Modalities for Treating Chronic Pain

David L. Caraway, M.D., Ph.D.

CEO, Medical Director

Center for Pain Relief, Tri-State

St. Mary's Regional Medical Center

Huntington, WV

Definitions

Acute Pain

- Usually cause is understood
- Often a result of injury, disease or surgery
- Treatment is short term and curative

  Analgesics, nerve blocks, PCA, epidural

Definitions

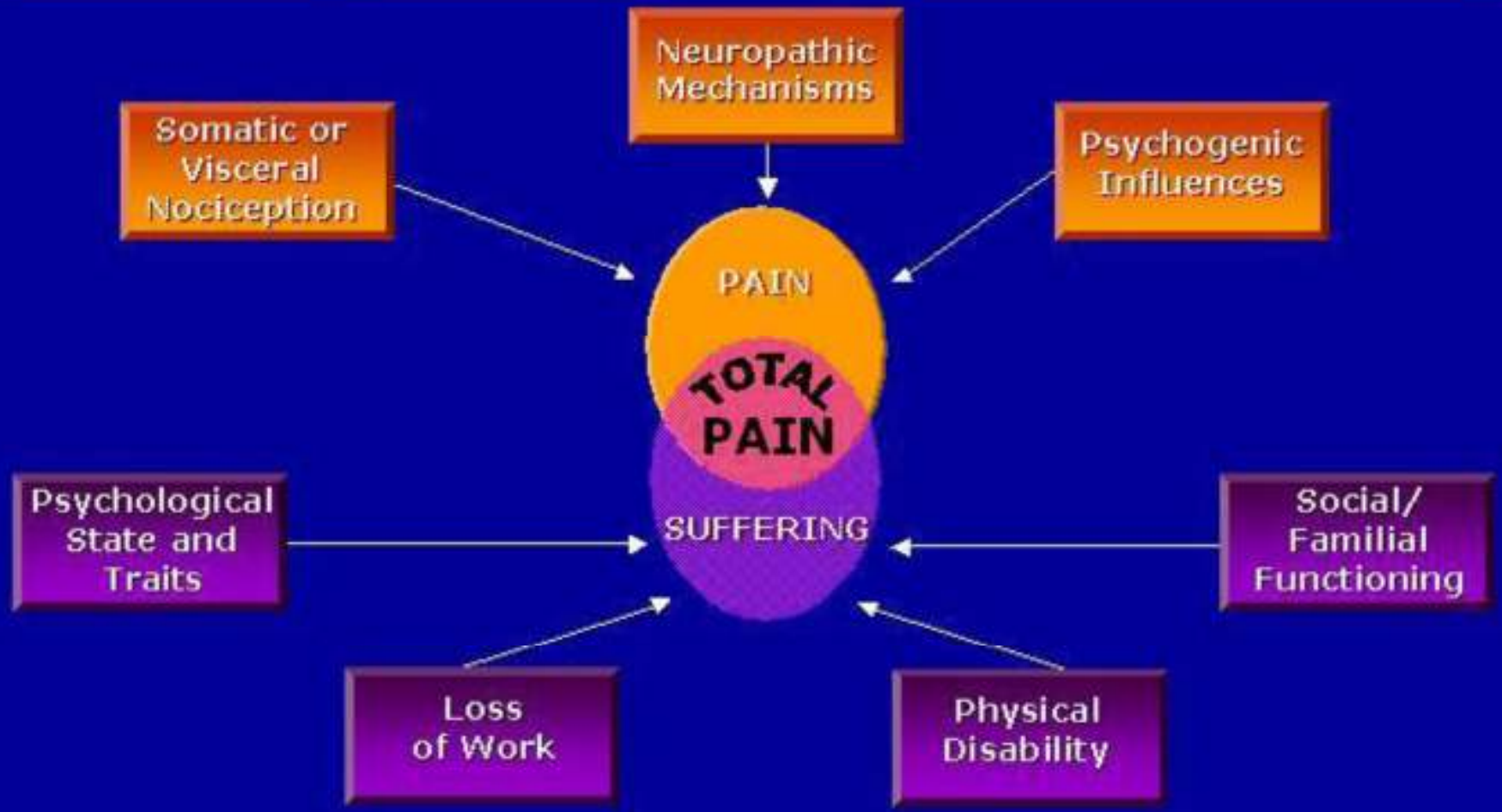
Chronic Pain

- Lasts more than three months
- May not be linked to an actual physiological event
- Often accompanied by other psycho-social disorders
- Treatment is goal oriented, multidisciplinary

Chronic Pain Patients

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

The Complex Nature of Pain



(Adapted from Barkin, 1996)

Treatments for Chronic Pain

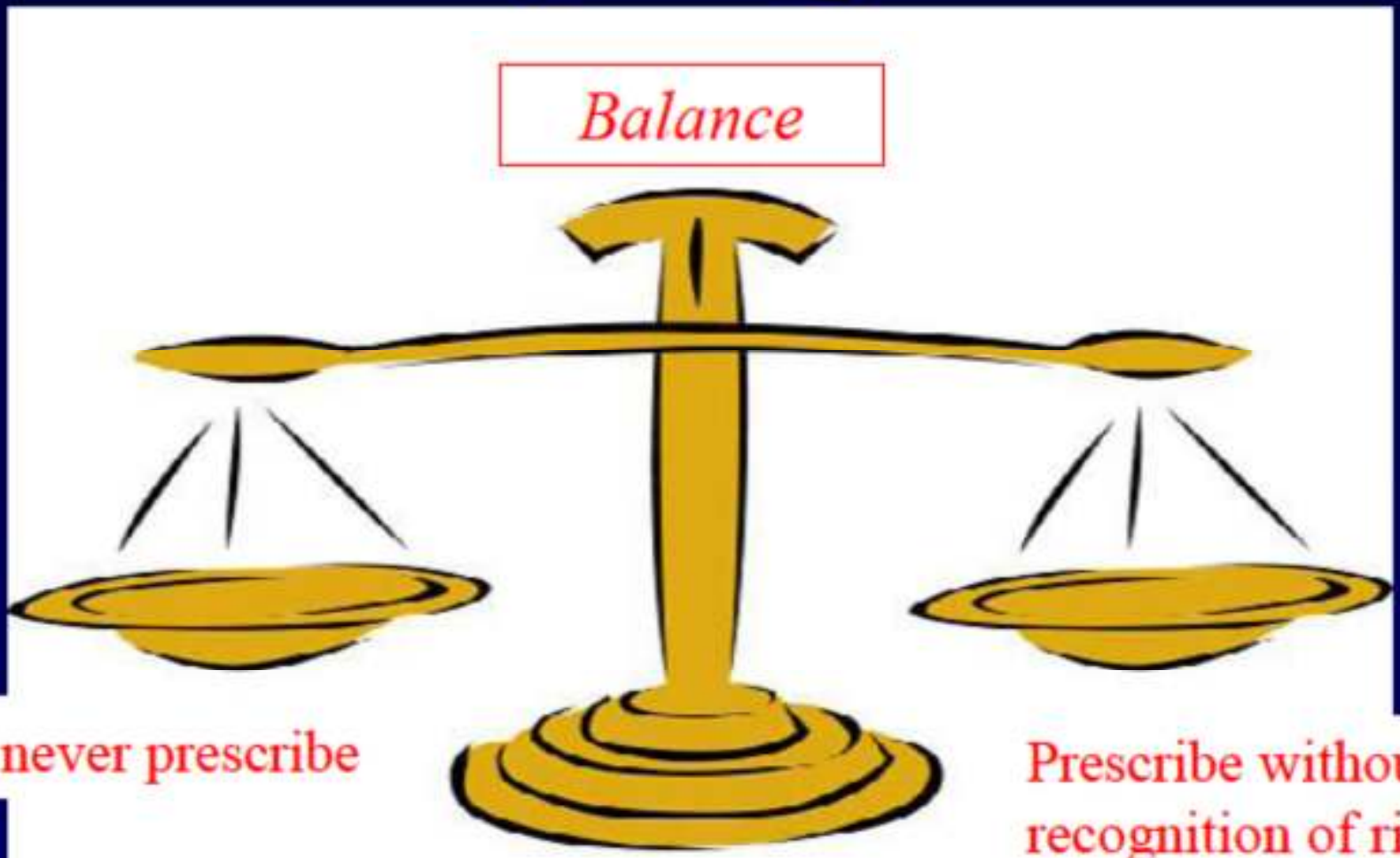
What is available?

- ✓Medications, PT
- ✓Spinal Injections
- ✓Intradiscal procedures
- ✓Implantable therapies

Non Opiate Pharmacotherapy

- Acetaminophen
- NSAIDS
- Antidepressants
- Anticonvulsants
- Anesthetics
- Alpha Adrenergic agents
- Neuroleptics
- NMDA receptor antagonists
- Muscle relaxants
- Topical agents
- Future possibilities

Opioid Prescribing
What is your approach?



Opioid Treatment in Nonterminal Chronic Pain

Efficacy

Safety

Not Lawyers, insurance companies, drug/device reps

Is Opioid Therapy Effective?

- Short term efficacy
  - Clear efficacy in multiple RCT's (up to 8 months) demonstrate improvement in pain
  - No evidence to support dosing of higher than 180 mg morphine equivalent per day
- Long term efficacy
  - No PCRTs for longer than 8 months
  - None for pump vs oral
  - Overall evidence is weak
  - Studies mostly look at VAS, little evidence of improved function

Ballantyne JC, Mao J. Opioid therapy for chroni pain. N Engl J Med Novembe 13, 2003;349:1943-5

Is Opioid Therapy Safe?

- Side effects
  - Dysphoria, constipation, urinary retention, somnolence, cognitive changes
- Immune and hormonal function
  - Testosterone, estrogen, cortisol suppression, decreased libido, infertility (1)
- Addiction
  - Social, psychological, physical and financial consequences

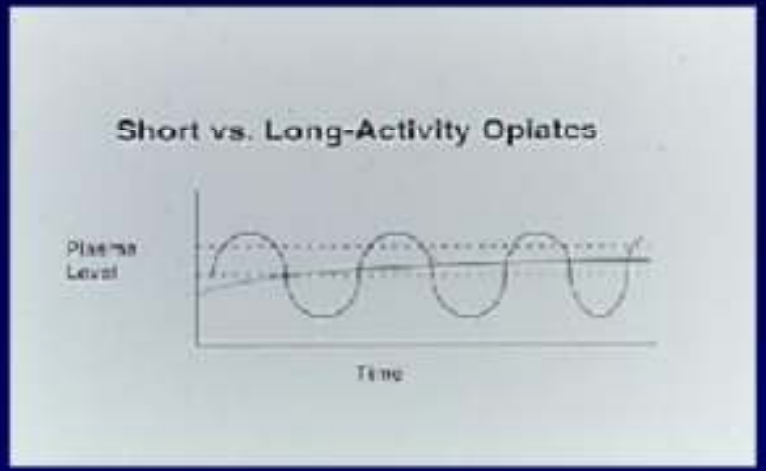
1. Lee C, et al. Low serum cortisol associated with opioid use: Case report and review of the literature. *Endocrinologist* 2002;12:5-8.

Dose Escalation

- Tolerance
  - Physiological
- Opioid Induced Hyperalgesia
  - Solid evidence in animal models
  - Emerging clinical data
- Disease progression
- Perception
  - Goals of therapy
  - Comorbid psychological/behavioral pathology

Continuous delivery /long acting –When "around the clock" opioids are required

- Improved analgesia by maintaining constant blood levels for patients with constant pain
- Euphoria (buzz) related to rapidly rising blood levels
- Withdrawal (and behaviors to avoid) is due to rapid dropping of opioid blood level



Universal Precautions in Pain Medicine

- Our understanding and assessment methods to select patient s that might benefit from opioid therapy are imperfect at best. Lack of rigorous guidelines
- "Gut" is often incorrect, frequently unfair and stigmatizing
- Standardized approach to the assessment and ongoing management of all chronic pain patients

Gourlay DL, Heit HA, Almahrezi A. Universal precautions in pain medicine: a rational approach to the treatment of chronic pain. *Pain Med* 2005;6:107-112.

The differences between systemic and spinal analgesia

Systemic analgesia

- Distributes drug via the blood stream
- High blood levels of drug
- Brain receives highest proportion of drug
- High dose of drug required
- Increase in mental side effects

Spinal analgesia

- Intrathecal or epidural drug distribution
- Low blood levels of drug
- Most drug binds to spinal cord pain receptors
- Low dose of drug is effective
- Minimal effect on brain and mentation

Intrathecal Opioids

Advantages:

- Achieves steady-state, around the clock dosing
- Reduced side effects (1), Use of intermittent dosing to reduce tolerance
- Intrathecal Adjuvants
- Compliance : Eliminate systemic opioids
  - Can provide patient activated rescue dosing
  - Reduction in longitudinal costs

1. Smith, T. J Clin Oncology, 2002

Intrathecal Opioids

Disadvantages:

- More invasive
- More difficult to discontinue therapy
- Acquisition costs
- If positioned as a salvage therapy for patients who have failed but remain on high dose systemic opioids outcomes are diminished

Practice of David Caraway, MD. St. Mary's Regional Medical Center Huntington, WV.

Intrathecal Opioids

- Requires same strategies as systemic delivery
  - Early titration to achieve analgesia and goals of therapy
  - Careful consideration of dose increases
  - Maintain moderate doses
  - Monitor for side effects, efficacy
  - IT adjuvants
  - Physician remains in control of dosing

Practice of David Caraway, MD. St. Mary's Regional Medical Center Huntington, WV.

Psychological Evaluation

- Consider recommendations and treat if indicated - *prior to trial*
- Ability to understand appropriate expectations
- Has patient come to terms with status, expected life span
- Is this someone you are willing to "marry"?
- Major active psychosis, current drug addiction, some personality disorders, cognitive deficits, progressive organic brain disorders, suicidal, homicidal behavior

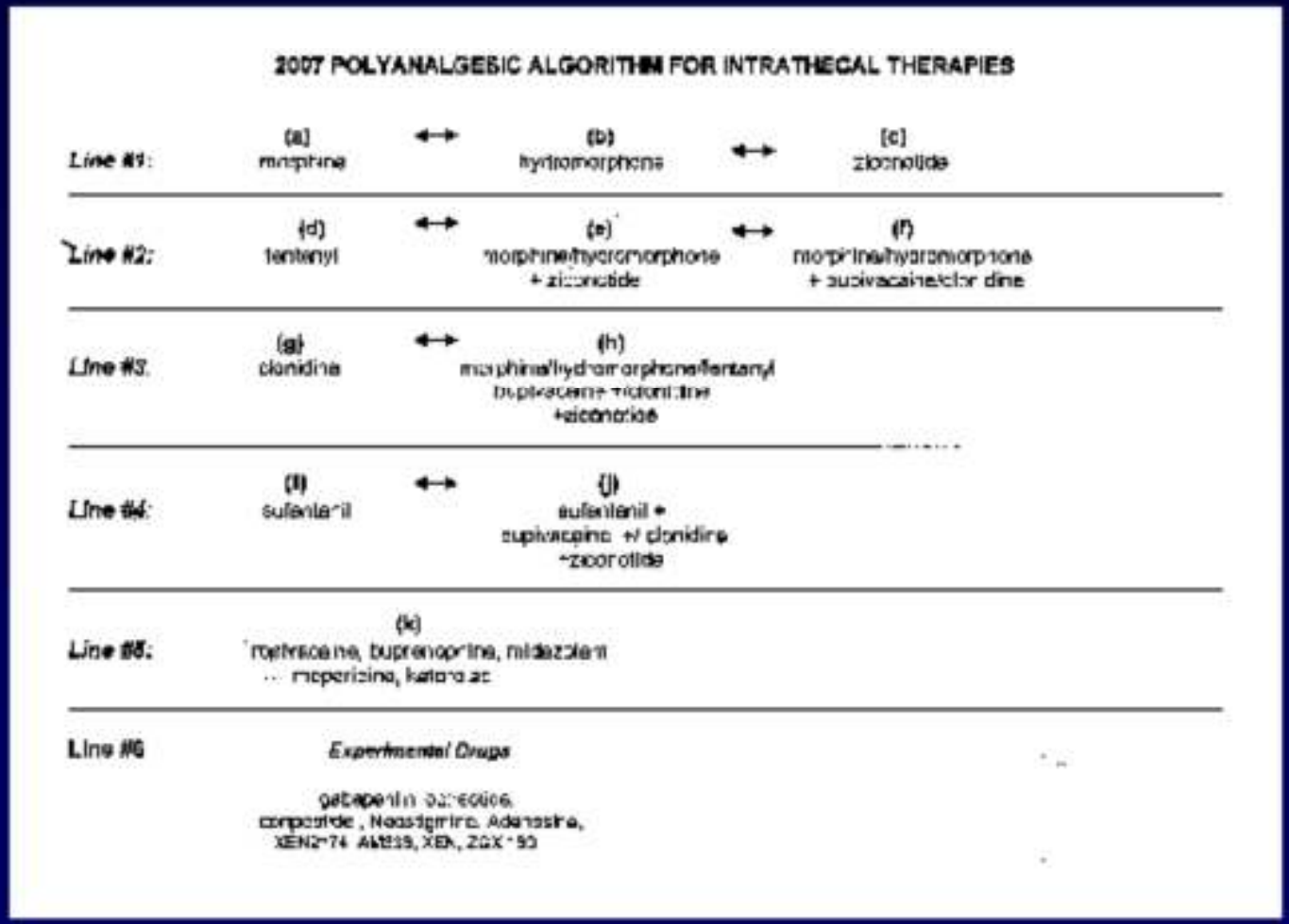
Are supplemental systemic opioids necessary?

- No Pharmacological rationale for multiple routes of delivery
- Defeats the advantages of intrathecal route of delivery
- Methylnaltrexone data in treatment of opioid induced constipation (OIC)[1]

- Blockade of peripheral mu receptors does not:
  - –change pain scores
  - –induce withdrawal
  - –increase opioid requirements

1. *Slatkin N, Thomas J, Lipman AG. Methylnaltrexone for treatment of opiod-induced constipation in advanced illness patients. J Support Oncol. 2009 Jan-Feb;7(1):39-46*

Polyanalgesia Consensus Conference 2007



2007 POLYANALGESIC ALGORITHM FOR INTRATHECAL THERAPIES

Line #1:	(a) morphine	↔	(b) hydromorphone	↔	(c) ziconotide
Line #2:	(d) fentanyl	↔	(e) morphine/hydromorphone + ziconotide	↔	(f) morphine/hydromorphone + bupivacaine/clonidine
Line #3:	(g) clonidine	↔	(h) morphine/hydromorphone/fentanyl bupivacaine ± clonidine ± ziconotide		
Line #4:	(i) sufentanil	↔	(j) sufentanil + bupivacaine ± clonidine ± ziconotide		
Line #5:	(k) ropivacaine, buprenorphine, midazolam ± meperidine, ketorolac				
Line #6	*Experimental Drugs* gabapentin, adenosine, ketamine, NMDA antagonists, Neostigmine, Adenosine, XEN2174, AM336, XEN, ZGX-50				

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page 300 – 328 October 2007

Treatments for Chronic Pain

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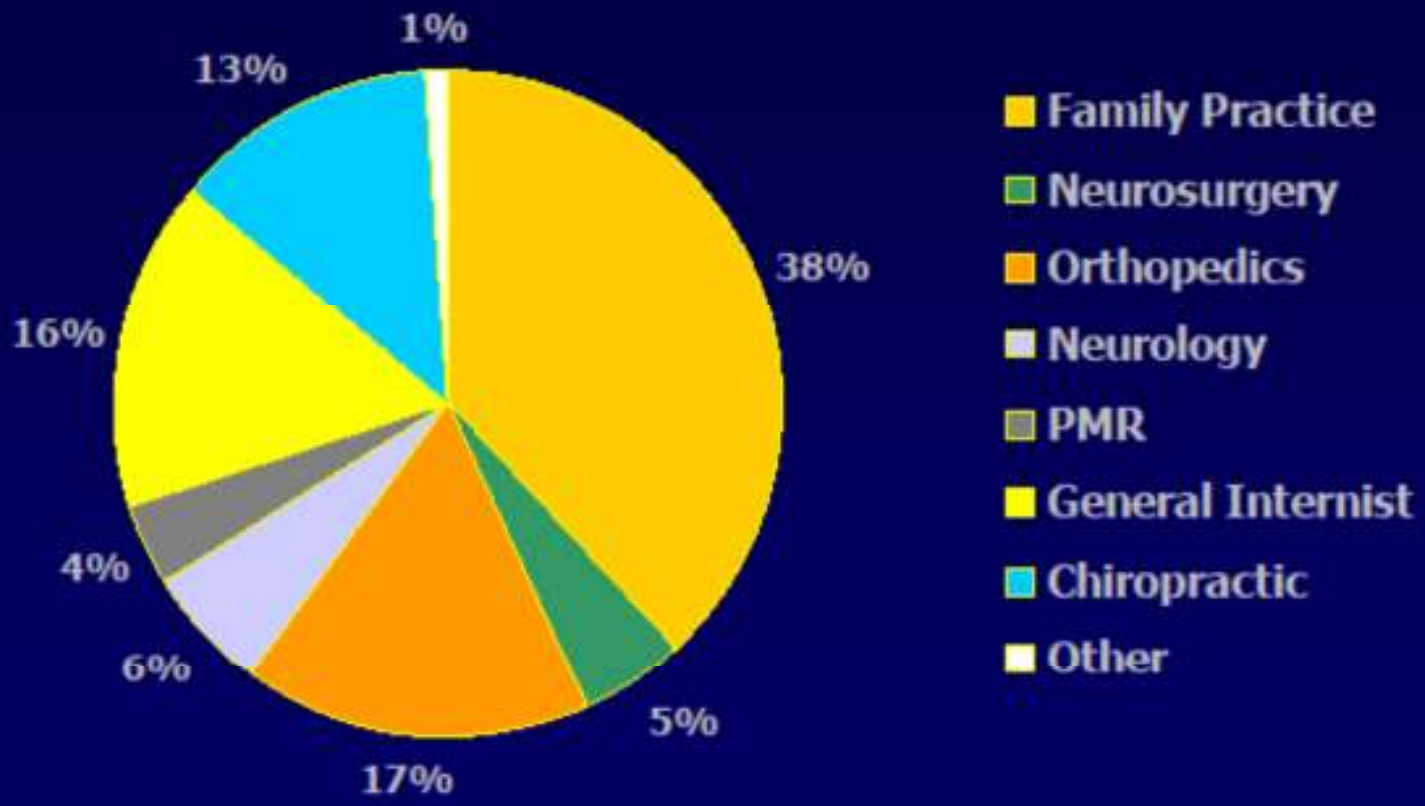
Specialties Treating Back Pain



Conservative Treatment for Low Back Pain Provides Relief for Most Patients

Borenstein D. *Curr Opin Rheumatol.*, 1991

Kelsey JL, Golden AL, Mundt DJ. *Rheum Dis Clin North Am*, 1990.

Natural History of Low Back Pain

- 90% of LBP resolves in 4-6 wks, another 5% resolve by 12 weeks and 5% become chronic
- With sciatica, >50% resolve in 6 wks, 75% resolve by 6 mos
- 50% of those with acute LBP have a recurrence in 1 yr

Characteristics of Patients with LBP

Characteristic	Description
Age	Most are 30 – 50 yrs; peak incidence 40 – 45 yrs for herniated discs
Height	Tall men (> 6') have relative risk of 2.3 – 3.7
Weight	Increased incidence with obesity (1.7 fold for heaviest quintile vs lightest quintile)
Gender	General equal among men and women; men have more pain radiating to legs from disc herniation
Tobacco	Smoking > 20 cigarettes/day – odds ratio (OR) of 1.5 (CI, 1.1 – 2.0) for having low back symptoms; OR of 9.6 (CI, 1.7 – 53.0) for farmers who smoked vs farmers who never smoked
Fitness level	1 study found 9-fold increase in LBP for the least fit firefighters vs the most physically fit
Trunk isometric strength	People with LBP have 60% the absolute trunk strength vs those with no LBP
Scoliosis	> 80% chance of LBP; no relation to degree or type of curve
Leg length inequality	Not associated with LBP if up to 1.5 cm difference, if > 2.5 cm possible association with LBP
Spondylolisthesis	Increases chance of LBP if > 10 mm on lateral film

Environmental Factors Affecting Low Back Pain

Risk	Example
Repetitive forward bending and twisting	Firefighters lifting > 18 lbs, opening structure and breaking window had increased risk of missing 1 day from work for LBP
Frequent lifting on the job	Nurses moving patients in bed >10 times per shift have more LBP
Whole body vibrations	Normal frequency is 4-6 Hz; increased LBP risk for helicopter pilots and employees spending > 50% of work time in a car (RR 2.75)

Initial Pain Treatment Considerations

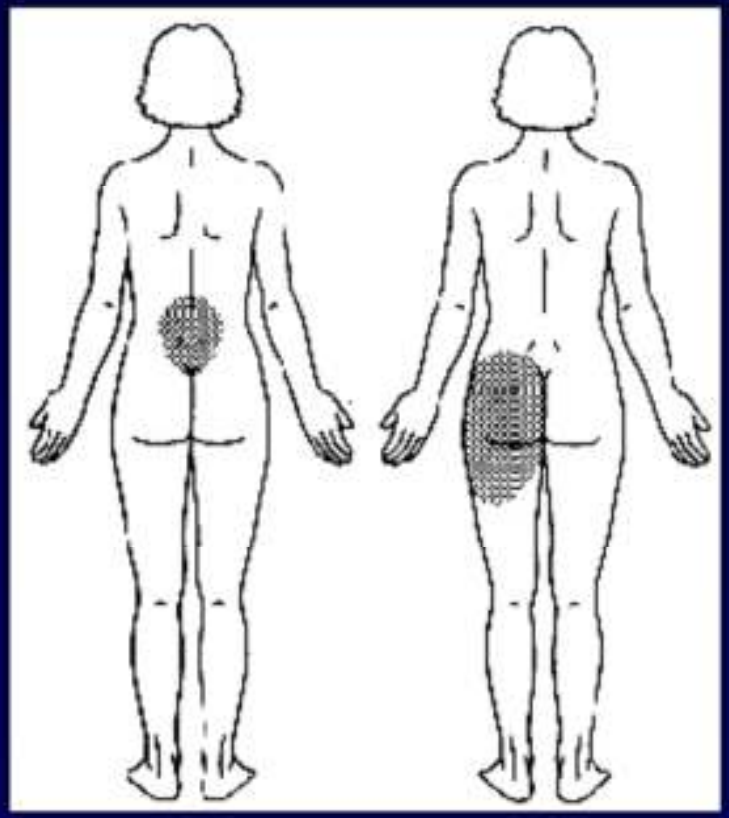
- Direct initial treatment at quickly reversing problem
- Establish clear goals with patient:
  - Pain reduction
  - Rehabilitation to improve function and enhance QOL
- Identify appropriate treatment options

Types of Pain

- Radicular: Pain in the distribution of a single nerve root; no neurologic loss
- Radiculopathy: Pain in the distribution of a single nerve root; neurologic loss required
- Referred: Pain felt remote from site of pathology; no neurologic loss
  - Variable and depend on the make-up of dermatomes, myotomes, and sclerotomes in an individual

EVALUATION AND TREATMENT OF THE BACK PAIN PATIENT

Axial v. radicular pain



Nerve root	L4	L5	S1
Pain			
Numbness			
Motor weakness	Extension of quadriceps.	Dorsiflexion of great toe and foot.	Plantar flexion of great toe and foot.
Screening exam	Squat & rise.	Heel walking.	Walking on toes.
Reflexes	Knee jerk diminished.	None reliable.	Ankle jerk diminished.

History

- Search for red flags
  - exclude the need for immediate medical testing
  - Exclude need for treatment due to fracture (non-pars), tumor or infection
- Exclude LBP from non-spinal (e.g. visceral) causes

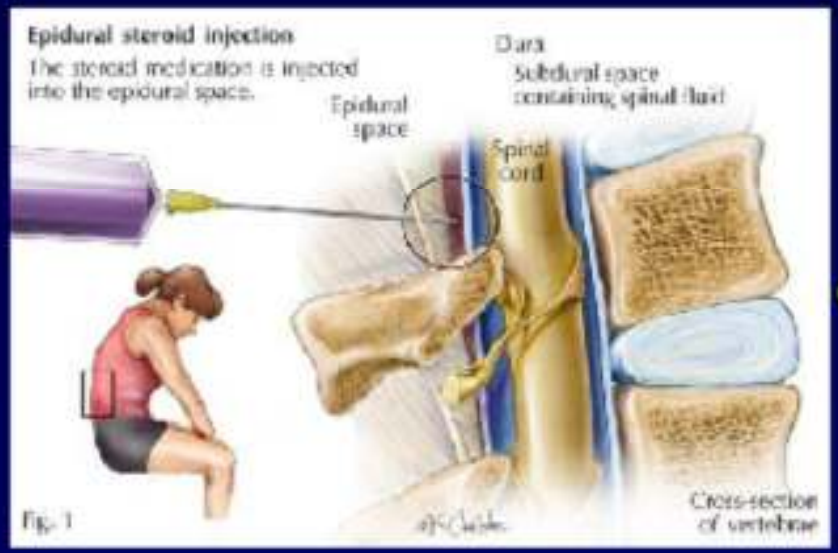
Physical Exam for Radiculopathy

- SLR (+ test: leg pain <60-70 degrees): sens. 80%, spec. 40%
- Crossed SLR: sens. 25%, spec. 90%
- Sensory loss: sens./spec. 50%
- EHL weakness: sens. 50%, spec. 70%
- PF weakness: sens. 60%, spec. 95%
- AJ reflex: sens. 50%, spec. 60%

Non-Organic Pain

- Malingering-exceedingly rare
- Symptom magnification-organic pain remains present
- Psycho-social-vocational distress
- Expression of disability (disability seeker) vs. impairment and functional loss

Epidural steroid injection: patient selection



- Persistent radicular pain despite conservative therapy associated with nerve root compression due to inflammation
- Acute exacerbations of radicular symptoms associated with chronic low back pain

Koes BW et al. Efficacy of epidural steroid injections for low back pain with sciatca: an

Epidural steroid injection: outcomes

Outcomes:

- Speeds resolution of radiculopathy
- Unclear if it will obviate ultimate need for surgical intervention
- Benefit in patients with axial back pain or chronic radiculopathy is unlikely

Koes BW et al. Efficacy of epidural steroid injections for low back pain with sciatca: an updated systematic review of randomized clinical trials. Pain Digest 1999; 9: 241-7

WHO DOES THE BEST?

- Younger patients
- Nonsmokers
- Not on workers' comp
- No previous surgery
- Pain less than six months

ROWLINGSON, J. APS. 1994.

Pain Physician 2009; 12:109-135 • ISSN 1533-3159

Systematic Review

Systematic Review of Caudal Epidural Injections in the Management of Chronic Low Back Pain

Ann Conn, MD[1], Ricardo M. Buenaventura, MD[2], Sukdeb Datta, MD[3], Salahadin Abdi, MD, PhD[4], and Sudhir Diwan, MD[5]

- 10 randomized trials,
- 6 studies evaluating disc herniation or radiculitis
- Only Manchikanti et al and Dashfield et al used fluoroscopy

Results in disc herniation and radiculitis

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief			Results	
				3 mos.	6 mos.	12 mos.	Short-term relief < 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2008 (63)*	RA, DB	72	84	81%	86%	79% to 81%	P	P
Derby et al 2006 (82)*	RA, DE	50	Caudal = 30 Endoscopy = 20	SI	SI	NA	P	NA
Smith and Miller 1969 (85)	RA, DB	55	25	SI	NSI	NSI	P	SI
Mathews et al 1987 (83)	RA, DB	62	C = 31 T = 23	SI	SI	SI	S	P
Ikeda and Tsubaki 1979 (86)	RA, DB	58	69 patients crossover design	77% vs 29%	39% vs 25%	39% vs 25%	P	P
Tsubaki et al 1978 (84)	RA, DB	68	C = 19 T = 16	53% vs 50%	53% vs 50%	NA	P	NA

- Of 6, 5 judged positive for short term relief;
- 4 trials reported positive results with long term f/u of more than 6 months.
- Results in two studies using fluoroscopy were superior

Caudal epidural injection: Spinal stenosis

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief			Results	
				3 mos	6 mos	12 mos	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2008 (71)	RA, DB	70	40	65% to 65%	60% to 65%	55% to 65%	P	P
Cuckoo et al 1984 (96)	O	57	30	SI	SI	NA	P	NA
Botwin et al 2007 (112)	O	61	34	65%	62%	54%	P	P

One randomized trial and two observational studies showed positive results for short and long term relief.

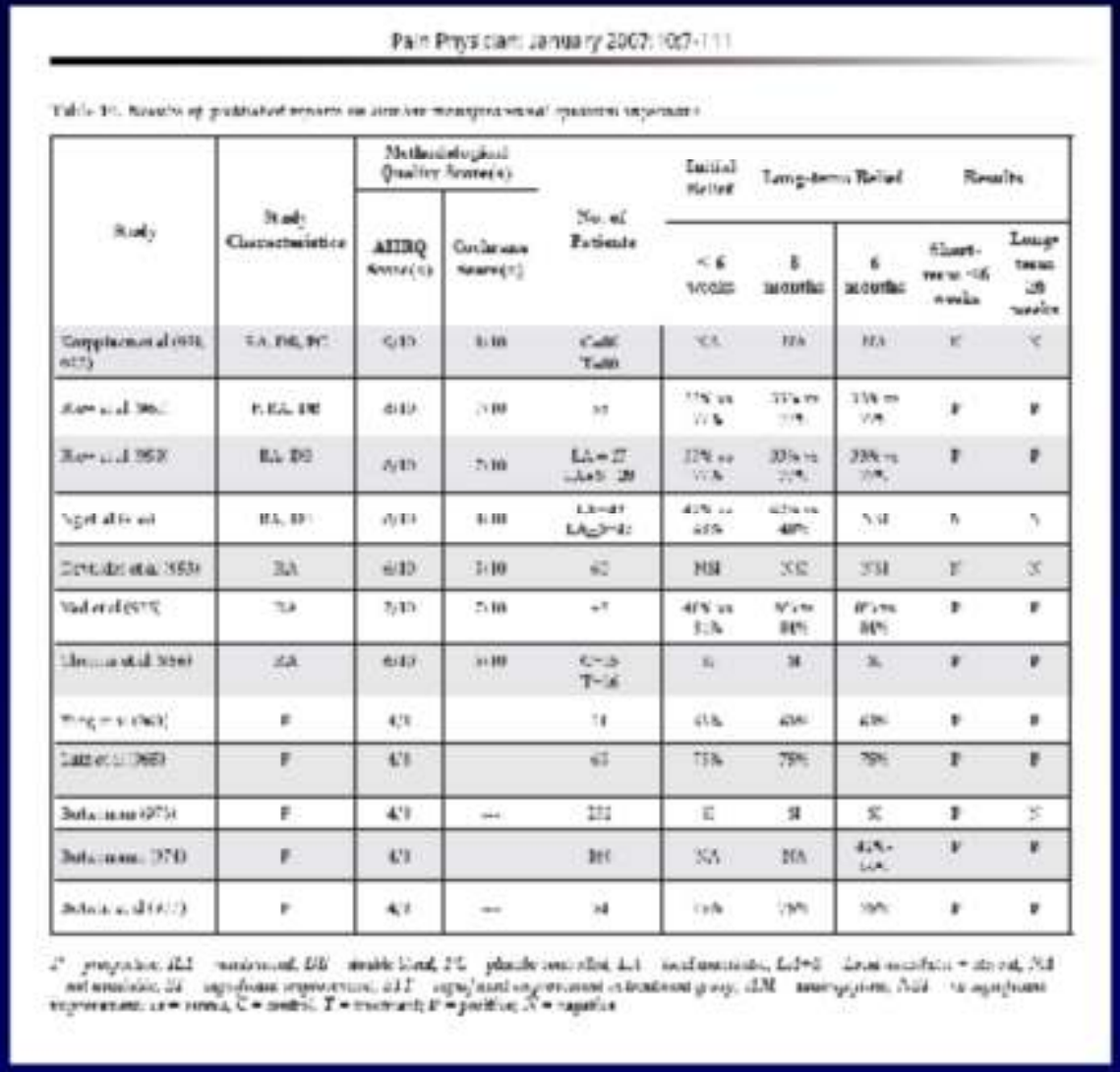
Huntoon and Burgher concluded in an editorial that results of caudal epidural were similar to surgery

Caudal epidural injections: Post surgery syndrome

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief			Results	
				3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2008 (70)	RA, DB	70	40	65% to 70%	60%	60% to 65%	P	P
Revel et al 1996 (86)	RA	62	Forceful injection = 29 Regular = 31	NA	49% vs 19%	NA	P	P
Hesla and Breivik 1979 (89)	RA, DB	58	69 patients: crossover design	77% vs 29%	59% vs 25%	59% vs 25%	P	P

All three trials positive for short and long term relief

Transforaminal Epidural Injections



Pain Physician: January 2007: 10

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief			Results	
				3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Karppinen et al 2001/2001 (855,856)	RA, DB	81	C = 80 T = 80	SICH	NSI	NSI	P	N
Riew et al 2000/ 2006 (857,858)	P, RA, DB	68	55	NA	NA	33% vs. 71% (avoided surgery)	P	P
Jeong et al 2007 (854)	RA, DB	63	239	PG 99 of 112 G 90 of 127	PG 64 of 106 G 78 of 116	NA	P	NA
Vad et al 2002 (859)	RA	58	48	NA	NA	48% vs. 84%	P	P

RA = randomized; DB = double blind; P = prospective; C = control; T = treatment; PG = pre-ganglioric; G = ganglionic; SICH = significant improvement in contained disc herniation; NSI = no significant improvement; vs. = versus; NA = not available; P = positive; N = negative

Transforaminal Epidural Injections

Evidence for transforaminal epidural steroid injections based on all available high level studies (1):

1. Strong for short term management of lumbar nerve root pain
2. Moderate for long term management
3. Limited in managing axial low back pain
4. European Guidelines also provide favorable evidence for use of TEESI (2)

1. Pain Physician: January 2007, 10: 7-111 2. Ear Spine J,15S192-S300

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief			Results	
				3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2008 (769)*	RA, DB	72	84	81%	86%	79% to 81%	P	P
Dashfeld et al 2005 (770)*	RA, DB	50	Caudal = 30 Endoscopy = 30	SI	SI	NA	P	NA
Bush and Hillier 1991 (768)	RA, DB	55	23	SI	NSI	NSI	P	N
Mathews et al 1987 (771)	RA, DB	62	C = 34 T = 23	SI	SI	SI	N	P
Hesla and Breivik 1979 (773)	RA, DB	58	69 patients: crossover design	77% vs 29%	59% vs 25%	59% vs 25%	P	P
Breivik et al 1976 (772)	RA, DB	68	C = 19 T = 16	20% vs 50%	20% vs 50%	NA	P	NA

*Indicates use of fluoroscopy

RA = randomized; DB = double blind; C = control; T = treatment; NA = not available; SI = significant improvement; NSI = no significant improvement; *vs = versus; P = positive; N = negative*

CESI for HNP/Radiculopathy

- Effectiveness
  - 6 Randomized Trials
  - 2 with Fluoroscopy
  - 5/6 Positive for Short Term Relief
  - 3/4 Positive for Long Term Relief
  - Fluoroscopic Greater Results than Blind CESI

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief			Results	
				3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2008 (774)*	RA, DB	70	40	65% to 70%	60%	60% to 65%	P	P
Revel et al 1996 (775)	RA	62	Forceful injection = 29 Regular = 31	NA	49% vs 19%	NA	P	P
Hesla and Breivik 1979 (773)	RA, DB	58	69 patients: crossover design	77% vs 29%	59% vs 25%	59% vs 25%	P	P

*Indicates use of fluoroscopy

RA = randomized; DB = double blind; NA = not available; vs = versus; P = positive; N = negative

CESI for Post Surgery Syndrome

- Effectiveness
  - 3 Randomized Trials
  - 1 with Fluoroscopy
  - 3/3 Positive for Short & Long Term Relief

Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief			Results	
				3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2008 (776)*	RA, DB	70	40	50% to 65%	60% to 65%	55% to 65%	P	P
Ciocon et al 1994 (777)	O	57	30	SI	SI	NA	P	NA
Botwin et al 2007 (778)*	O	61	34	65%	62%	54%	P	P

*Indicates use of fluoroscopy

RA = randomized; DB = double blind; O = observational; NA = not available; SI = significant improvement; vs = versus; P = positive; N = negative

CESI for Spinal Stenosis

- Effectiveness
  - 1 Randomized Trial
  - 2 Observational Trials
  - Randomized Trial
    - Steroid & Local Anesthetic
    - Local Anesthetic Only
    - Positive Short & Long Term Relief
  - 2 Observational Trials
    - Positive for Short & Long Term Relief

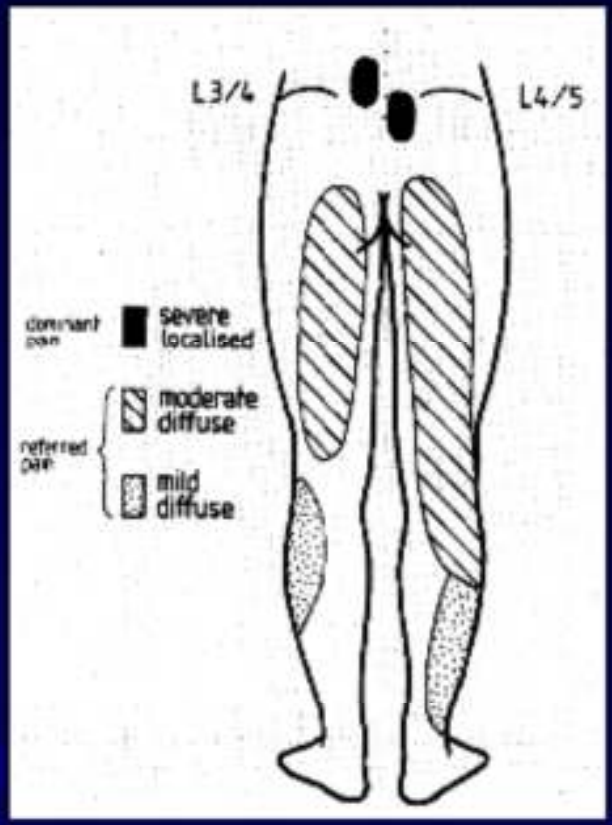
Study	Study Characteristics	Methodological Quality Scoring	Participants	Pain Relief			Results	
				3 mos.	6 mos.	12 mos.	Short-term relief ≤ 6 mos.	Long-term relief > 6 mos.
Manchikanti et al 2008 (780)	RA, DB	72	64	78%	75% to 81%	72%	P	P
Manchikanti et al 2001 (782)*	O	76	70	95%	85%	61% to 73%	P	P
Manchikanti et al 2002 (781)*	O	73	62	86%	60%	NA	P	NA

*Indicates use of fluoroscopy

CESI Evidence

- HNP/Radiculopathy - Strong
- Post Surgery Syndrome - Strong
- Spinal Stenosis - Strong
- Discogenic Pain - Strong

Facet-related pain



Lumbar facet syndrome

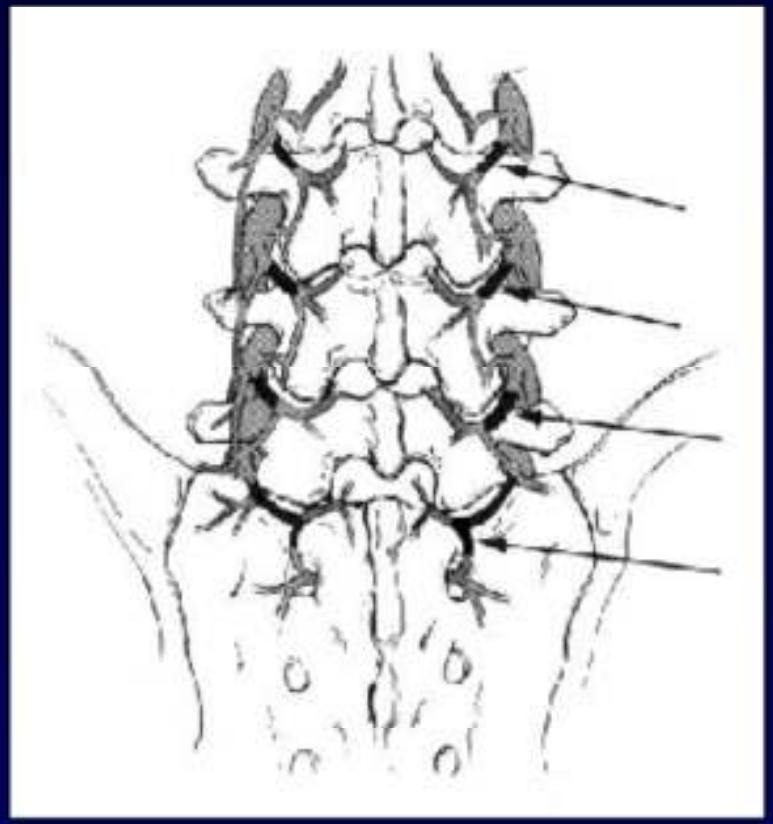
- Axial back pain
- Worse with extension
- Radiographic evidence of facet arthropathy is not always present

Bous RA. Facet joint injections. In: Stanton-Hicks MA, Bous RA (eds), Chronic low back pain. Raven Press, NY, 1982

Diagnosis of Facet Arthropathy with Medial Branch Blocks

- Criteria for success varies between 50-90%
- False-positive rate varies between 25-38%
  - Highest in the lumbar region, lowest in c-spine
- Controversy exists regarding use of placebo controls, confirmatory blocks, and even the utility of performing diagnostic blocks prior to proceeding to RF denervation

Radiofrequency facet denervation: technique

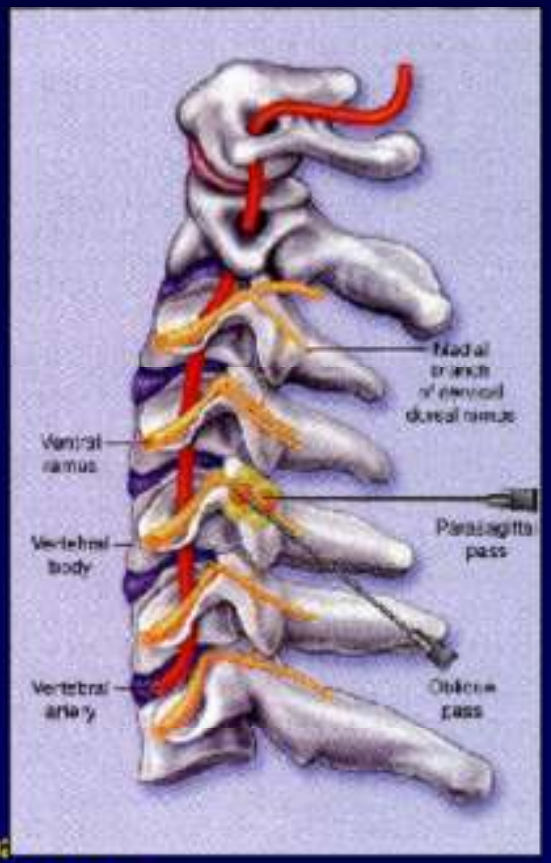


Kline MT. Radiofrequency techniques in clinical practice. In: Waldman SD, Winnie AP. Interventional pain management. WB Saunders. Philadelphia. 1996.

Radiofrequency facet denervation outcomes

Outcomes:

- Complications are rare
- >50% pain reduction occurs in 50-75% of patients lasting until >3 month follow-up
- Moderate to strong evidence for long term relief (1,2)



(1) Geurts *et* al, Efficacy of radiofrequency procedures for the treament of spinal p:
A systematic review of randomized clinical trials. *Reg Anesth Pain Med.* 2001; 26: 394-400.

(2) Manchikanti *et al.* Medial branch neurotomy in management of chronic spinal pain. *Pain Physician* 2002; 5: 405-418.

Treatments for Chronic Pain

What is available?

- ✓Medications, PT
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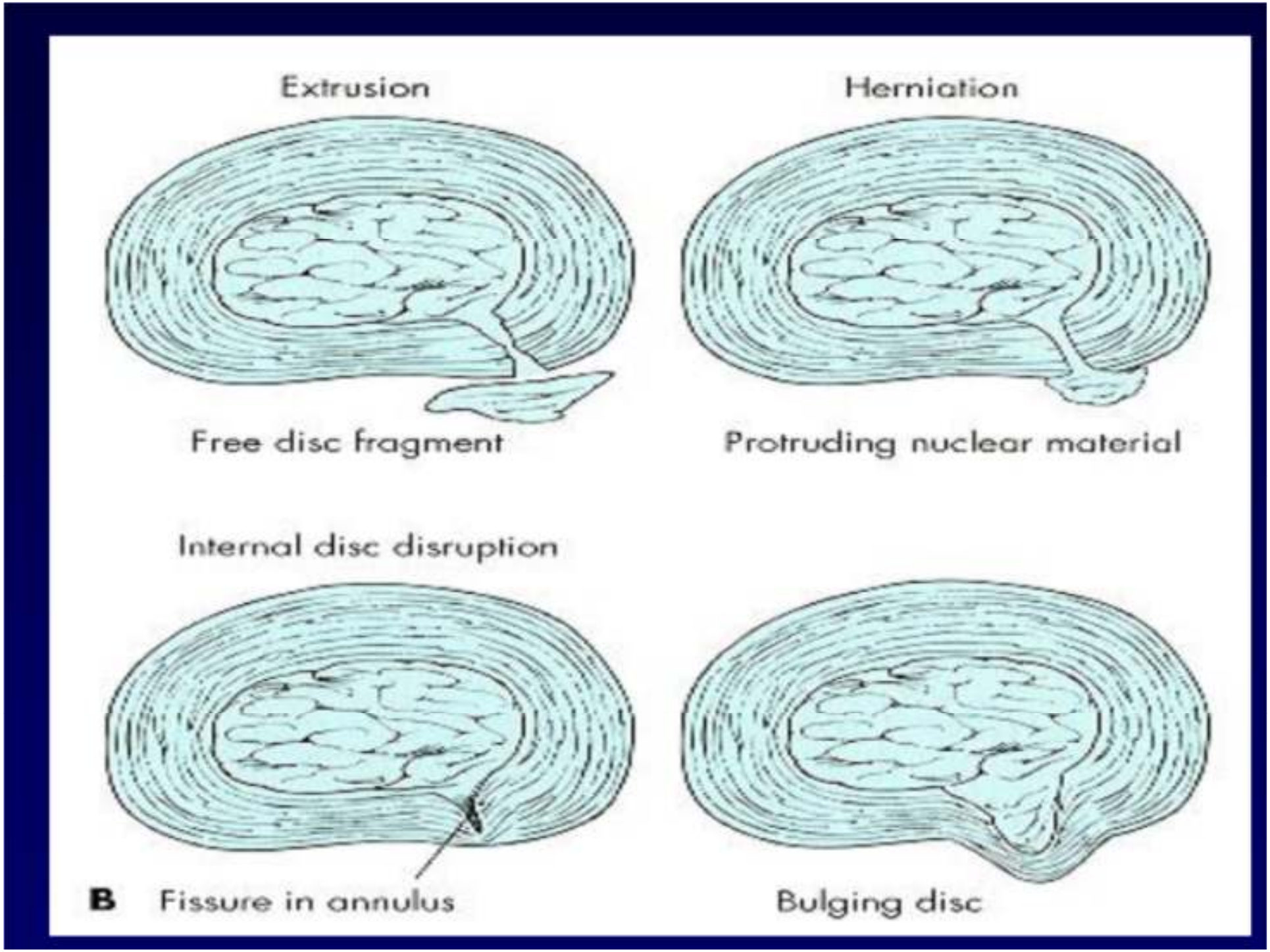
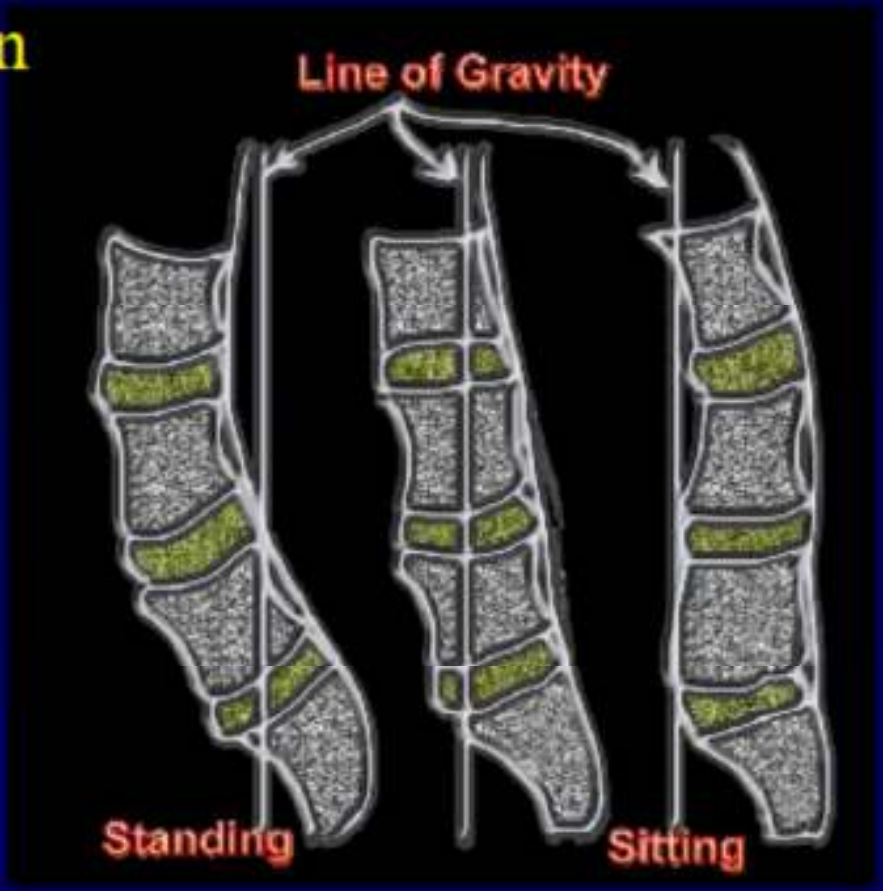
- ✓Implantable therapies


Extrusion
Herniation
Free disc fragment
Protruding nuclear material
Internal disc disruption
B
Fissure in annulus
Bulging disc

The Injury

- Disc loading and disruption
  - Mechanism of injury
    - Supine pressure
    - Standing
    - Sitting
    - Sitting + leaning forward
    - + Twisting



Disc pressure measurements
Spine. 1981 Jan-Feb;6(1):93-7
Nachemson AL

PathoPhysiological basis for Discogenic pain

Discogenic pain

Compared with the pressure of load in the upright standing position:

- Reclining reduces the pressure by 50-80%
- Unsupported sitting increases the load by 40%
- Forward leaning and weight lifting by more than 100%
- Forward flexion and rotation by 400%.

Disc pressure measurements
Spine. 1981 Jan-Feb;6(1):93-7
Nachemson AL

Degenerative disc disease

- Axial back pain
- Pain worsened with prolonged sitting or standing
- Radiographic changes are variable
- Pain reproduction with provocative discography

Schwarzer A, Aprill C, Derby R et al. The prevalence and clinical features of internal disc disruption in patents with chronic low back pain. Spine 1995; 20: 1878 – 1883.

Treatment Options - The sentence

- Decompression
  - Open surgical
    - Discectomy, Laminectomy, Fusion
  - Percutaneous
    - Mechanical decompression (aspiration)
    - Thermo-chemical decompression (co-ablation)
    - Laser assisted decompression

Treatment Options

- Decompression
  - Open surgical
  - Percutaneous
- Annuloplasty
  - IDET
- Fusion
  - Surgical options

Selection Criteria for Intradiscal Procedures

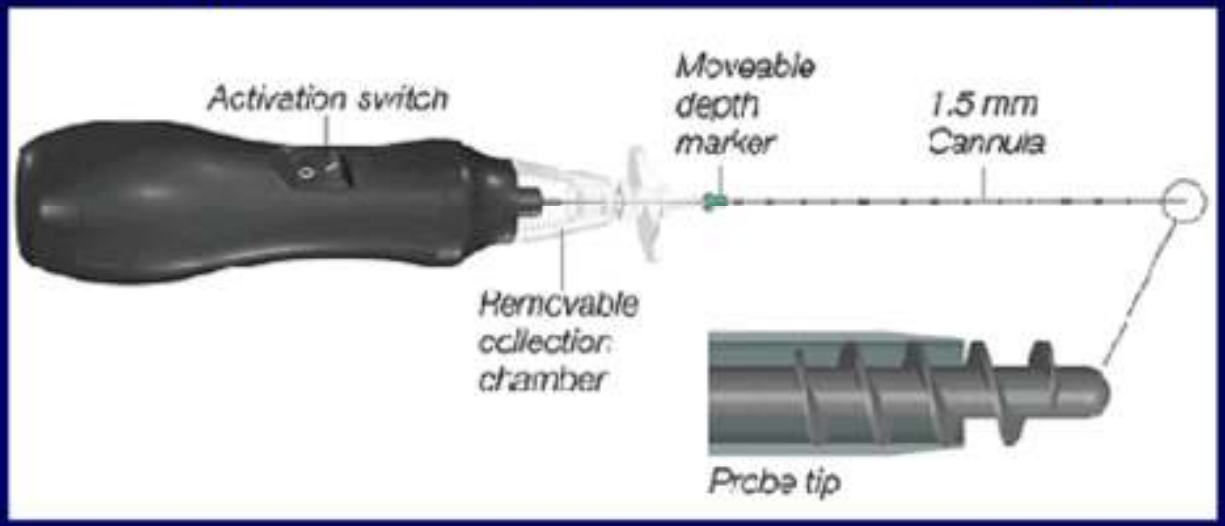
- Predominant axial / mechanical pain
- Positive concordant pain during provocative lumbar discography at low pressures (<50 psi) with negative control disc
- Physical examination
- Chronic pain (>6 months)
- At least 50% preserved disc height

Exclusionary Considerations

- Intervertebral disc herniations greater than 6mm
- Extruded/sequestered disc herniations
- Spinal pathology: spina bifida occulta, spondylolisthesis
- Moderate to severe foraminal or central canal stenosis
- Existing endplate damage or Schmorl's nodes
- Greater than grade 4 annular tear (MDDS)
- Segmental instability
- Neurological deficit

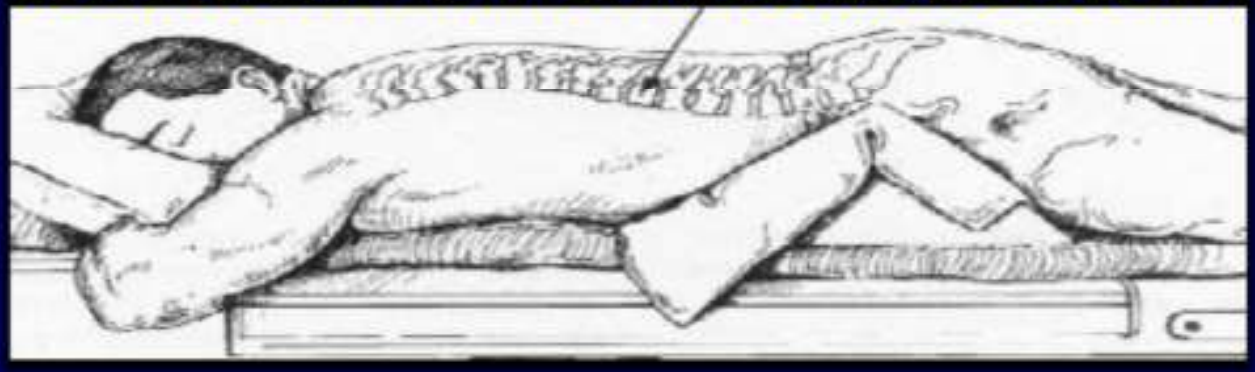
Percutaneous Discectomy

- Objective
  - Reduce intradiscal and adjacent nerve root pressure.
  - Provide pain relief from back and leg pain.



Percutaneous Discectomy

- The Procedure
  - Patient is prone on the procedure table and kept comfortable with mild intravenous sedation.

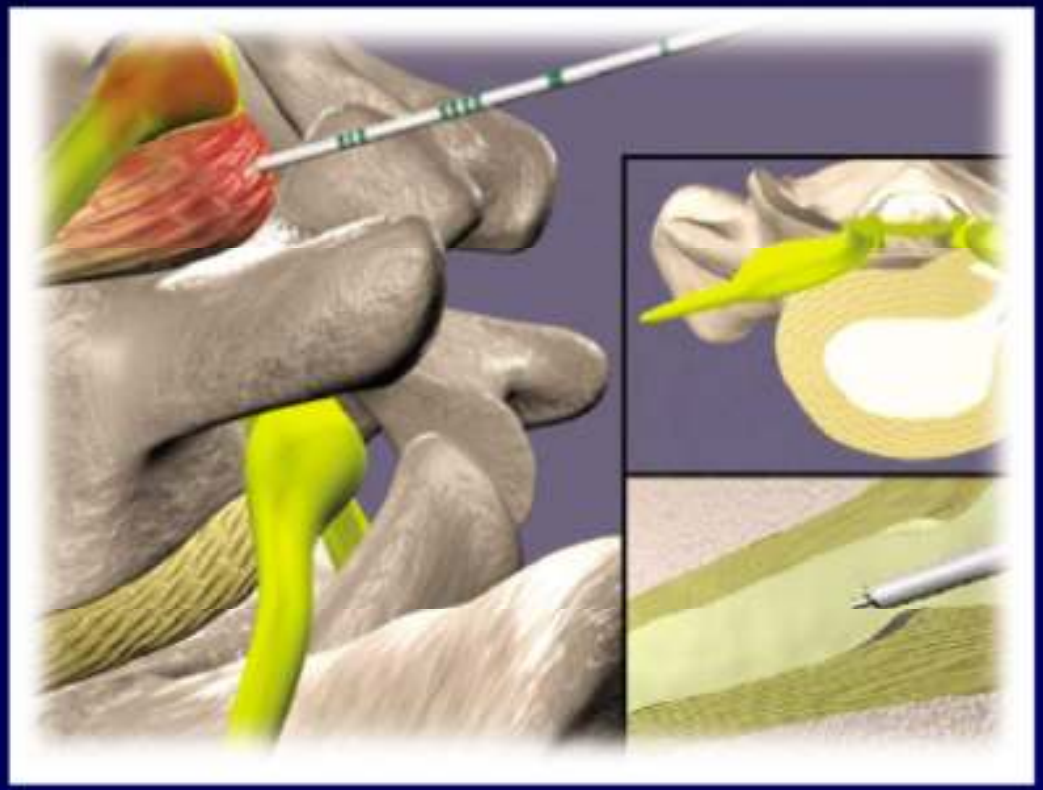


  - Under sterile conditions, hollow needle passed into the disc using live imaging guidance.

Percutaneous Discectomy

The Procedure

Nuclear material is extracted – disc decompressed



Percutaneous Discectomy

- Who is a candidate?

-Failed conservative therapy
-Leg pain > back pain
-MRI indicates contained herniation
-Non-operative level with height
-Facet pain excluded
-Positive low volume diagnostic selective nerve root block
-Discogram and post-disco CT consistent with above (for classification only)

Percutaneous Discectomy

- Clinical Studies

Hoppenfeld S.

Percutaneous removal of herniated lumbar discs. 50 cases with ten-year follow-up periods. Clin Orthop. 1989 Jan;(238):92-7.

-Forty-three patients (86%) had relief of sciatica and sensory deficit.

Davis GW, et al.

Automated percutaneous discectomy.

Spine. 1991 Mar;16(3):359-63.

- In this series, 518 patients were treated using this technique for an overall success rate of 85%.

Gill K, et al.

Clinical experience with automated percutaneous discectomy: the Nucleotome system.

Orthopedics. 1991 Jul;14(7):757-60.

- The overall success rate was 79%; 93% in private pay and 65% in workers' compensation.

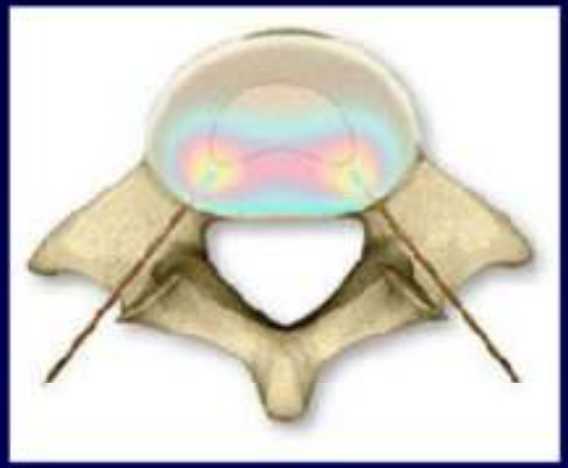
Percutaneous Discectomy

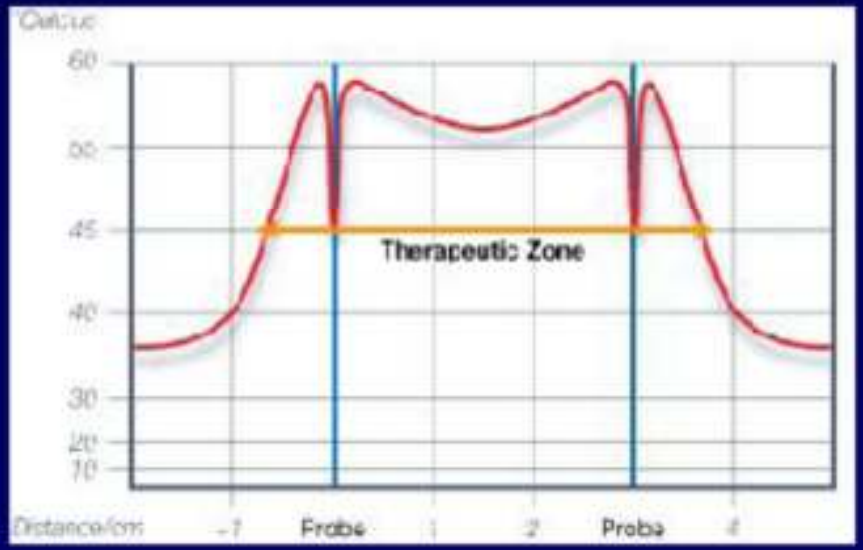
- Clinical Studies

Kenneth M. Alo, MD
Percutaneous Lumbar Discectomy: Clinical Response in an Initial Cohort of Fifty Consecutive Patients With Chronic Back and Leg Pain

- 50 patients (62 levels)
- Average reduction in VAS of 62.5%, which resulted in a 77% decrease of analgesic use, 92% improvement in functional status and overall satisfaction greater than 80%.
- There were no procedure related complications.

Disc Biacuplasty





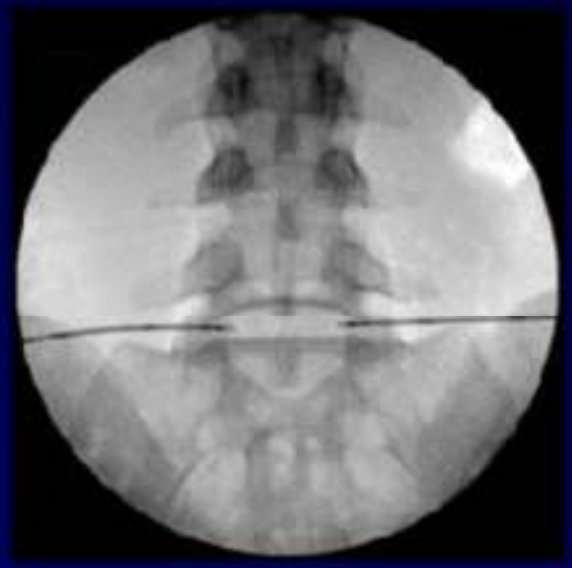
Disc Biacuplasty

No intra- and postoperative complications

Significant improvements in patient functional capacity, and pain scores were noted.

VAS: 5 to 1 cm at 6-month foll
Oswestry improved from 14 (28% or moderate disability) to 6 points (12% or minimal disability)

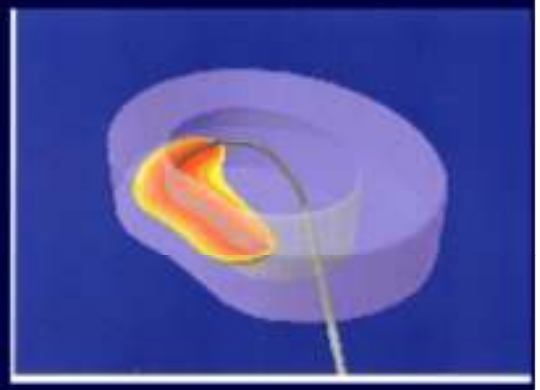
SF-36-PF (physical function) score changed from 67 to 82.



Leonardo Kapural MDPhD, Nagy Mekhail MDPhD (2007) Novel Intradiscal Biacuplasty (IDB) for the Treatment of Lumbar Discogenic Pain Pain Practice 7 (2), 130–134.

IDET

IDET

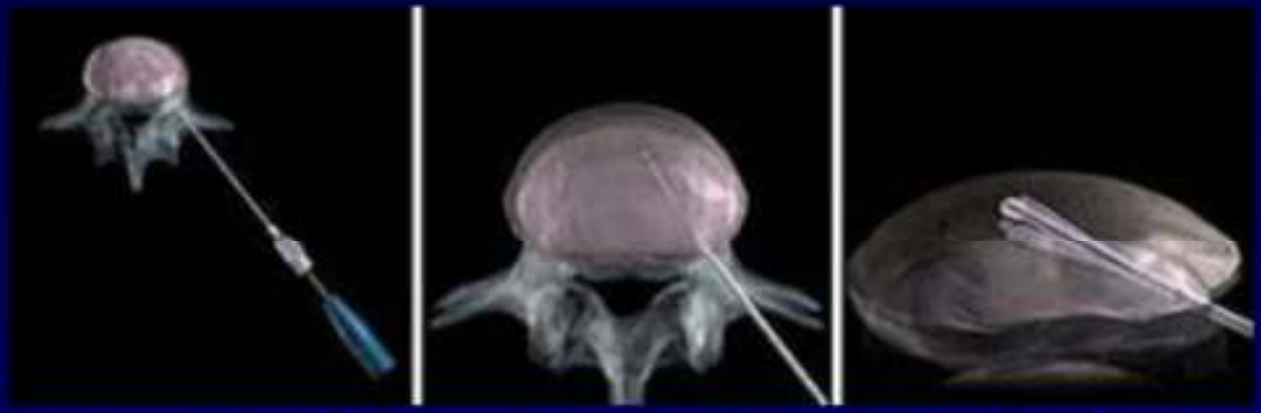


- Thermocoagulates annular tissue
- Thermally modulates collagen
- Vascular, Innervated granulation tissue is Cauterized

IDET

- This intradiscal catheter delivers thermal energy directly to the annular wall and disk through resistive heating coils.
- Temp is slowly raised from 65C to 90C in 1degree increments every 30 seconds. Then held for 4 minutes

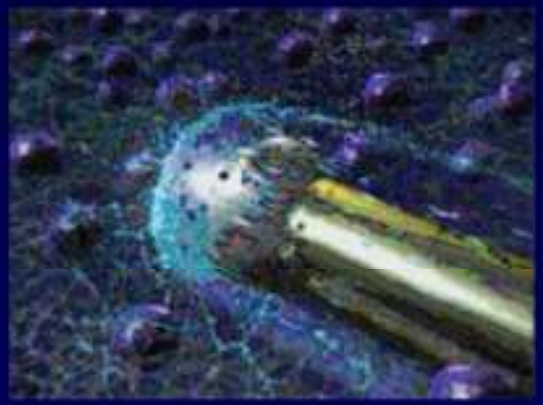
Nucleoplasty™

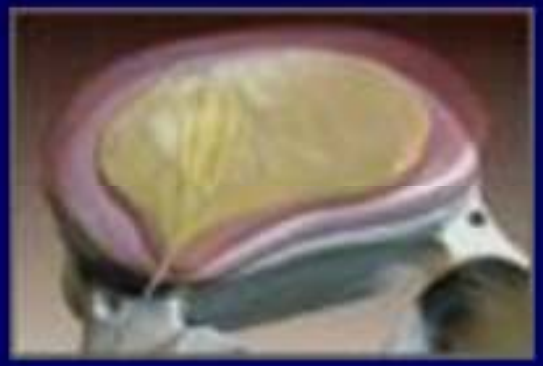


Nucleoplasty catheter creates a small, highly localized plasma field using radio wave energy

Small amounts of disc material may be ablated within the disc space and disc decompression may be effected

Nucleoplasty™





Low Temperature

Perhaps 1cc (no more than about 10% of nucleus) is removed

Carragee ISSLS Scotland 2001

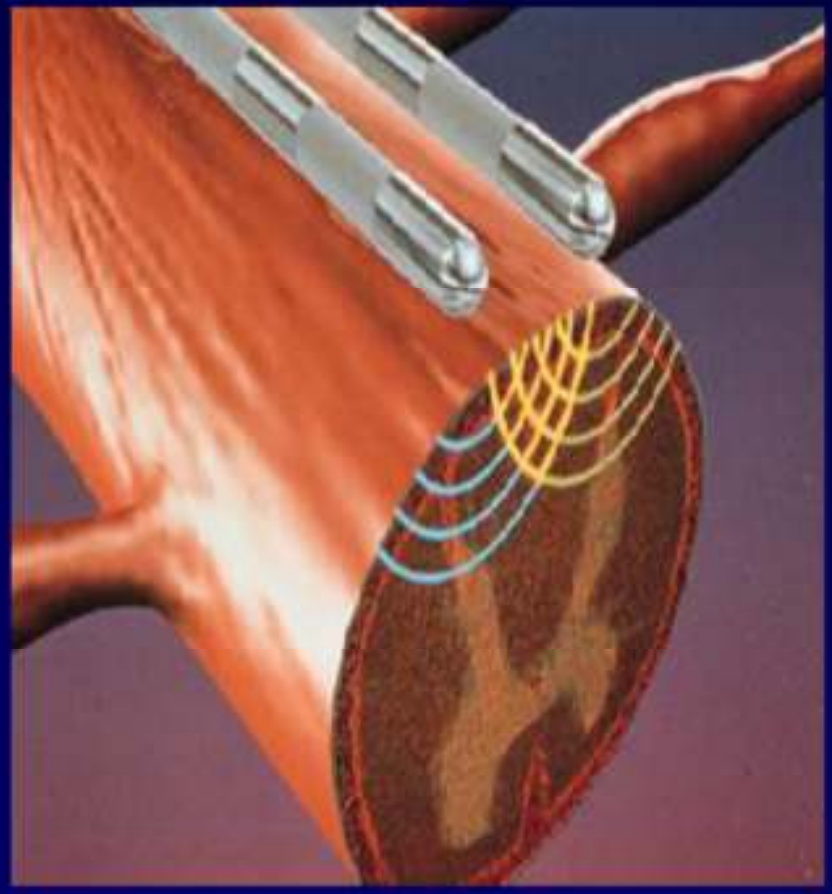
Treatments for Chronic Pain

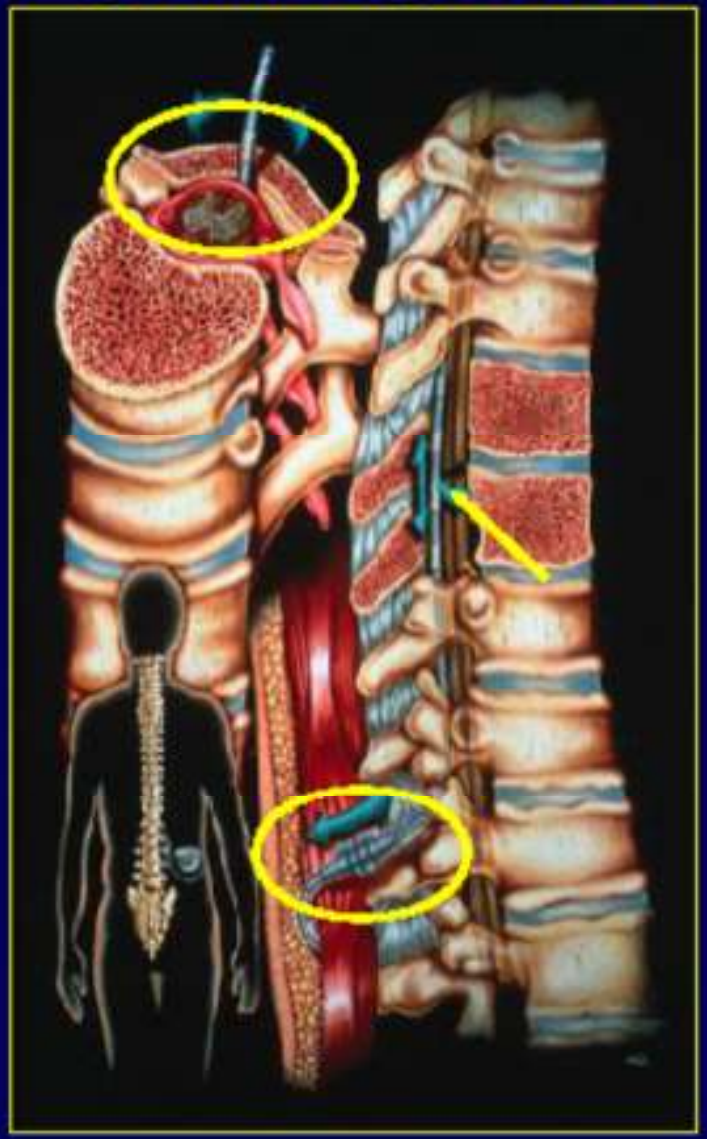
What is available?

- ✓Medications, PT
- ✓Spinal Injections
- ✓Intradiscal procedures
- ✓Implantable therapies

Neurostimulation Therapy

SPINAL CORD STIMULATION





Spinal Cord Stimulation (SCS)

Implanted medical device that delivers electrical pulses to nerves in the dorsal aspect of the spinal cord that can interfere with the transmission of pain signals to the brain and replace them with a more pleasant sensation called paresthesia.

Spinal Cord Stimulation

- Mechanism of action is complex and not fully elucidated
- Probably related to large fiber stimulation (gate control theory) inhibiting pain transmission, GABA, SEROTONIN, SUBSTANCE P and other transmitters involved
- Point is that it often works
- Trial to determine efficacy

Practice of David Caraway, MD. St. Mary's Regional Medical Center Huntington, WV.

SUCCESSFUL TRIAL

- Stimulation covers area of pain
- Stimulation is pleasant
- Treatment objective attained
  - Improved function
  - Improved pain control by at least 50% ?
  - Improved vascular studies
  - Improved physical exam

Practice of David Caraway, MD. St. Mary's Regional Medical Center Huntington, WV.

Neurostimulation Indications

Indicated for unilateral or bilateral pain associated with:

- Failed Back Syndrome or Low Back Syndrome or Failed Back
- Radicular Pain Syndrome or Radiculopathies resulting in pain secondary to Failed Back Syndrome or Herniated Disk
- Post-laminectomy Pain
- Multiple Back Operations
- Unsuccessful Disk Surgery
- Degenerative Disk Disease (DDD)/Herniated Disk pain refractory to conservative and surgical interventions
- Peripheral Causalgia
- Epidural Fibrosis
- Arachnoiditis or Lumbar Adhesive Arachnoiditis
- Complex Regional Pain Syndrome (CRPS) or Reflex Sympathetic Dystrophy (RSD) or Causalgia

Refer to the package labeling for a complete list of indications.

Purpose of Psychological Assessment

- Exposes psychological factors that should be addressed in treatment
- Suggests specific treatments that may help resolve psychological risk factors
- Facilitates patient selection for specific pain therapies
- Provides clues to evaluate the patient's response to a screening test or treatment

Block AR, Ohnmeiss DD, Guyer RD et al. The use of pre-surgical psychological screening to predict the outcome of spine surgery. *Spine J.* 2001; 1(4): 274-282.

QUALITY OF PAIN

- Easy first choices for STIMULATION
  - Burning pain, allodynia in extremities (CRPS I)
  - Dermatomal, mononeuropathy, CRPS II
  - "Failed Back Surgery Syndrome" with significant extremity pain
  - Trunk (chest wall pain)
  - *Temporarily* highly effective diagnostic nerve blocks

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QUALITY OF PAIN

- Difficult choices for stimulation
  - High dose opioid dependent
    - Careful trial, monitor opioid requirements, delineation of expectations
  - Visceral pain
  - Compression Fx.
  - Joint pain
  - "Mechanical" back pain

    Severe pain with flexion and extension, no radicular component, minimal rest pain

While case reports may exist these are not approved indications or lack strong support for clinical success

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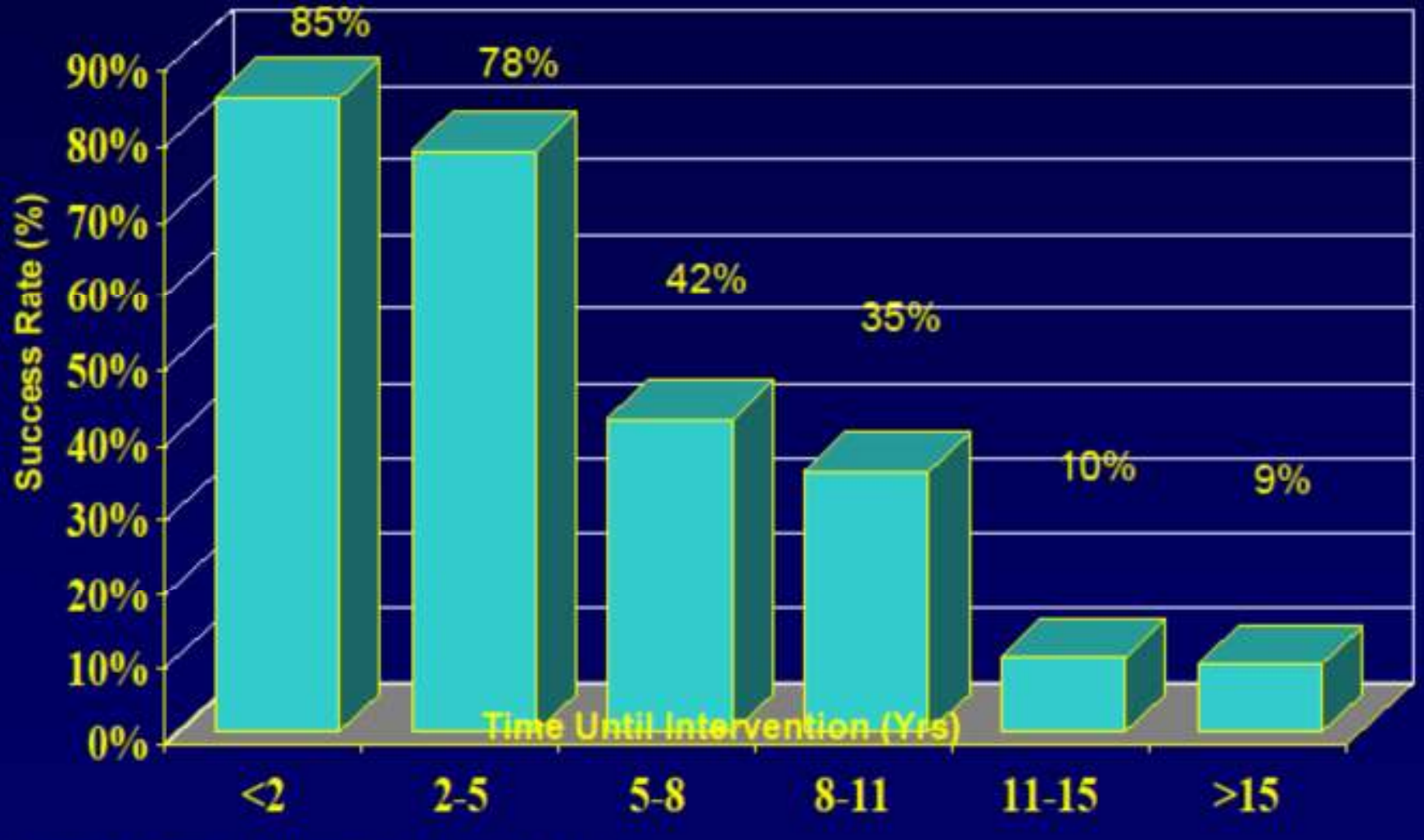
NS is Most Effective When Considered Early



Kumar K, et al. *Neurosurg.* 2006;58;481-496.

Matching Devices to Patients

Key Considerations:

- Underlying disease process
- Pain pattern and location
- Power requirements for optimal stimulation
- Programming capabilities
- Lead choices
- Cognitive ability

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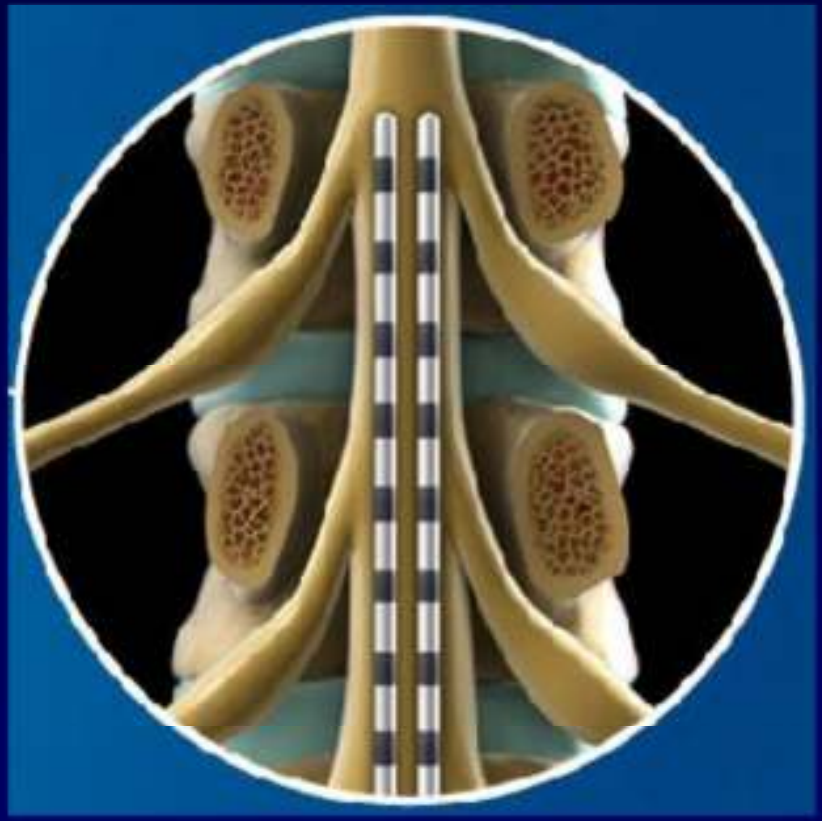
Percutaneous Leads

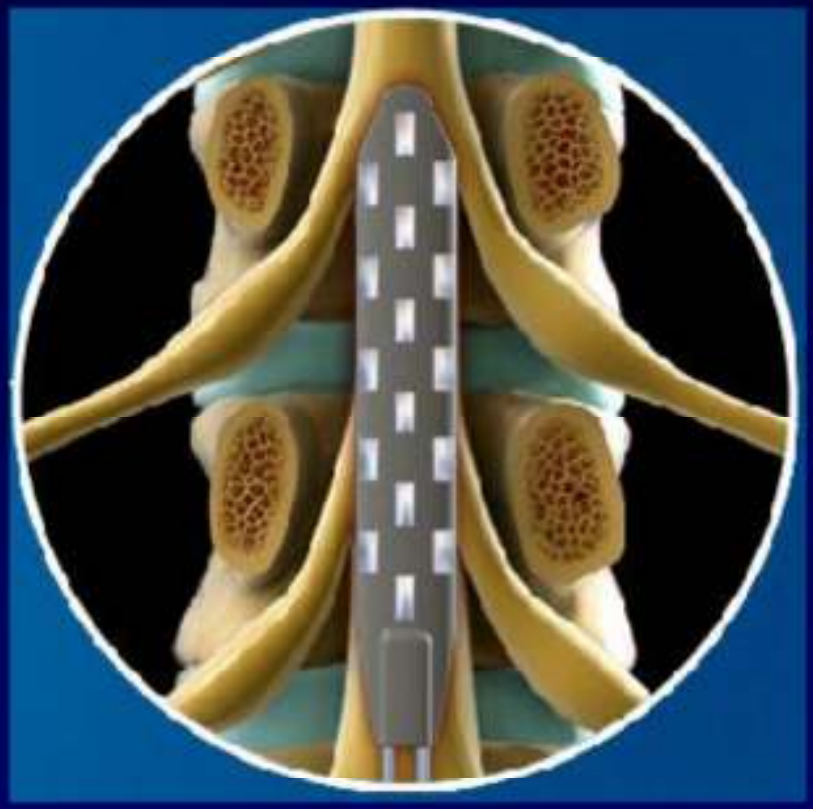
- Catheter style
- Minimal or no sedation
- Trial and implant arrays are the same
- Less invasive
- Flexible lead positioning
- More prone to migration[1]
- Cylindrical electrodes



[1]Villavicenio AT, Leveque JC, Rubin L, et al. Laminectomy versus percutaneous electrode placement for spinal cord stimulation. *Neurosurgery*. 2000;46(2):399-405.

Surgical Leads

- Paddle style
- Placed via incision (laminectomy)
- Stable array
- Unidirectional field
- More invasive
- Lead fracture



Device Therapy: Compared to What?

- Medications
  - NSAIDS, opioids, anticonvulsants
- Physical medicine
  - Chiropractic, manipulation, physical therapy
- Injections
  - Epidural steroid injections, trigger point, nerve blocks
- Surgery for back pain

Process Study

- First large multi-center, RCT on the effectiveness and cost-effectiveness of SCS vs. CMM in patients with FBSS
- 100 patients with chronic neuropathic pain predominantly in the leg(s) following at least one spinal surgery, randomized 1:1
- 12 centers in Europe, Australia, Canada and Israel
- Pragmatic trial:
  - Intent-to-treat (ITT) analysis until 6 months with crossover allowed after 6 months
  - Long-term follow-up to 24 months
  - CMM: any therapy advised by a physician, except reoperation and intrathecal drug delivery (IDD)
  - SCS (+CMM): implantable stimulation system (Synergy® system)

Kumar, Pain 2007, NANS 2007

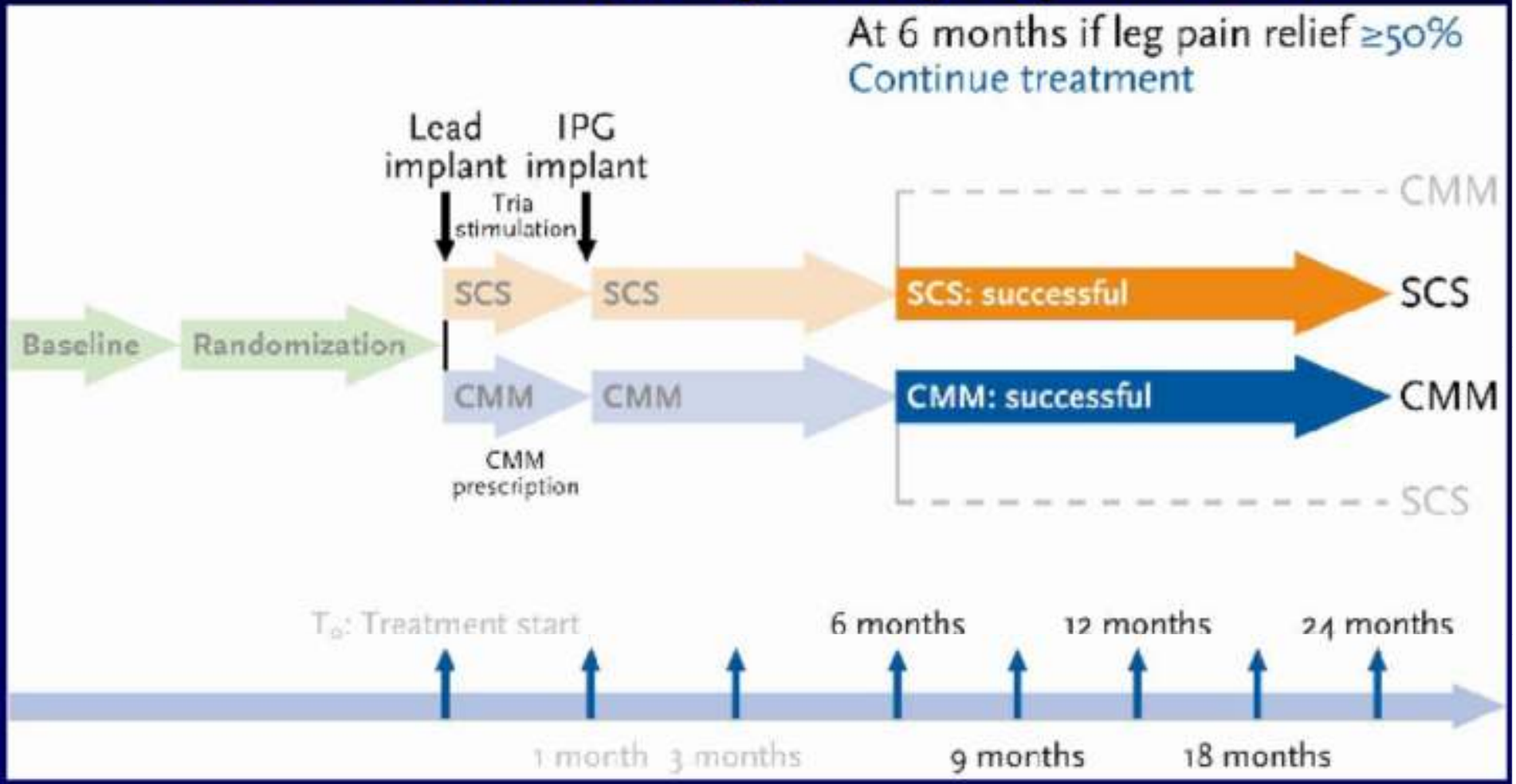
PROCESS Study Objectives

- Primary outcome:
  - Number of patients with ≥50% leg pain relief at 6 months (≥50% reduction in leg VAS)
- Secondary outcomes to be evaluated at 1, 3, 6, 9, 12, 18 and 24 months:
  - Pain relief (leg and axial back VAS)
  - Quality of life (SF-36 and EQ-5D)
  - Function (Oswestry Disability Index [ODI])
  - Patient satisfaction
  - Need for drug/non-drug therapy for pain
  - Time away from work
  - Adverse events

Kumar K, et al. *Neuromodulation* 2005;8:213-218.

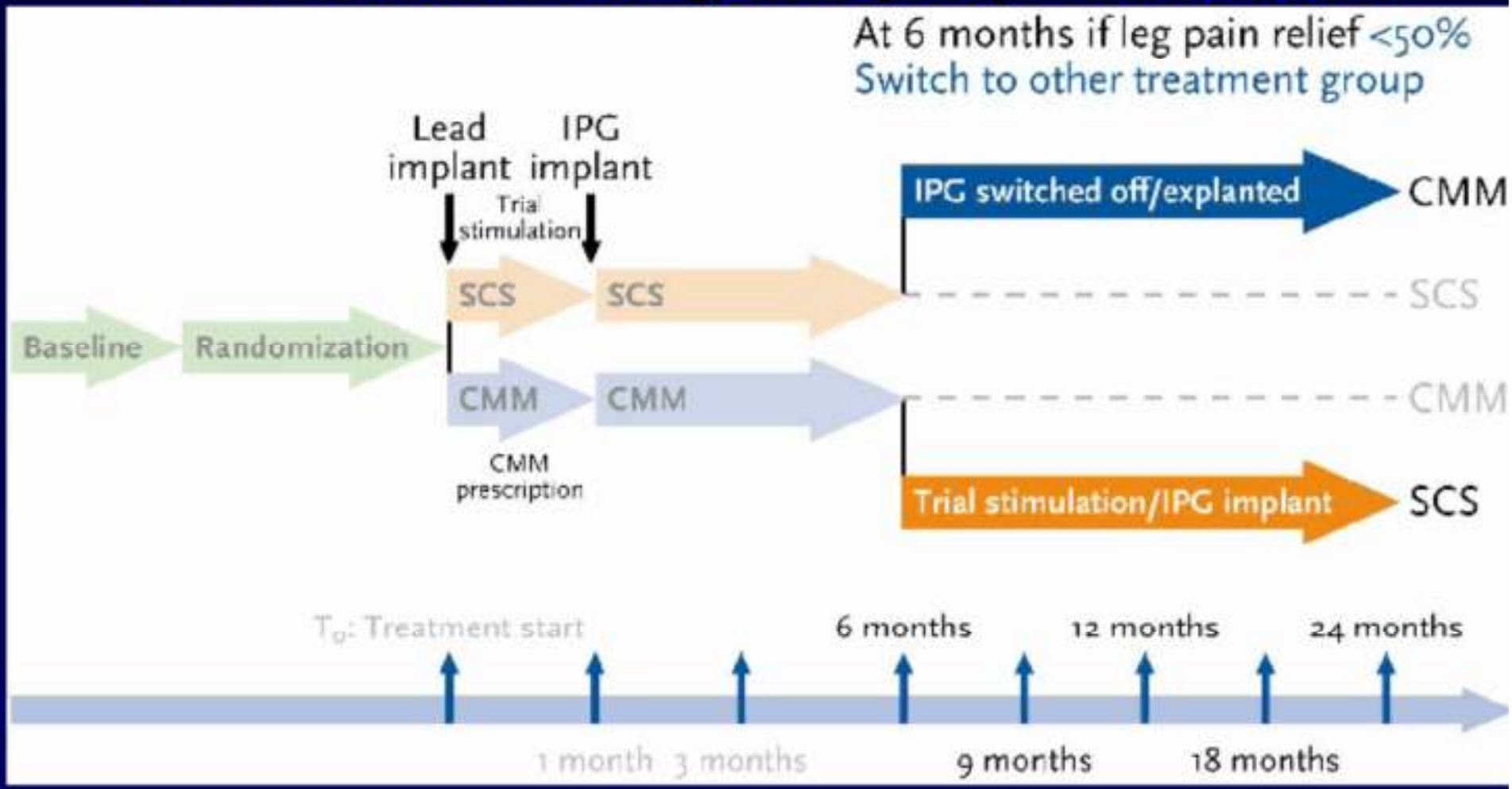
Study design

Post 6-months visit: primary objective met

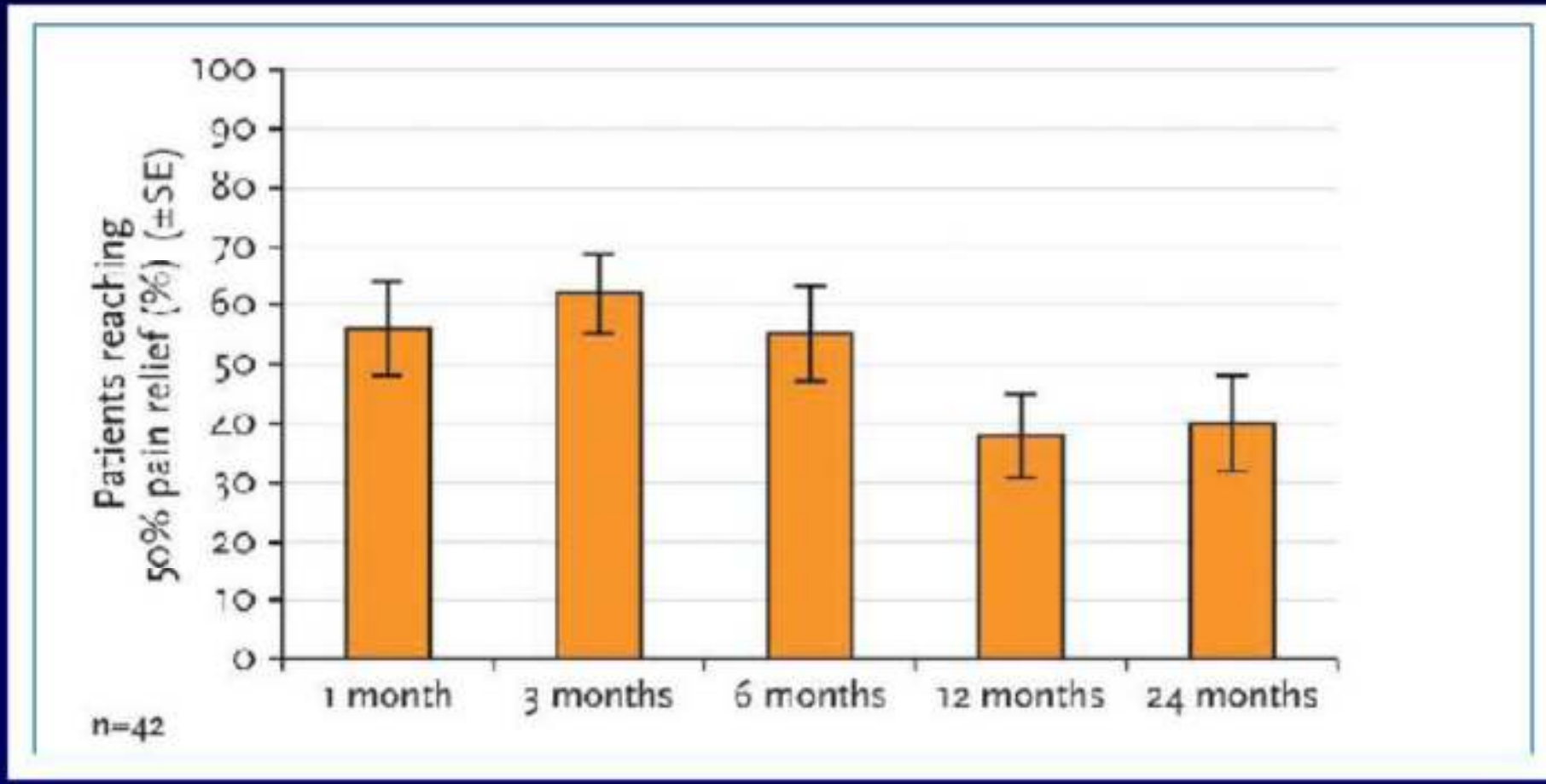


Study design

Post 6-months visit: primary objective not met



Primary Outcome thru 24 months: ≥50% Leg Pain Relief

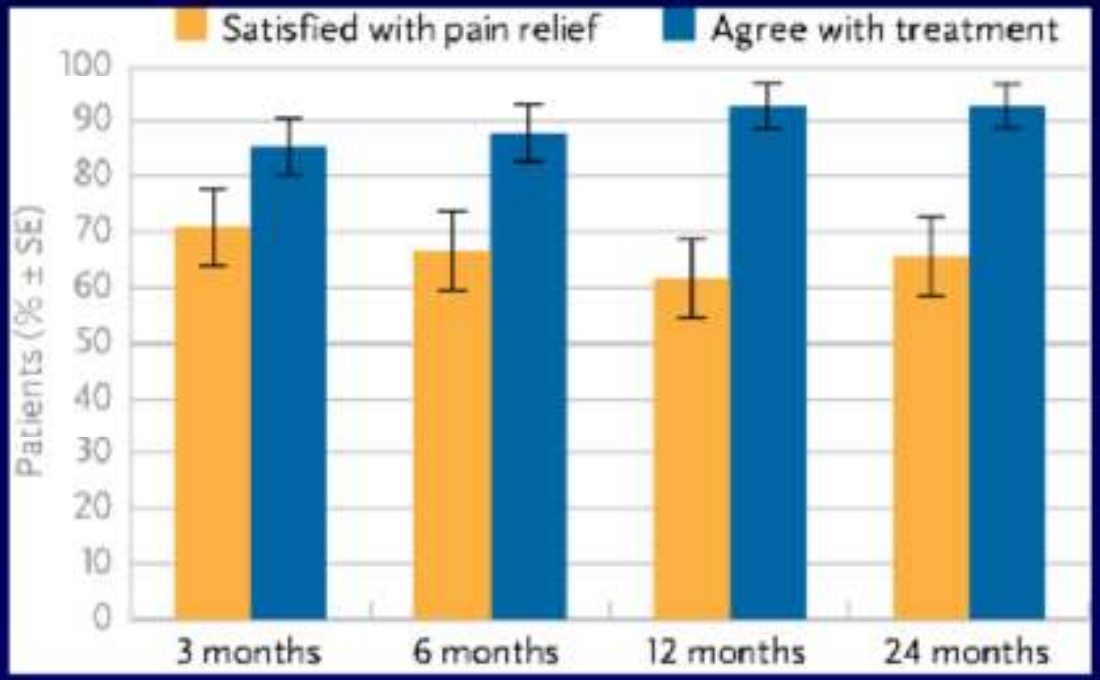


Satisfaction in SCS+CMM-continue group over 24 months

High patient satisfaction maintained over 24 months

"Are you **satisfied** with the pain relief provided by your treatment?"

"Based on your experience so far, would you have **agreed** to this treatment?"



Over 90% replied yes at 24 months!

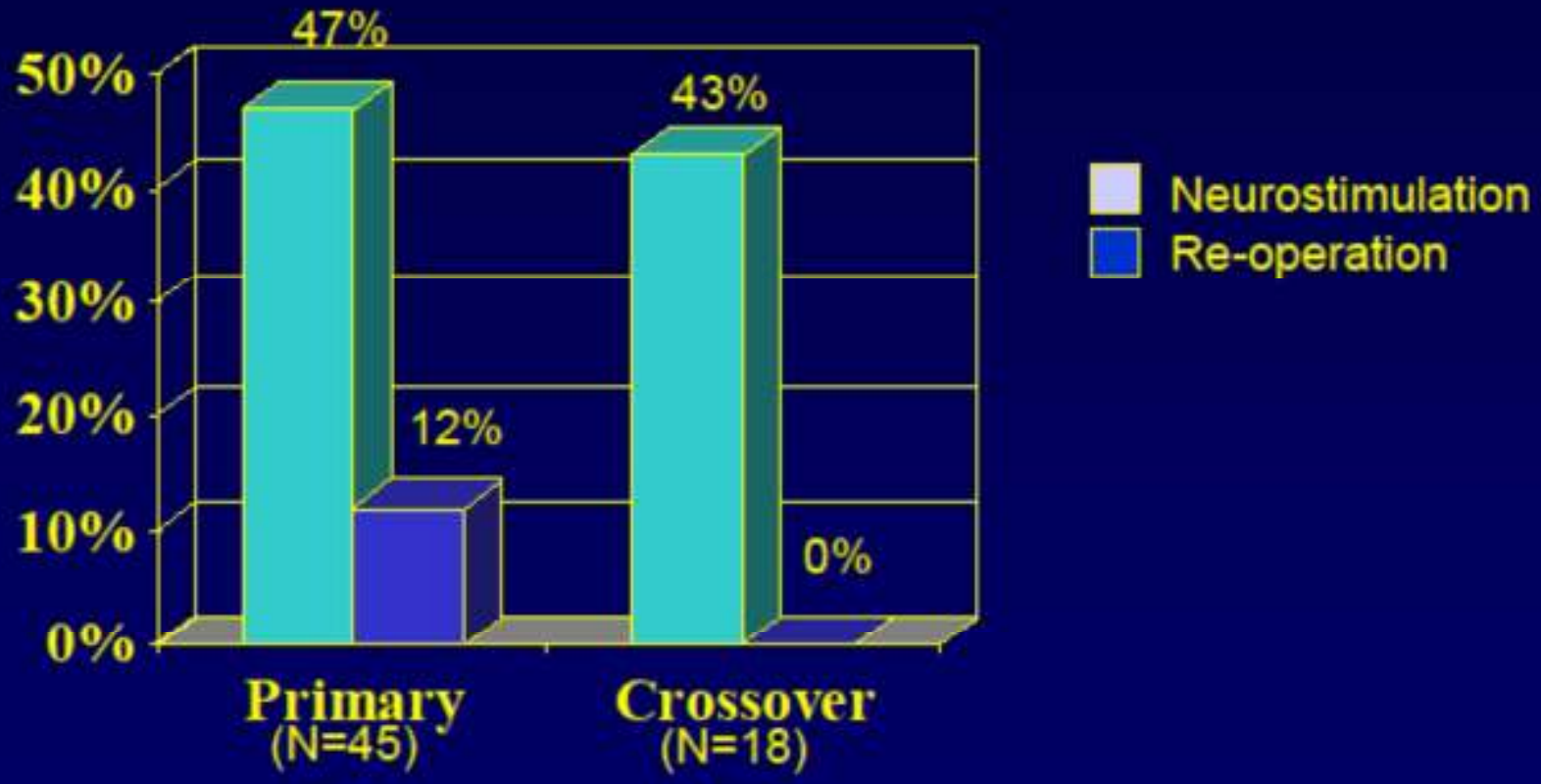
Neurostimulation vs. Repeated Lumbosacral Spine Surgery

- Prospective, randomized, controlled trial of reoperation vs NS for chronic pain
  - 60 patients randomized
  - Optional crossover to alternative after 6 months
- Measurements:
  - Pain rating
  - Patient satisfaction
  - Medication requirement
  - Work status
  - Activities of daily living
- 54% (14/26) crossed over to NS, 21% (5/24) to reoperation (p=0.02)
- SCS significantly improved pain scores and reduced opioid use

North R, et al. *Neurosurgery* 2005;56:98-107.

Neurostimulation is More Effective Than Repeat Surgery

Success* at mean 3-year follow-up



* at least 50% pain relief; would undergo treatment again for same result

North R, et al. *Neurosurgery* 2005;56:98-107.

JAMA April 7, 2010

- From 2002 to 2007 complex spinal fusion surgery increased 15 fold
- Complication rates near 40%, life threatening rate of 5.6% compared to (2.3% for decompression)
- Failure rate of 40%, no evidence that outcomes better than simple decompression
- Despite no increase in overall number of back surgeries Medicare hospital charges increased by 40%
  - Average charge for complicated fusion: $80,888 compared to average charge for decompression $23,724

JAMA April 7, 2010

Companion editorial by Carragee:

"Newer and more complex technologies are being used for patients with little specific indication for the approaches and for whom there is good evidence that simpler methods are highly effective."

"The fact that lumbar decompression is well studied and highly effective in spinal stenosis does not mean that it is well-compensated. In the Medicare population studied by Deyo et al, surgeon reimbursement for a simple decompression for spinal stenosis is approximately US $600 to $800, whereas the reimbursement for a complex fusion may be 10-fold greater."

With Medicare footing the bill, doctors get paid more for the complex procedure, hospitals get paid more and medical device companies eagerly watch their profits grow.

CER Challenges for Interventional Pain Physicians

- Techniques and devices are constantly evolving
  - Potential for future innovation/improvement likely hampered
- Few RCTs or other "high-quality" designs for many IPM procedures
- Viewed as largely short-term results (*eg.* ESI)
- New interventions not compared to best alternatives
- Lack of consistency in outcome measures
- Guidelines for use by experts not insurance companies or "commercial guidelines producers" (*eg. ACOEM)*
- Best hands problem