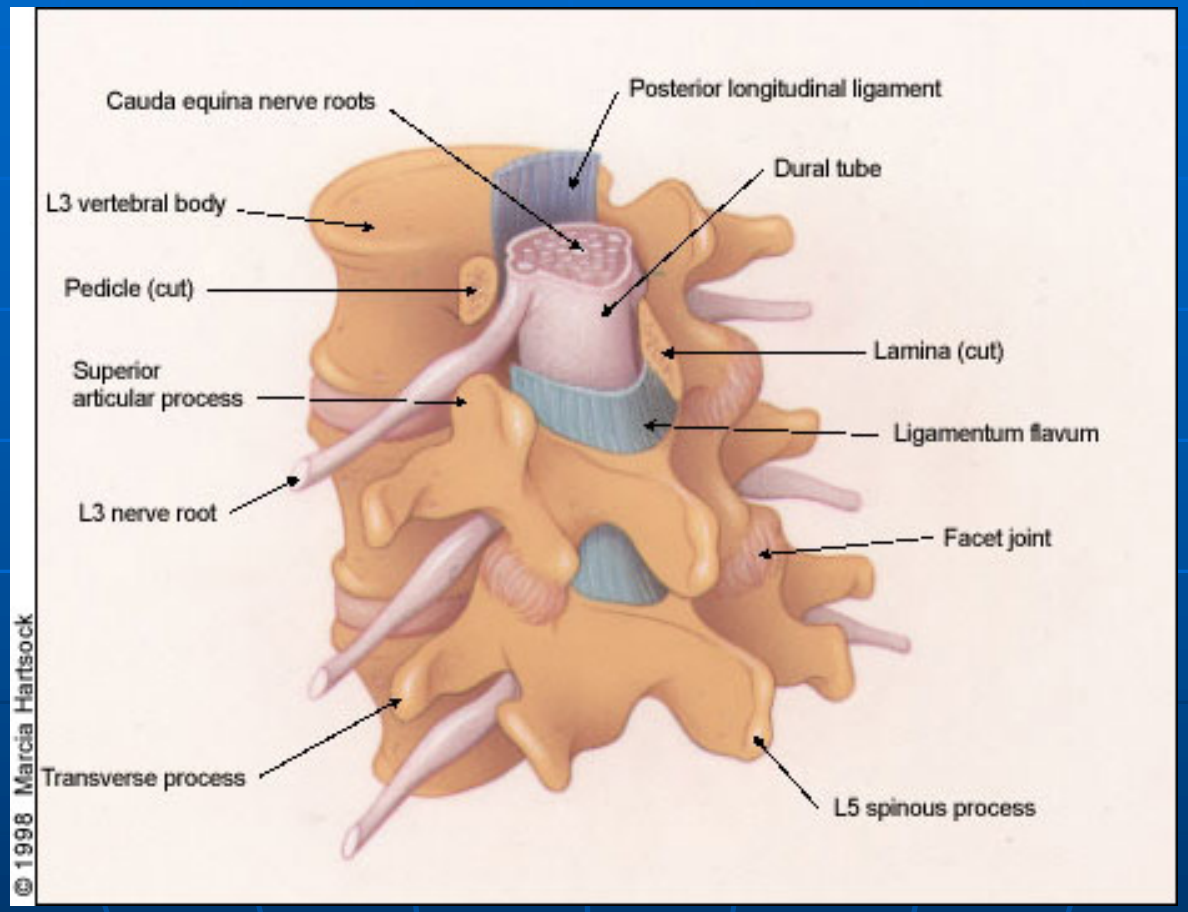
Etiology of Low Back Pain

- Facetogenic
  - 10%-25%
- SI joint pain
  - 15%-35%
- Neuropathic (stenosis, HNP)
  - 37-54%
- Discogenic:
  - 35%-50%
- Myofascial:
  - 20%

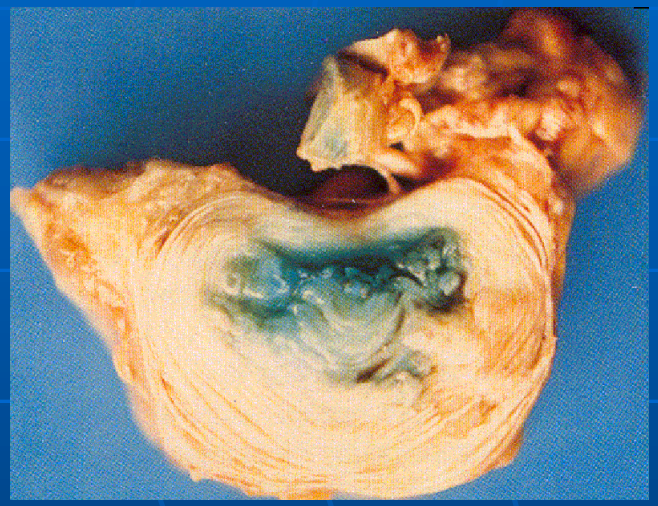
Common Spinal Procedures

- Epidural Steroid Injection (ESI)
  - Indications:
    - Neck, back, buttock, shooting leg pain past knee, or shooting arm pain, or shooting thoracic pain
  - Source:
    - Nerve root irritation or compression, or spinal narrowing from herniated discs/spinal stenosis
  - Approaches:
    - Interlaminar: Cervical, Thoracic, Lumbar, Caudal
    - Transforaminal/Nerve Root
    - Performed under fluoroscopy and preceded by radiographic contrast

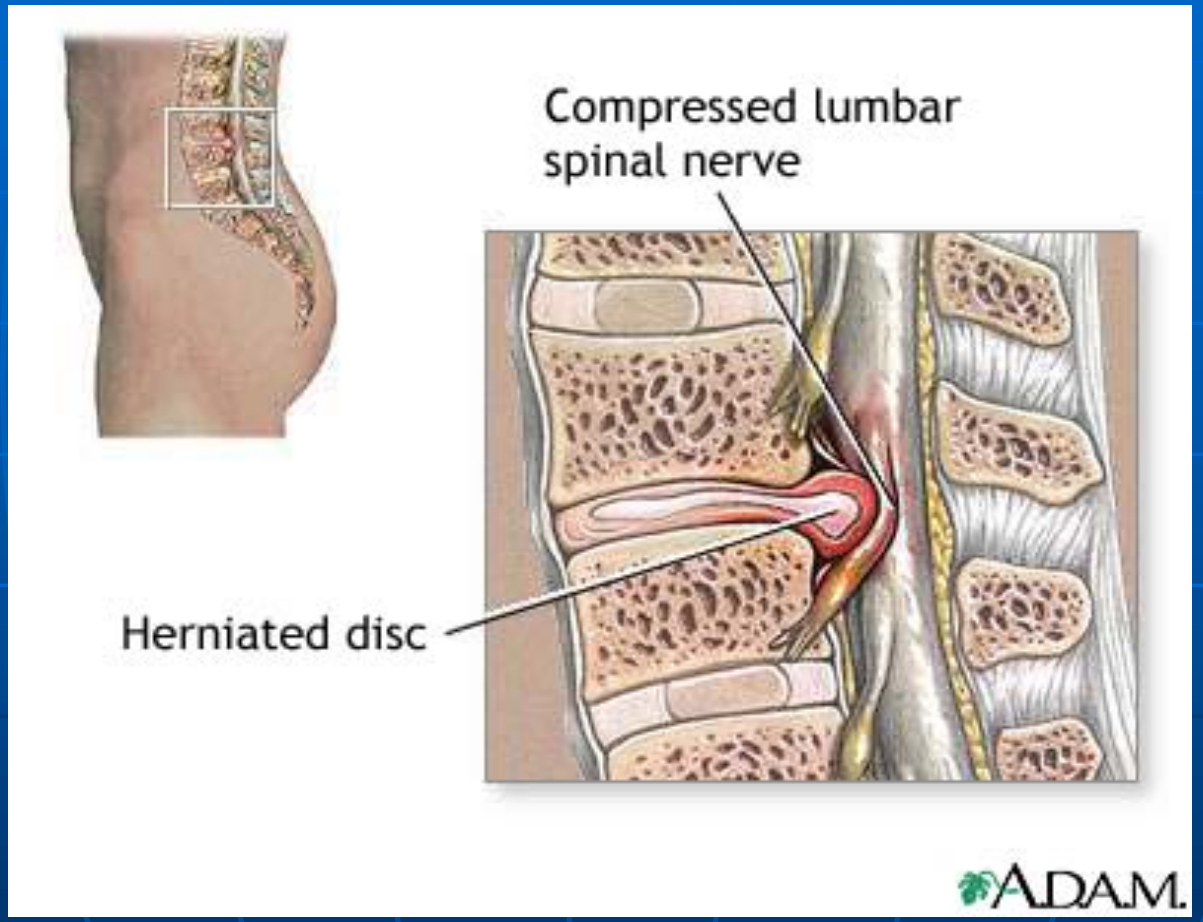
Lumbar Spine

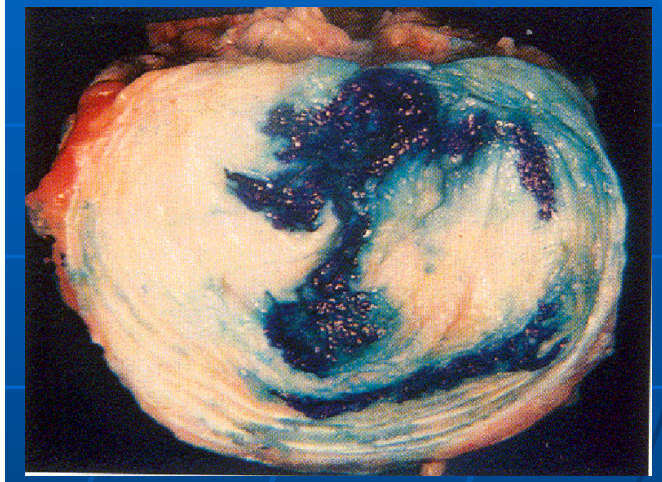


Disc Herniation/Degeneration



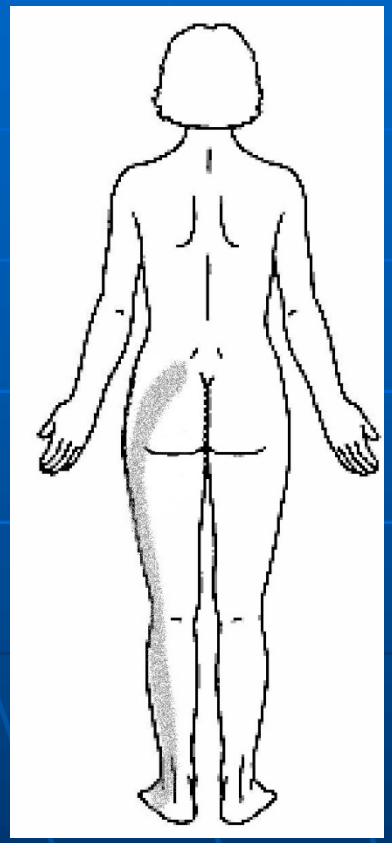
Healthy Disc

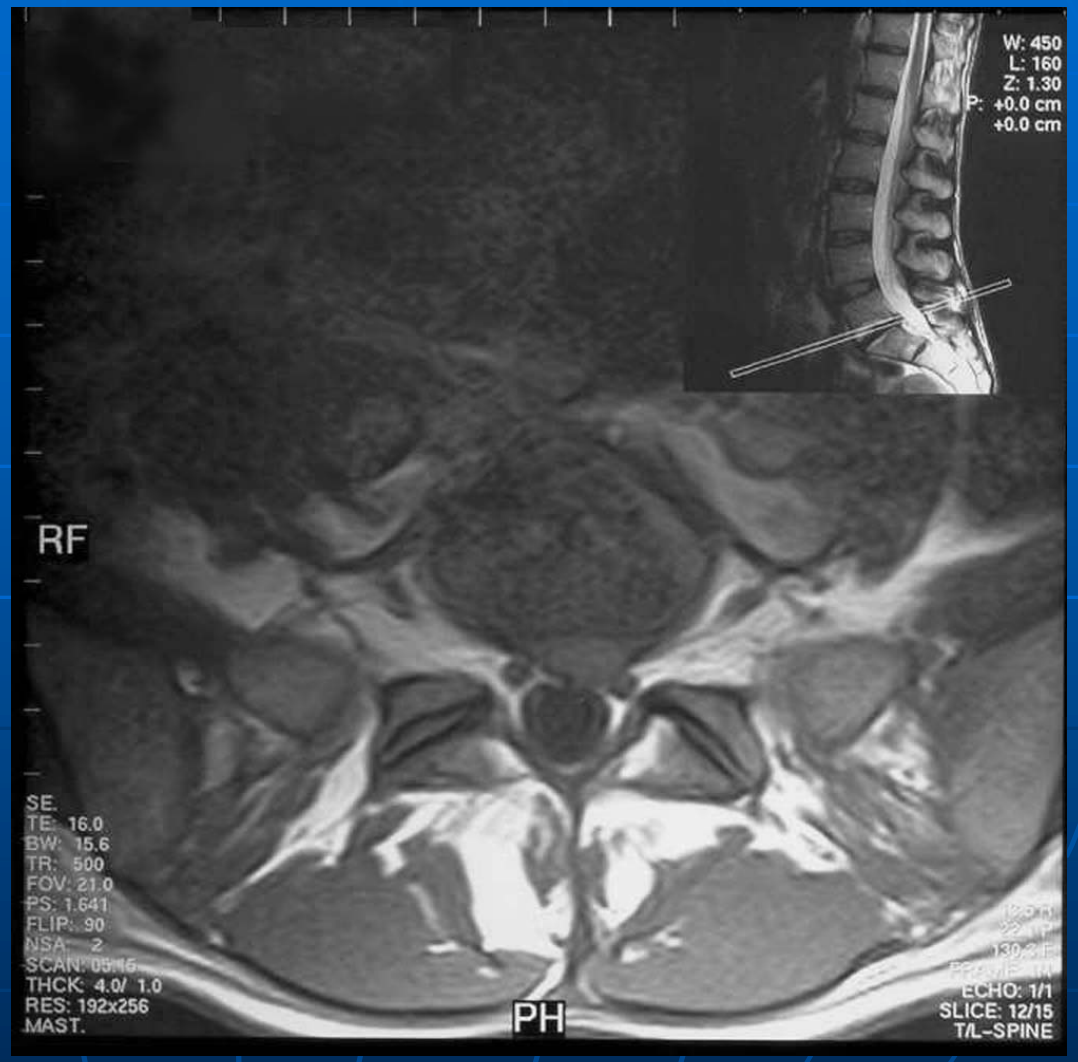




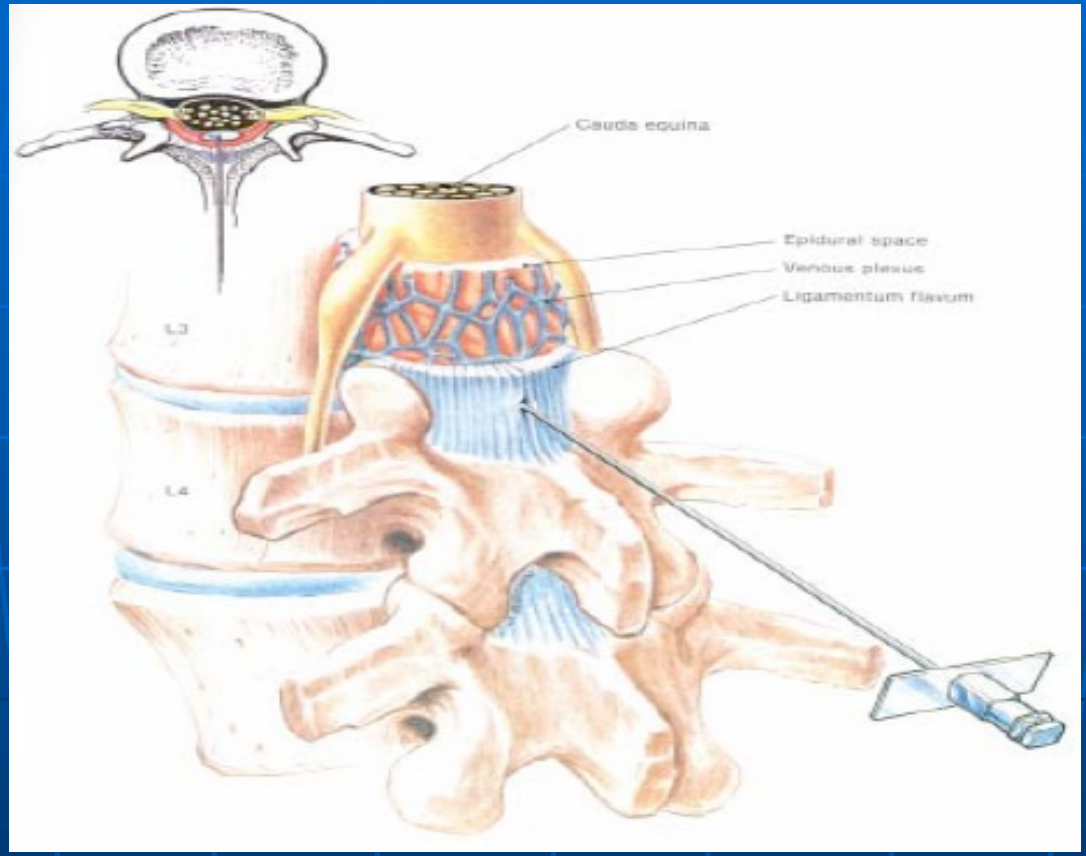
Degenerated Disc

MRI - Disc Herniation

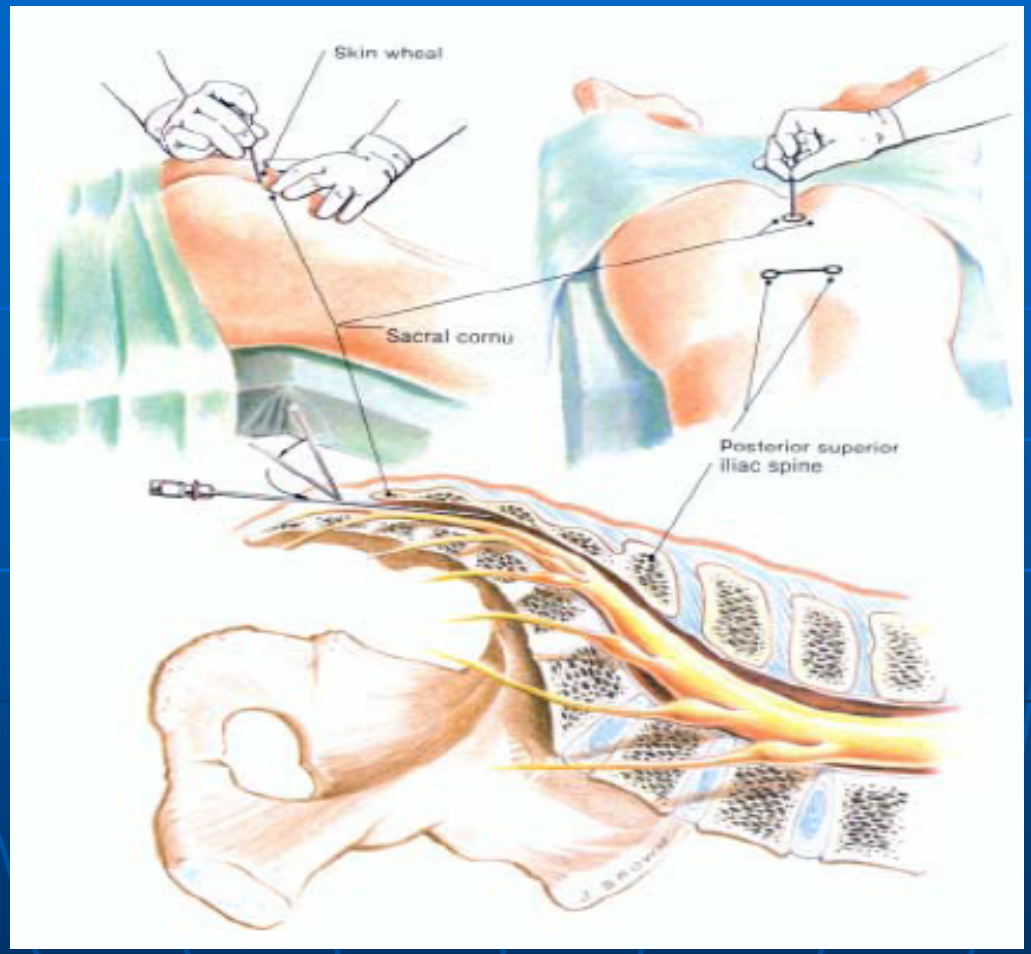




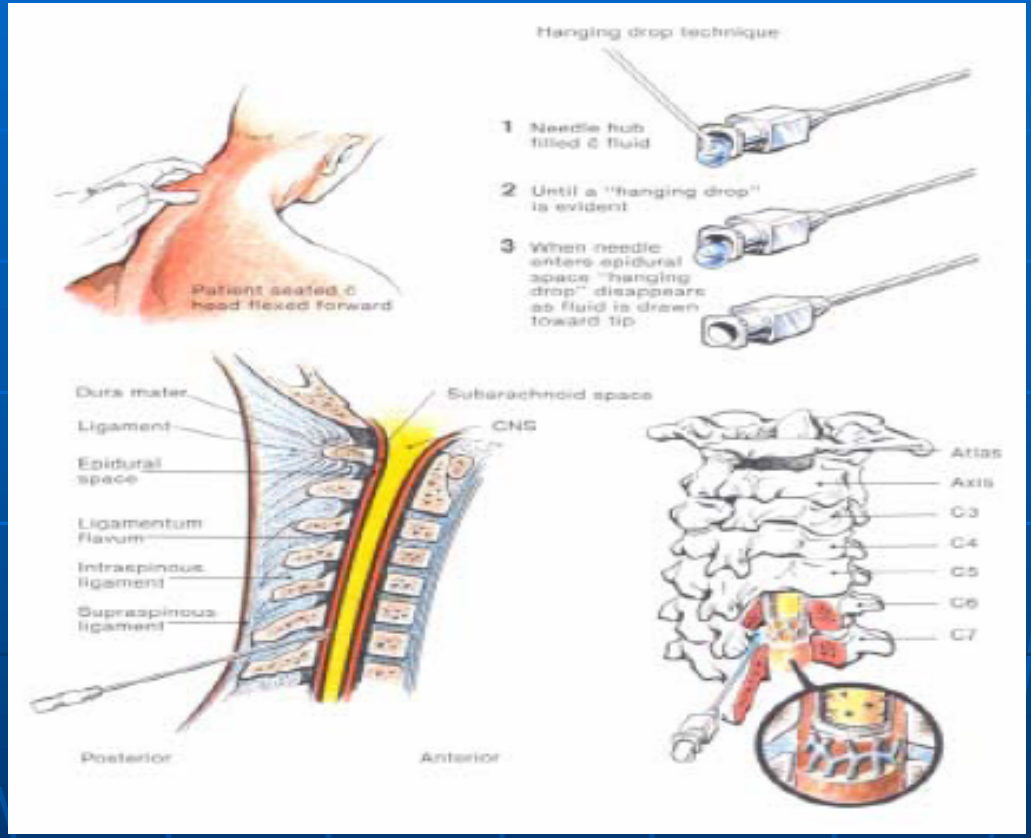
Interlaminar Epidural Steroid Injection -Lumbar



Caudal Epidural Steroid Injection

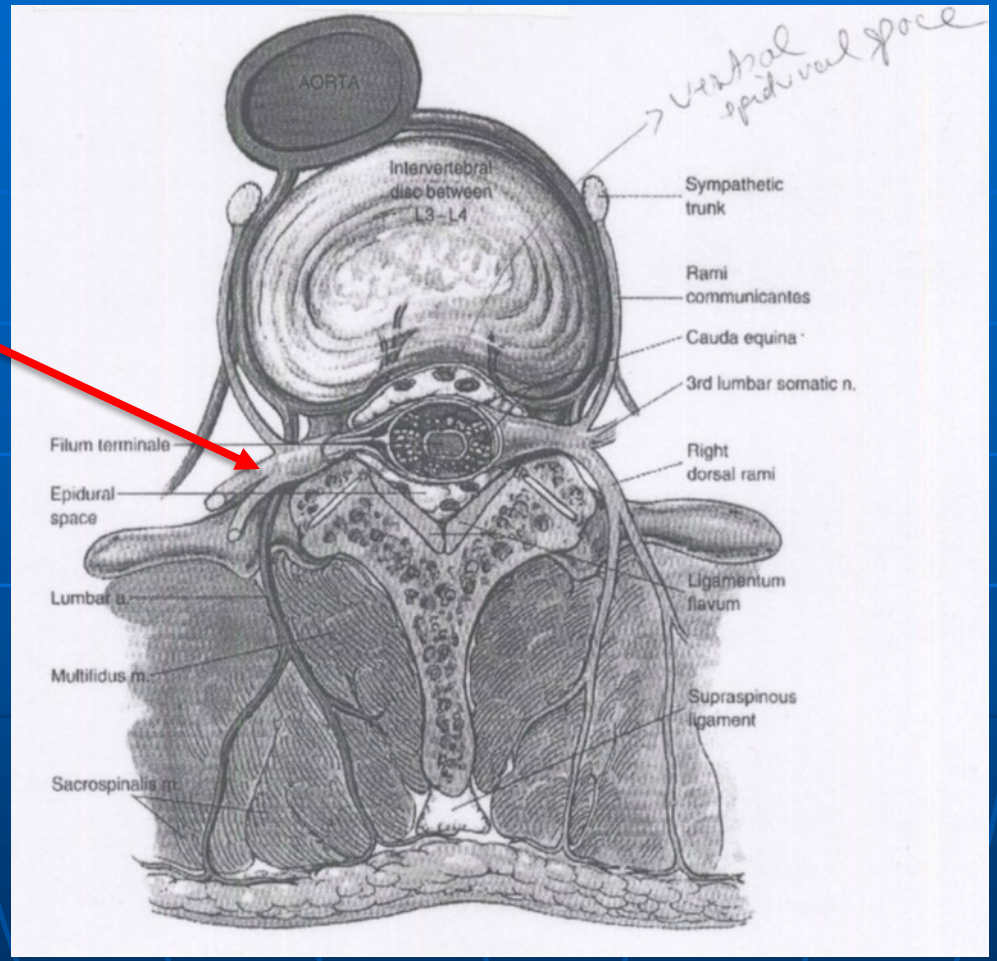


Interlaminar Cervical Epidural Steroid Injection



Transforaminal Epidural Steroid Injection

Needle Insertion



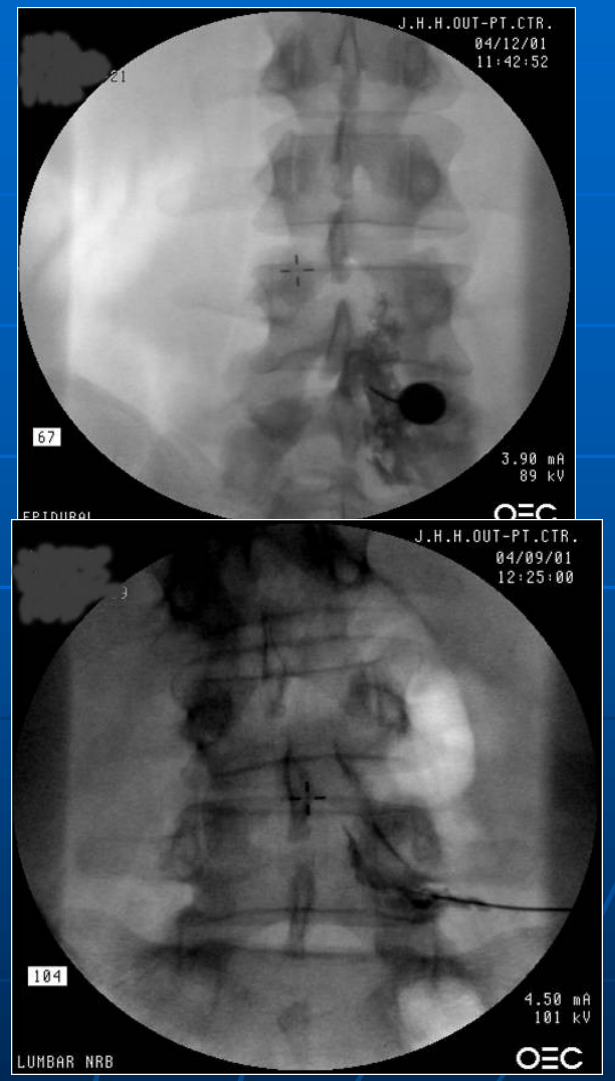
Ideal Candidates for ESI

Favorable Prognosis	Unfavorable Prognosis
▪ Radiculopathy caused by HNP ▪ Short duration of pain ▪ Leg pain > back pain • Signs of nerve root tension ▪ No psychological overlay ▪ Self-employed ▪ Intermittent pain ▪ Young age	▪ Degenerative disc disease or spinal stenosis ▪ Pain > 6 months duration ▪ Back pain > leg pain ▪ Psychological overlay ▪ Unemployed due to pain ▪ Constant pain ▪ Failed interventions (e.g. spine surgery, injections, opioids) ▪ Poor imaging correlation

Epidural Steroid Injections

- About 60% of > 40 controlled studies show short-term benefit

- Two-thirds of comparative studies suggest TFESI are superior to ILESI
  - Higher volumes associated with better outcomes
  - No evidence for steroid dosages > 40 mg



Epidural Steroid Injections

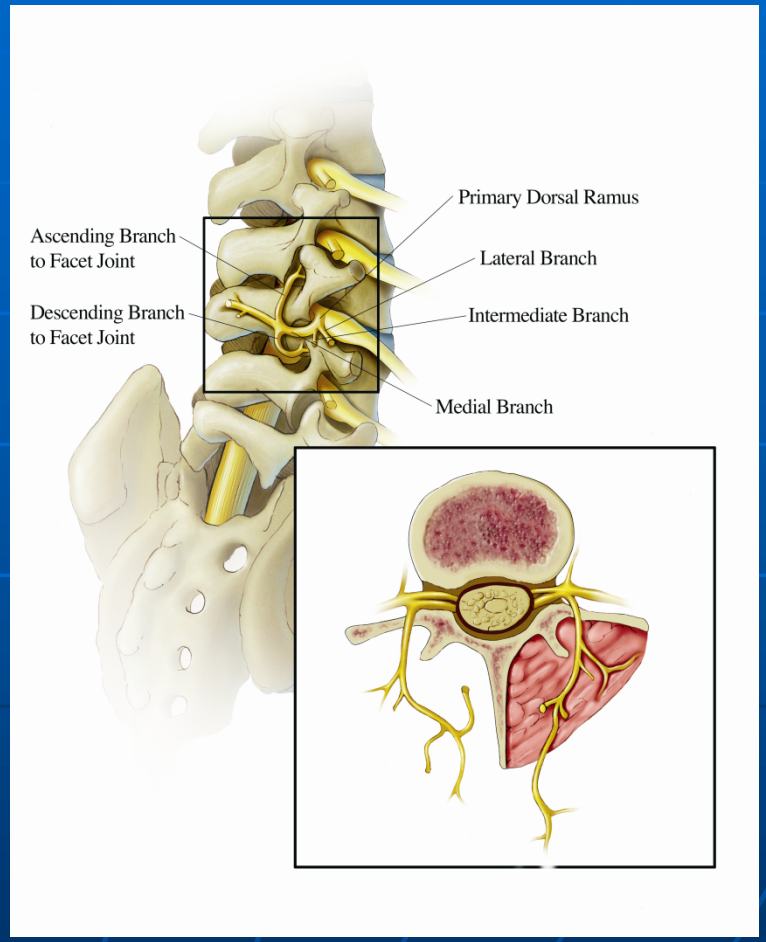
Outcomes:

- Interlaminar*
  - "Steroids appear to speed the rate of recovery and return to function…"
- Transforaminal/Selective nerve root**
  - 6 randomized, controlled trials
  - Moderate (level III) evidence supports the usefulness of TFESI for treating radicular pain
- Interlaminar and transforaminal equal in pain relief and functional improvement for lumbosacral radicular pain
- Strong evidence for short-term efficacy (<6 months), moderate for long-term efficacy (≥ 6 months) in managing pain and disability from lumbar disc herniation
- May prevent need for surgery
  - Chronic sciatica patients

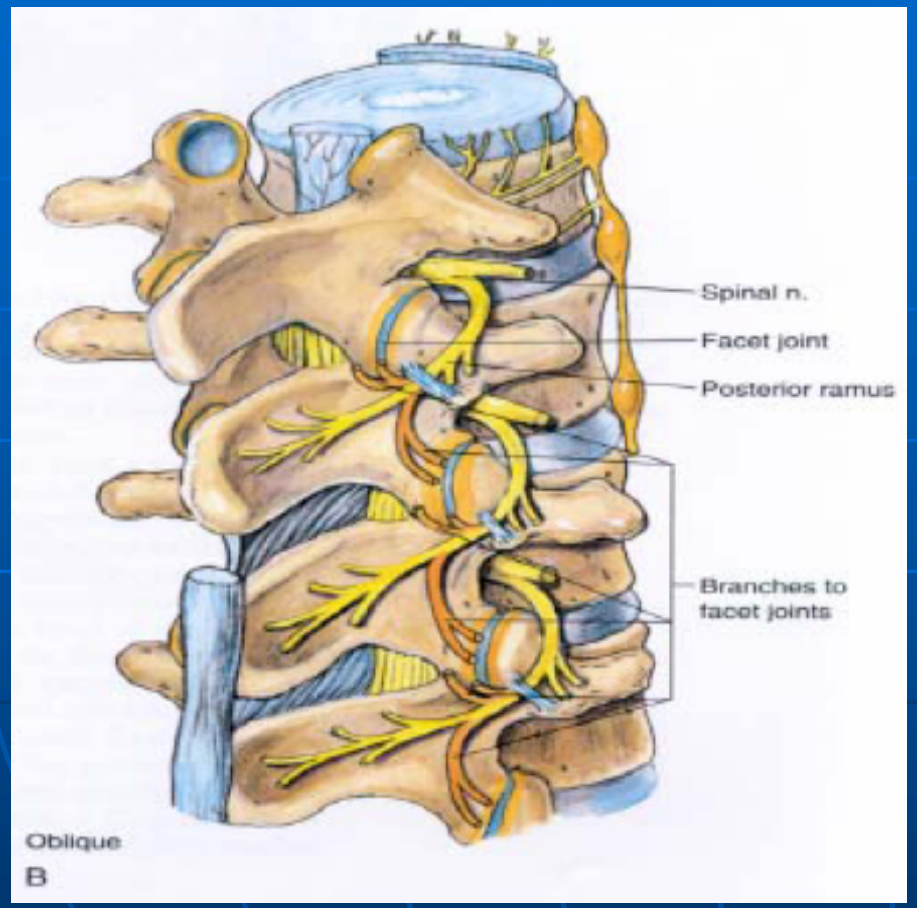
Bhatti et al. Cureus 2016; *McLain RF et al. Spin J 2005;5:191-201
Ghai B et al. Pain Physician 2014 17(4):277-90
Chien GC, Knezevic N et al. Pain Physician 2014; 17:E509-E524.
Manchikanti L et al. Clin Orthop Relat Res (2015) 473:1940-1956; **DePalma MJ et al. Arch Phys Med Rehabil 2005;86:1477-83.

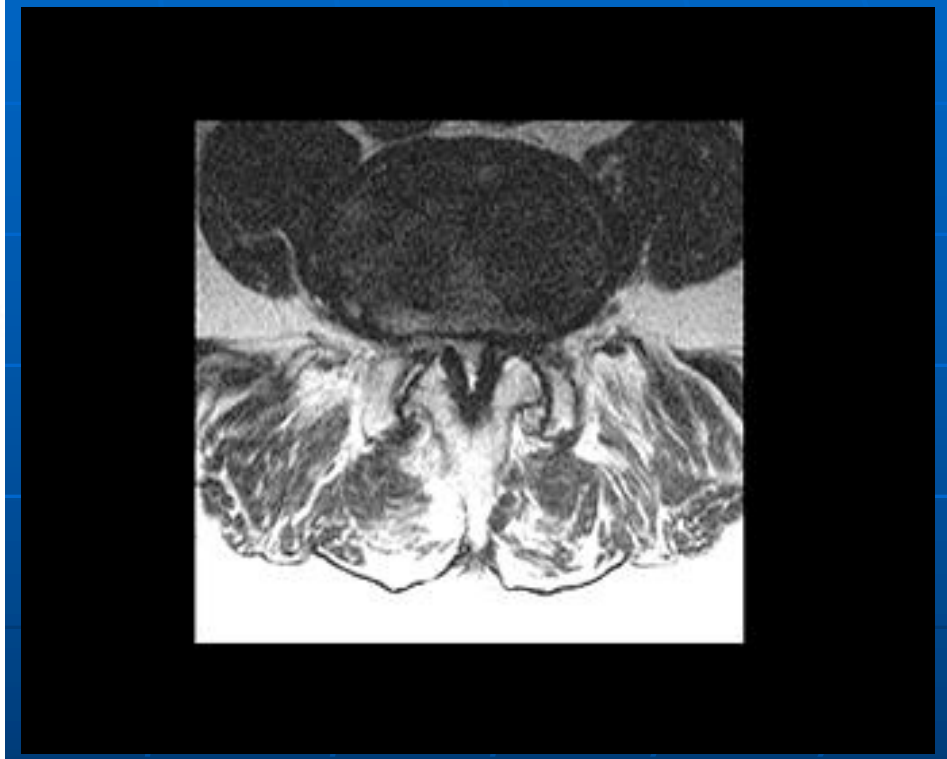
Facet Joint Anatomy

- True synovial joints
- Innervation by 2 medial branches
- Protect against axial rotation, shearing forces, and assist disc in resisting compressive forces in lordotic postures
- Load borne by lumbar facet joints varies between 3-25% of axial load
- Prevalence varies between 5-15% in L-spine, 35-50% in C-spine, and 35-45% in T-spine



Facet Anatomy



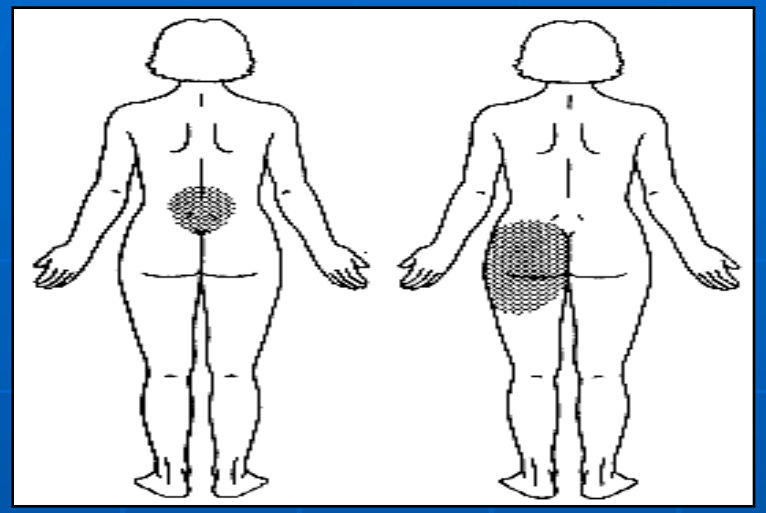


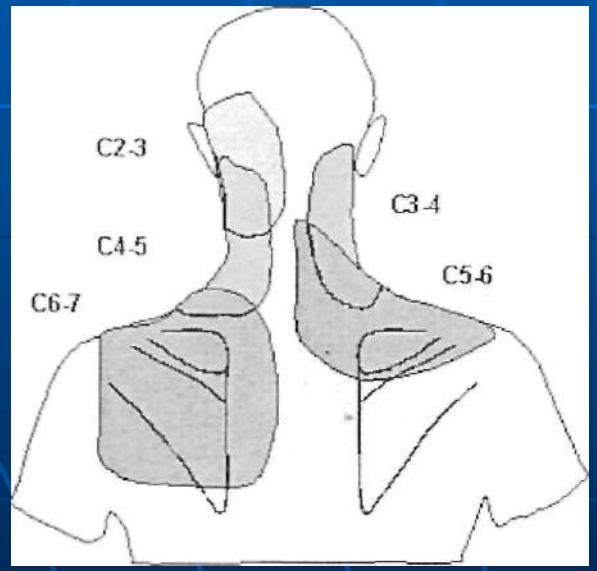
Facet Blocks (medial branch blocks)

- Indication:
  - Deep, aching, diffuse pain in the neck, shoulder, base of skull, thorax, or low back
- Source:
  - Whiplash, joint arthritis, joint enlargement, spine surgery, inflammation, trauma
    - Studies don’t support specific activities associated with lumbar and cervical facetogenic pain
- Approach:
  - Needle inserted with fluoroscopy, patient lying on belly, region of medial branch nerve identified with needle, then local anesthetic injected to block nerve transmission

Cohen SP et al. Nature Reviews (Rheumatology); 2013

Axial Back & Neck Pain

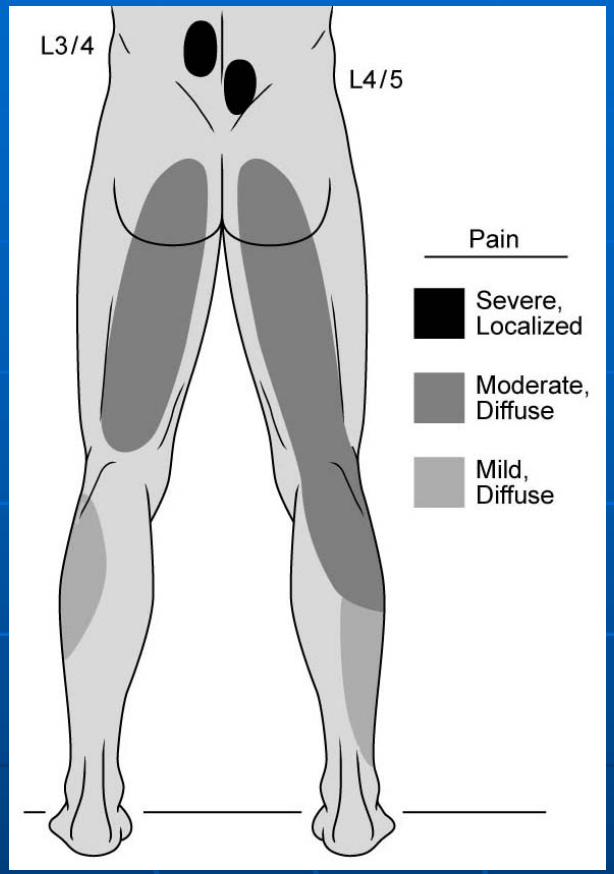




Pain limited to the area of the lumbo-sacral junction

- Facet arthopathy
- Referral patterns from cervical facets

Lumbar Facet Syndrome



- Axial back pain
- Worse with extension
- Radiographic evidence of facet arthropathy is not always present

Rathmell JP. *Atlas of Image-Guided Intervention in Regional Anesthesia and Pain Medicine.* Lippincott Williams & Wilkins, 2006.

Lumbar Facet Blocks/Denervation

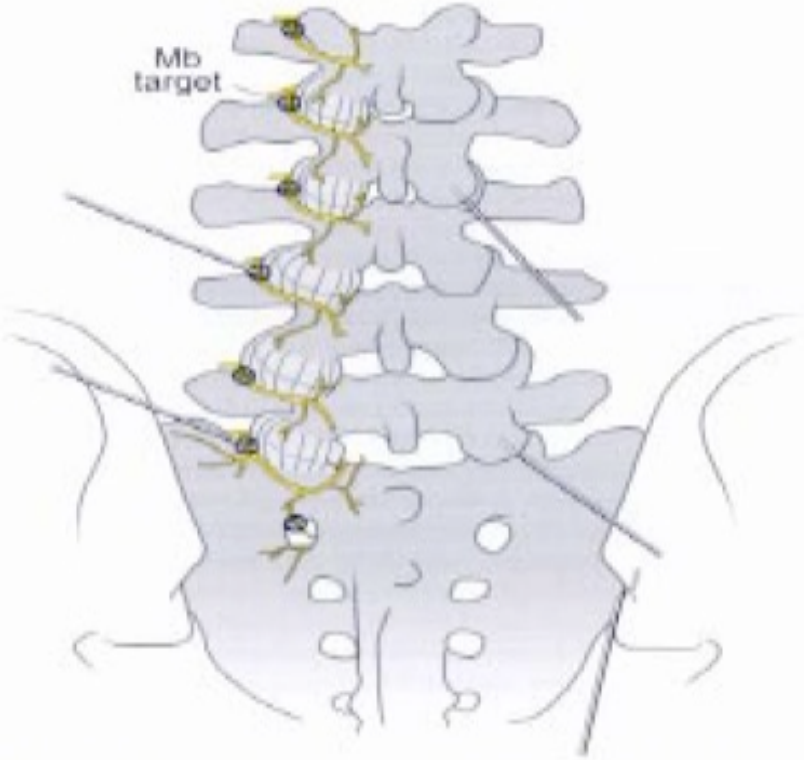
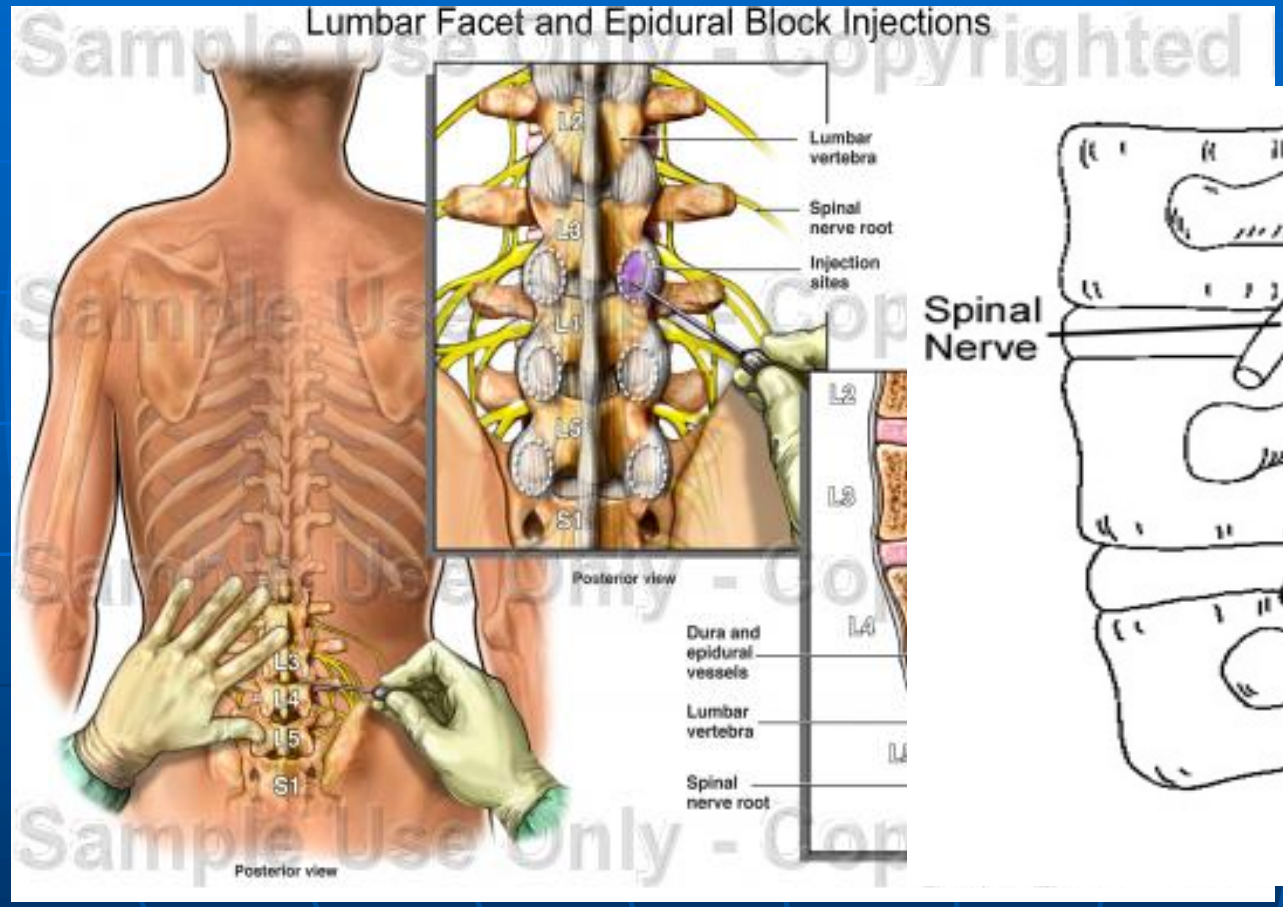
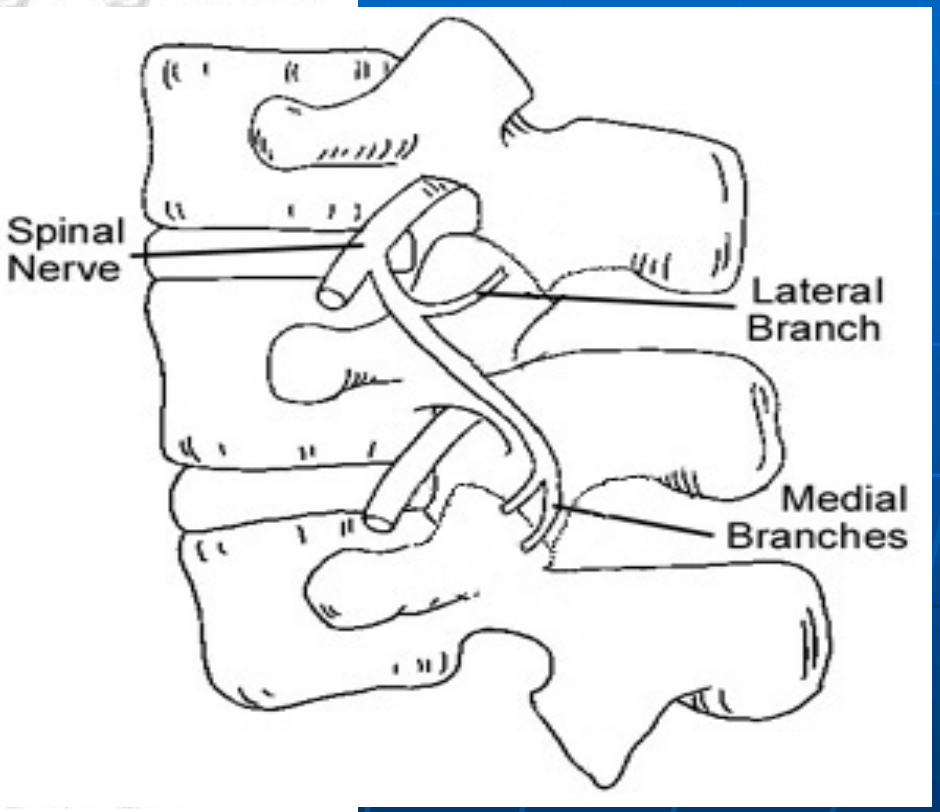


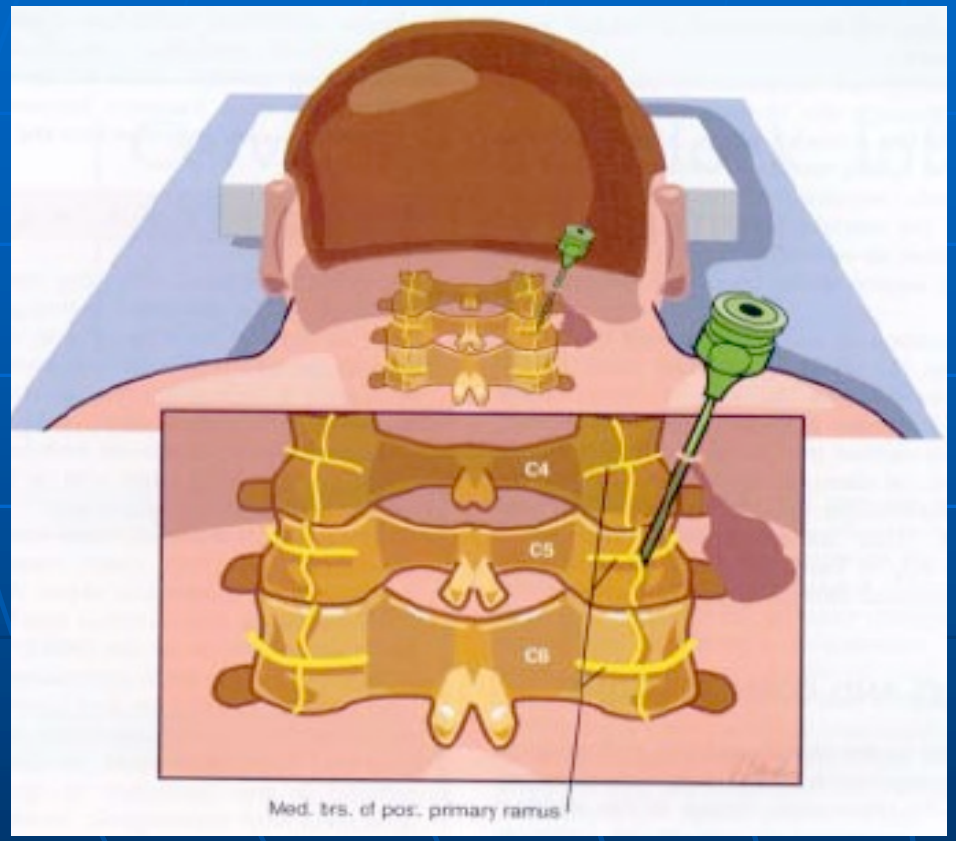
FIG. 28-11. Diagram of lumbar zygapophysial joint blocks (medial branch (M.) and intra-articular). Diagram of needle placements for media branch *(left)* and intra-articular *(right)* injections in the lumbar spine. The joint capsule has been removed to demonstrate the intra-articular entry on the right. The targets for medial branch block are indicated on the left *(hatched circles)*. The sacro-iliac joint is most easily entered from the inferior aspect of the joint as indicated in the diagram. The optimum aperture can be obtained by manipulation of the angle of the fluoroscopic beam as discussed in the text.

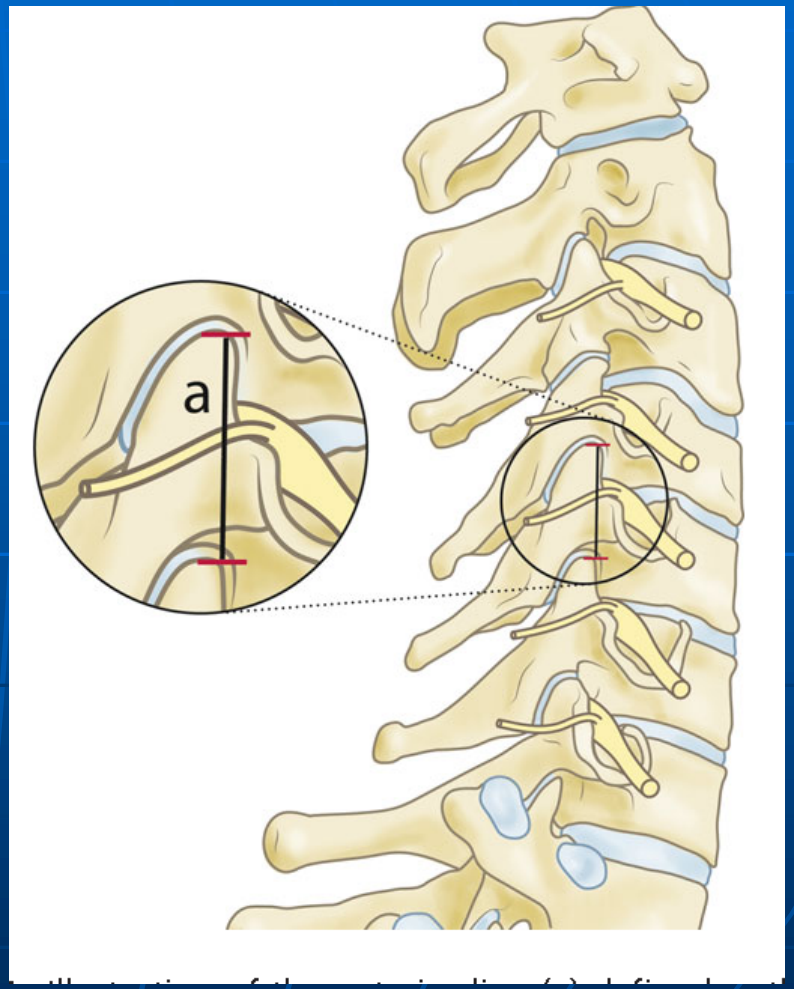
Lumbar Facet Blocks/Denervation





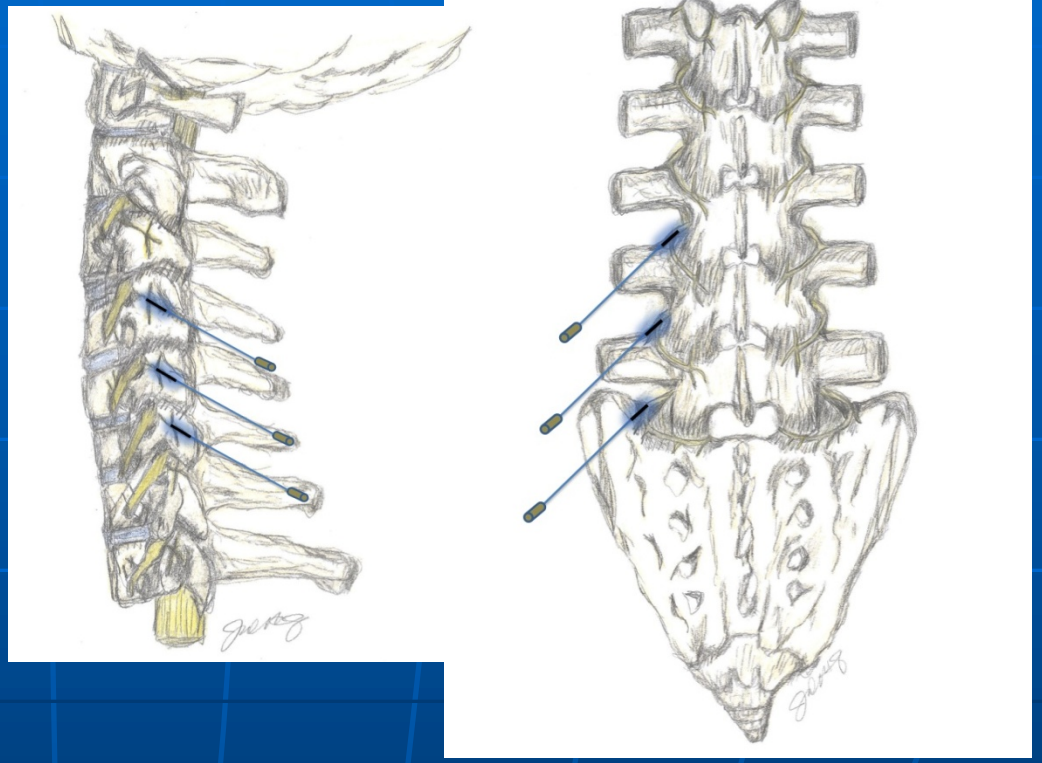
Cervical Facet Blocks/Denervation





Is Radiofrequency Denervation Effective?

- Well-conducted controlled studies have established the efficacy of RF denervation (neck and low back)
- Good evidence for managing low back pain - short & and long term relief



Manchikanti L[1], Abdi S, Atluri S,Pain Physician. 2013 Apr;16(2 Suppl):S49-283
Manchikanti L, Kaye AD, Soin A, Albers SL, Beall D, Shah RS, Atluri S, Abd-Elsayed A, Abdi S, Aydin S, Buenaventura SB, Cabaret J, Calodney AK, Candido KD, Christo PJ, et al Comprehensive Evidence-Based Guidelines for Facet Joint Interventions in the Management of Chronic Spinal Pain: American Society of Interventional Pain Physicians (ASIPP) Guidelines Facet Joint Interventions 2020 Guidelines. *Pain Physician* 2020; 23 (3S):S1-S127.

Clinical Predictors of Success and Failure for Lumbar Facet Radiofrequency Denervation

Steven P. Cohen, MD,† Robert W. Hurley, MD, PhD,* Paul J. Christo, MD,* James Winkley, MD,† Meraj M. Mohiuddin, MD,‡ and Milan P. Stojanovic, MD‡*

Success Predictors

- Paraspinal tenderness
- Absence of psychopathology
- Fewer levels treated/ affected

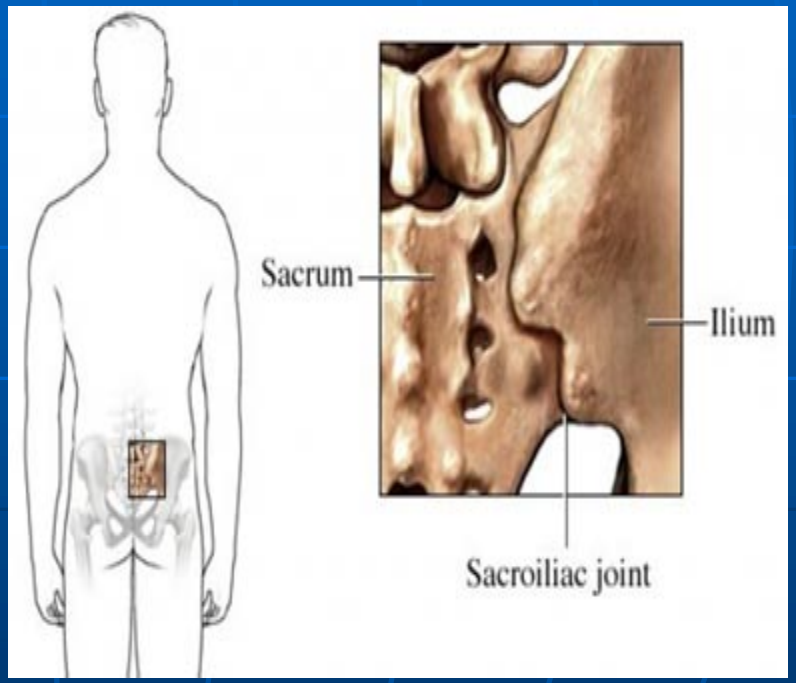
- **Repeat RF** – 85% success in lumbar and cervical spine with similar previous duration
- **Complications** – Serious <1%
  - Neuritis <5% and decrease with steroid use

Failure Predictors

- Long duration of symptoms (6.6 V 4.9 yrs)
- Higher baseline pain scores & disability
- "Facet loading"
- Previous back surgery
- Opioid use

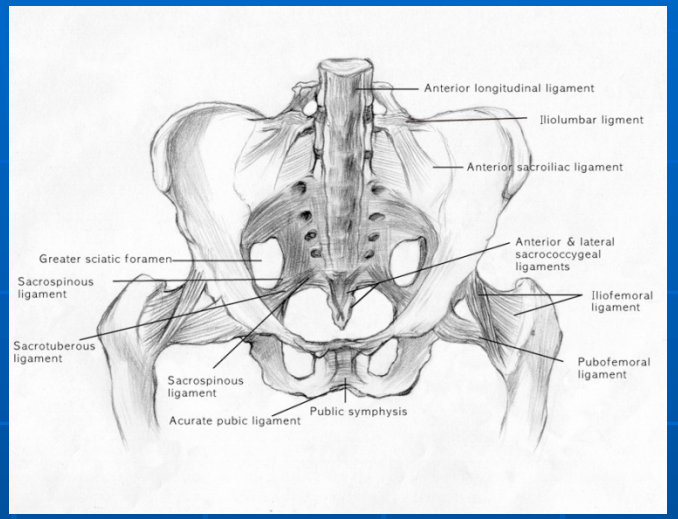
Cohen SP et al. Nature Reviews (Rheumatology); 2013

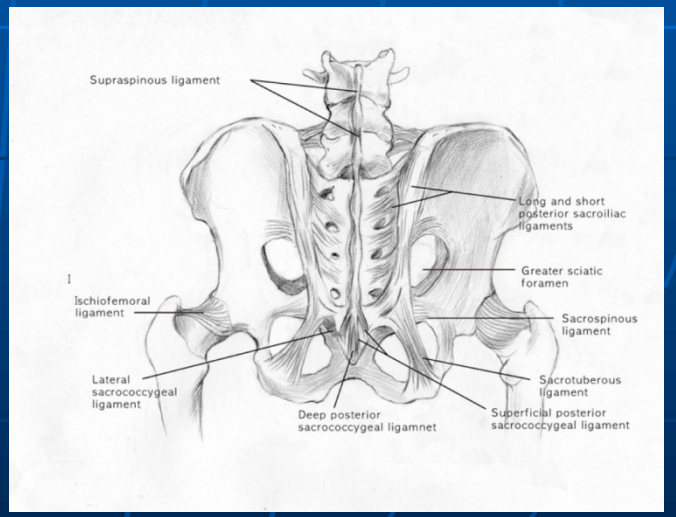
Sacroiliac Joint Disease



Sacroiliac Joint Pain Prevalence Rates

- Underestimated by surgeons & PCPs
- Heterogeneous condition
- Represents 15%-30% of cases of axial LBP below L5 (PSIS)
- Bi-modal peaks in prevalence rates (young and older pts)
- Intra- and extra-articular (ligamentous) etiologies
- 40%-50% 2^{o} to trauma



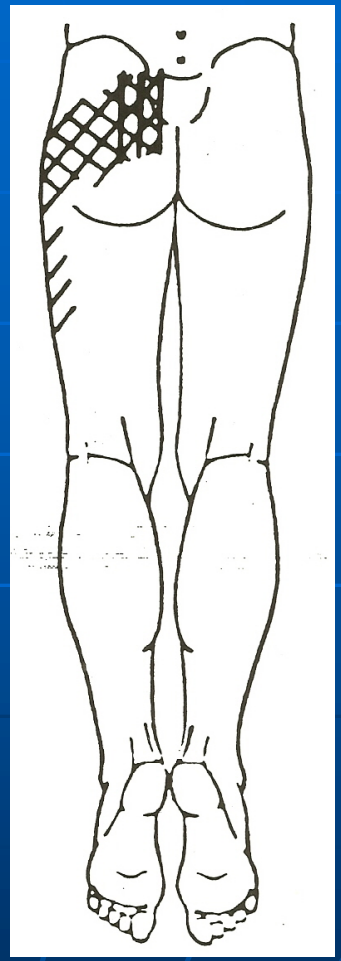


Predisposing Factors

- Rotation and axial loading
- Leg length discrepancy
- Pelvic & scapular obliquity
- Scoliosis
- Previous back surgery
- Lumbar pathology/ Transitional anatomy
- Pregnancy

SI Joint Pain Referral Zones

- Retrospective analysis in 50 pts dx'ed with SIJ pain based on diagnostic blocks
  - 47 described buttock pain (94%)
  - 36 described lower lumbar pain (72%)
  - 25 had lower extremity pain (50%)
  - 14 had leg pain distal to the knee (28%)
  - 7 described groin pain (14%)
  - 6 reported foot pain (12%)



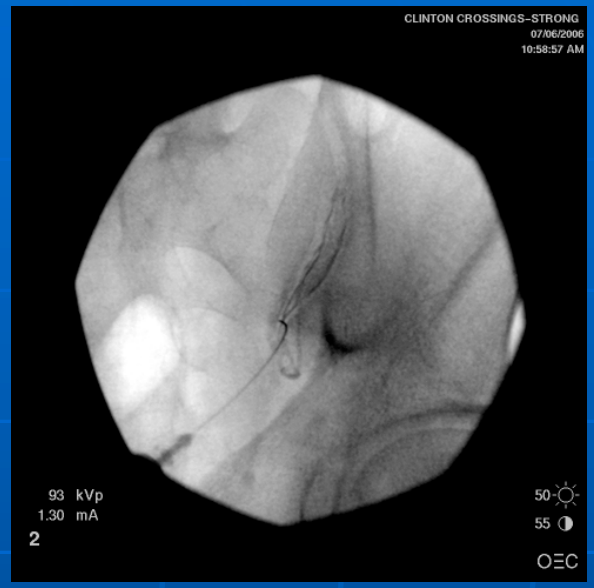
Michael J Depalma , Jessica M Ketchum, Brian S Trussell, Thomas R Saullo, Curtis W Slipman. Does the location of low back pain predict its source? PMR 2011 Jan;3(1):33-9

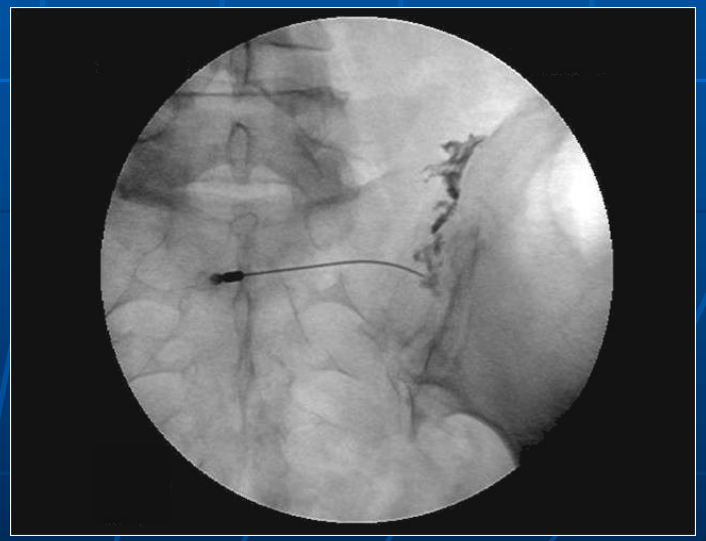
Sacroiliac Joint Injection

- Indications:
  - Pain in the lumbar spine, buttock, groin, back of thigh
- Source:
  - Fall, sudden heavy lifting, prolonged lifting & bending, arthritis
- Approaches:
  - Intraarticular injection under x-ray or CT/Ultrasound
  - Patient is on belly, needle inserted into joint, contrast injected, local anesthetic with steroid deposited

Are SI Joint Injections Effective?

- Controlled studies have demonstrated short-term relief with sacroiliac joint injections
- Limited evidence for chronic SI joint pain





Manchikanti L[1], Abdi S, Atluri S,Pain Physician. 2013 Apr;16(2 Suppl):S49-283.

Radiofrequency Denervation for SIJ Pain

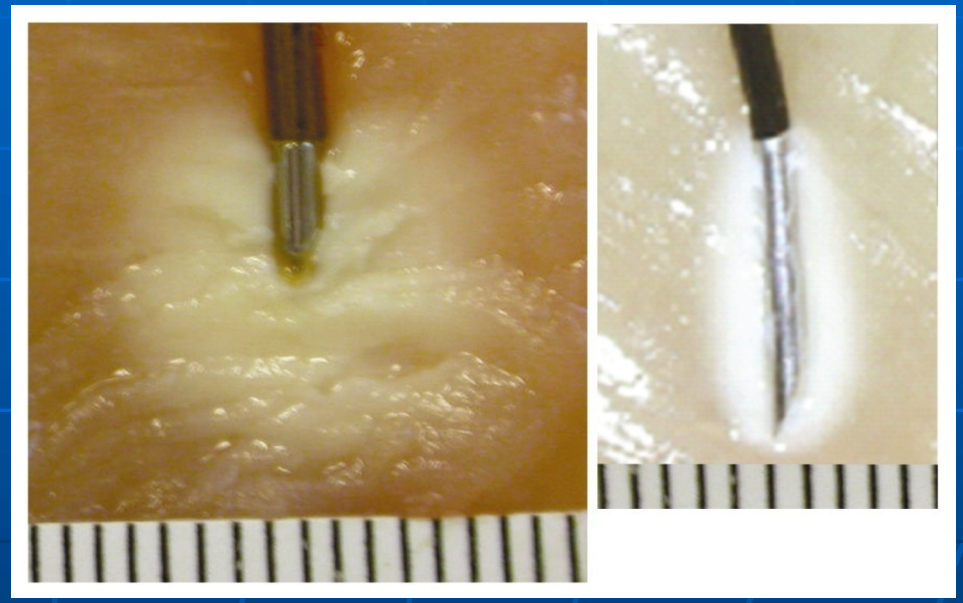
Challenges & Effectiveness

- May provide long-term relief to those who obtain temporary relief from blocks
- Lateral branches from L(4)5-S4 innervate ligamentous structure, not capsule
- Wide variability in number and location of nerves
- Small lesions w/ conventional RF and variability in nerve location increase chance for treatment failure (elliptical lesion)
  - Larger lesions may increase success rate **(Cooled RF) – spherical lesion**
- Evidence fair for cooled RF
  - 3-12 months of relief
- Limited evidence for conventional RF
- Factors associated with (+) outcome: short duration of sxs, no opioids, lower baseline pain scores, no psychopathology, younger age

Manchikanti L[1], Abdi S, Atluri S,Pain Physician. 2013 Apr;16(2 Suppl):S49-283.

Cooled vs. Conventional Radiofrequency

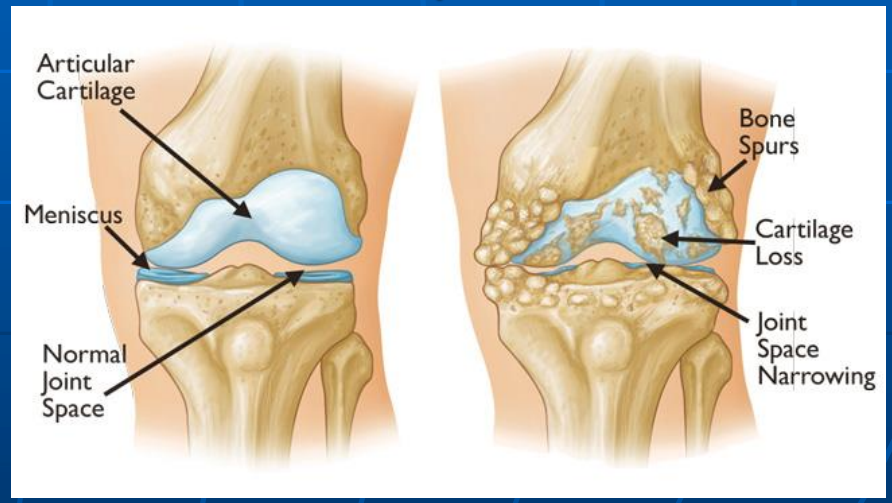
- Without cooling, lesion size is constrained by heat generated in tissue adjacent to electrode
- Cooling electrode removes constraints of tissue charring
- Lesion size is increased > 2-fold and extends distal to electrode



Spherical Shape Elliptical Shape

Osteoarthritic Knee Pain

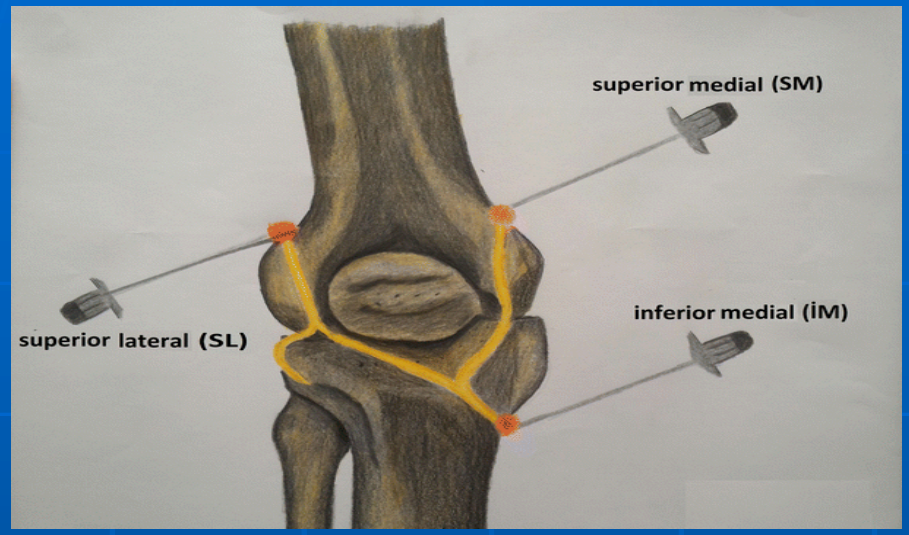
- Chronic knee pain is common
  - Affects 250 million people worldwide
- 15% with persistent pain after total knee arthroplasty (TKA)
- Some studies show that 50% report continued knee pain after surgery
- Not all patients candidates (TKA)
  - Age
  - Comorbidity (obesity)
- Current therapies
  - Intraarticular steroids, hyaluronic acid, topical NSAID, oral NSAIDS, PT → **If** not work or short term relief?



Davis T, Loudermilk E, DePalma et al. Reg. Anesh Pain Medicine (2018);43 (1)
Lewis GN, Rice DA, McNair PJ, et al. Pain Medicine 2018;19:1628-1638
Murray CJ, Vos T, Lozano R, et al. Lancet. 2012;380;2197-2223

Cooled Radiofrequency Ablation

Genicular Nerve Targets

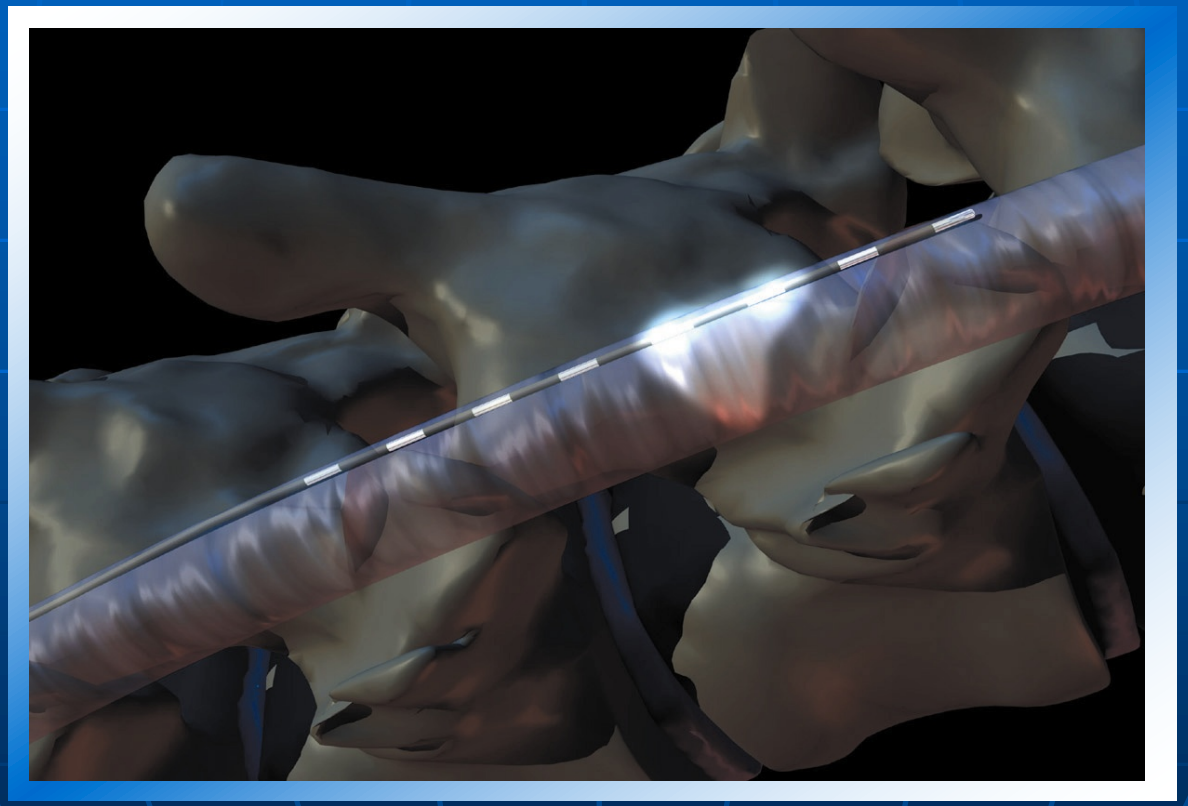


- Genicular sensory nerve innervation to the knee joint
- Prognostic blocks ⟶ genicular nerve ablation
- Outpatient procedure, sedation, <45 min
- At least 50% relief at 6 months compared with 16% relief with intraarticular steroid
- At 1 year, some patients still report at least 50% relief
- Improved knee function

Davis T, Loudermilk E, DePalma et al. Reg. Anesh Pain Medicine (2018);43 (1)
Santana Pineda MM, Vanlinthout LE, Moreno MA, et al. Reg Anesth Pain Med. 2017;42:62-68

Neuromodulation

Precise delivery of small doses of electricity or drugs directly to targeted nerve sites.



Spinal Cord Stimulation
Device Components

- Pulse generators: Conventional IPG (2-5 yrs), **Rechargeable IPG (9-10 yrs)**
- Transmitter/ patient controller (programmer)
- Leads/Electrodes
- Clinician programmer

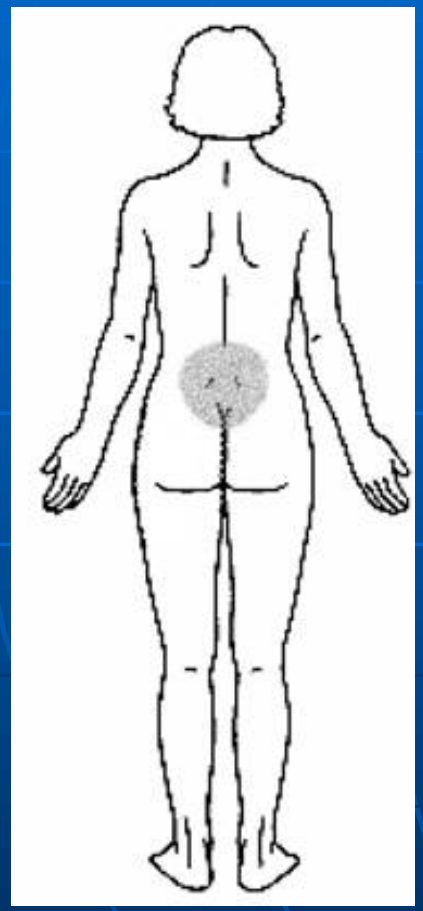
Patient Programmer

Pulse Generator

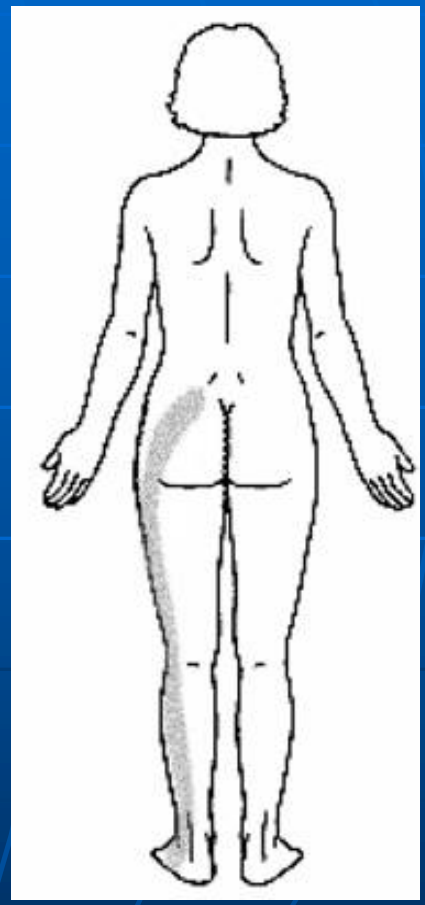
Lead

Spinal Cord Stimulation

indications/*applications*



- Failed Back Surgery Syndrome
- Radicular Pain
- Postlaminectomy Pain
- Degen Disc Dz
- CRPS (RSD)
- Interstitial cystitis
- Epidural Fibrosis
- Arachnoiditis
- *Inoperable ischemic leg pain*
- *Refractory angina*



Trial

- Trial carried out first under fluoroscopy
- Electrode placed on top of epidural space
- At home trial lasts approx. 6 days
- If effective, implantation of electrode and battery occurs in the operating room

Candidates

- Failure of more conservative therapies
- 50% pain reduction with test lead
- Area of pain relieved or covered by paresthesias, or experience relief without paresthesias, and well tolerated
- Mood/sleep/activity improvement
- Psychosocial comorbidities addressed

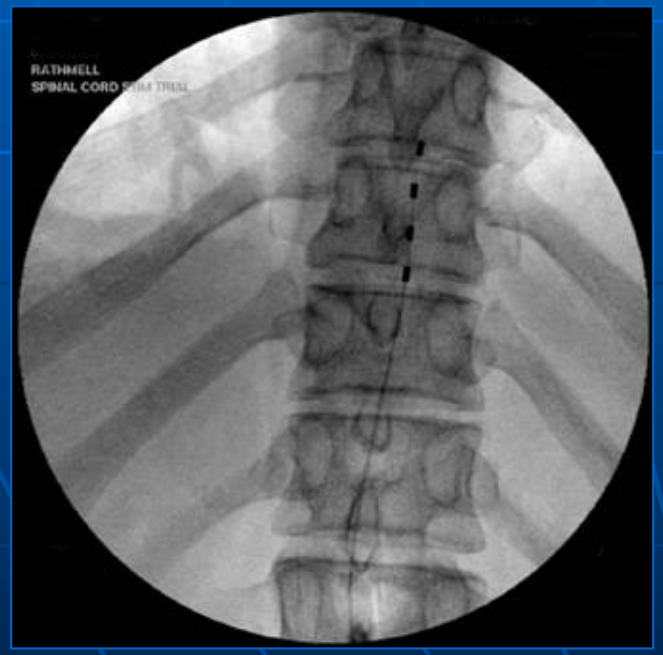
Current Mechanism
Animal Studies

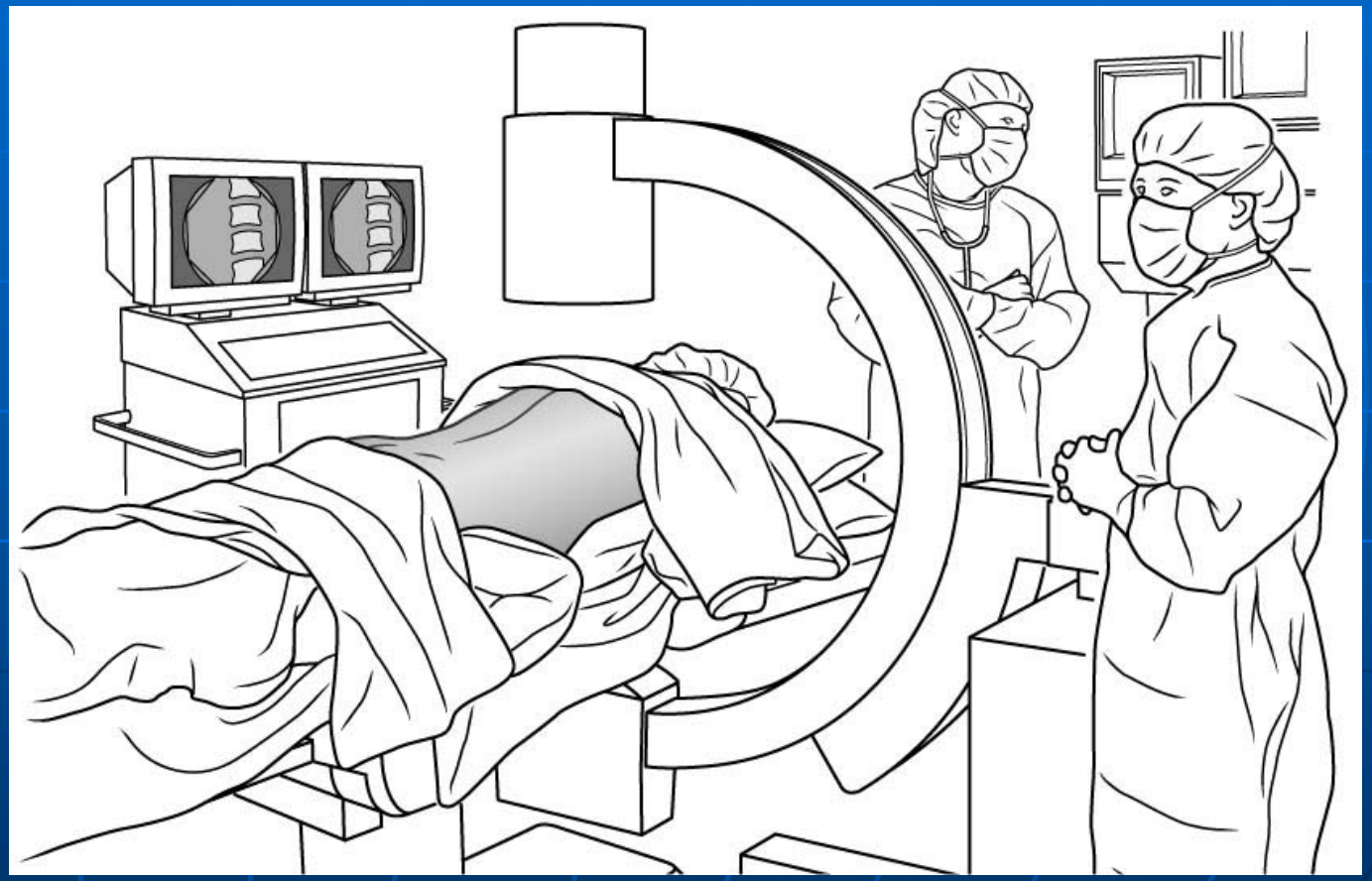
- Electrical stimulation may activate A alpha and A Beta afferent fibers, trigger spinal inhibitory interneurons, and interrupt pain signals in dorsal horn
- SCS may release serotonin and NE into dorsal horn to decrease pain transmission pre- and post synaptically
- Releases inhibitory neurotransmitter, GABA ⟹ decreases nerve hyperexcitability
- May release acetylcholine ⟹ binds to muscarinic receptors for analgesia
- SCS capable of blocking, and reversing central sensitization in the spinal cord
  - Central sensitization – changes in the spinal cord that lead to pain amplification following an injury or in chronic pain conditions
  - *Early intervention may be quite important*
- Pain suppression in the brain (supraspinal effects)

Guan Y. Spinal Cord Stimulation: Neurophysiological and Neurochemical Mechanisms of Action. *Current Pain Headache Rep* (2012) 16:217-225
Cui JG et al. Spinal cord stimulation attenuates augmented dorsal horn release of excitatory amino acids in mononeuropathy via GABAergic mechanism. *Pain* 1997, 73,87-95
Schechtmann, G et al. Cholinergic mechanisms involved in the pain relieving effect of spinal cord stimulation in a model of neuropathy. *Pain* 2008, 139, 136-145

Implantation

(Operating Room)





Manufacturers

Boston Scientific

Abbott

Nevro

Nalu

Medtronic

High Frequency SCS Therapy (10 kHz)

Device

- Capable of HF10 therapy (**no paresthesias**)
- Senza® SCS System
- Pulse rate of 2 to 10,000 Hz
- Full body MRI Senza I; Head, neck extremities Senza II for 1.5T and 3T scanners
- CE marked and FDA approved with 10+ year, rechargeable battery life

- RCT comparative study using HF SCS versus traditional SCS for Chronic LBP & Leg Pain
  - 198 patients randomized with chronic, intractable pain of trunk and/or limbs
  - HF SCS superior to traditional (low frequency) SCS for back and leg pain
  - Effects persisted for 12 months
  - Value – SCS often relieves radicular pain, but less effective for back pain. High frequency may better address back pain

Kapural L, Yu C, Doust MW, et al. *Anesthesiology* 2015, V 123, (4)

Battery-Free System

- **No Implantable Batteries**
- Percutaneous IPGs (battery) and Anchors
- Circuitry enclosed within lead
- Wireless Power Transfer and Recharging
- Wireless Programming
- Eight contact lead

Dorsal Root Ganglion

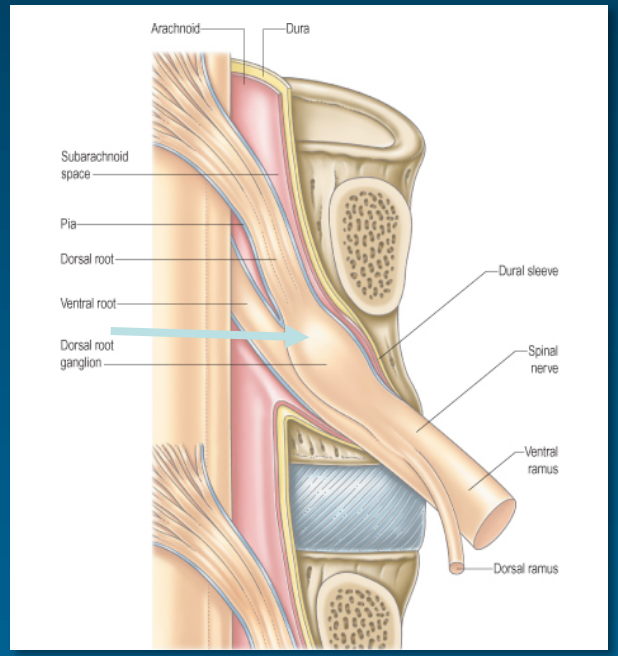


Image from: Gray's Anatomy (2005). Standring, S. (Ed.).

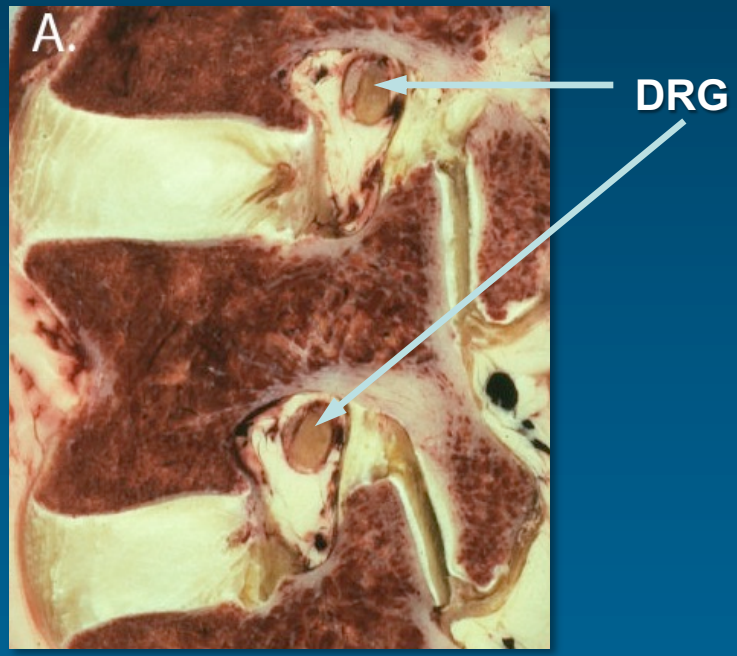
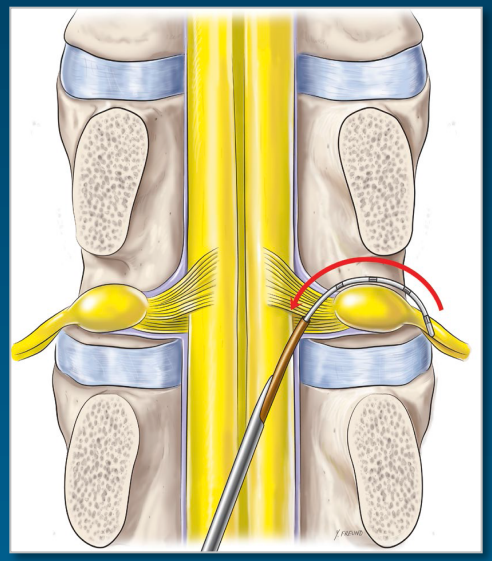


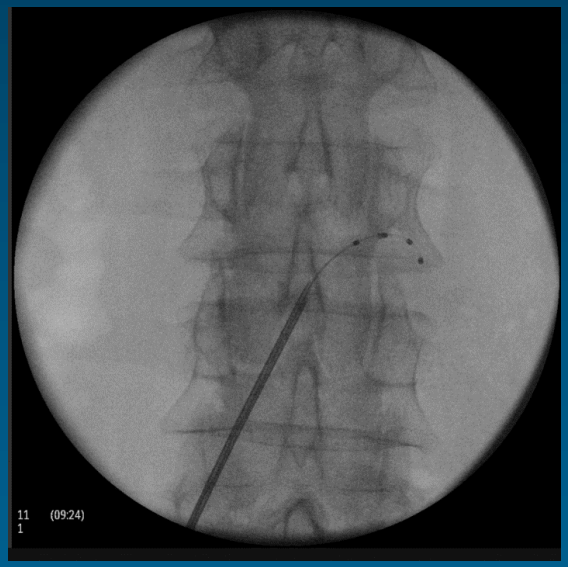
Image from: Hogan Q. Reg Anesth Pain Med. 2010.

The DRG is a critical structure, not only in pain transmission, but even more in transduction and modulation

Hogan, Q. Labat Lecture: The Primary Sensory Neuron: Where it is, What it Does and Why it Matters. Reg Anesth Pain Med. 2010; 35 (3): 306-311.

Dorsal Root Ganglion Stimulation



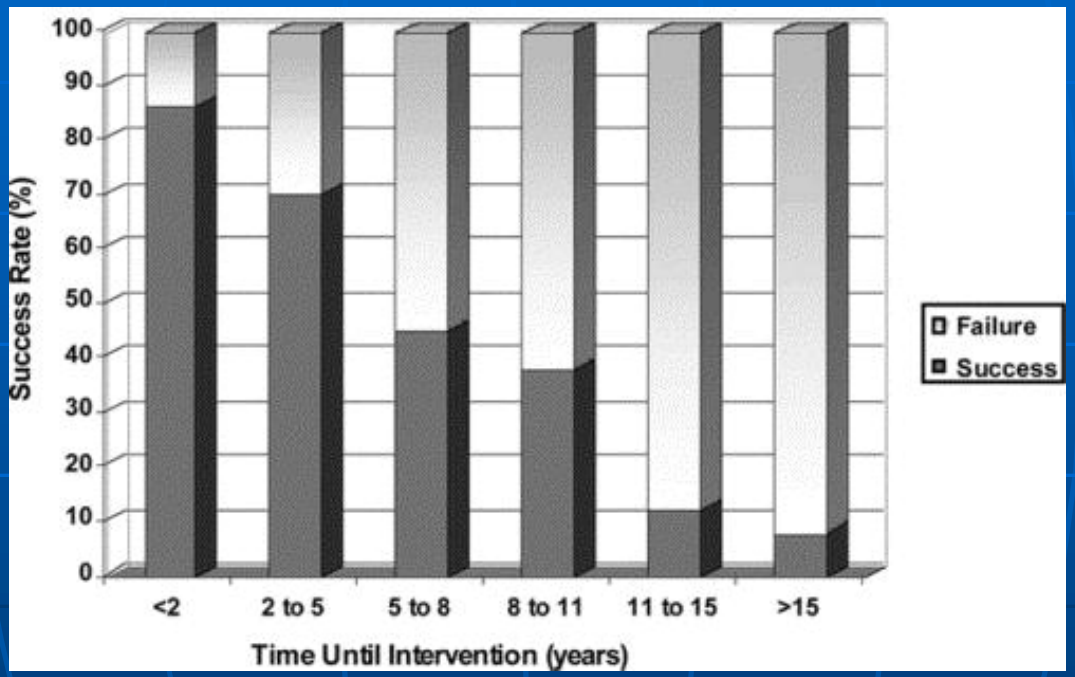


- More precise targeting and less energy requirements due to limited CSF around the DRG
- Prevention of unintentional stimulation due to the separation of sensory and motor fibers
- After 12 months, significantly more DRG stimulation patients with **CRPS** achieved pain relief and treatment success versus control SCS (74.2% vs. 53.0%)
- Approved for CRPS I and II in the U.S.

Deer TR, Levy RM, Kramer J et al. 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. Pain 2017;158:669–681.

Success Rate

Time elapsed prior to intervention affects pain relief



Kumar K, Rizvi S, Nguyen R, et al. Impact of Wait times on Spinal Cord Stimulation Therapy Outcomes. *Pain Practice* (2013)

Cost-Effectiveness: SCS vs Alternative

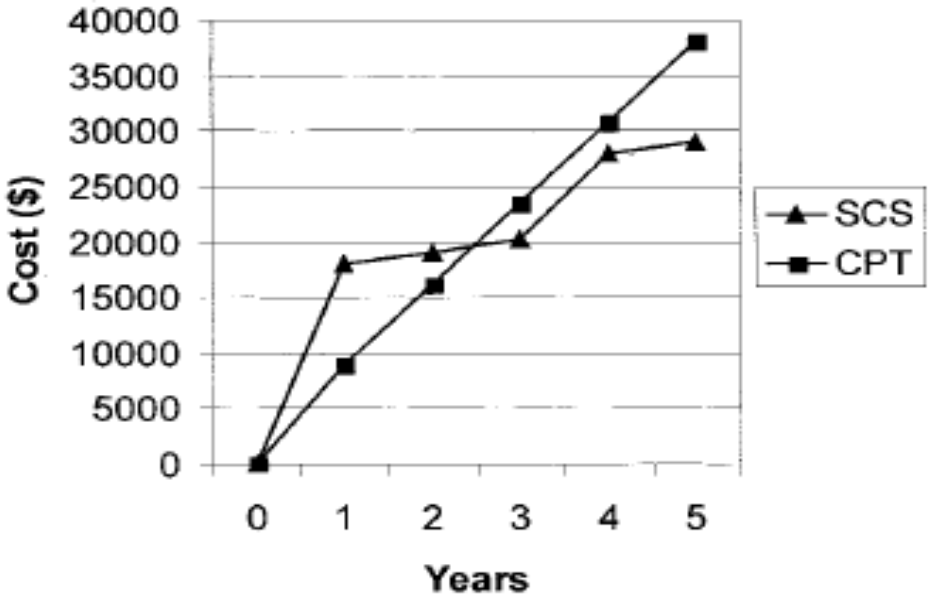


FIGURE 1. *Graph illustrating the cumulative costs of SCS versus CPT for a 5-year period. The 2.5-year payoff period should be noted.*

Kumar et al, Treatment of Chronic Pain with Spinal Cord Stimulation vs. Alternative therapies: Cost-effectiveness analysis . *Neurosurgery* 2002;51:106-115

Pain Medicine, 0(0), 2019, 1–16
doi: 10.1093/pm/pnz185
Review Article

OXFORD

Spinal Cord Stimulation vs Conventional Therapies for the Treatment of Chronic Low Back and Leg Pain: A Systematic Review of Health Care Resource Utilization and Outcomes in the Last Decade

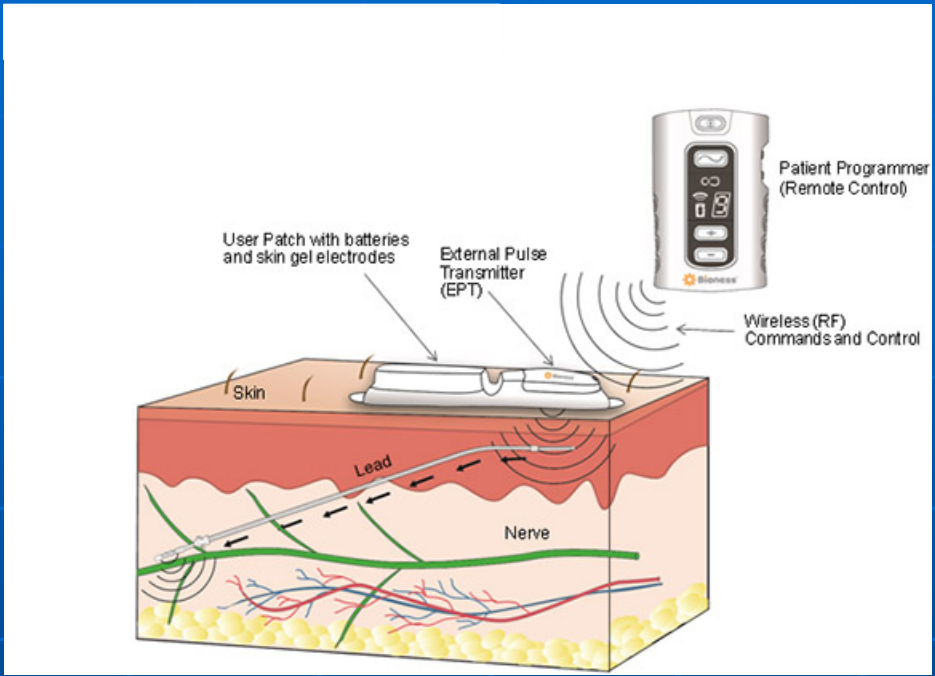
Charles A. Odonkor, MD,* Sebastian Orman,† Vwaire Orhurhu, MD, MPH,‡ Martha E. Stone, MS,§ and Shihab Ahmed, MBBS*

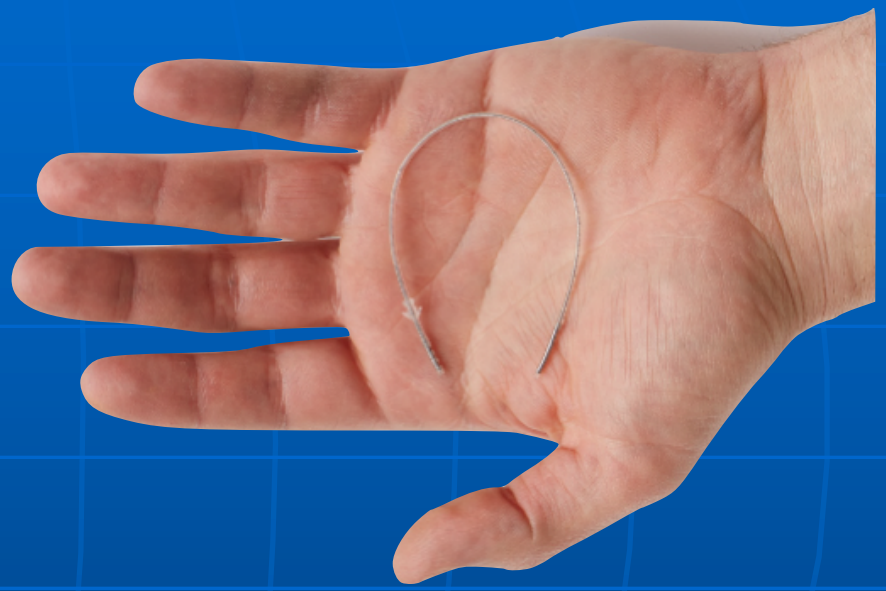
*Division of Pain, Department of Anesthesia, Critical Care and Pain Medicine, Harvard Medical School, Massachusetts General Hospital, Boston, Massachusetts; †Department of Orthopaedics, Georgetown University School of Medicine, Washington, DC; ‡Department of Anesthesiology, Critical Care and Pain, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts; §Treadwell Library, Massachusetts General Hospital, Boston, Massachusetts, USA

"Evidence is low to fairly favorable of SCS as cost effective treatment of chronic low back and leg pain."

2019 Study

Peripheral Nerve Stimulation

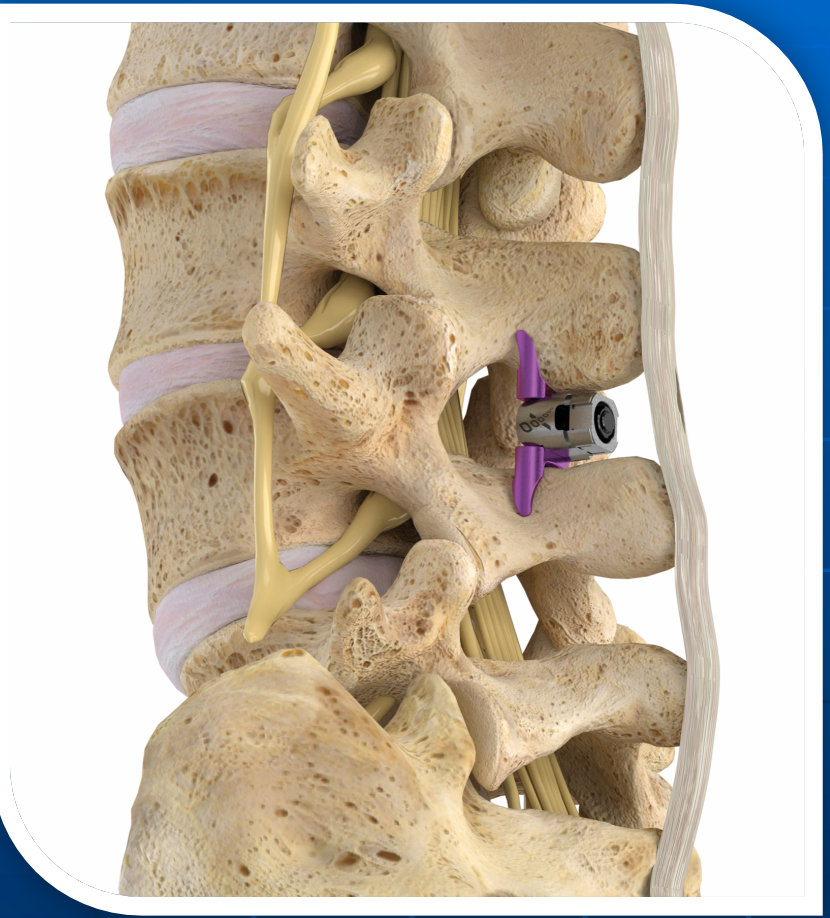




- Peripheral, intractable chronic pain (neuropathic) from posttraumatic/postsurgical neuralgia
- Entrapment syndromes, intercostal neuralgias, post stroke shoulder pain (axillary nerve)
- Upper extremity, lower extremity, trunk. Not face
- Significant pain reduction at 3 months, and safe at 12 months
- FDA cleared

Deer T, Pope J, Benyamin R, et al. Prospective, multicenter, randomized double blind, partial crossover study to assess safety and efficacy of the novel neuromodulation system in the treatment of patients with chronic pain of peripheral origin. *Neuromodulation* 2016;19:91-100

Vertiflex
Lumbar Spinal Stenosis



Basic Indications

Persistent leg/buttock/groin pain relieved in flexion/ LBP

≥6 mos. of conservative treatment without significant relief

Diagnosis of degenerative moderate lumbar spinal stenosis

Clinical Interventions in Aging

Dovepress
open access to scientific and medical research

Open Access Full Text Article

ORIGINAL RESEARCH

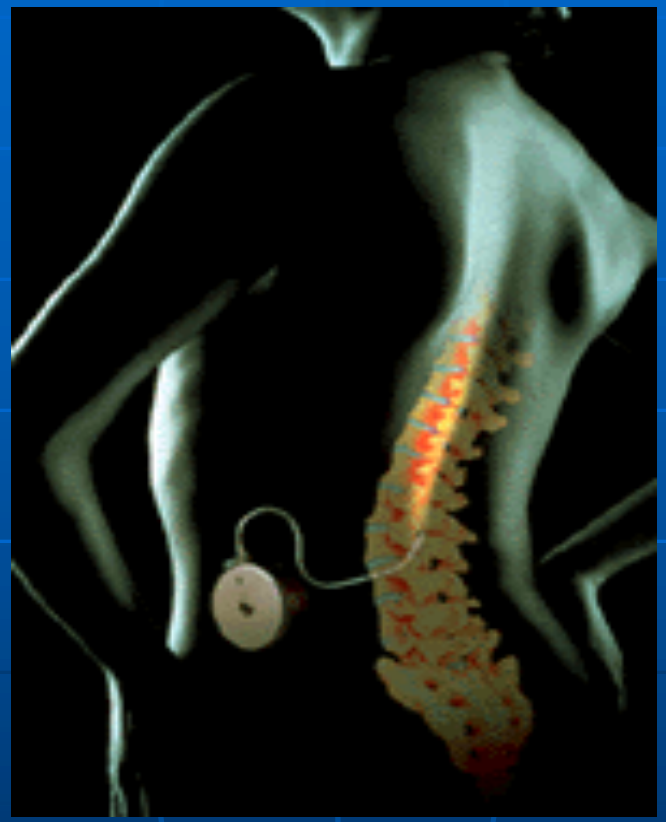
Five-year durability of stand-alone interspinous process decompression for lumbar spinal stenosis

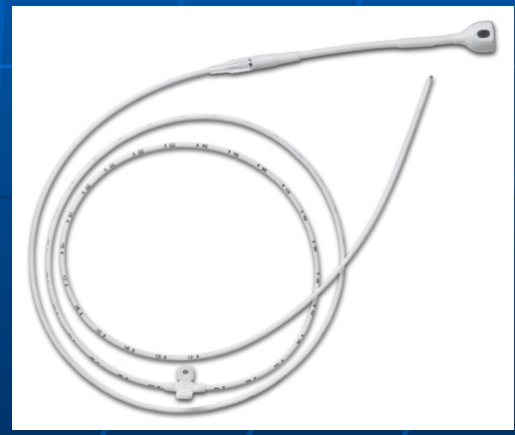
This article was published in the following Dove Press journal:
Clinical Interventions in Aging
6 September 2017
Number of times this article has been viewed

75% improvement in leg pain scores from baseline at 5 years

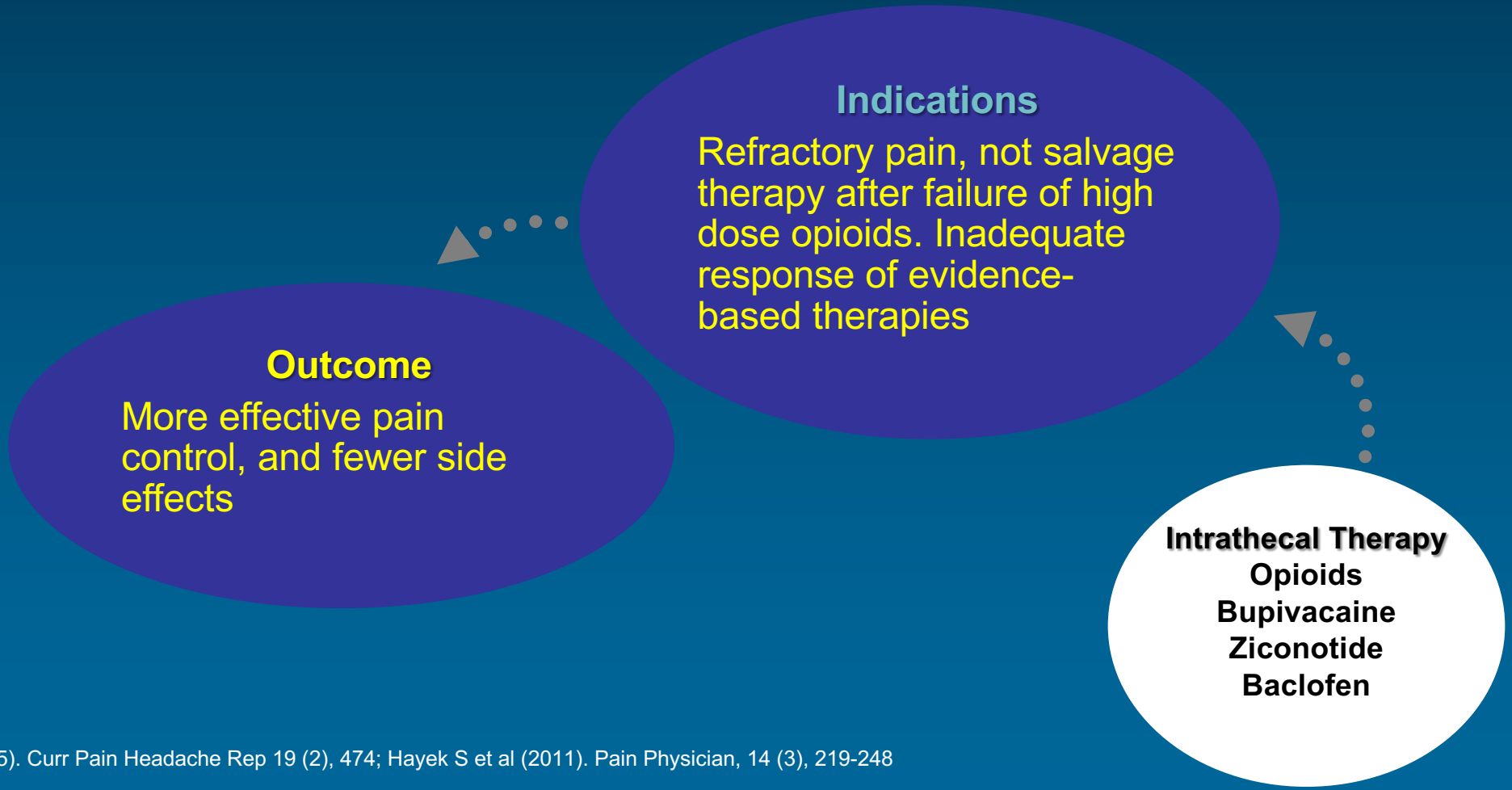
Implantable Drug Delivery System

Pain Pumps





Implantable Drug Delivery System



Rizvi S, Kumar K (2015). Curr Pain Headache Rep 19 (2), 474; Hayek S et al (2011). Pain Physician, 14 (3), 219-248

Deer TR, Hayek SM, Pope JE….Christo P, Kim P, Huntoon EM, Krames E, Mekhail N. 2017. The Polyanalgesic Consensus Conference (PACC): Recommendations for Trialing of Intrathecal Drug Delivery Infusion Therapy. Neuromodulation 2017;20:133-154; Deer TR, Pope JE, Hayek SM, et al. The Polyanalgesic Consensus Conference (PACC) Recommendations on Intrathecal Drug Infusion Systems Best Practices and Guidelines. Neuromodulation 2017;20:96-132