

# EPIDURAL STEROID INJECTION SAFETY & EFFECTIVENESS: FREQUENTLY ASKED QUESTIONS

#### What are epidural corticosteroid spinal injections (ESIs)?

Epidural corticosteroid injections (ESI) deliver anti-inflammatory drugs into the spine to provide relief from unremitting back pain. These anti-inflammatories -- known as corticosteroids -- can reduce swelling that puts pressure on the nerves in the spinal cord causing pain in the back and sometimes leg (sciatica).

Most often, the injections also contain a local anesthetic for immediate pain relief. The corticosteroid, however, may provide longer-term relief for weeks or even months.

During the 15- to 20-minute procedure, a specially trained physician uses fluoroscopy, real-time X-ray guidance, to visualize the spine. Then the physician injects the medication into the area around the spinal cord and nerve roots called the epidural space.

## Who is a candidate for epidural steroid injections for pain?

Patients who have not found relief from chronic, debilitating back pain with other types of pain management techniques, who aren't candidates for surgery, may benefit from steroid spine injections. For some people who have had surgery that has failed, epidural steroid injections are the only alternative to another invasive procedure. The injections are also particularly effective for patients who are suffering from an acute episode of pain by providing enough relief that they can participate in exercise or physical therapy.

Several common conditions that cause back pain can be treated with epidural steroid injections. These include:

- Lumbar disc herniation
- Degenerative disc disease
- Lumbar spinal stenosis, a narrowing of the spinal canal
- Compression fractures in a vertebra
- Cysts in the nerve root of the spine
- Annular tear ( a tear in the outer layer of the disc)

Physicians should not perform epidural steroid injections on patients whose pain is from a tumor or infection.

#### **Are these injections safe?**

Physicians have been using epidural steroid injections for back pain for more than 60 years. It is a safe procedure when a qualified physician performs it in a sterile setting, using the drugs appropriately and only after a proper diagnosis.

Like any medical procedure, some patients may experience side effects, although these *are very rare*. The side effects of epidural injections include:

- Infection
- Dural puncture, the accidental puncture of the membrane that protects the spinal cord
- Bleeding
- Nerve damage from trauma from the needle, or from infection or bleeding

#### Who is qualified to perform the procedures?

Physicians qualified to perform injections for back pain have extensive training in pain management. They trained for four years and received either an MD (doctor of medicine) or DO (doctor of osteopathy) degree, and then completed four years of residency training in a specialty, such as anesthesiology, physical medicine and rehabilitation or neurology.

After their residency training, they completed a fellowship in pain management to become board certified, with subspecialty training in interventional pain management. Not all pain medicine physicians are qualified to conduct interventional pain procedures, such as epidural injections. This is the subspecialty of medicine in which pain specialists use minimally invasive, needleguided treatments to relieve painful conditions.

# How do I know if my doctor is qualified to perform these procedures?

Before you undergo any procedure, ask your physician these questions:

- What is your medical specialty and are you board certified?
- Did you complete special training in interventional pain management?
- How many spinal injections have you performed and what is your success rate?
- Have your patients experienced any serious side effects from epidural injections?
- Why are you recommending spinal injections for my pain?
- Are there other treatment options available that may help?
- What is your hospital affiliation?

To find a qualified physician in Tennessee, visit <u>tnsipp.com</u> and search by region or physician name for a TNSIPP member. You may also contact your local hospital to find a pain physician on staff. For additional information about pain management, visit <u>asipp.org</u>.

#### What caused the recent outbreak of meningitis tied to these injections?

The U.S. Centers for Disease Control and Prevention (CDC) has linked a fungal meningitis outbreak to a tainted epidural corticosteroid called methylprednisolone acetate used in epidural injections for pain relief made by the New England Compounding Center (NECC) in Framingham, Mass. To date, cases of meningitis have been reported in 16 states, including Tennessee, where 69 cases and nine deaths have been reported. Earlier this month, NECC voluntarily recalled *all* of its products. (Data updated October 23, 2012.)

This is an evolving situation and the CDC and the U.S. Food and Drug Administration (FDA) continue to investigate. A recent alert from the FDA stated that another possible meningitis case may be linked to an epidural injection with a NECC product called triamcinolone acretonide. There have also been reports of joint infection that may be linked to the tainted steroid.

NECC is a compounding pharmacy, which creates special formulations of medications to meet patients' unique health care needs. Sometimes doctors are not be able to obtain certain medications commercially. A compounding pharmacy may change a dose or a formulation of a medication from a solid to a liquid, and compounding drugs are used in many settings.

However, these pharmacies aren't regulated by the FDA, accreditation is voluntary, and adherence to state regulations may be inconsistent. TNSIPP believes that a review of safety protocols in compounding pharmacies is important, and will work closely with both national and state leaders to help strengthen industry standards.

## What do I do if I think I may have received the tainted steroid injection?

If you received an epidural injection with steroids in the spine after May 21, 2012, and are concerned about what product your physician used in your procedure, the FDA advises you to contact your physician immediately.

For up-to-date information on the investigation, visit the CDC website at <a href="http://www.cdc.gov/hai/outbreaks/meningitis.html">http://www.cdc.gov/hai/outbreaks/meningitis.html</a> or the FDA website at <a href="http://www.fda.gov/Drugs/DrugSafety/ucm322734.htm">http://www.fda.gov/Drugs/DrugSafety/ucm322734.htm</a>.

#### Are there other ways to manage my pain?

Steroid cervical, thoracic and lumbar epidural steroid injections are just one tool used to relieve neck, back and leg pain (sciatica). There are other non-surgical options for pain management.

Physicians design tailored treatment plans focused on individual needs. In many cases, your physician will employ multiple therapies that may include:

- Detailed exercise prescriptions
- Physical and occupational therapy
- Pain medications including NSAID's, muscle relaxants, and nerve pain medications
- Behavioral methods
- Electrotherapy, such as transcutaneous electrical nerve stimulation
- Selective nerve root block used to diagnose the source of nerve root pain and for relief of low back pain and/or leg pain
- Facet joint block or sacroiliac joint block to numb the area for patients in which spinal joints are the source of pain
- Radio Frequency Neurotomy (RF) or "burning the nerves"
- Spinal Cord Stimulation, an electric device implanted under the skin that "tricks" the nerves by replacing the painful sensation with a more pleasant one

This document was published on October 22, 2012 by the Tennessee Society of Interventional Pain Physicians (TNSIPP), a state chapter of the American Society of Interventional Pain Physicians, organizations of physicians who perform procedures to diagnose and relieve pain. TNSIPP's mission is to promote safe, high-quality, cost-effective interventional pain management techniques, and to ensure patient access to interventional pain management physicians in Tennessee. Visit <u>TNSIPP.com</u> for further information.