



Chronic Pain Management

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Objectives

- Background and Significance of Chronic Pain (lower back pain)
- What is Pain?
- Assessment and treatment approaches.
- Pharmacology for Pain Management
- Pain Treatment Agreements/Toxicology Screening.
- Lower back pain and interventional treatment options.
- Intrathecal Drug Delivery for chronic Pain

Background & Significance

- Chronic pain affects > 50 million Americans
 - 35% to 50% of adults
 - \$100 billion per year in healthcare
 - \$200 Billion per year disability costs
 - Chronic low back pain: most prevalent & costly subgroup

Lower Back Pain

- The prevalence of CLBP in U.S.
 - ~11% population
 - Many severely disabling symptoms
- The financial burdens to the patient, the healthcare system, and society are immense.
- Estimated medical costs CLBP \$35-55Billion
- Indirect costs much higher
- Low back pain is the leading cause of disability for Americans under 45 years of age.
- Only the common cold has outnumbered the number of primary care visits for LBP presentations.

What is Pain?

- **International Association for the Study of Pain Definition:** An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage
- **Margo McCaffery's Definition:** "Pain is whatever the experiencing person says it is, existing whenever the experiencing person says it does".

TYPES OF PAIN

Duration	Cause	Location
Acute	Nociceptive	Somatic
Chronic	Neuropathic	Visceral

Duration



Acute pain

- Relatively brief duration
- Etiology known
- Pain proportionate to damage
- ~ Transient objective signs
- Anxiety, anger, fear common



Chronic pain

- Longer duration
- Etiology ~ unknown
- Pain ~ disproportionate
- Often no objective sign
- Depression is common

Consequences of Unrelieved Pain

- Physical stress, emotional distress, & suffering
- Insomnia
- Immobility & de-conditioning
- Impaired hormonal & immune function
- Atelectasis, hypoxia, & increase cardiac workload
- Increases morbidity and mortality
- Sensitization & neuroplasticity

Assessing the Body

- Comprehensive pain assessment
- Examination of affected body part(s)
- Symmetry
- Effect of medications (desired / undesired)
- ROM, Strength, Functioning
- General health
- Review of Systems

Assessing the Mind

- Emotional state (sad, mad, scared, frustrated)
 - Stress / distress level
- Memory, concentration (MMSE)
- Cognitions
 - Self doubts, learned helplessness
 - Rumination, self-pity
 - Distortions, catastrophizing
 - Acceptance

Assessing Social Interactions

- Impact of pain on activities (meaningful, pleasurable)
- Relationships with family members / friends
- Abusive relationships?
- Assistance given / received from others
- Use of alcohol, drugs, tobacco
- Talk with patient and S.O.'s
- Self awareness re: therapeutic relationship

Targeting the Body: Principle of balance

- **Balanced approach to analgesics**
 - Drug class selection
 - Concerns of effect vs. side effect
 - Therapeutic vs. Legal concerns
 - Consensus statements vs. Media
- **Balance pain reduction & functioning**

Targeting the Body

- **Fix treatable causes of the pain**
 - **Cure-directed**
 - **Block or damage malfunctioning nerves**
- **Strengthen defenses to dampen pain**
 - **Increase endorphin production / release**
- **Prevent Pain Flares**
 - **Avoid factors that exacerbate pain**
 - **Promote wellness and develop strength**

Targeting the Body: Selected techniques

- **Medications**
- **Invasive procedures**
 - Nerve blocks / neuroablation
 - Implanted devices
- **Acupuncture**
- **Massage / manipulation**
- **Apply heat / ice**
- **Avoid pain triggers**
 - environmental,
 - dietary,
 - overexertion
- **Exercise**
- **Positioning**
- **Sleep Hygeine**

Chronic Pain Treatment Continuum



Diagnosis

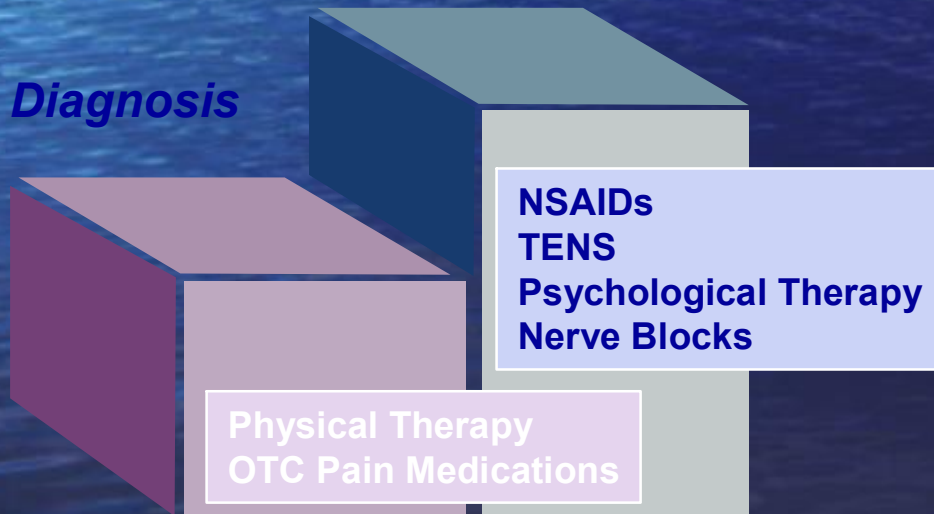


Chronic Pain Treatment Continuum

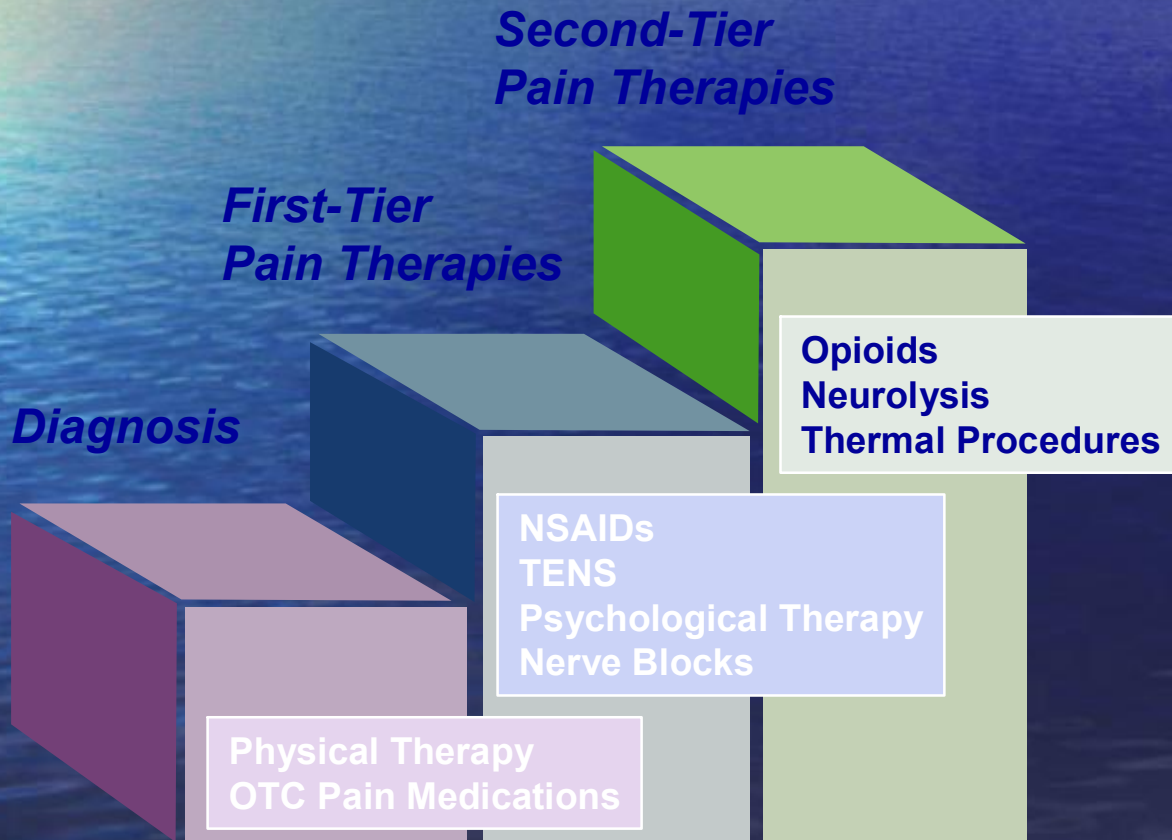


First-Tier Pain Therapies

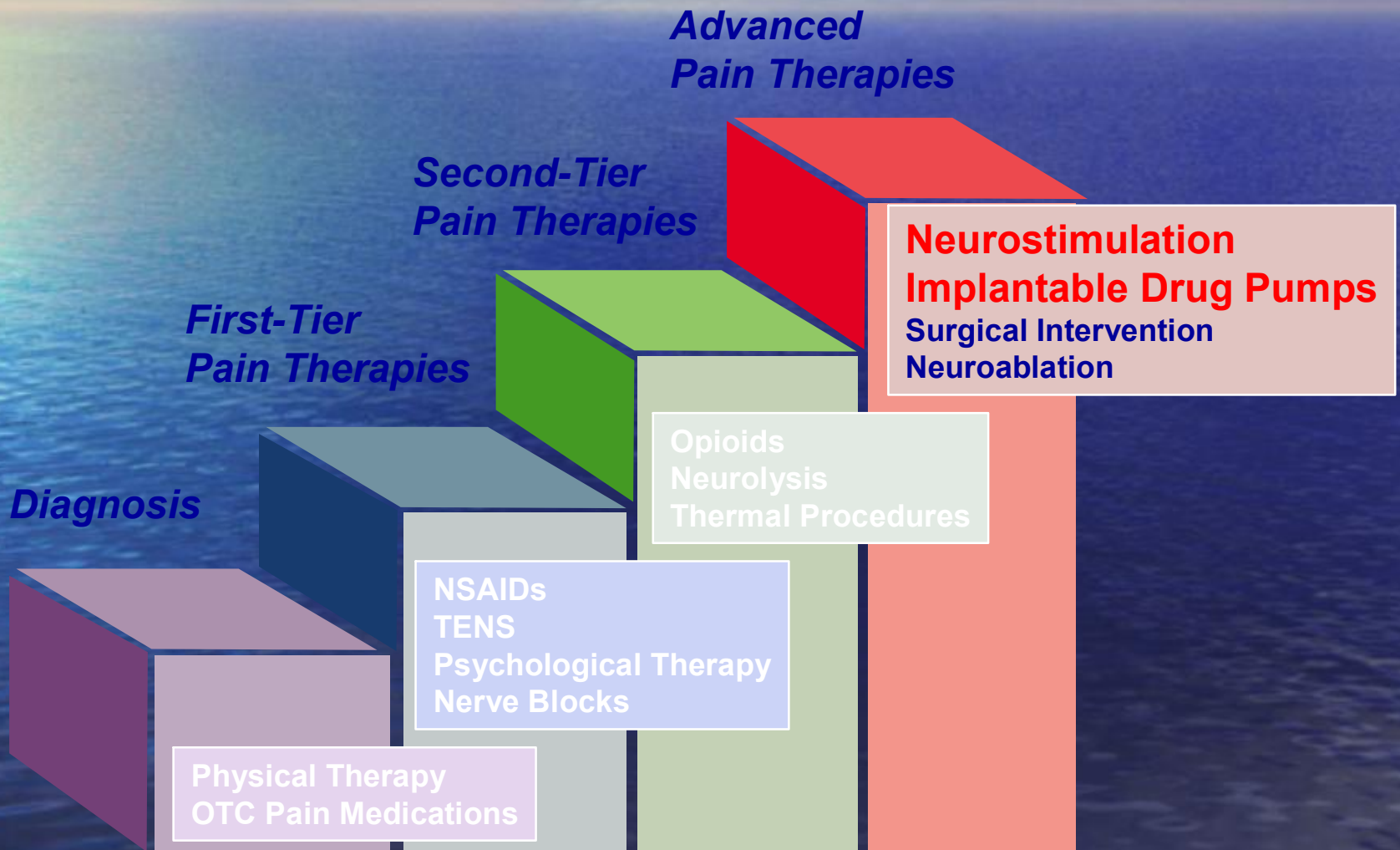
Diagnosis



Chronic Pain Treatment Continuum



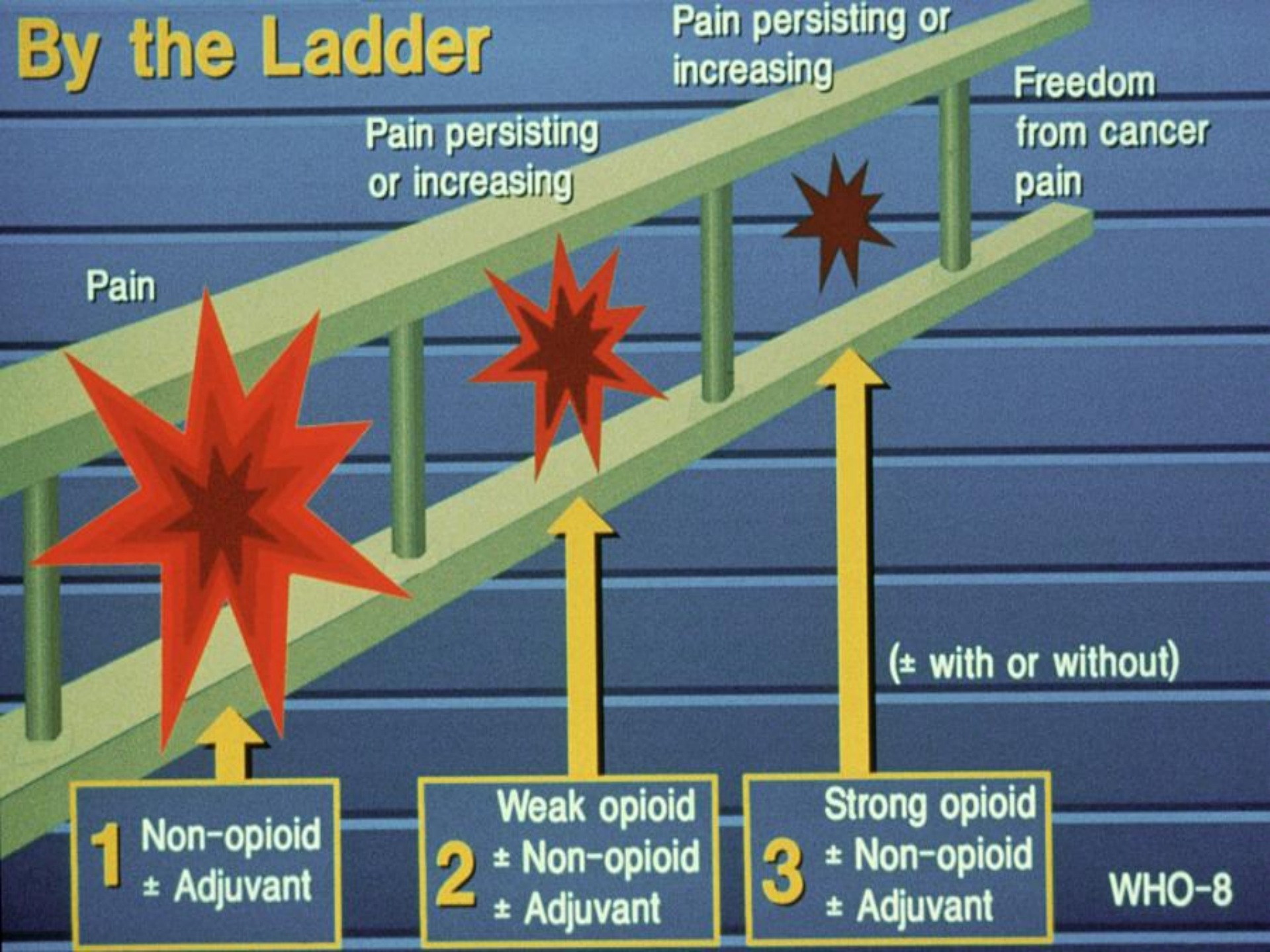
Chronic Pain Treatment Continuum



Principles for Using Analgesics

- By the Step (WHO ladder)
- By the Clock
- Adequately trial each drug
- Stay low and go slow

By the Ladder



Non-Opioids / NSAIDs

- **Benefits**

- Good for mild pain
- Helps sore, aching pain
- Treats inflammation
- Treats fever
- Many products
- Available in many routes
- Not habit forming

- **Risks / problems**

- Ceiling effect
- May delay healing
- GI toxicity
- Renal toxicity
- Hepatic toxicity
- Asthma, HTN warning

Opioid Benefits:

- Highly effective, sometime the only effective Rx
- Promotes healing
- Improves mood
- Products with low or “no” ceiling
- Accumulation ~ occur
- Pure agonists have no known end-organ damage

Opioids: Potential Problems

- **Side effects**

- Respiratory depression
- Sedation
- Nausea / vomiting
- Urinary retention
- Hormonal changes
- Sexual dysfunction
- Constipation

- **Risks**

- Addiction
- Physical dependence
- Tolerance
- Safety concerns (driving)
- Drug interactions

Risk Evaluation and Mitigation Strategy (REMS)

● Pros

- Address the potential problems associated with prescribing opioids.
- Education on proper patient selection and tools for patient education.
- Paid for by Pharmaceutical manufacturers.

Cons

- Could limit access for patients.
- Time requirements for providers to train on each drug.
- Limited to Long acting opioids only.

A Range of Products

- Weak or Mixed Opioids

- Codeine
- Propoxyphene
- Tramadol
- Pentazocine
- Nalbuphine

- Strong Opioids

- Hydrocodone
- Oxycodone
- Morphine
- Levorphanol
- Hydromorphone
- Fentanyl
- Oxymorphone
- Tapentadol

Long-Acting Opioids Currently Available

Drug	Dosing Interval	Available Strengths	Administration	Bolus	Ceiling dose
KADIAN®	q12hr q24hr	20, 30, 50, 60, 100 mg	Capsule, Sprinkle, G-Tube	No	—
AVINZA®	q24hr	30, 60, 90, 120 mg	Capsule, Sprinkle	Yes	1600 mg/day
OxyContin®	q12hr	10, 20, 40, 80, 160 mg	Tablet	Yes	—
MS Contin®	q8hr q12hr	15, 30, 60, 100, 200 mg	Tablet	No	—
Duragesic®	q48 hr q72hr	12, 25, 50, 75, 100 mcg/hr	Transdermal Patch	No	—
Opana ER®	q 12hr	5, 10, 20, 40	Tablet	No	-

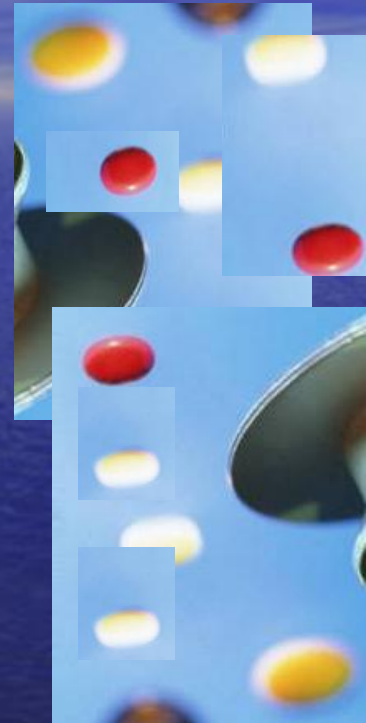
Products to avoid (or use cautiously)

- **DO NOT USE PLACEBOS**
- **Avoid**
 - Demerol
- **Use Cautiously**
 - Codeine
 - Tramadol
 - Agonist/antagonist drugs
 - Methadone

Polypharmacy

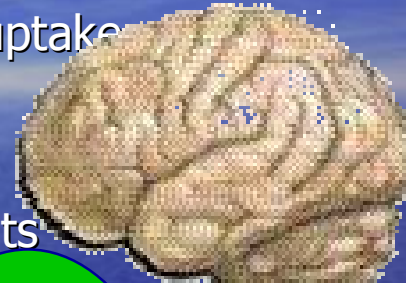
- For predictable/steady pain
 - Provide estimated need in LA meds
 - Have 10-25% of daily dose for breakthrough pain episodes
- One drug per class (exc. LA / SR MS)
- Different metabolism / excretion
- Different toxicity / Side effect

profile



Co-Analgesics

- Descending Inhibitory Pathways
 - Opioids
 - Selective norepinephrine reuptake inhibitors (SNRIs)
 - Selective serotonin reuptake inhibitors (SSRIs)
 - Tramadol
 - Tricyclic antidepressants

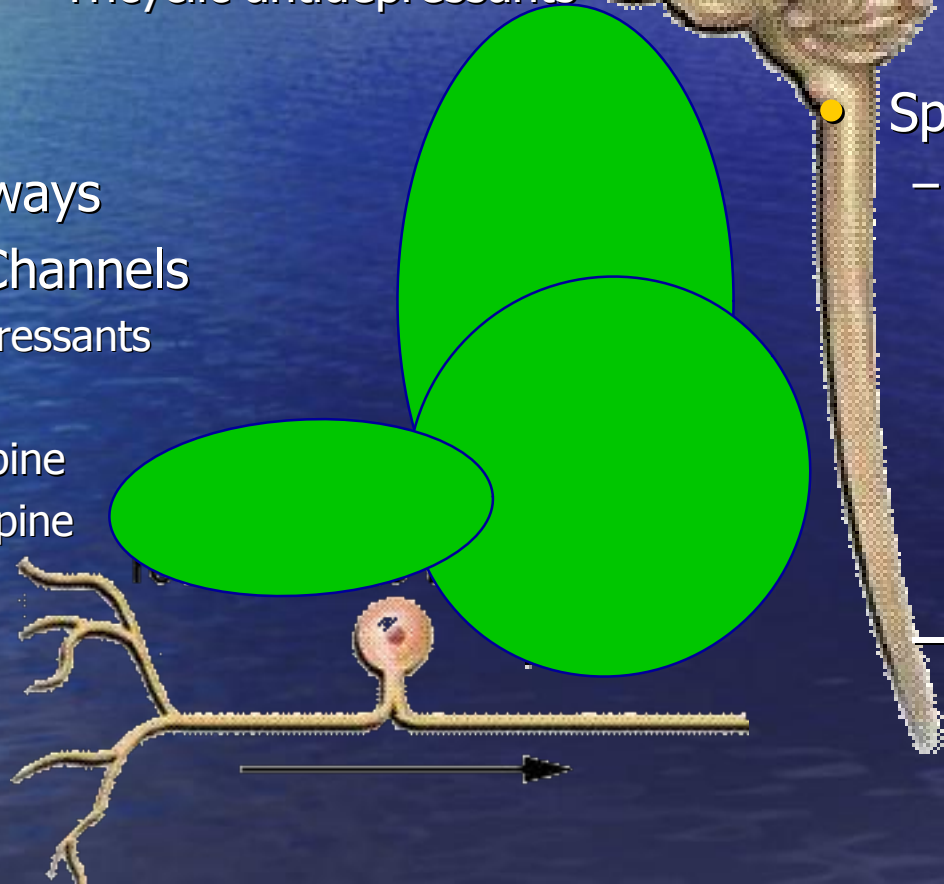


Spinal Pathways

- N-type Ca^{++} Channels
 - Gabapentin
 - Lamotrigine
 - Levetiracetam
 - Oxycarbazepine
 - Carbamazepine
 - Pregabalin

NMDA receptors

- Dextromethorphan
- Ketamine
- Methadone



Peripheral Pathways

Voltage D. Na^{+} Channels

- Tricyclic antidepressants
- Anticonvulsants
 - Carbamazepine
 - Oxycarbazepine
 - Phenytoin
 - Lamotrigine
- Lidocaine
- Mexiletine

Pain Treatment Agreements

Positives

- Clear expectations
- Informed Consent
- Documentation
- Patient safety
- Safe Guarding Practice

Negatives

- Patient Perceptions about agreements
- Open to interpretation.
- Time and staff power needed to keep agreements up to date.

Compliance Monitoring

Positives

- Necessary to protect the patient, provider, and society.
- Monitors adherence to treatment protocol

Negatives

- Cost
- Staffing
- Time
- Patient complaints

Chronic Back Pain

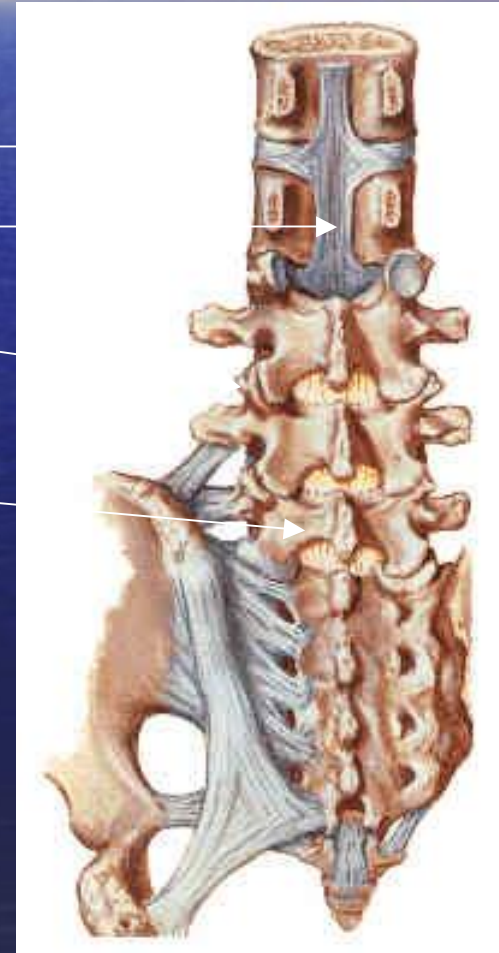
- Sources of Pain
- Diagnostics
- Treatment
 - interventional spine procedures (epidural steroid injections, facet joint injections, spinal cord stimulator)



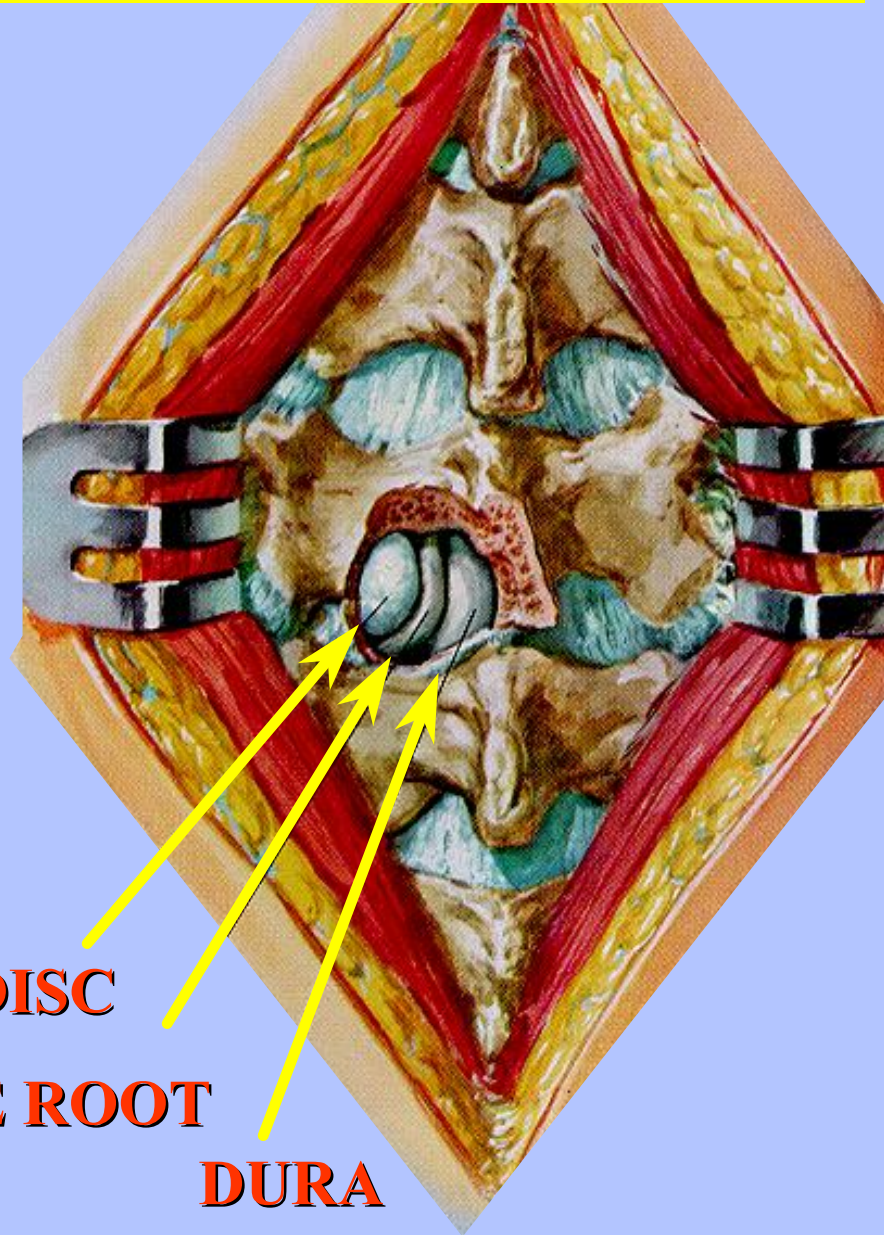
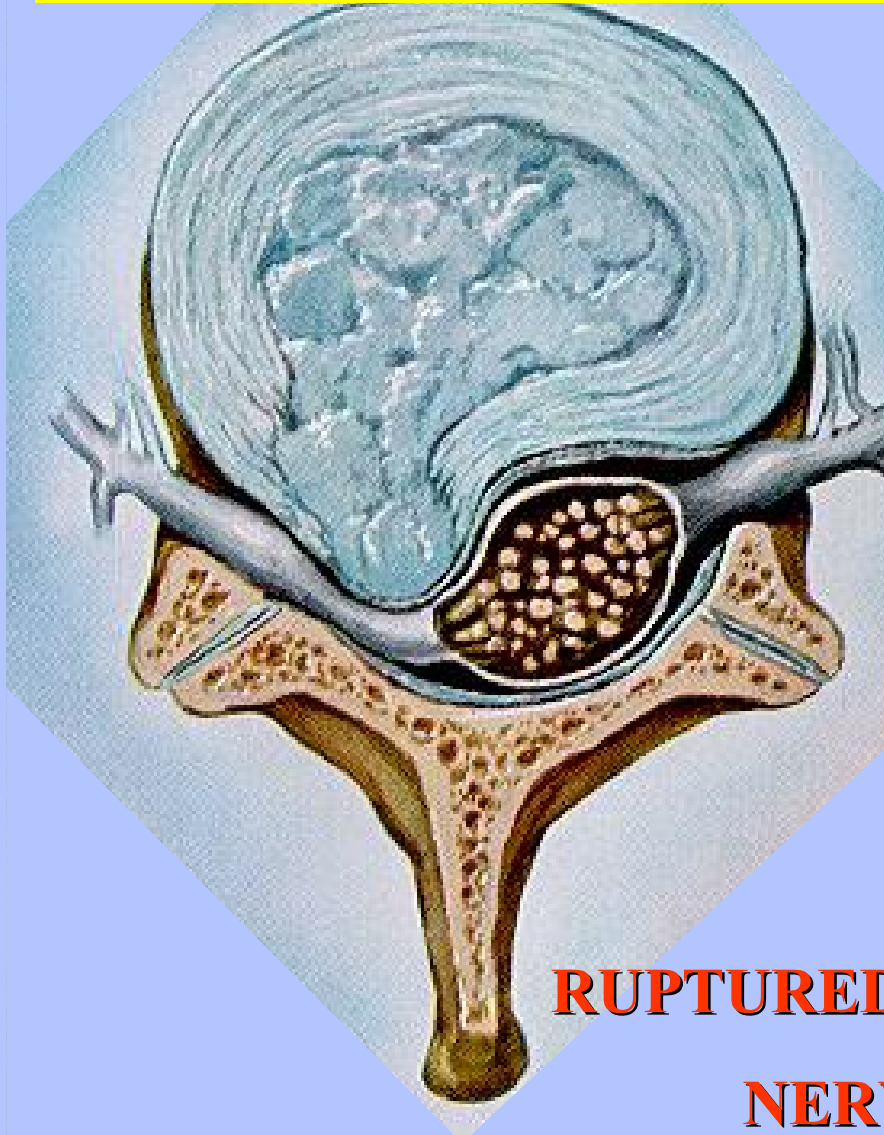
THE NORMAL BACK

SOURCES OF SPINAL PAIN

- Discs
- Ligaments
- Facet (zygapophyseal) joints
- Vertebrae
- Muscles
- Nerve roots
- Spinal cord and dura



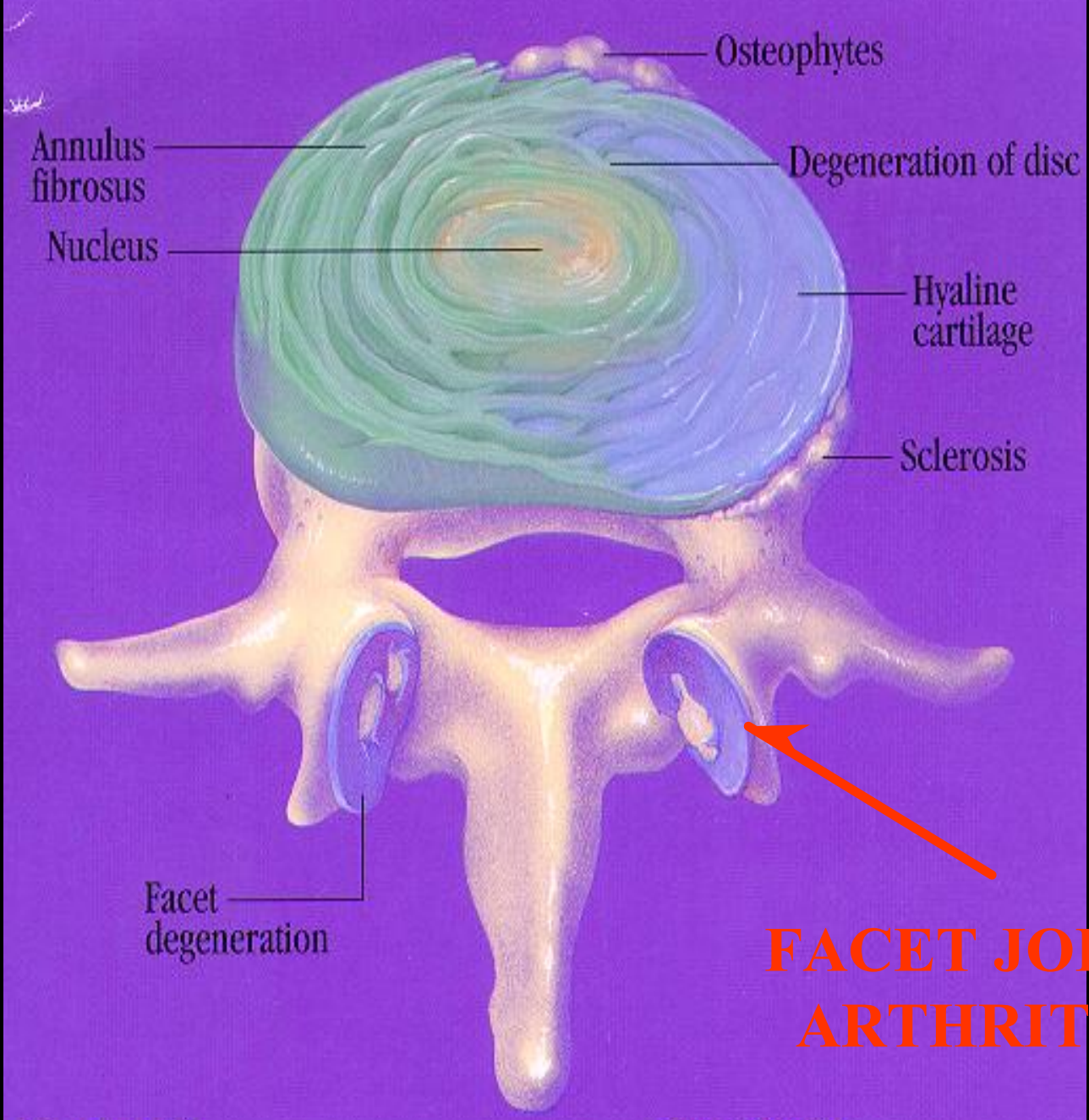
RUPTURED DISC-SURGICAL TREATMENT



RUPTURED DISC

NERVE ROOT

DURA

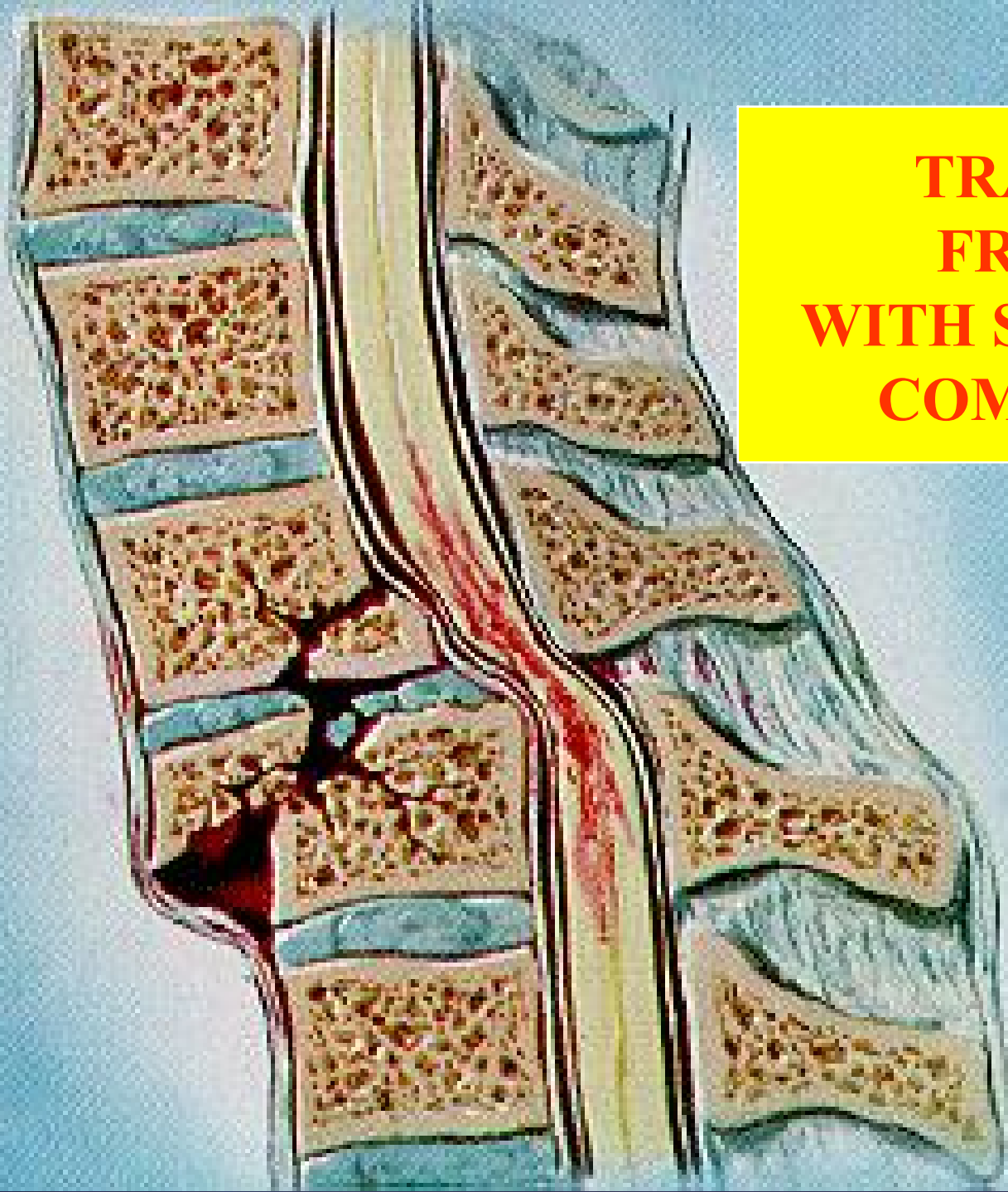


Lumbar L3

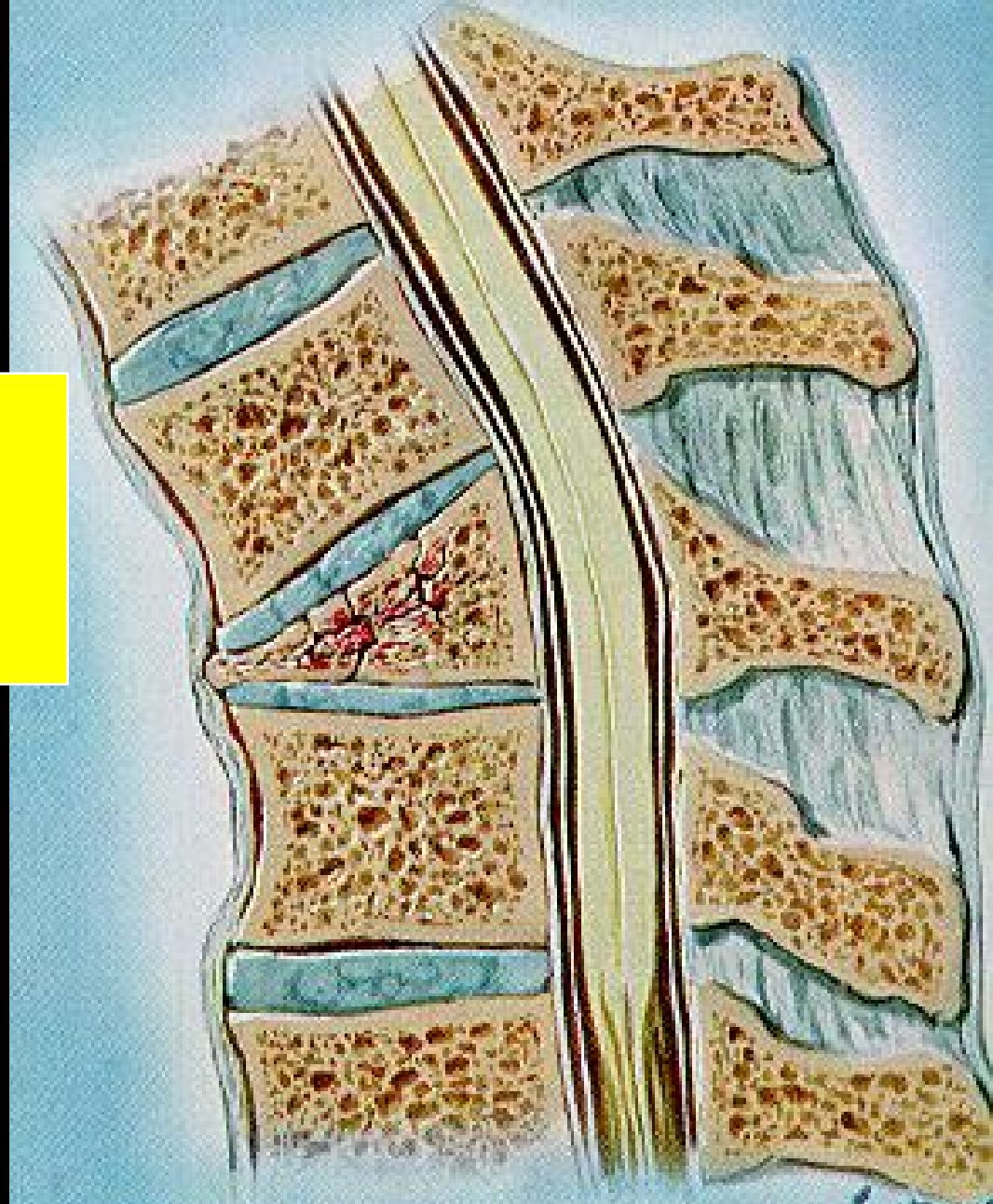
Superior V.

**FACET JOINT
ARTHRITIS**

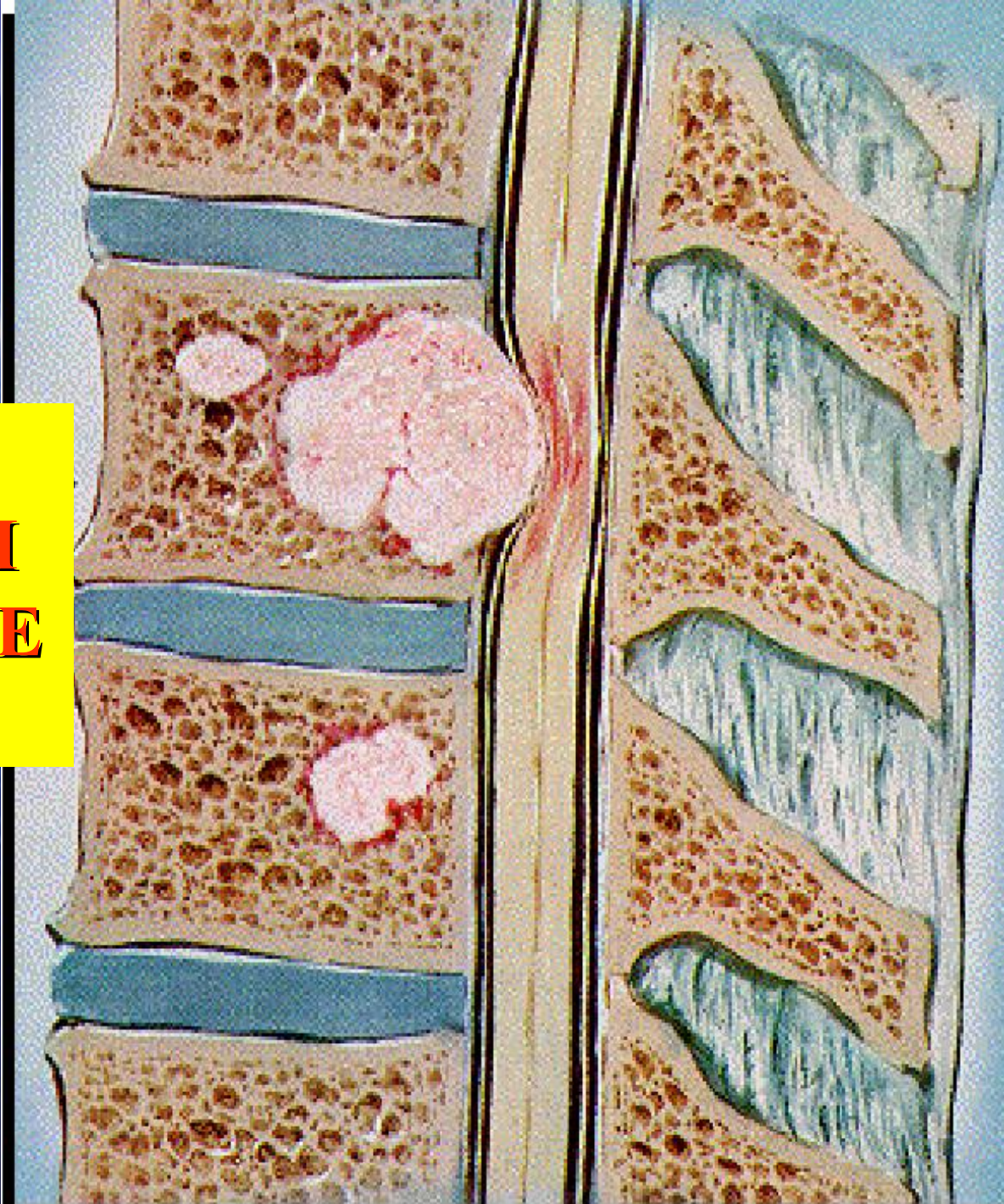
**TRAUMATIC
FRACTURE
WITH SPINAL CORD
COMPRESSION**



**WEDGE COMPRESSION
FRACTURE DUE TO
OSTEOPOROSIS**



**METASTATIC
CANCER WITH
SPREAD TO THE
SPINE**



Back Pain and Sciatica: Imaging Evaluation

- Lumbosacral **x-ray** studies with flexion/extension/oblique views
- **MRI** of the spine
- **CT** with 3-D reconstruction
- CT plus myelography

Basic Interventional Techniques

- **Nerve Blocks**
 - Epidural steroid injection
 - Z-joint (facet joint) injection
 - Sacroiliac joint injection

Advanced Techniques

New advanced techniques for treatment of
back and neck pain

- n Radiofrequency

- n IDET (Intradiscal Electrothermal
Therapy)

- n Nucleoplasty

- n Implants

 - n Spinal cord stimulation

 - n Infusion pumps

ZYGAPOPHYSEAL JOINT INTERVENTIONS

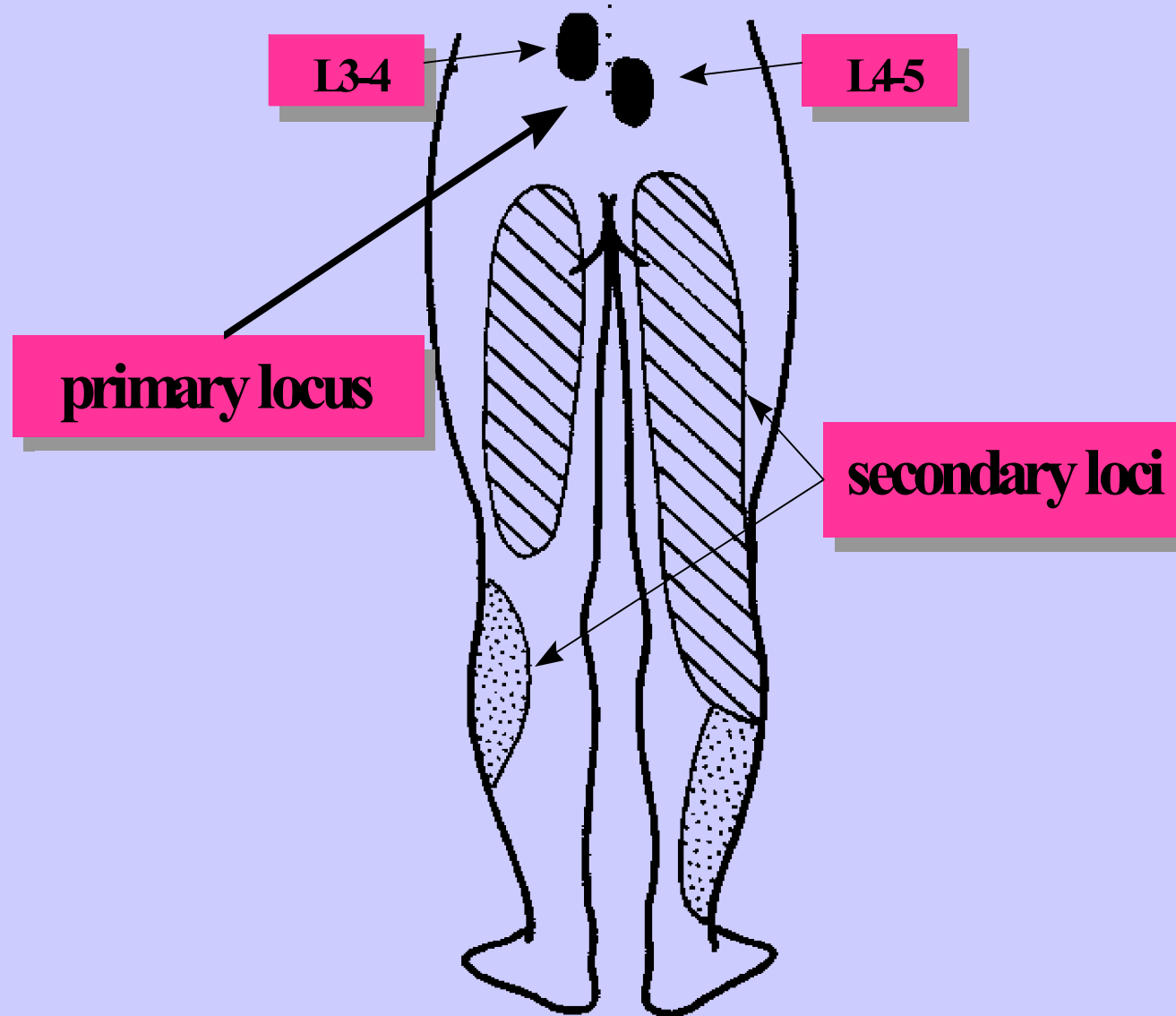
- Diagnostic intraarticular injection
- Diagnostic medial branch block
- Therapeutic intraarticular injection
- Radiofrequency treatment of medial branch
- Z joints = Most common cause of spinal pain (40-60%)

Bogduk N et al., Clin J Pain, 1997

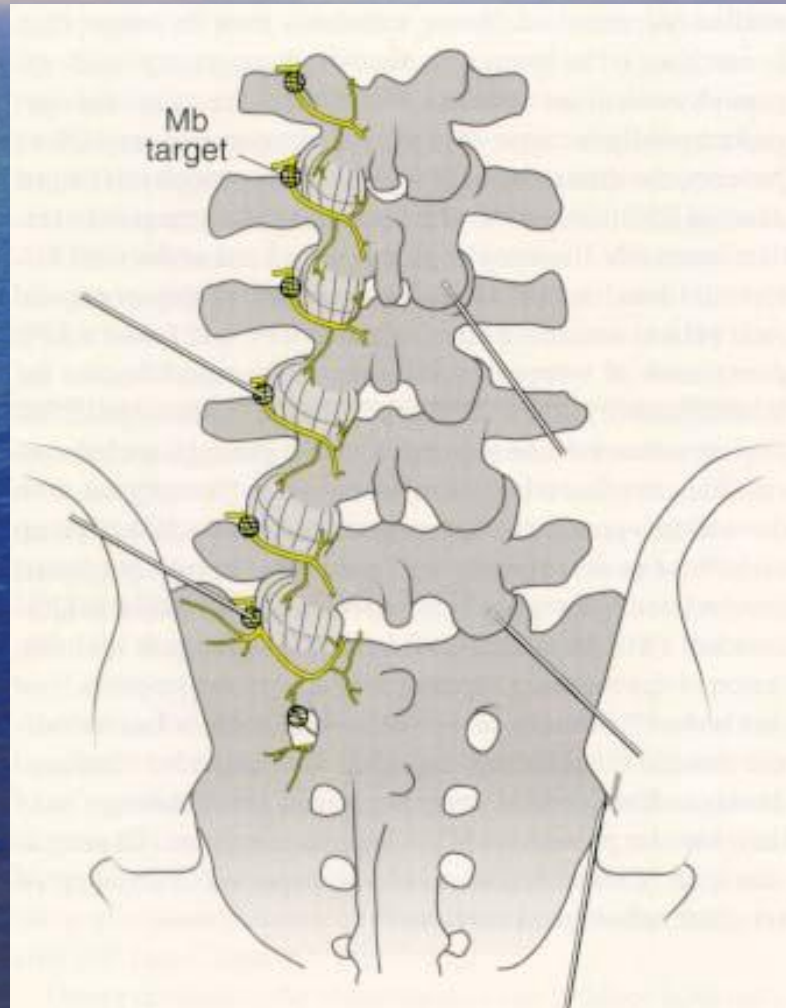
Schwarzer AC et al., Clin J Pain, 1994

Barnsley L et al., Spine, 1995

lumbar facet referral pattern

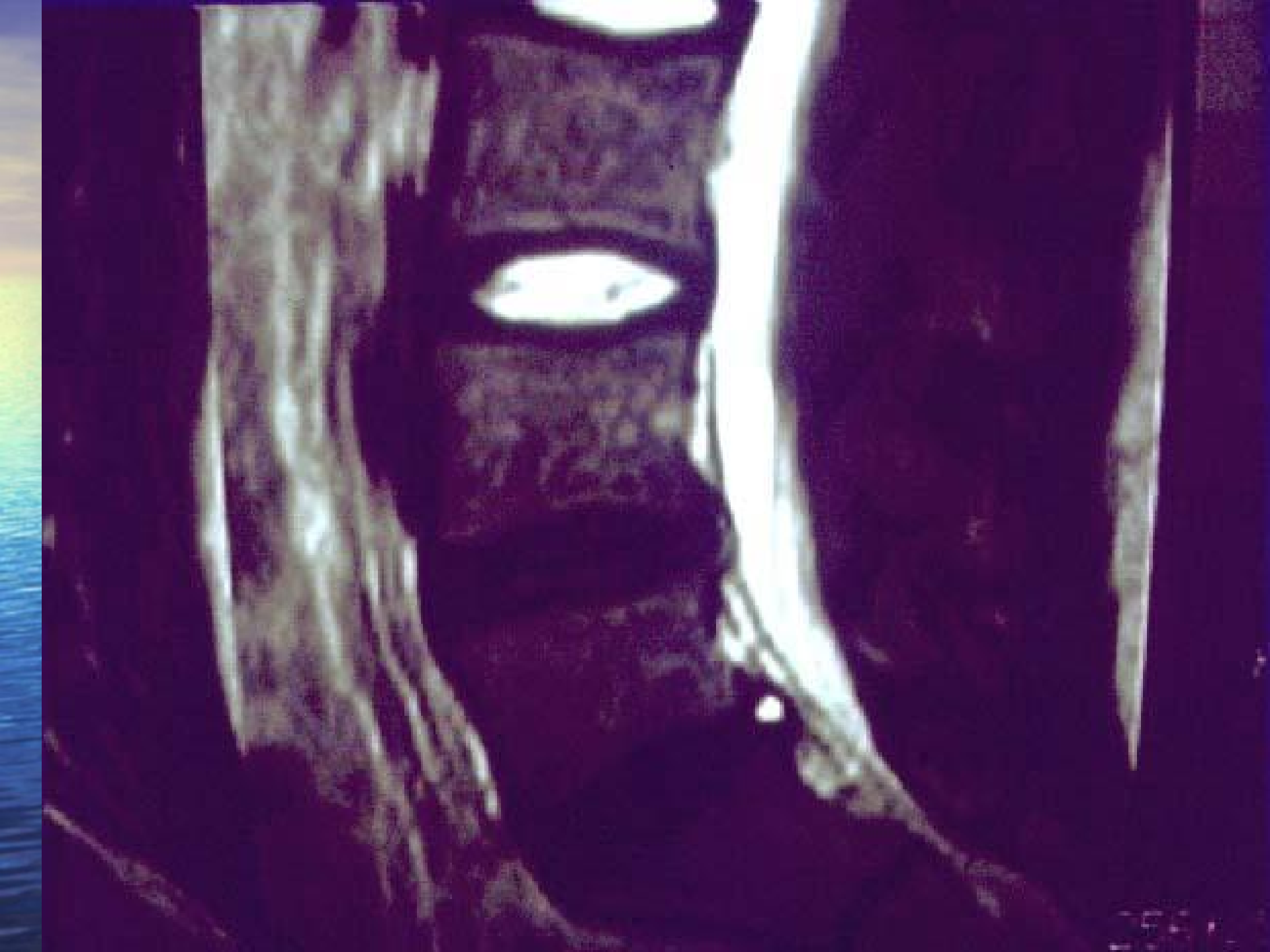


Z-Joint treatment



DDD of lumbar spine



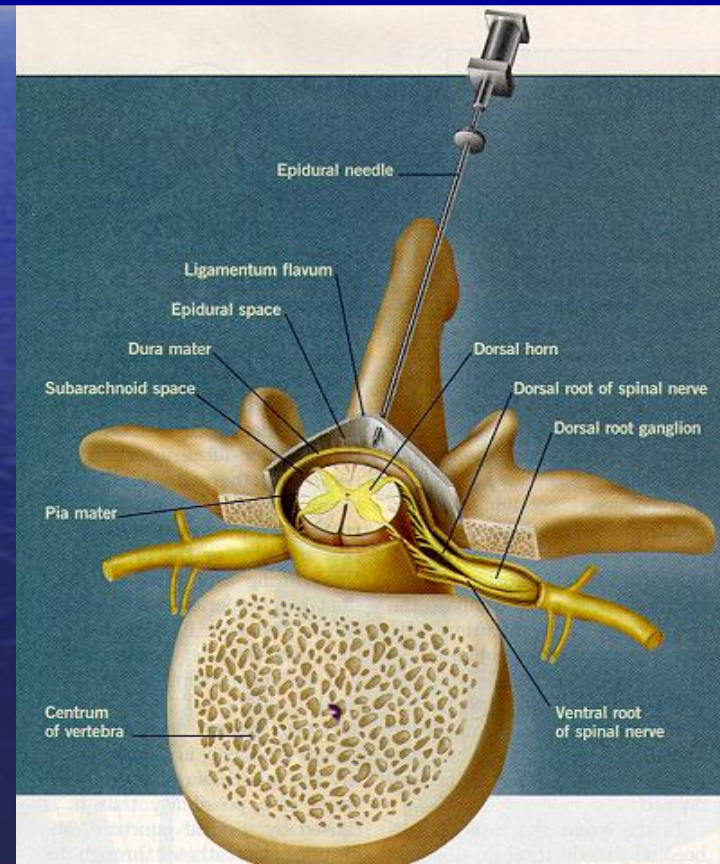


TREATMENT Options for DISCOGENIC LOW BACK PAIN

- Lifestyle modification
- Exercise/Physical therapy
- Medication therapy
- Epidural steroid injections
- Discography
- IDET
- Fusion surgery
- Disc Replacement Surgery

EPIDURAL STEROID INJECTIONS

- Interlaminar
 - Cervical
 - Thoracic
 - Lumbar
- Transforaminal
 - Cervical
 - Thoracic
 - Lumbar
- Caudal



EPIDURAL STEROID INJECTIONS

Author	Study Characteristics	No. of Patients	Relief Control vs. Treatment [%]			Results P-pos., N-neg.
			1-4 w	3 m	6 m	
Breivik et al 1973	Caudal [P, DB, RA]	35	25 vs. 63	20 vs. 50	20 vs. 50	P
Bush et al 1991	Caudal [P, DB, RA,PC]	23	100	N/A	64 vs.83	P
Goebert et al 1961	Caudal [R]	113	N/A	72	N/A	P
Beliveau et al 1971	Caudal [P, RA]	48	70 vs. 75	70 vs. 75	N/A	N
Dilke et al 1973	Lumbar[P, DB, RA,PC]	100	31 vs. 60	74 vs. 91	N/A	P
Ridley et al 1988	Lumbar [RA, PC,DB]	35	19 vs. 90	19 vs. 90	65	P
Scott et al 1987	Lumbar [P, RA, PC]	150	22 vs. 22	N/A	N/A	N

Discography and Percutaneous Annuloplasty

- Pressure-controlled discography
 - Provocation of familiar pain
 - Enables grading disc sensitivity (chemical, mechanical, indeterminate, normal)
 - May predict surgical outcome (Derby et al, 1999)
 - “positive” result (pain intensity, concordance, pain behavior, psychological factors, WC, etc.)

Patient Selection Criteria for Spinal Cord Stimulation and Intrathecal Pumps.

- More conservative therapies have failed
- An observable pathology exists that is concordant with the pain complaint
- Further surgical intervention is not indicated
- No serious untreated drug habituation exists
- Psychological evaluation and clearance for implantation has been obtained
- No contraindications to implantation exist. These include sepsis, coagulopathy, etc.
- Trial screening has been successful

Indications for Advanced Pain Therapies

Neurostim Pain Therapy

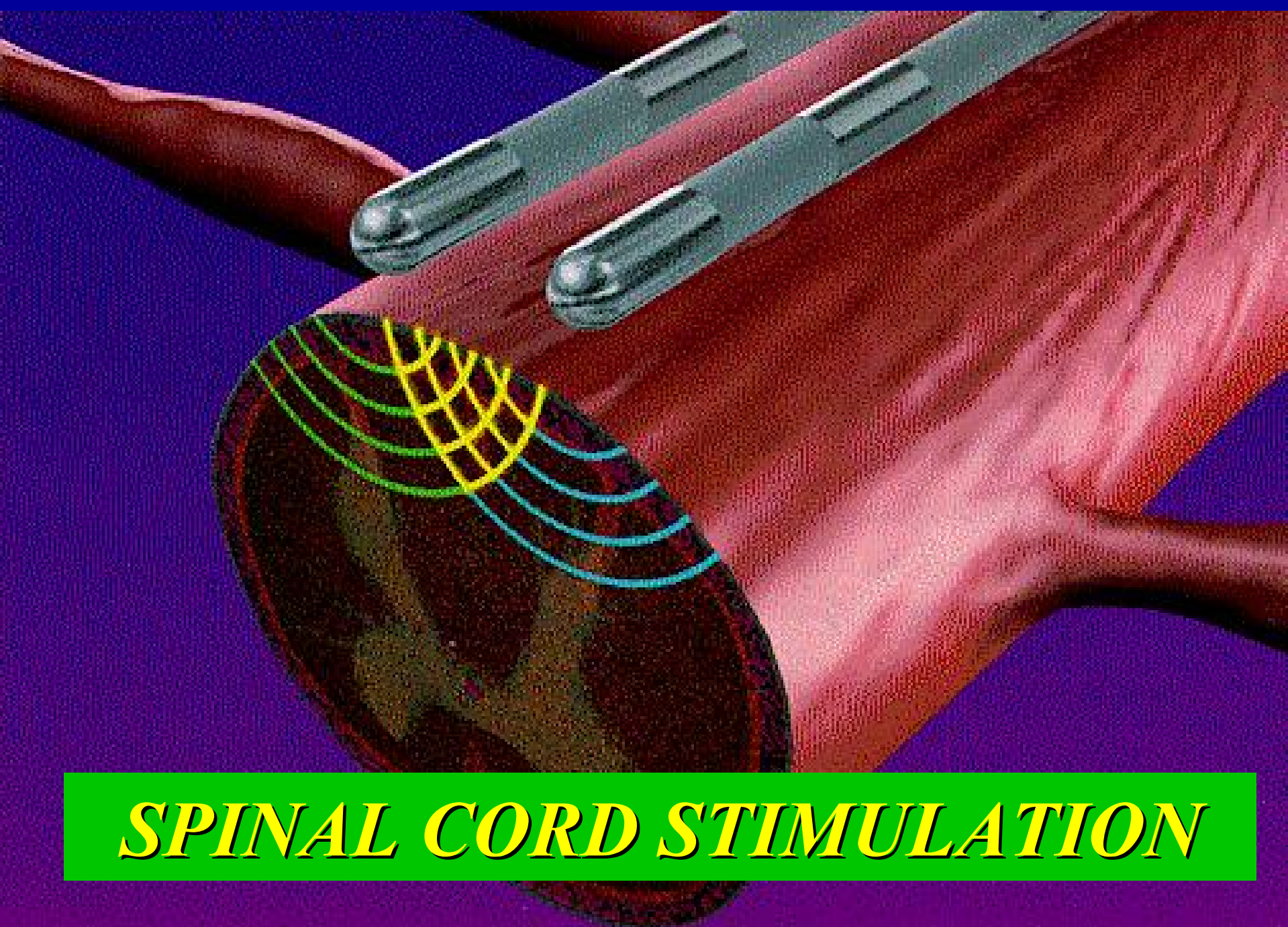
- Failed Back Syndrome (FBS)
- Complex Regional Pain Syndrome
- Arachnoiditis
- Radiculopathies
- Peripheral Ischemic Pain
- Neuralgias
- Intractable Angina

Neurostim Pain Therapy or Intrathecal Pain Therapy

- Failed Back Syndrome
- Complex Regional Pain Syndrome
- CRPS
- Arachnoiditis
- Painful Neuropathies
- Spinal Cord Injury
- Post-Herpetic Neuralgia
- Phantom Limb Pain

Intrathecal Pain Therapy

- Diffuse Cancer Pain
- Failed Back Syndrome
- Axial Somatic Pain
- Osteoporosis
- Arachnoiditis
- Visceral Pain
- Head, Neck Pain

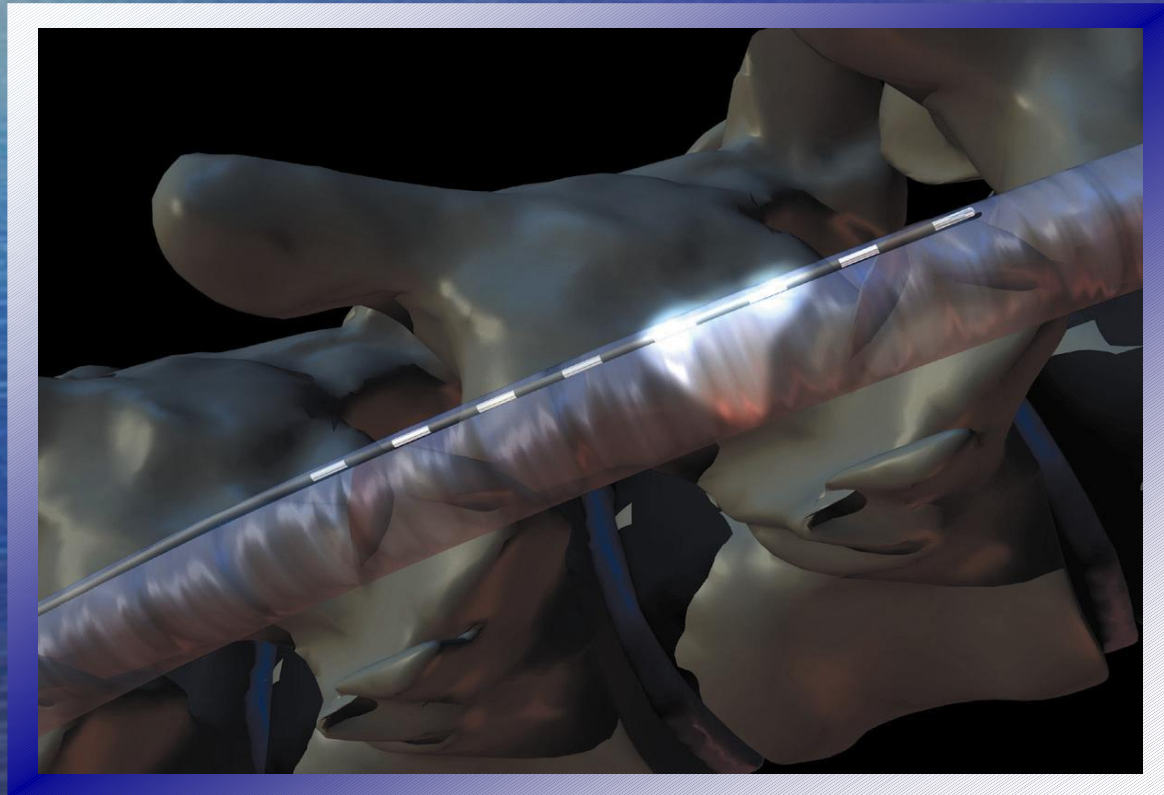


SPINAL CORD STIMULATION

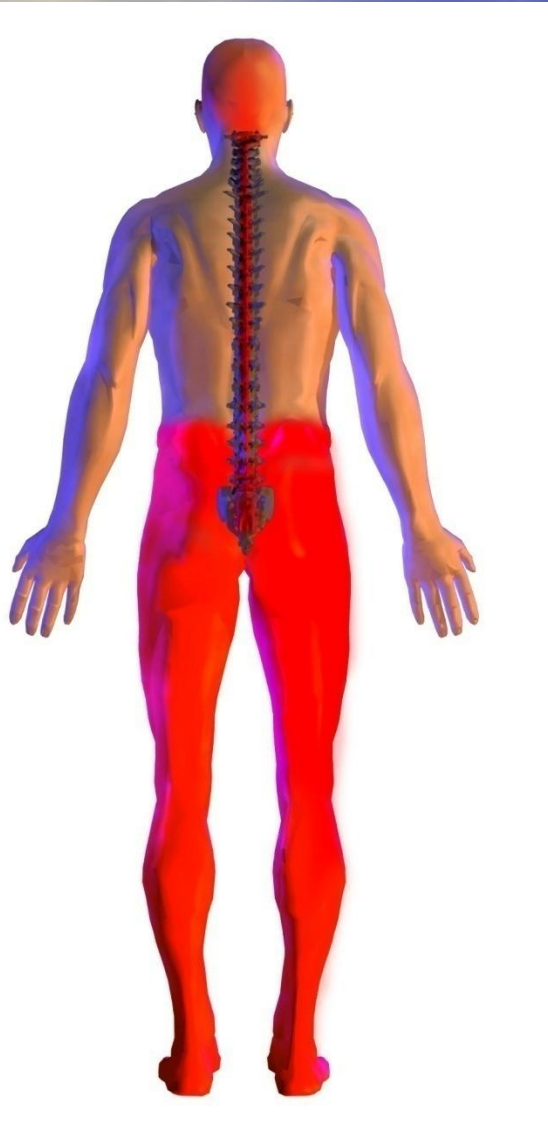
Neuromodulation Devices

Electrical Stimulators and Drug Pumps

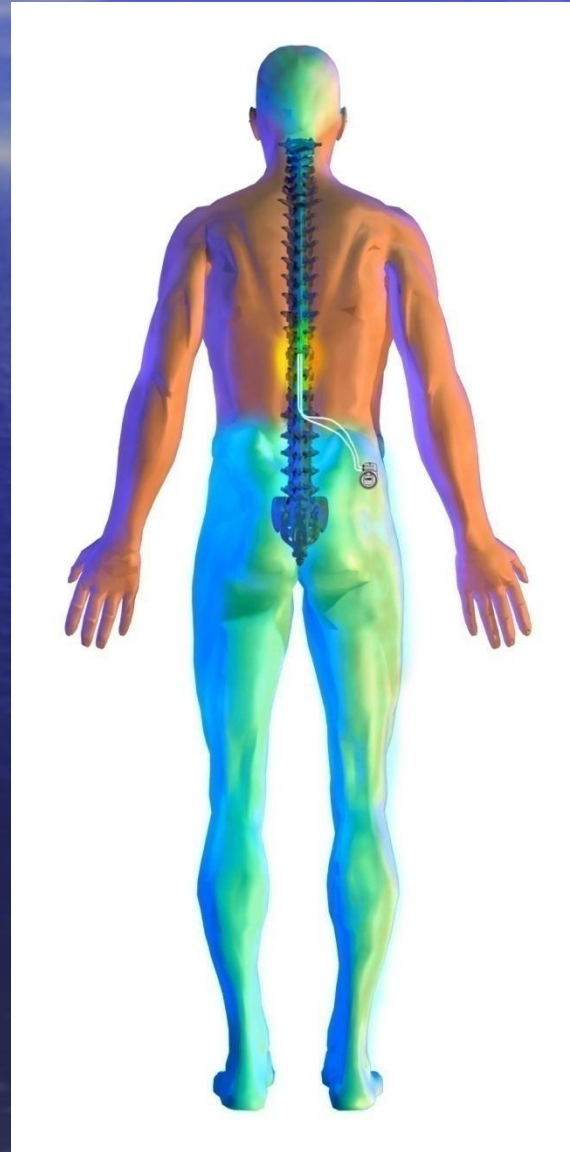
Precise delivery of small doses of electricity or drugs directly to targeted nerve sites.



Spinal Cord Stimulation (SCS)



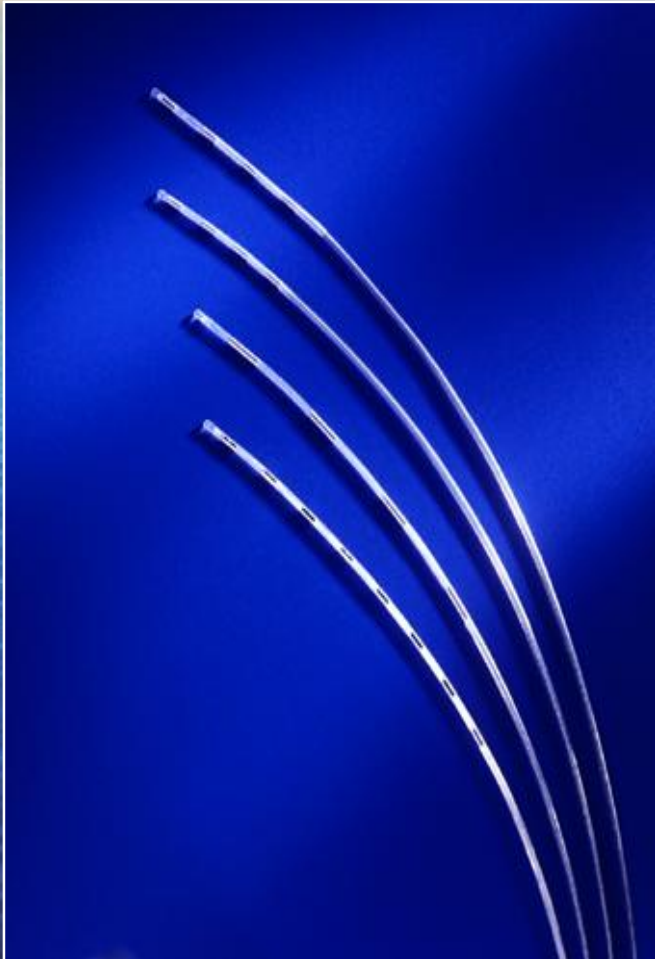
Implanted medical device that delivers electrical pulses to nerves in the dorsal aspect of the spinal cord that can interfere with the transmission of pain signals to the brain and replace them with a more pleasant sensation called paresthesia.



What is Neurostim Pain Therapy?

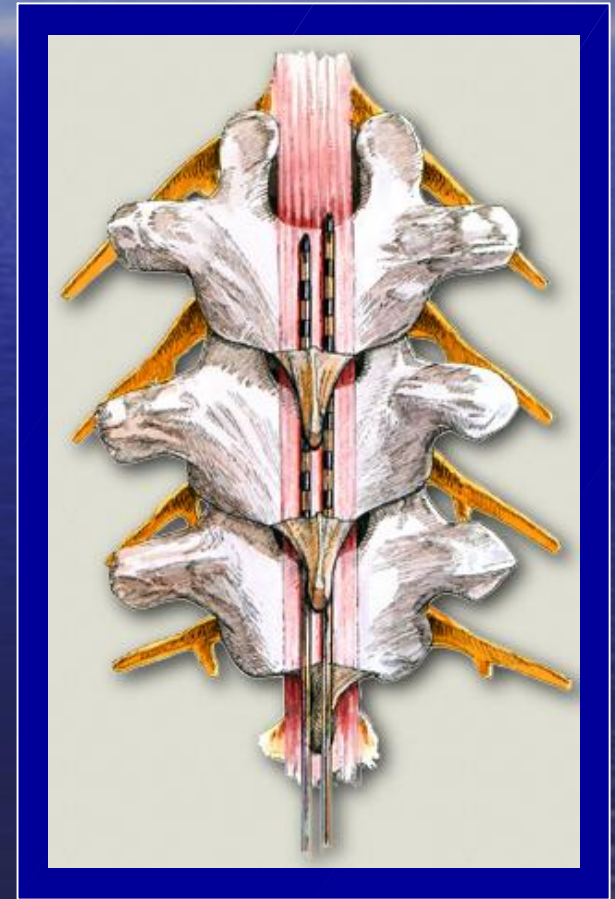


Percutaneous Leads

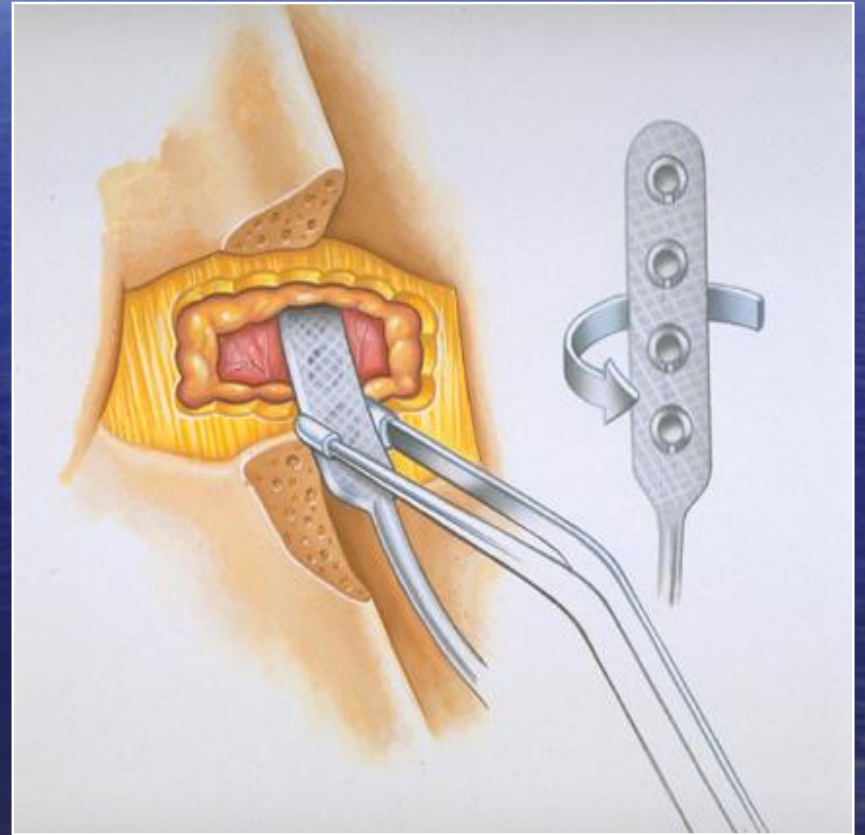


Percutaneous Leads

- Catheter style
- Placed via special needle
- Less invasive
- More prone to migration
- Cylindrical electrodes



Surgical Leads

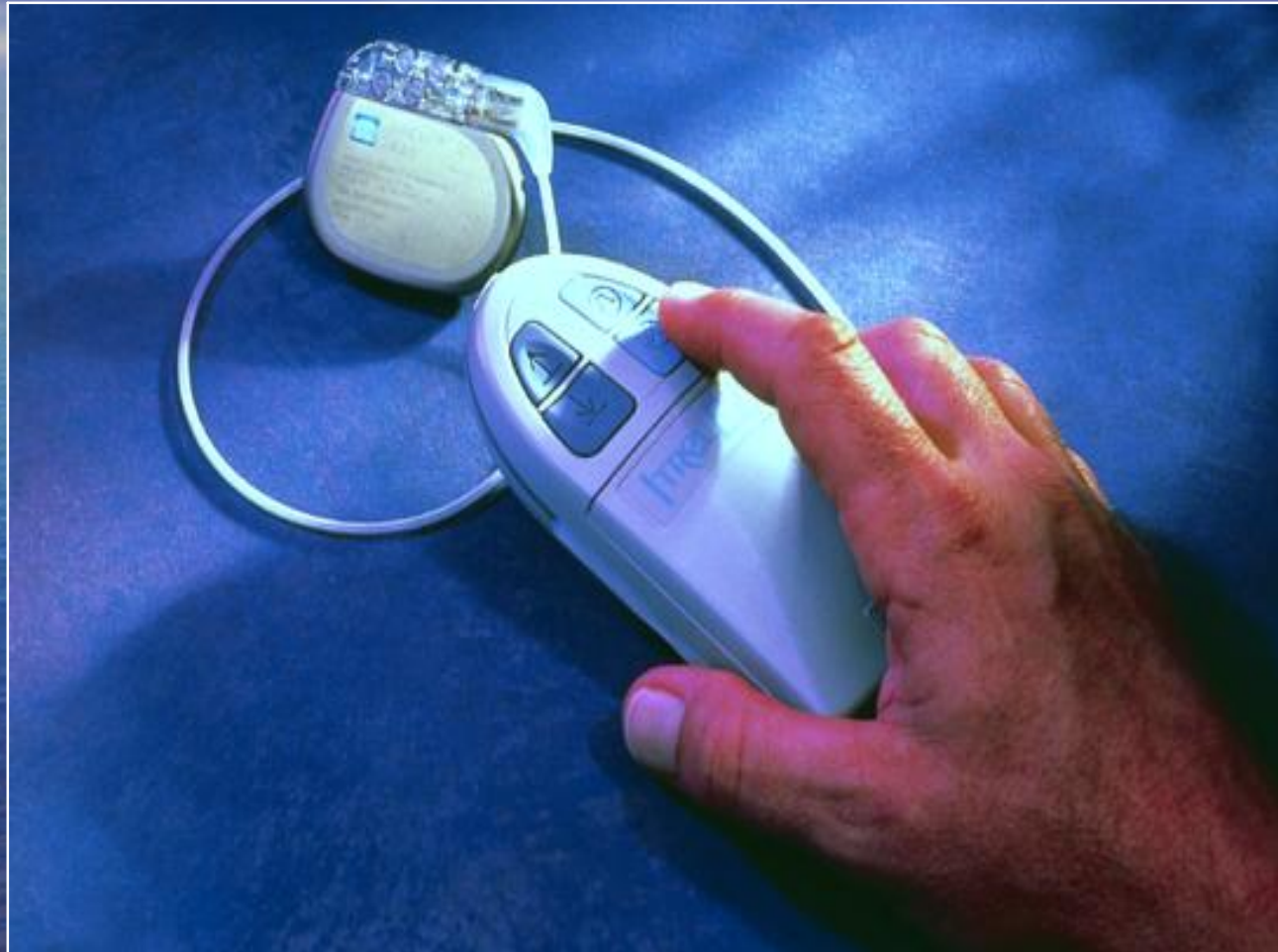


Surgical Leads

- Paddle style
- Placed via incision (laminectomy)
- More invasive
- Very stable
- Plate electrodes



Internal Pulse Generator



SCS Systems

Two Types of Systems

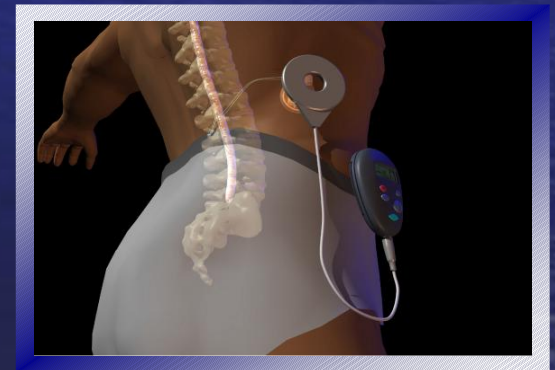
1. Implanted Pulse Generator (IPG)

- Pulse generator and battery inside
- Power controls outside



2. Radio Frequency (RF)

- Pulse generator inside
- Battery and power controls outside



The Renew[®] RF System



When a Single Lead Trial is Unsatisfactory

Dual Leads Improve Likelihood of Success



C

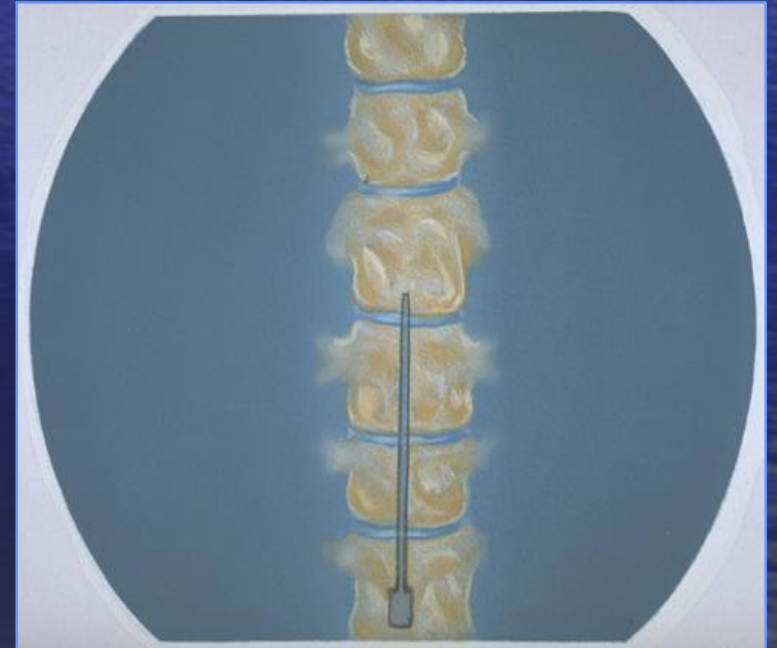
- Totally Implantable Dual Lead Therapy
- Single Stim™ Only



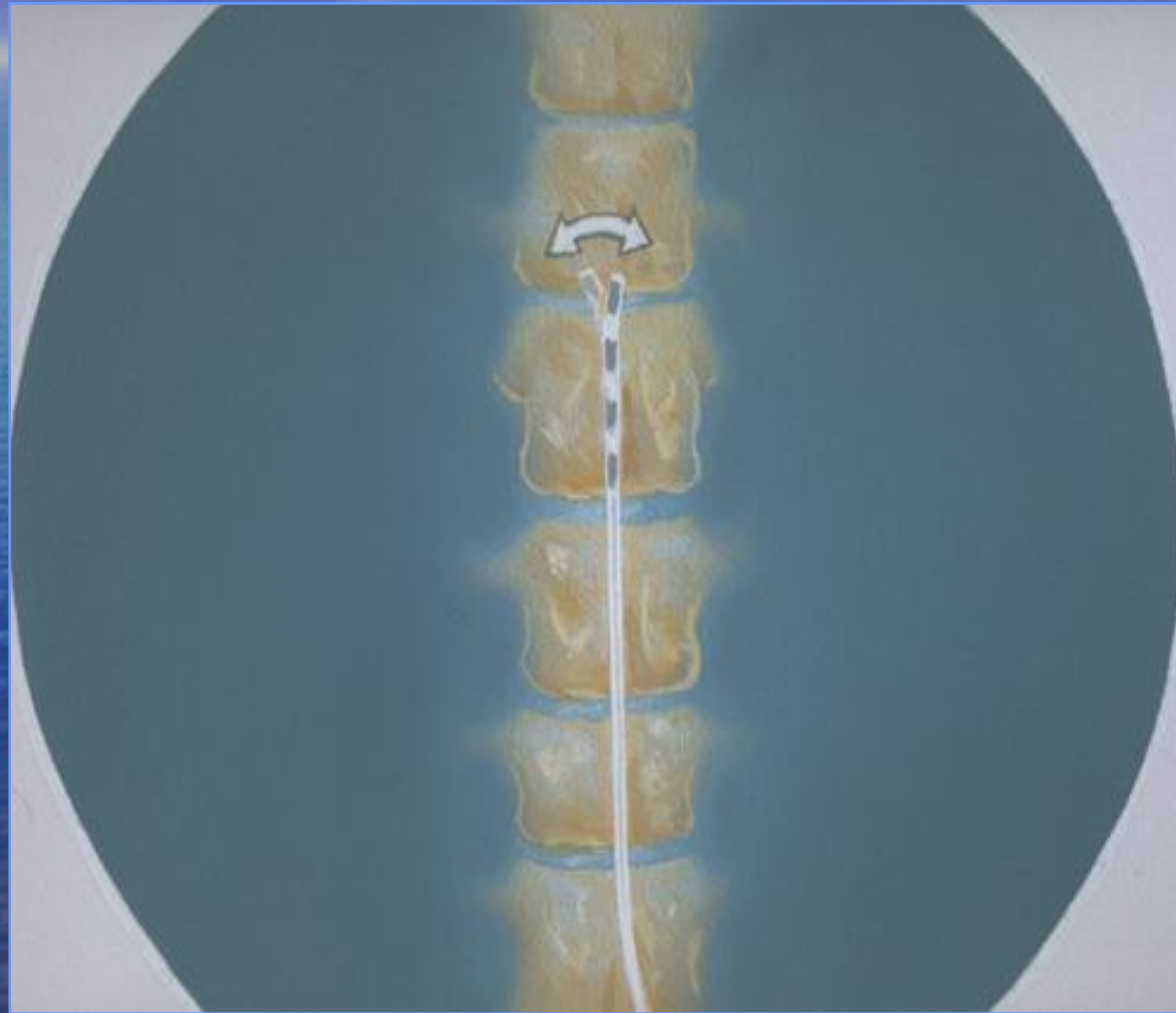
M

- Steerable Dual Lead Therapy
- Single Stim™ or Dual

Percutaneous Lead Placement: Insert Touhy Needle



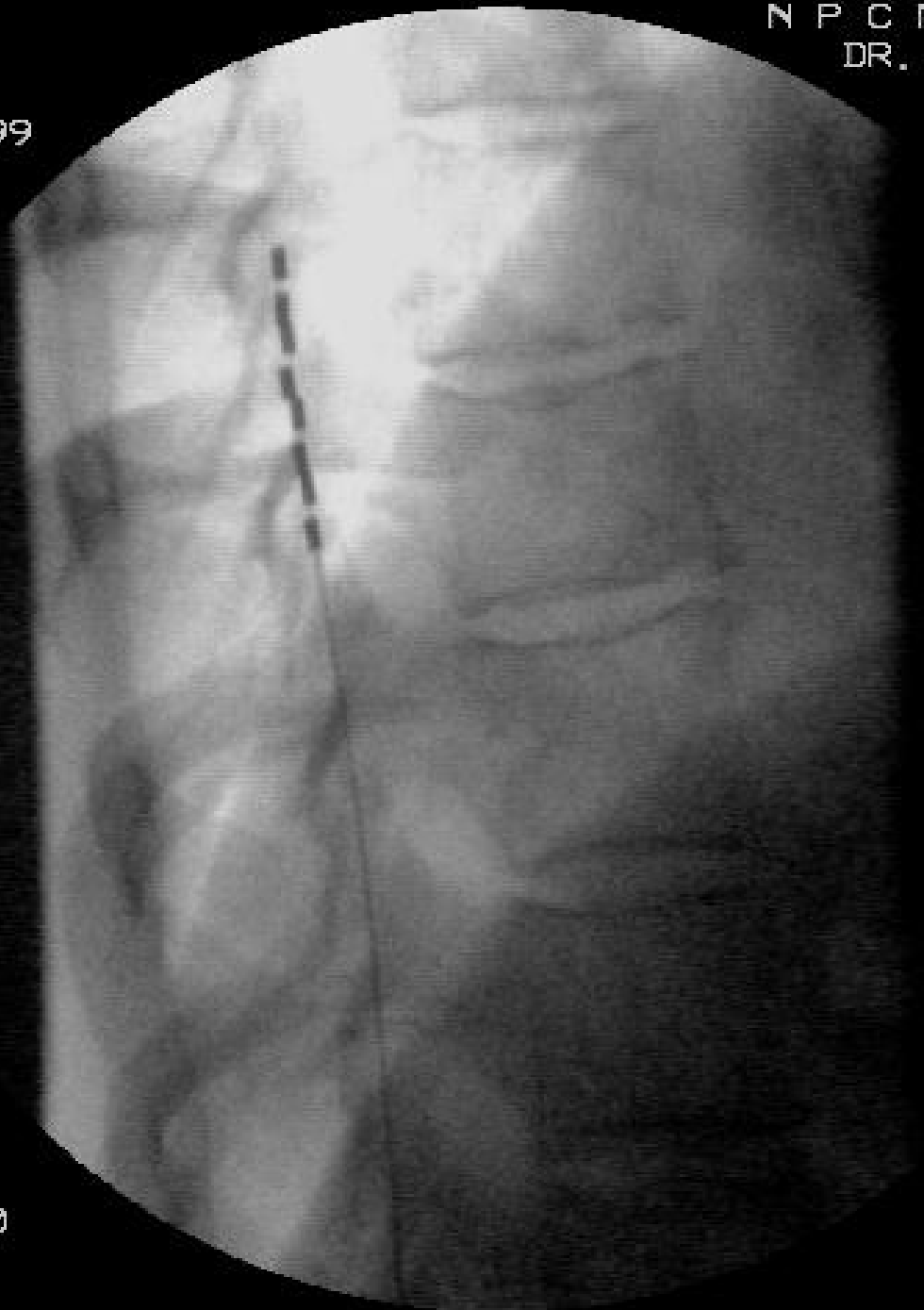
Percutaneous Lead Placement: Confirm Lead Position



N P C M
DR. JC JS

12/08/99

9:28:



kV 80
mA 5.9
Xt 1.50

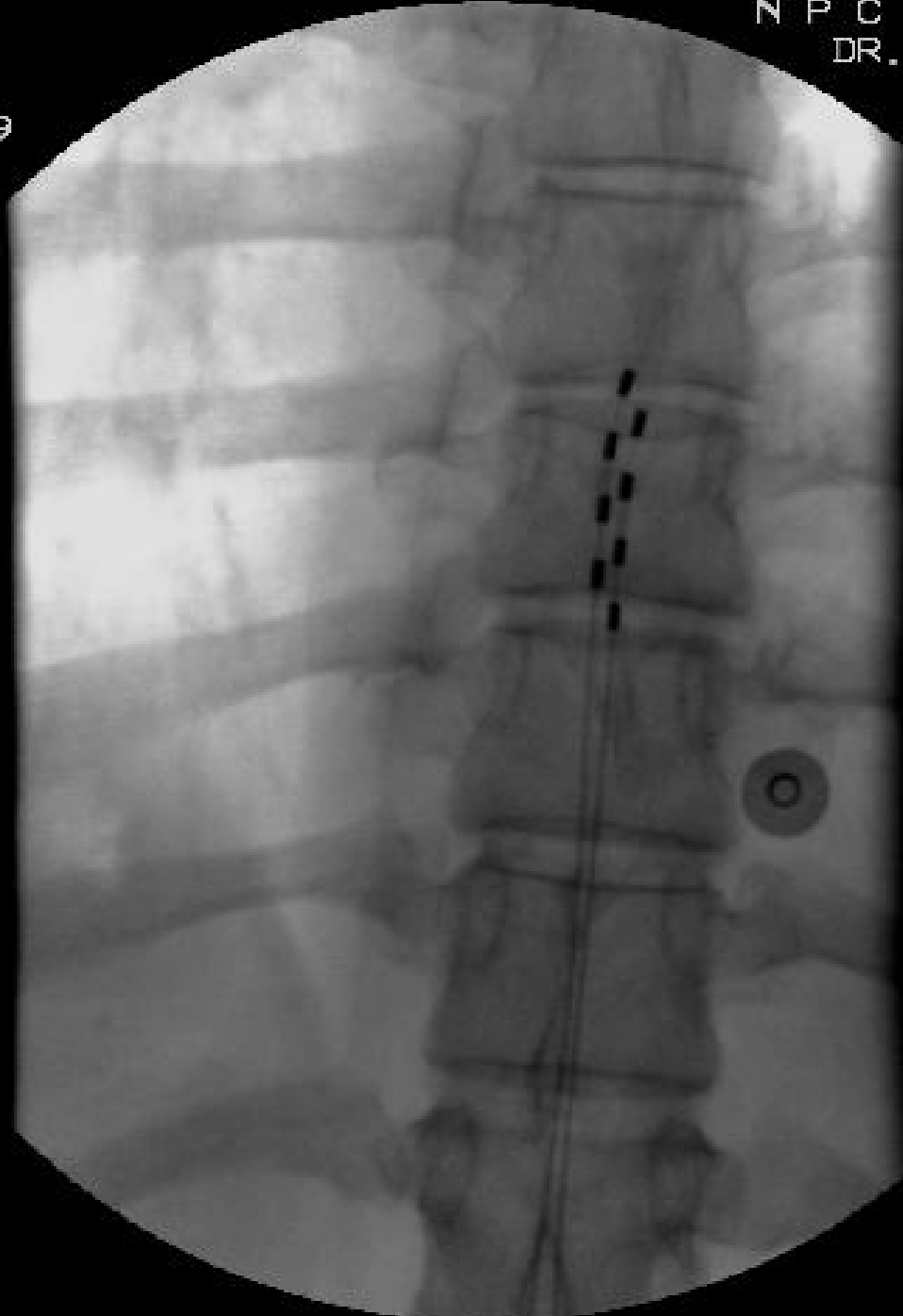
L STIM

IMS

N P C M
DR. JC JS

12/08/99

10:53:



KV 75
mA 8.0
Xt 4.52

L STIM

IMS

History of Neurostim Pain Therapy

- More than 50,000 patients have received Neurostim Pain Therapy systems
- 1967 - Development of first "Dorsal Column" Stimulator
- 1970s- Spinal Cord Stimulator becomes widely used
- 1980 - Medtronic introduces first programmable electrode system in U.S.
- 1982 - First clinical implant of Itrel® totally implantable pulse generator

Neurostim: Reduction in Pain

Reference	# of Patients	Mean Follow-up	Results
North <i>Pain</i> , 1993	171	7 years	<ul style="list-style-type: none">• 52% with \geq 50% relief• 60% would repeat
Turner <i>Neurosurgery</i> , 1995	39 study meta analysis	16 months	<ul style="list-style-type: none">• 59% with \geq 50% relief
De La Porte <i>Pain</i> , 1993	64	4 years	<ul style="list-style-type: none">• 55% good to excellent relief
Kupers <i>Pain</i> , 1994	70	3.5 years	<ul style="list-style-type: none">• 52% good to very good effect
Kumar <i>Neurosurgery</i> , 1991	94	3+ years	<ul style="list-style-type: none">• 66% good to excellent results
Burchiel <i>Spine</i> , 1996	70 Multi-center	1 year	<ul style="list-style-type: none">• 55% with \geq 50% relief

Neurostim: Reduced Consumption of Analgesics

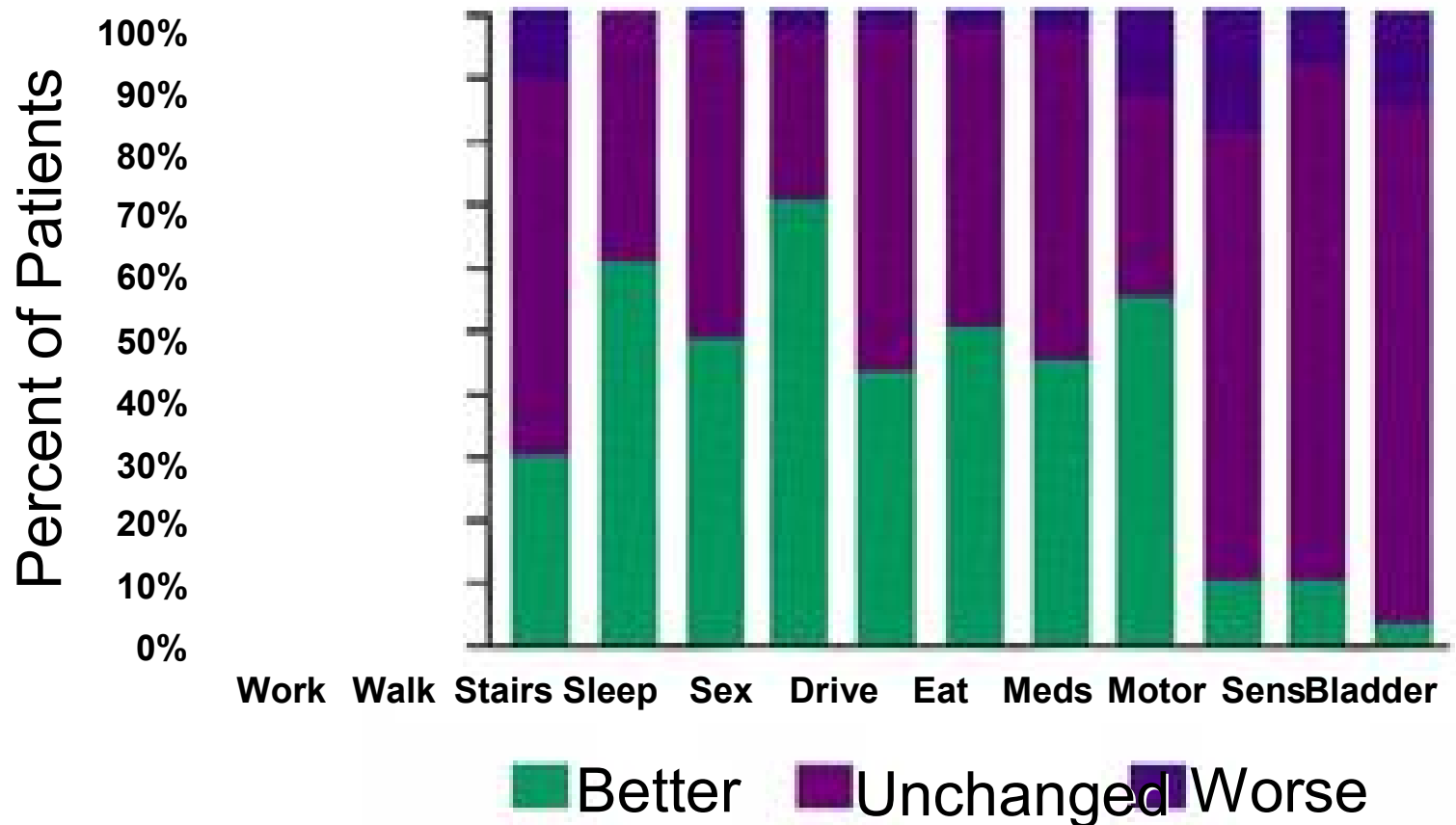
Reference	# of Patients	Mean Follow-up	Results
Ohnmeiss <i>Spine</i> , 1996	40	2 years	<ul style="list-style-type: none">• 84% decreased or eliminated opioid use
North <i>Neurosurg</i> , 1993	171	7 years	<ul style="list-style-type: none">• 58% reduced or eliminated analgesics
De La Porte <i>Pain</i> , 1993	64	4 years	<ul style="list-style-type: none">• 90% reduced medication
Kumar <i>Neurosurg</i> , 1991	94	3+ years	<ul style="list-style-type: none">• 40% no longer needed analgesics
Racz <i>Spine</i> , 1989	26	1.8 years	<ul style="list-style-type: none">• 81% reduced or eliminated opioid use

Neurostim: Enhanced ADLs

Reference	# of Patients	Mean Follow-up	Results
De La Porte <i>Pain</i> , 1993	64	4 years	• 61% improved ADLs
Racz <i>Spine</i> , 1989	26	1.8 years	• 66% improved ADLs
Ohnmeiss <i>Spine</i> , 1996	40	2 years	• Statistically significant improvement in “pain’s effect on lifestyle”

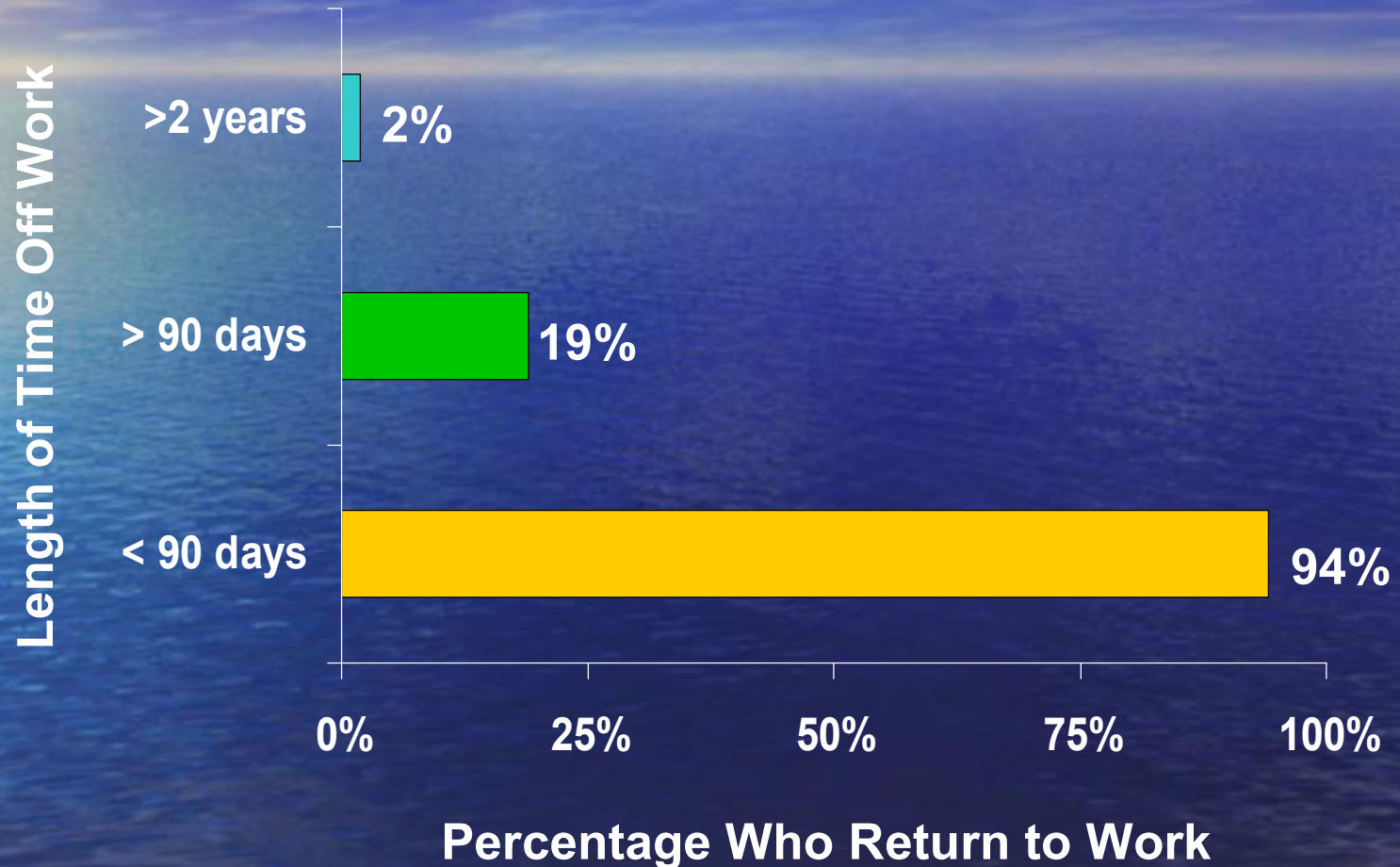
Neurostim: Enhanced ADLs

Patient Self-Rating of Changes at Long-Term Follow-Up



North, et al. *Neurosurgery*, 1993¹⁴

Neurostim: Percentage of Patients Who Return to Work



Inrathecal Drug Delivery System

The background of the slide features a wide expanse of blue water meeting a blue sky at a distant horizon. On the left side, a vibrant rainbow is visible, its colors blending into the blue of the sky and water. The overall scene is serene and expansive.

History of Intrathecal Pain Therapy

- More than 25,000 patients worldwide have received the Medtronic SynchroMed[®] Infusion System
- 1982 -First clinical implant of programmable pump for intrathecal morphine
- 1988 -Market release of implantable programmable pump (vascular use for cancer chemotherapy)
- 1991 -Market release of implantable pump (intraspinal morphine for cancer and non-malignant pain)

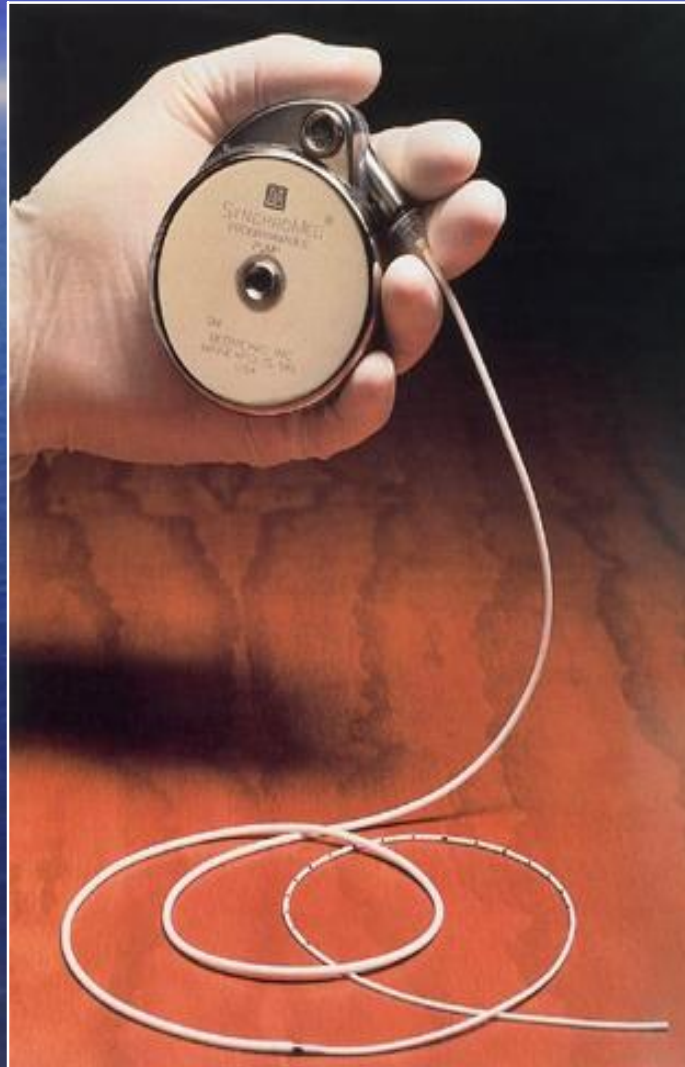
Advantages of Intrathecal Therapy in Nonmalignant Pain

- Effective pain relief
- Reduced side effects for patients
- Reduced consumption of systemic medication
- Improved ability to perform ADLs, increased productivity, return to work, and enhanced quality of life
- Long-term cost effectiveness

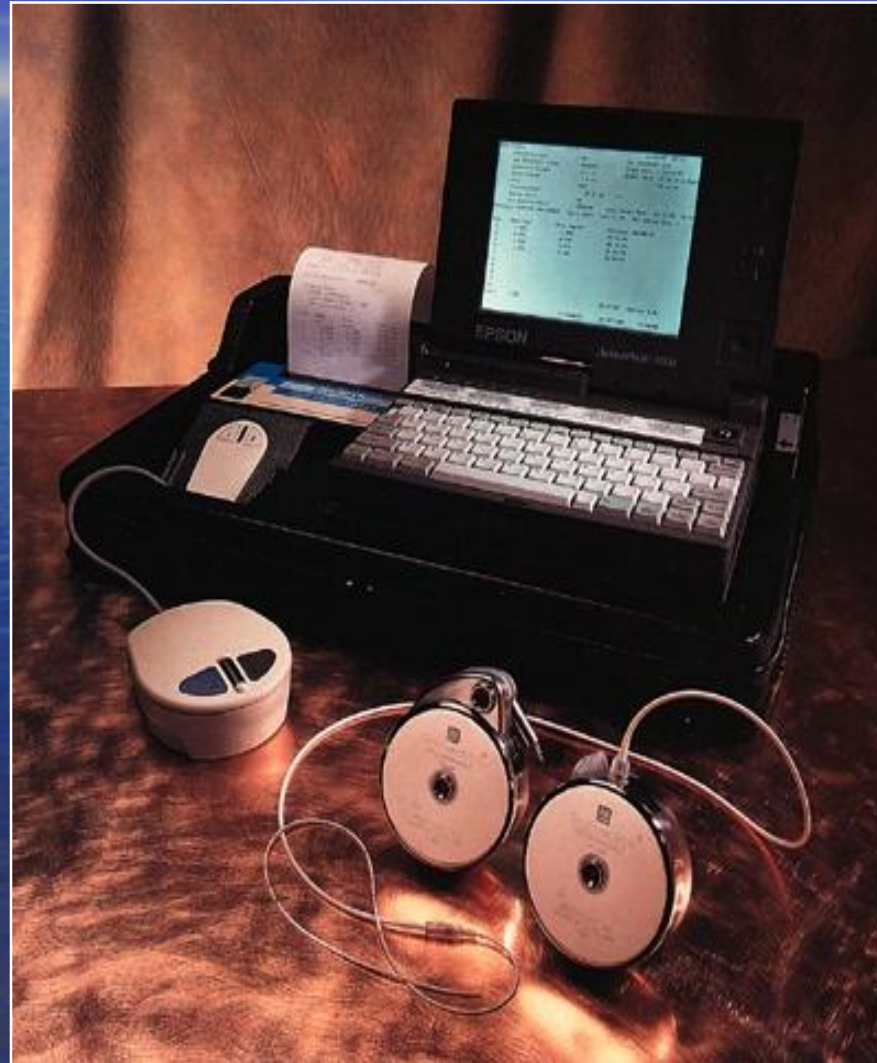
Screening Techniques Intrathecal Pain Therapy

- The purpose of the trial is to assess the efficacy and side effects of intrathecal morphine
- Trialing methods include:
 - Continuous epidural
 - Continuous intrathecal
 - Bolus intrathecal
 - Bolus epidural
- At least 50% reduction in pain may indicate a successful trial

Infusion System



PC-based Programmer

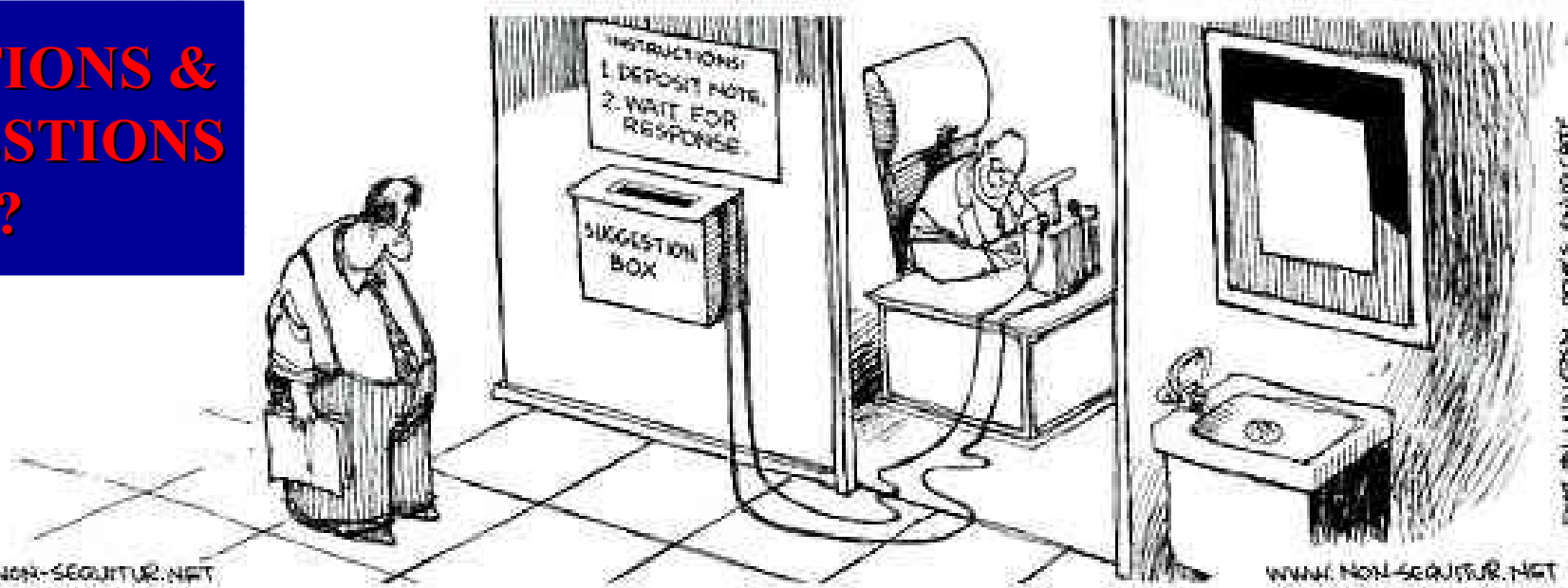


Options



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QUESTIONS & SUGGESTIONS ?



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