UNDERSTANDING SPINAL (EPIDURAL) INJECTIONS

Mehul Garala, M.D.

Illinois Bone & Joint Institute

9/20/2018

GOALS

- Background
- Misconception about Epidural Steroid Injections
- Epidural Steroid Injections
 - Medical literature
 - Why do them?
- Worker Compensation Issues

BACK PAIN

- Low back pain (LBP) is extremely common: 80% of the population have at least one episode in their lifetimes.
 - 26% working population
 - Disables 2-8% of working population.
 - Compensation accounts for 33% of all workers' compensation costs.
 - 75% of compensation payments go to LBP patients, although they constitute only 3% of total compensation patients.
- Low back pain is the second most common reason for a visit to a primary care physician.

BACK PAIN

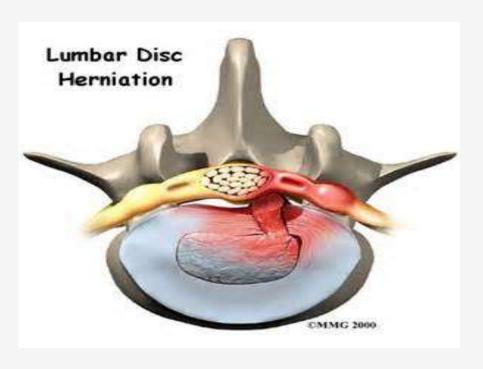
- Approximately 60-70% recover within 6 weeks and up to 90% recover within 12 weeks.
- Lifetime prevalence of lumbar radicular pain with or without radiculopathy ranges from 12.2% to 43%; annual prevalence of 2.2% to 34%.
- Natural history is generally favorable, but radicular pain patients tend to have poorer outcomes, consume more health care resources, and have greater disability than patients with purely axial back pain.

CAUSES OF LOW BACK PAIN

- Muscles: Strains, Myofascial Pain
- Bone: Fractures, Cancer, Spondylolysis/Spondylolithesis
- Joint: Facet, Sacroiliac Joint Dysfunction
- Disc: Annular fissures, Herniated Nucleus Pulposus
- Nerve: Radiculopathy, Stenosis



RADICULAR PAIN



- Radicular Pain
 - Mechanical compression
 - Inflammation
 - Immunomodulation

STANDARD TREATMENT

- Modified duty work/activities
- Nonsteroidal anti-inflammatory medications/ Steroids/muscle relaxants
- Physical Therapy program
- If no improvement, a lumbar spine MRI is ordered

LUMBAR SPINE MRI FINDINGS

- Issue: What is pre-existing, what is caused by work injury?
- Boden Study: 67 asymptomatic subjects,
 - < 60 y/o, 20% had HNP
 - > 60 y/o, 57% abnormal findings (36% HNP, 21% spinal stenosis)
 - Degeneration or bulging disk at one lumbar level in 35% of patients between 20-39 y/o; in all but one of patients between 60-89 y/o.

ROLE OF A PHYSIATRIST

- Treat the patient, not the imaging study.
- Assess the mechanism of injury, perform the physical exam and see if the MRI correlates with them both.
- Evaluate how the patient's function and ability to work is limited.
 - Is it because of pain or because of another factor such as weakness?
- If pain is a limiting factor for function and there is supporting evidence for radicular pain, the decision needs to be made for an epidural steroid injection (ESI).

IS AN ESITOO RISKY TO EVEN PERFORM?

In April 2014, the FDA issued a Drug Safety Communication

- Corticosteroid labeling is to include warnings that injection of corticosteroids into the epidural space may result in rare but serious adverse events, including loss of vision, stroke, paralysis and death.
- The effectiveness and safety of the drugs for this use have not been established, and FDA has not approved corticosteroids for such use.

MULTIPLE PAIN SOCIETY WORK GROUP

- American Association of Neurological Surgeons/ Congress of Neurological Surgeons Joint Section on Disorders of the Spine and Peripheral Nerves
- American Association of Neurological Surgeons/ Congress of Neurological Surgeons Joint Section on Pain
- American Academy of Pain Medicine
- American Academy of Physical Medicine and Rehabilitation
- American Association of Neurological Surgeons
- American College of Radiology
- American Pain Society

- American Society of Anesthesiologists
- American Society of Regional Anesthesia and Pain Medicine
- Congress of Neurological Surgeons
- International Spine Intervention Society
- North American Neuromodulation Society
- North American Spine Society
- Society of Interventional Radiology

MULTIPLE PAIN SOCIETY WORK GROUP RESPONSE

- Safety is well established
 - Serious complications are reported, but related to use of particulate steroids in TFESIs
- Risks of alternative medications are also well known (Opioids, NSAIDS)
- There is ample evidence on the effectiveness of ESIs to help patients

SAFETY

- 16,638 consecutive procedures in all spine segments
- Adverse Event Rates:
 - Vasovagal reactions (1.2%), dural punctures (0.06%) more common in IL (0.2% vs 0.4%).
 - Central steroid response (sleeplessness, flushing, nonpositional headaches) was seen in 2.6% of both TFESI and ILESI patients.
 - 2.1% of TFESI and 1.8% of ILESI patients reported increased pain.
- No long term sequelae were seen from any immediate or delayed minor adverse events.
- No major adverse events of neurological injury, hemorrhage, or infection.

SAFETY

- Documented side effects of ESIs are generally minor and temporary: reported side effects include injection site pain (17.1%), increased radicular pain (0.6%-8.8%), lightheadedness (6.5%), increased spine pain (2.4%-5.1%), nausea (3.7%), nonpositional headache (1.4%-3.1%), vomiting (0.5%), facial flushing (1.2%), vasovagal reaction (0.3%), elevated blood sugar (0.3%), and intraprocedural hypertension (0.3%).
- The reported overall infection rate with spinal injections is 1% to 2% with severe infections being extremely rare with an incidence of 0.1% to 0.0001%. Case reports of epidural abscess, discitis, osteomyelitis, and meningitis.
- Epidural hematomas occur in approximately I in 150,000 epidurals and may cause compression of the spinal cord and spinal nerves.

SERIOUS COMPLICATIONS

- Serious complications were due to inadvertent injection of particulate steroids into the radicular or vertebral artery that perfuses the spinal cord and brain.
 - Light microscopy studies have shown that particles in the steroid preparations (methylprednisolone acetate, triamcinolone) are either larger than red blood cells or form aggregates larger than red blood cells.
 - Animal studies have shown central nervous system infarction with intra-arterial injection of particulate steroids.

SERIOUS COMPLICATIONS

- Dexamethasone (soluble): 5-10 x smaller than red blood cells on microscopy
 - No adverse sequelae with direct injection into the arterial supply of the neuroaxis in animals.
 - No case report of a serious neurologic adverse event to date.

ALTERNATIVES

- Serious risks of alternative medications are well known as documented in the following US <u>annual rates</u>:
 - ~15,000 opioid related deaths
 - ~16,500 NSAID-related deaths
 - >100,000 hospitalized for serious GI complications from NSAIDS

SURGICAL ALTERNATIVE

- High cost of care.
- Not a guarantee that the patient's pain/function will improve.
- Is it truly better than conservative treatment?

CONSERVATIVE CARE VS. SURGERY

- Weber: 280 patients, 3 groups, 126 patients with uncertain indication for surgery, 67 patients required surgery, 87 patients treated conservatively.
 - Longitudinal study where surgical group did better at one year, a little bit better at 4 years but no longer statistically significant, only minor changes took place during the last 6 years.

SPORT Trial:

- 501 surgical candidates assigned to surgical and non-surgical groups. 30% of those assigned to nonoperative treatment received surgery so it was difficult to conclude the superiority or equivalence of treatments.
- Patients in both the surgery and nonoperative treatment groups improved substantially over a 2-year period: primary outcomes SF-36, Oswestry Disability, Physical function.
- Secondary measure: working full or part time
 - 3 months surgery group 63.8% vs 69.4, I year surgery group 76.4% vs 77%, 2 year surgery group 74.2% vs 76.4%.

Weber H. lumbar disc herniation: A controlled, prospective study with ten years of observation. Spine. 1983; 8: 131-140.

Weinstein, et. al. Surgical vs. Nonoperative Treatment for lumbar disk herniation. The Spine Patient Outcomes Research Trial (SPORT): A Randomized Trial. JAMA, November 22/29, 2006: Vol 296: 2441-2450.

INJECTIONS VS. SURGERY

- 55 patients with radicular pain who were found to be surgical candidates.
 - Randomized into bupivacaine injection group or bupivacaine with betamethasone group
 - 29/55 decided not to have surgery during follow up (13-28 months)
 - 9 of bupivacaine injection group
 - 20 of bupivacaine + steroid injection group (statistically significant)
 - 5 year follow up: 21/29 contacted. 17/21 still had no surgery. Even if the 8 lost in follow up had surgery, there is still 59% non-operative rate.

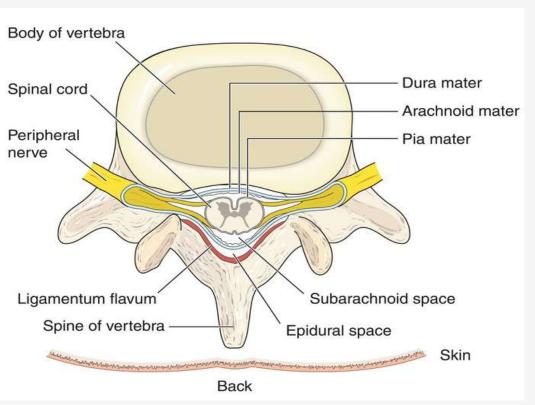
BENEFITS OF EPIDURAL STEROID INJECTIONS

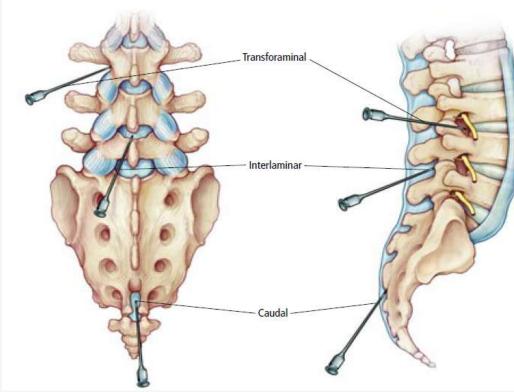
- Reduces/eliminates pain
- Improves function
- Decreases reliance on opioids
- Surgery sparing effects
- Cost effective

BENEFITS FROM ESI

- Recent systematic reviews with metaanalyses have summarized the large volume of research on this topic.
- Up to 70% of patients achieve 50% pain relief for 1-2 months; 30% achieve complete pain relief.
- For patients with disc herniations, up to 70% may achieve 50% for 6 months. Pain relief is accompanied by functional recovery and reduced reliance on other health care resources.

EPIDURAL STEROID INJECTIONS





EPIDURALS

Route of Administration	Advantages	Disadvantages
Transforaminal	 Anterior spread (herniated disc) Low volumes of injectate required Unilateral or bilateral medication delivery Low dural puncture risk with spinal stenosis and postoperative spines Treatment of far lateral disc herniations Possibly diagnostic 	Difficult technique after lateral lumbar fusion
Interlaminar	Good for multilevel or bilateral pathology	 Not diagnostic Not useful after posterior spinal surgery Not useful at levels of central spinal stenosis Unknown anterior epidural steroid Highest epidural bleeding risk
Caudal	Least technically demandingLowest risk of dural punctureGood for multilevel or bilateral pathology	 Not diagnostic Limited spread above L4-5 disc space

TRANSFORAMINAL - THE WAY TO GO???

- A comparison trial of fluoroscopic guided caudal, interlaminar, and transforaminal injections deemed all efficacious; however, the transforaminal group had better short- and long-term outcomes.
 - Anterior epidural space was seen with all the TF ESI injections compared to 50-53% with the other injections.
 - Studies have shown that IL spread to anterior space is only 36%

TRANSFORAMINAL EPIDURAL STEROID INJECTIONS

- The majority of patients who undergo TFESIs for radicular pain require only a single injection; in a comprehensive review of the literature, MacVicar and colleagues identified nine studies with categorical outcomes of >50% pain relief, ~94% required a single injection and 4% required a second injection to achieve this level of pain relief.
- Repeat TFESI may be performed for recurrence of radicular pain with the
 expectation of recovery of most or all previously achieved benefit; acute pain
 patients (pain for less than 3 months) will likely recover all prior benefit.
 Repeat TFESIs within 3 months of the index injection can provide cumulative
 benefit.

REMEMBER...

- Official Disability Guidelines:
 - The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, reduction of medication use and avoiding surgery.
- ESIs can help reduce pain and improve a patient's function and allow them to tolerate active treatment programs like physical therapy and/or work conditioning.
- GOAL: We want the patient to return to work.
 - ESIs can help facilitate that.

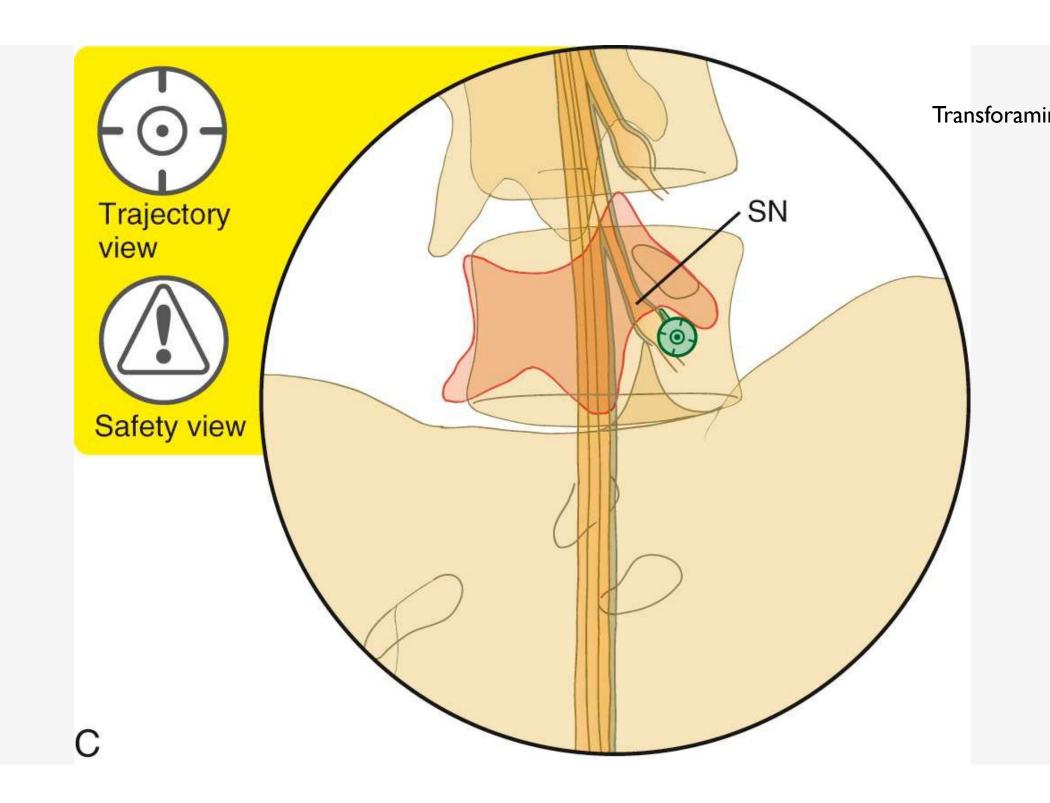
EPIDURAL STEROID INJECTIONS

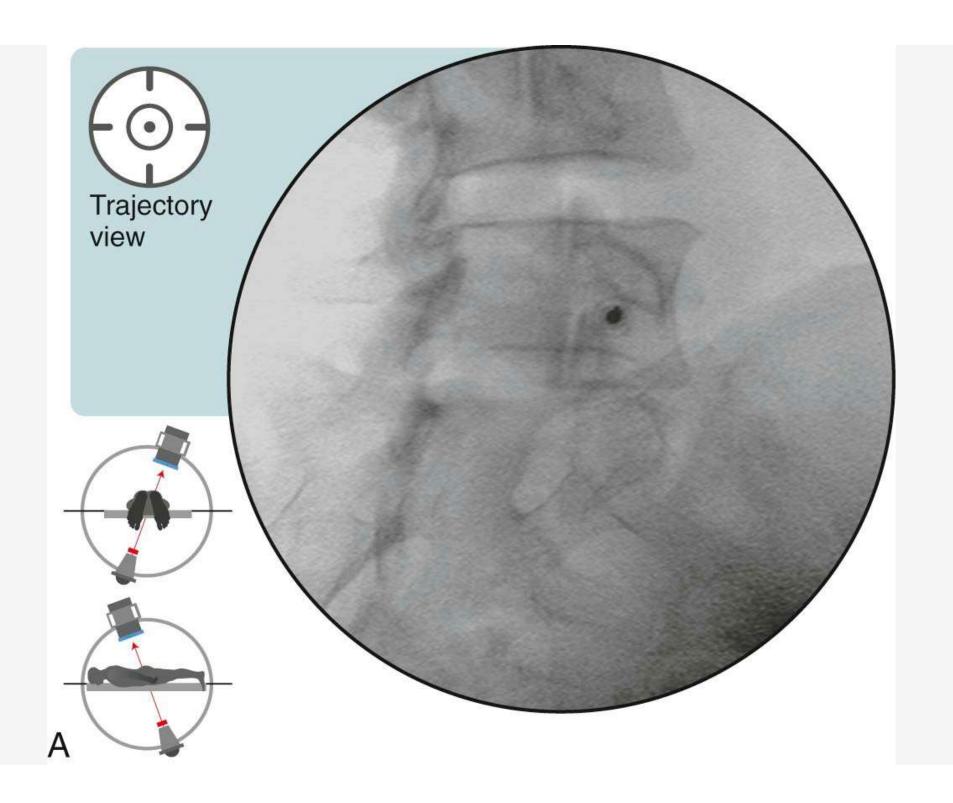
- Epidural steroid injections (ESI):
 - Radicular pain: delivering medication close to the interface of the etiology where the nerve root is being impinged (herniated disc, fixed lesion).
 - Decreases local inflammatory response
 - Inhibition of phospholipase 2
 - Inhibit leukocyte functions
 - Blocking transmissions from nociceptive C-fibers
 - Stabilize neuronal membranes
 - Axial back pain (Degenerative Disc Disease, Annular Fissures)
 - Lumbar Stenosis

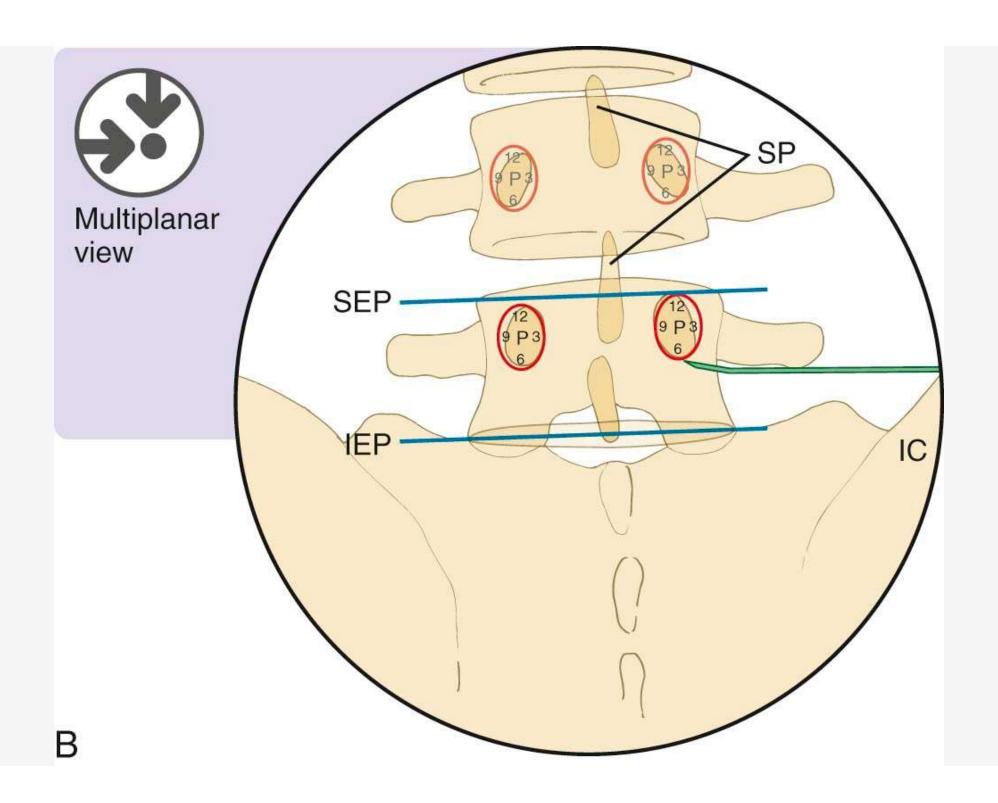


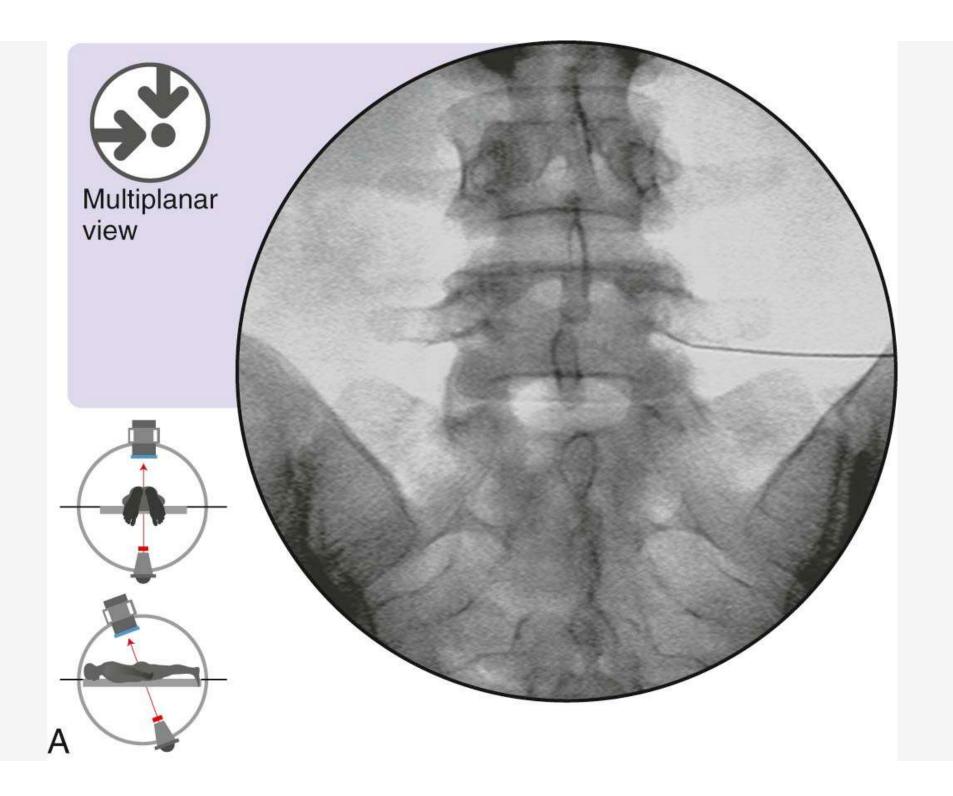


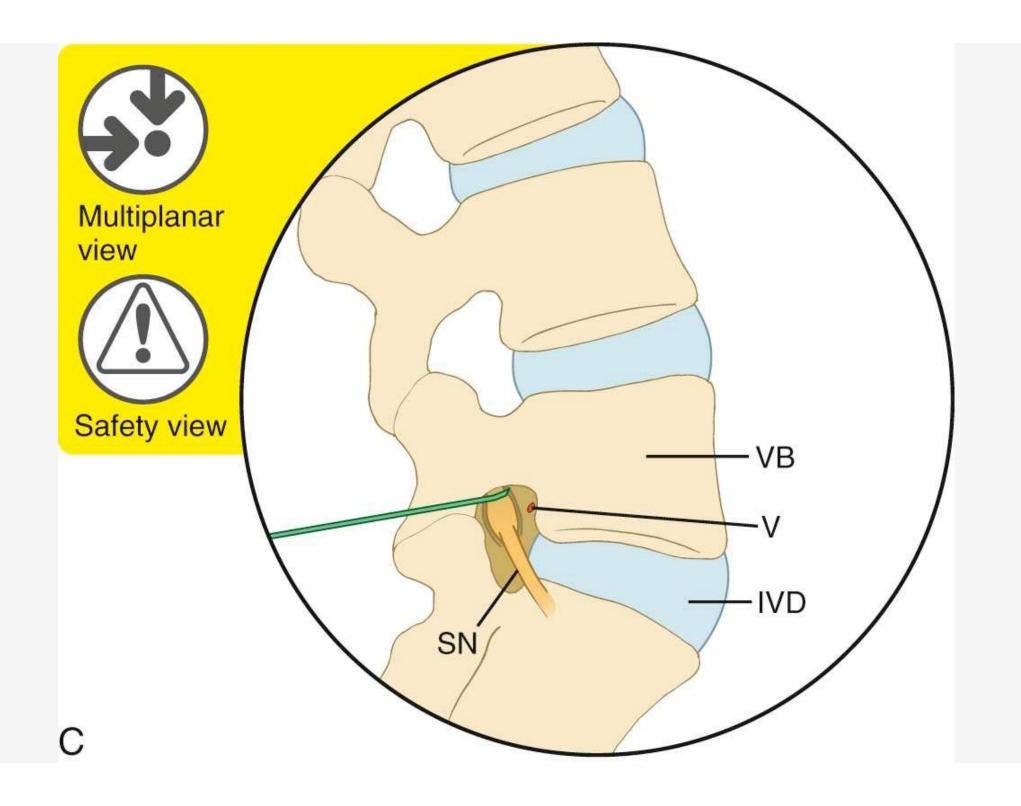


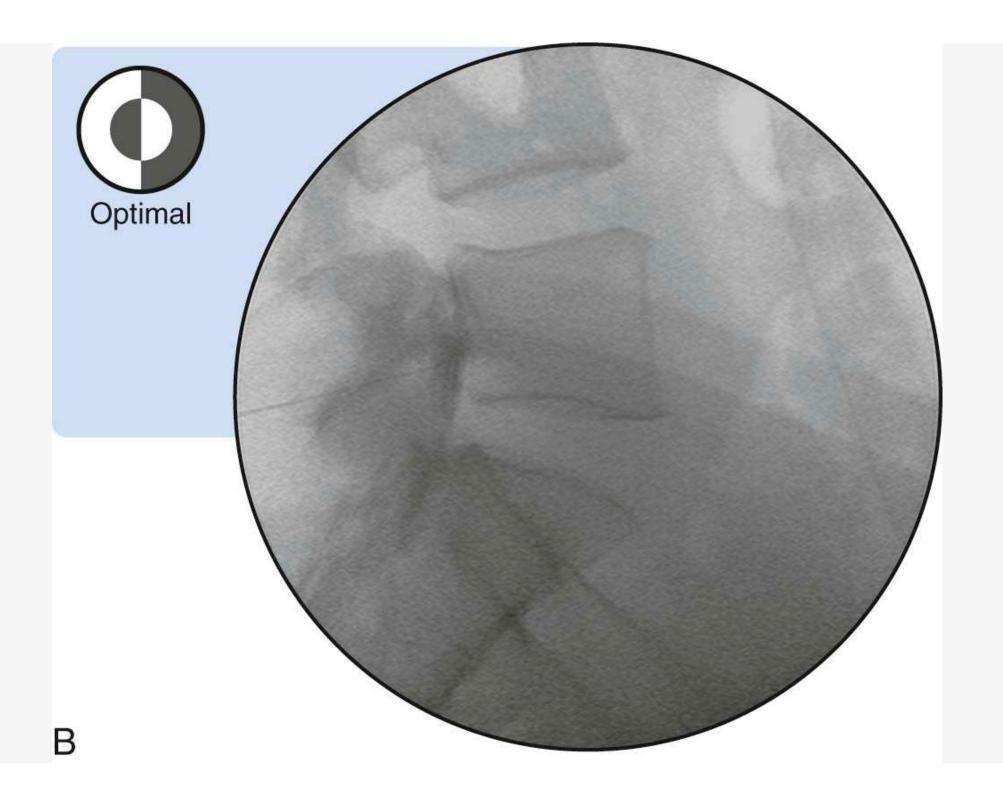


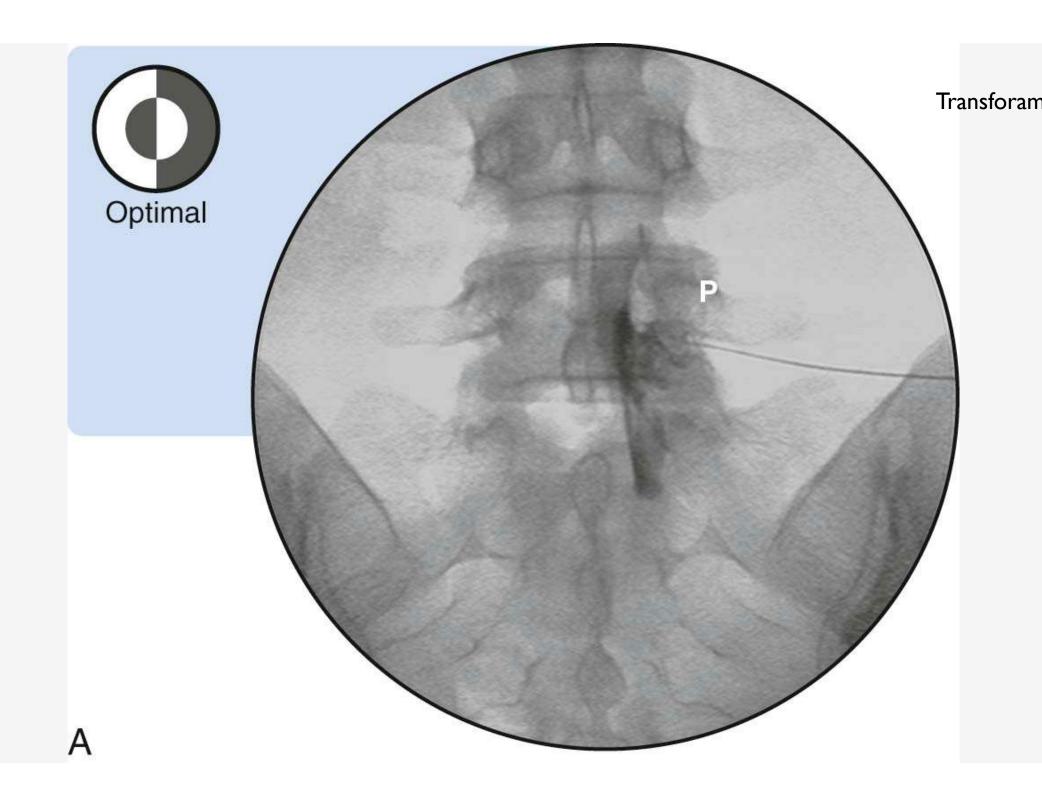


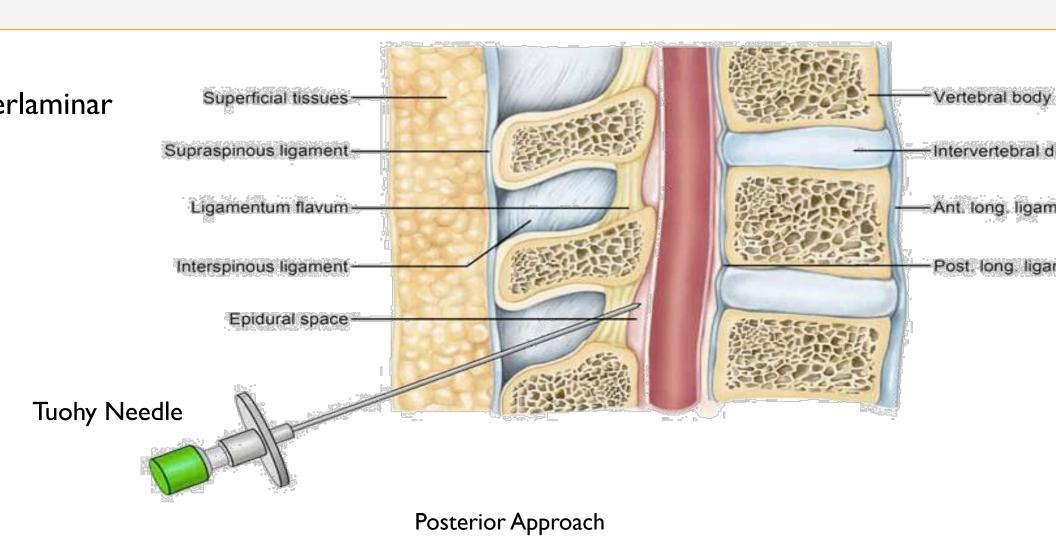




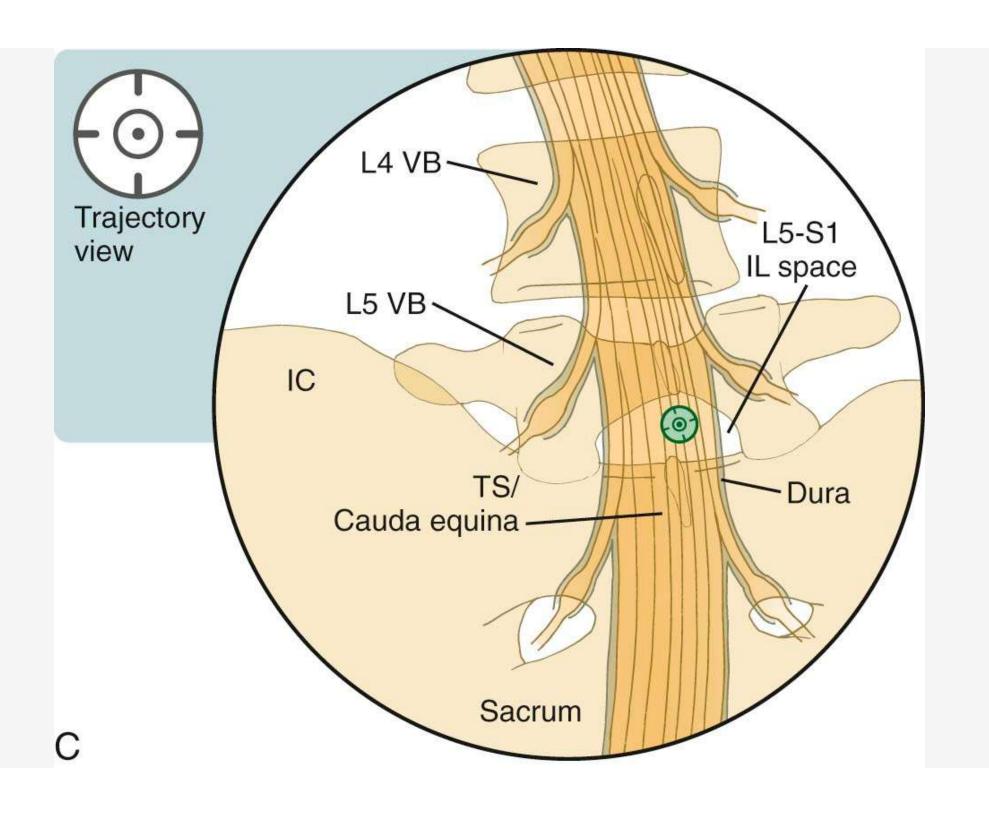


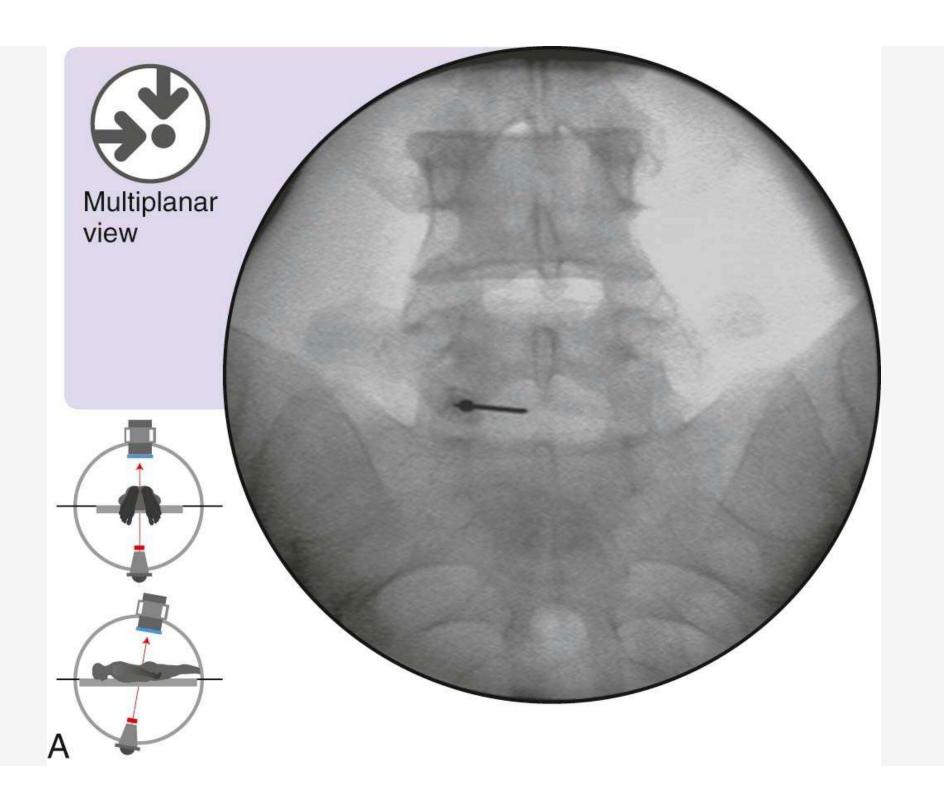


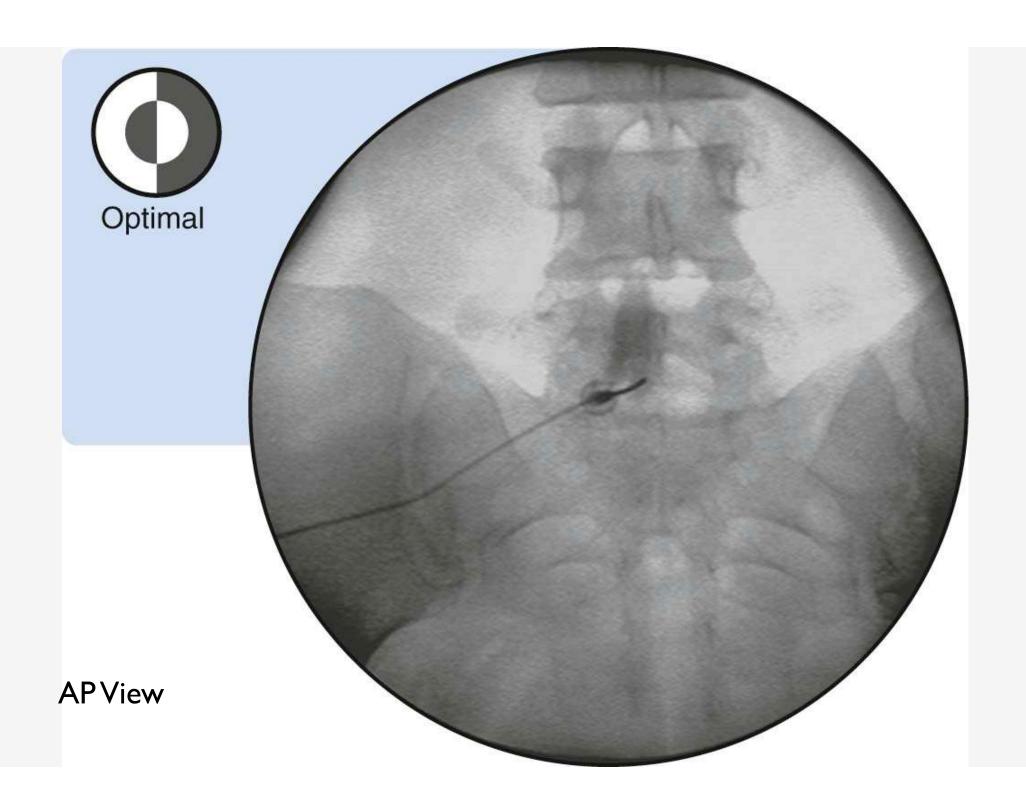


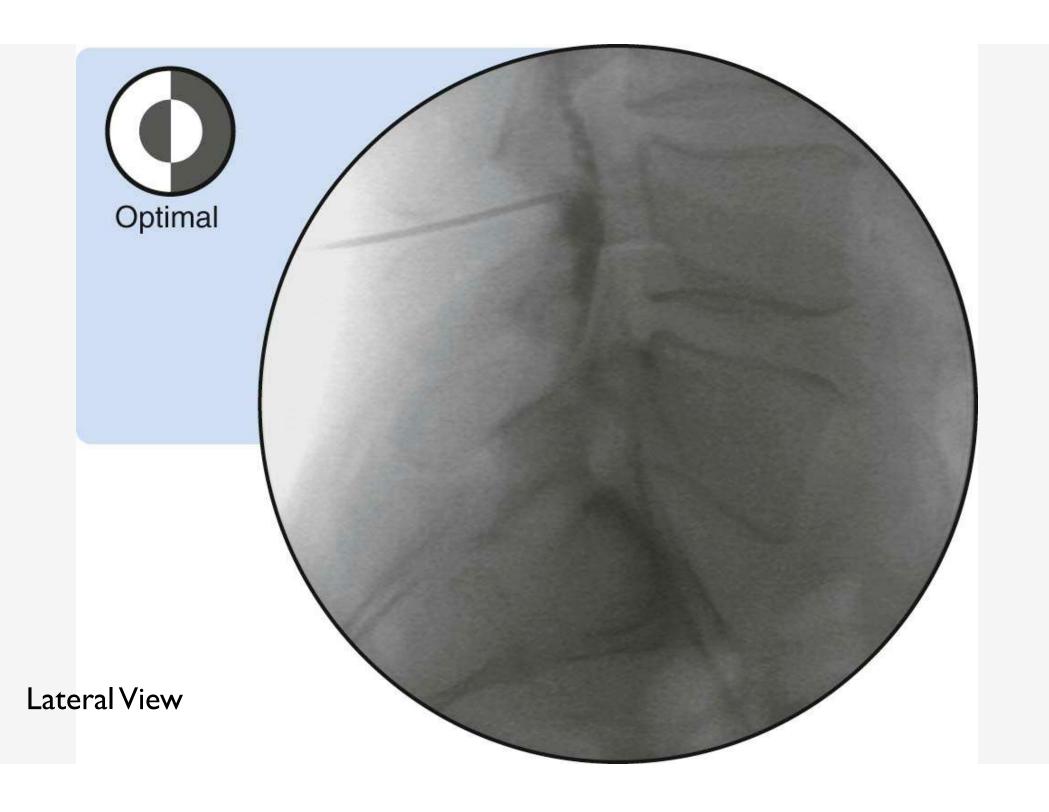


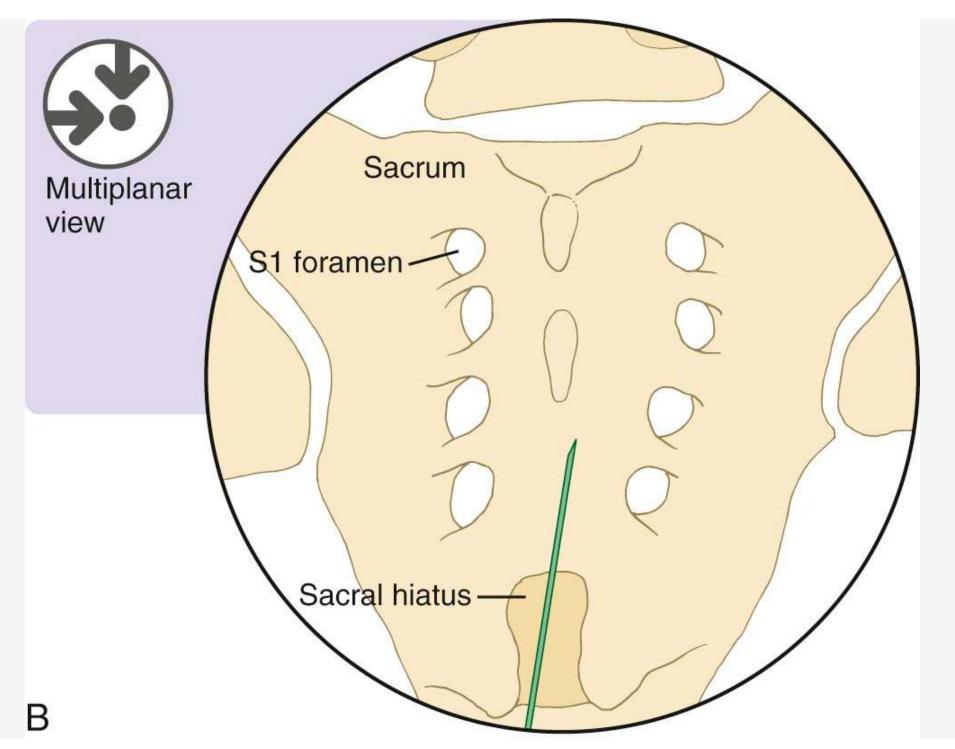
tin -> Subcutaneous tissue/muscle ->Supraspinous ligament -> Interspinous ligament -> Ligamentum Flavum



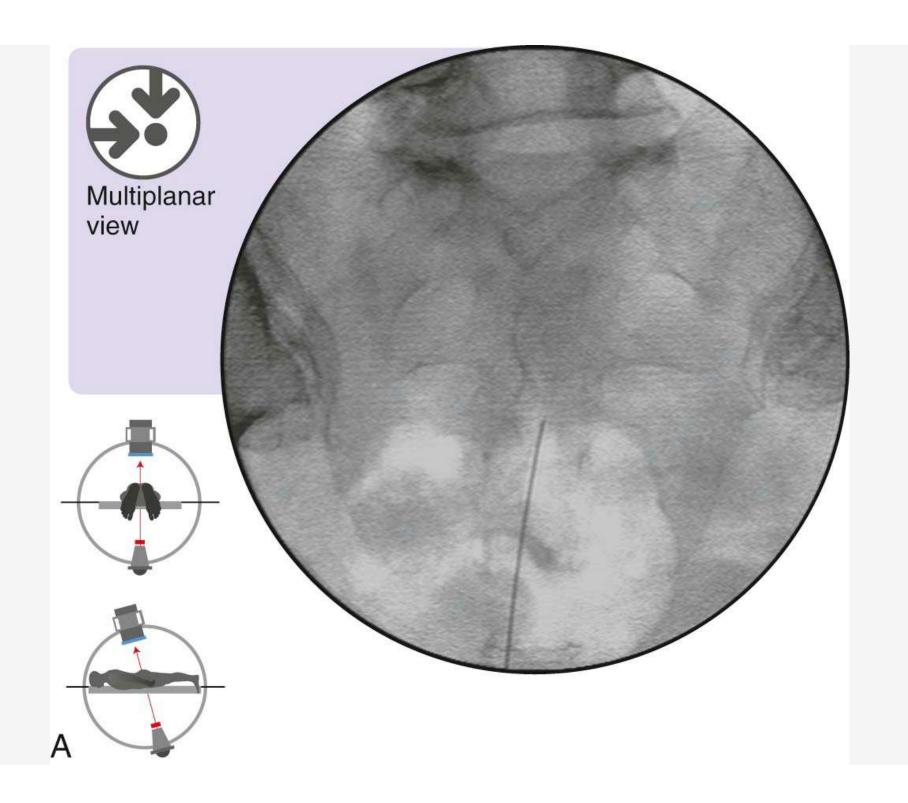


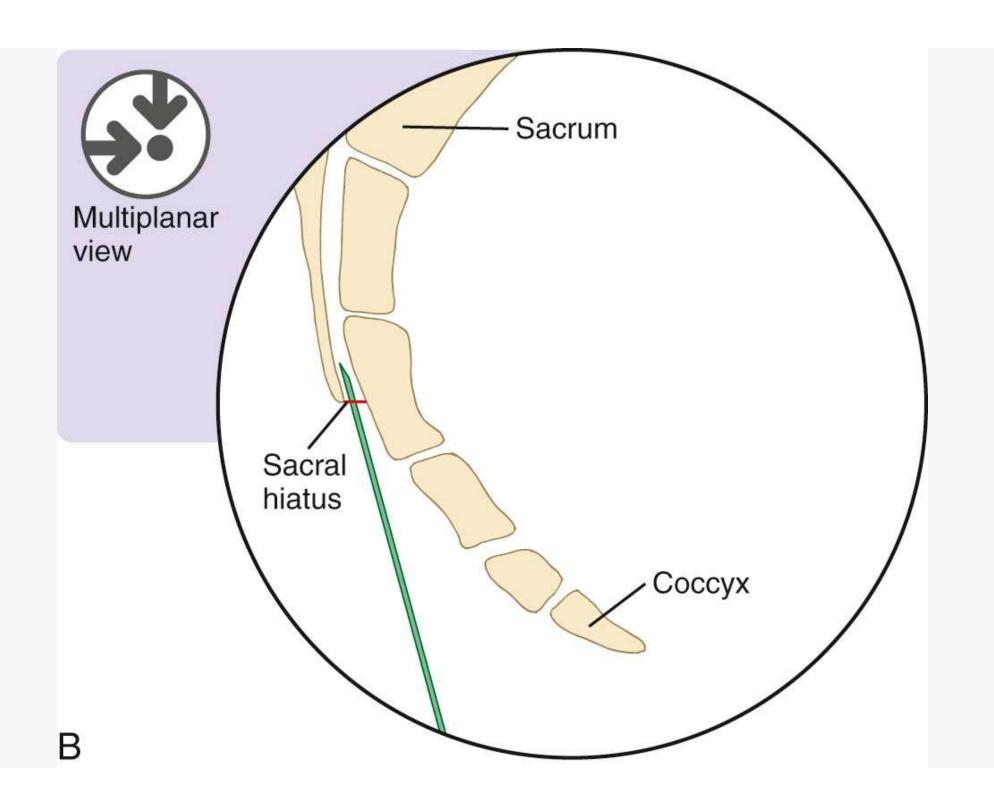


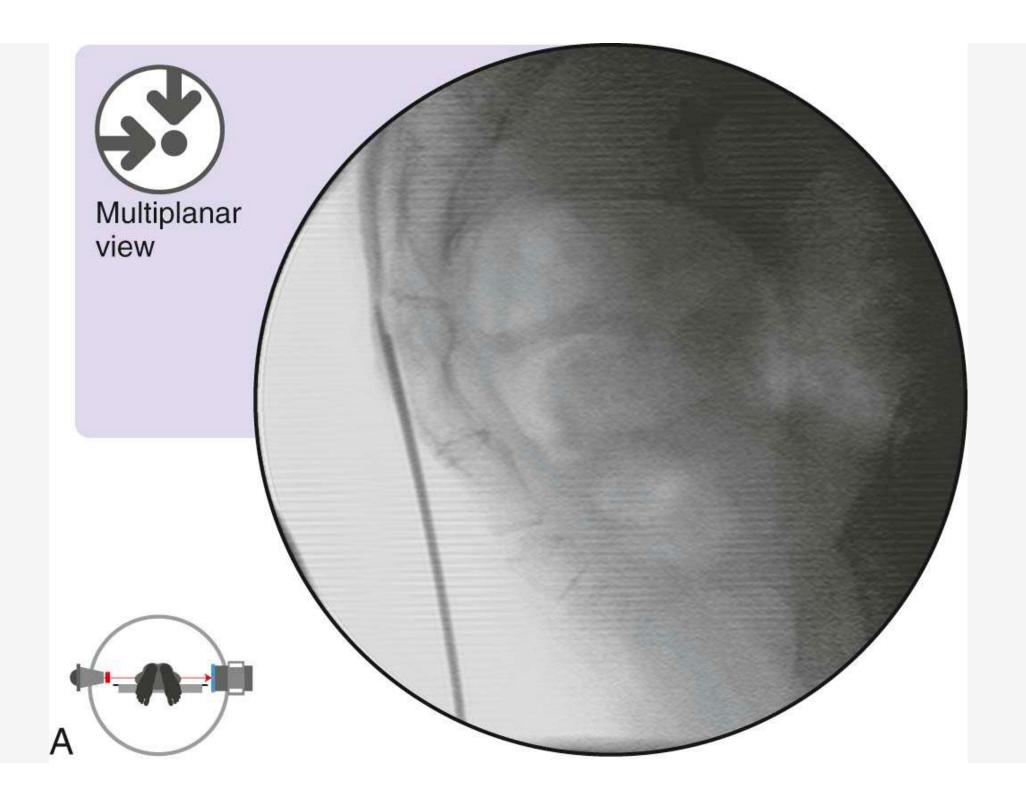


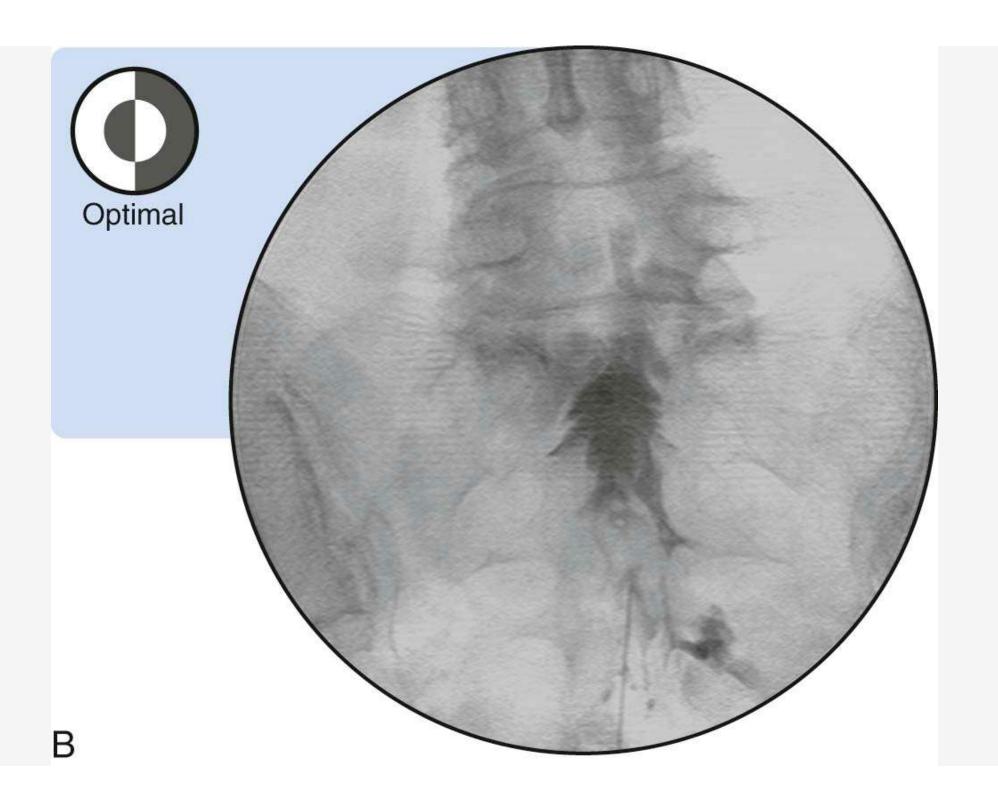


Cau









REDUCING THE RISK OF COMPLICATIONS

- Screening for bleeding risks
 - Stopping blood thinners prior to injections for IL ESIs
- Performing injections in a sterile environment
- Performing injections without/limiting conscious sedation
- Performing all spinal injections under fluoroscopy

REDUCING THE RISK OF COMPLICATIONS

- Injecting adequate amount of contrast media under continuous AP fluoroscopic imaging to visualize if there is any intraspinal vascular uptake.
 - Digital Subtraction Imaging
- Use of low-volume extension tubing to minimize needle movement.
- Administering a test injection of local anesthetic before injecting any steroid.
- Use soluble steroids (dexamethasone) instead of particulate steroids.
 - Noninferiority of dexamethasone.

houchi C. etc. The Noninferiority of the Nonparticulate Steroid Dexamethasone vs. the Particulate Steroids Betamethasone and Triamcinolone in the Lumbar Transforaminal Epidural injections. Pain Medicine 2013; 14: 1650-1657.

etc. Randomized Double-Blind Controlled Trial Comparing the Effectiveness of the Lumbar Transforaminal Epidural Injections of Particulate and Nonparticulate Corticosteroids for sacral Radicular Pain. Pain Medicine 2015: 16: 1697-1708

ly D, etc. Comparative Effectiveness of Lumbar Transforaminal Epidural Steroid Injections with Particulate Versus Nonparticulate Corticosteroids for Lumbar Radicular Pain due to rtebral Disc Herniation: A Prospective, Randomized, Double-Blind Trial. Pain Medicine 2014; 15: 548-555.

STEROID INJECTIONS

- Steroid and lidocaine injection
- ESI: Patients should begin to feel the full affect of the procedure in approximately 72 hours, but up to I week may be necessary to achieve therapeutic benefit.
- Patient should take it easy for the day of the procedure
 - Ensure there are no immediate complications
 - Allow for the effects of the anesthetic to wear off; transient motor weakness
- No changes need to be taken for the patients work status
 - They can continue with their modified duty work
- The patient is typically followed up for reevaluation in 2 weeks.

WORKER COMPENSATION ISSUES

- Who is reviewing the lumbar spine MRI with the patient? What are they being told?
- What is pre-existing and what is a new issue?
- How long before a patient can be seen by a spine specialist?
- If a patient only has radicular pain and has failed conservative treatment, will an ESI be approved by the insurance company?
 - ODG patient needs to have radiculopathy and to have failed conservative treatment
- Will a repeat ESI be approved?
- Will further diagnostic injections be allowed or would the patient be sent for an IME?

PERSONAL THOUGHTS

- I use an epidural steroid injection as an adjunct for a patient's treatment.
- Even if I suspect the patient to have radicular pain/radiculopathy, as long as the patient is tolerating his/her therapy program, I will usually take a wait and see approach.
 - I ensure proper communication with the therapist to ensure that pain is not limiting or impeding the patient's progress/function.
 - If radicular pain is a limiting factor in a patient's function, I will consider performing an epidural steroid injection (if the MRI gives supporting diagnostic evidence)
- I try to educate a patient to "chase" function, not "pain."

THANK YOU!

- Questions???
- Contact:
 - mgarala@ibji.com