CLINICAL GUIDELINES

CDI Quality Institute Epidural Steroid Injection Guideline

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Over the last 15 years it has become apparent that there is a small but real risk of catastrophic neurologic injury with the performance of transforaminal injections in the cervical and lumbar spine. This has prompted increased attention and debate concerning several technical aspects in the performance of these procedures including, but not limited to, the following factors:

- The use of particulate v. nonparticulate steroids,
- The use of real time fluoroscopy or digital subtraction fluoroscopy rather than intermittent fluoroscopy,
- The use of a retroneural approach or retrodiscal approach rather than a subpedicular approach,
- The use of a blunt tip needle rather than a sharp tip needle,
- The use of extension tubing, and
- The use of a test dose of lidocaine.

We have highlighted a number of recent publications, FDA announcements, CMS regulations and subspecialty publications made in this regard to assist each group and radiologists in evaluating their ESI techniques and policies.

FDA Warnings and Safe Use Initiatives

The FDA issued a safety warning on 4-23-2014 requiring label changes to steroid medications concerning the risk of severe neurologic injury with epidural steroid injections.[1] (Figure 1) The FDA subsequently convened a group of experts through the Safe Use Initiative to consider safeguards and techniques that would decrease the risk of preventable complications arising from the use of steroids in the performance of epidural steroid injections (ESI).

The mission of the Safe Use Initiative is "to create and facilitate public and private collaborations… to reduce preventable harm by identifying specific, preventable medication risks and by developing, implementing and evaluating cross-sector interventions with partners who are committed to safe medication use."[2] The statutory directive for the Safe Use Initiative is as follows:

8.5.1 Develop innovative methods to create, facilitate and encourage research in the area of safe medication use that seeks to reduce preventable harm from drugs. Approaches could include the use of clinical studies, education, innovative messaging strategies, electronic health records, or mobile technologies.

Figure 1 – FDA safety announcement concerning the safety of steroids used in transforaminal ESIs.

[04-23-2014] The U.S. Food and Drug Administration (FDA) is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. The injections are given to treat neck and back pain, and radiating pain in the arms and legs. We are requiring the addition of a *Warning* to the drug labels of injectable corticosteroids to describe these risks. Patients should discuss the benefits and risks of epidural corticosteroid injections with their health care professionals, along with the benefits and risks associated with other possible treatments.

Injectable corticosteroids are commonly used to reduce swelling or inflammation. Injecting corticosteroids into the epidural space of the spine has been a widespread practice for many decades; however, the effectiveness and safety of the drugs for this use have not been established, and FDA has not approved corticosteroids for such use. We started investigating this safety issue when we became aware of medical professionals' concerns about epidural corticosteroid injections and the risk of serious neurologic adverse events.[1] This concern prompted us to review cases in the FDA Adverse Event Reporting System (FAERS) database and in the medical literature (see Data Summary).[2-16]

To raise awareness of the risks of epidural corticosteroid injections in the medical community, FDA's Safe Use Initiative[3] convened a panel of experts, including pain management experts to help define the techniques for such injections which would reduce preventable harm. The expert panel's recommendations will be released when they are finalized.

As part of FDA's ongoing effort to investigate this issue, we plan to convene an Advisory Committee meeting of external experts in late 2014 to discuss the benefits and risks of epidural corticosteroid injections and to determine if further FDA actions

The ESI working group was comprised of experts from 13 subspecialty societies and included representatives from anesthesiologist, pain medicine, physical medicine and rehabilitation specialist, neurosurgeon, orthopedic surgeon and radiologist societies. The goal of this multidisciplinary group was to review the existing literature and assemble consensus recommendations aimed at reducing the risk of severe neurologic complications with the performance of ESIs. The recommended safeguards were published in the May 2015 issue of *Anesthesiology*[3] and are reproduced below in Table 1.

Table 1 - From: Safeguards to Prevent Neurologic Complications after Epidural Steroid Injections: Consensus Opinions from a Multidisciplinary Working Group and National Organizations. Anesthesiology 2015;122(5):974-984.

Statement/Clinical Consideration	Number of Organizations Agreeing	Number of Organizations Disagreeing	Number of Organizations Unable to Reach Consensus
1. Cervical IL ESIs are associated with a rare risk of catastrophic neurologic injury (fig. 1).	13	0	0
2. TF ESI using particulate steroid is associated with a rare risk of catastrophic neurovascular complications (fig. 3).	13	0	0
3. All cervical IL ESIs should be performed using image guidance, with appropriate AP, lateral, or contralateral oblique views and a test dose of contrast medium (fig. 5).	13	0	0
4. Cervical TF ESIs should be performed by injecting contrast medium under real-time fluoroscopy and/or digital subtraction imaging, using an AP view, before injecting any substance that may be hazardous to the patient (fig. 6).	11	1*	1
5. Cervical IL ESIs are recommended to be performed at C7-T1, but preferably not higher than the C6-C7 level.	13	0	0
6. No cervical IL ESI should be undertaken, at any segmental level, without reviewing, before the procedure, prior imaging studies that show there is adequate epidural space for needle placement at the target level.	13	0	0
7. Particulate steroids should not be used in therapeutic cervical TF injections.	13	0	0
8. All lumbar IL ESIs should be performed using image guidance, with appropriate AP, lateral, or contralateral oblique views and a test dose of contrast medium.	13	0	0
9. Lumbar TF ESIs should be performed by injecting contrast medium under real-time fluoroscopy and/or digital subtraction imaging, using an AP view, before injecting any substance that may be hazardous to the patient (fig. 7).	12	1*	0
10. A nonparticulate steroid (*e.g.*, dexamethasone) should be used for the initial injection in lumbar transforaminal epidural injections.	11	0	2
11. There are situations where particulate steroids could be used in the performance of lumbar TF ESIs.	13	0	0
12. Extension tubing is recommended for all TF ESIs.	12	1	0
13. A face mask and sterile gloves must be worn during the procedure.	13	0	0
14. The ultimate choice of what approach or technique (IL *vs.* TF ESI) to use should be made by the treating physician by balancing potential risks *vs.* benefits with each technique for each given patient	13	0	0
15. Cervical and lumbar IL ESIs can be performed without contrast in patients with documented contraindication to use of contrast (*e.g.*, significant history of contrast allergy or anaphylactic reaction)	11	0	2
16. TF ESIs can be performed without contrast in patients with documented contraindication to use, but in these circumstances, particulate steroids are contraindicated and only preservative-free, particulate-free steroids should be used.	13	0	0
17. Moderate-to-heavy sedation is not recommended for ESIs, but if light sedation is used, the patient should remain able to communicate pain or other adverse sensations or events	13	0	0

* The organization voting against questions 4 and 9 commented, "Digital Subtraction Imaging should be mandatory before injecting a potentially hazardous substance transforaminally."

AP = anteroposterior; C6-C7 = the interspace between the sixth and seventh cervical vertebrae; C7-T1 = the interspace between the seventh cervical and first thoracic vertebrae; ESI = epidural steroid injection; IL = interlaminar; TF = trasforaminal.

The FDA also convened an Anesthetic and Analgesic Drug Products Advisory Committee Meeting on November 24-25, 2014 to discuss the risk of serious neurologic adverse reactions associated with ESIs performed for pain management. These proceedings help the Agency in considering possible regulatory options and changes to product labeling. An article summarizing this effort has been published in a May 2015 issue of the *Journal of the American Medical Association* (JAMA).[4] A summary of the recommendations made in this article is reproduced in Table 2.

Table 2 – Recommendations for improving the safety of epidural steroid injections reprinted in *JAMA*.

1. All cervical and lumbar interlaminar epidural steroid injections should be performed using image guidance, with appropriate anteroposterior, lateral, or contralateral oblique views and a test dose of contrast medium. (There has been a case report of lower extremity paralysis after lumbar interlaminar injection without fluoroscopy and a case report of paraplegia after thoracic interlaminar injection when fluoroscopy was used but contrast was not injected.)
2. Cervical and lumbar transforaminal epidural steroid injections should be performed by injecting contrast medium under real-time fluoroscopy or digital subtraction imaging, before injecting any substance that may be hazardous to the patient. (The use of digital subtraction imaging has been shown to be more effective in detecting intravascular injection than syringe aspiration alone.)
3. Cervical interlaminar epidural steroid injections are recommended to be performed at C7-T1, but preferably not higher than the C6-7 level. (The cervical epidural space is widest at the C6-T1 levels. Gaps in the ligamentum flavum are more frequent with ascending cervical levels.)
4. No cervical interlaminar epidural steroid injection should be undertaken, at any segmental level, without preprocedural review of prior imaging studies demonstrating sufficient epidural spatial dimensions for needle placement at the target level.
5. Particulate steroids should not be used in therapeutic cervical transforaminal injections. (Injuries following nonparticulate injections were temporary, whereas paraplegias after particulate steroids were permanent. If the nerve root involved is at a higher level, ie, C5, most pain medicine physicians perform an interlaminar injection at C6-7 or C7-T1, insert a catheter, and advance it to C5. For diagnostic injections, to help the surgeon identify the affected nerve root, pain physicians perform transforaminal injections using local anesthetic, with or without a nonparticulate dexamethasone.)
6. A nonparticulate steroid (e.g., dexamethasone) should be used for the initial injection in lumbar transforaminal epidural injections.
7. There are situations in which particulate steroids could be used in the performance of lumbar transforaminal epidural steroid injections. (This is because the lumbar transforaminal area is wider than in the cervical regions. If relief from a nonparticulate steroid is of short duration, some physicians will inject a steroid containing smaller particles, either betamethasone or triamcinolone.)

North American Spine Society Coverage Policy Recommendations

The NASS documents make several explicit statements as to the *appropriateness of epidural steroid injections*.

In cervical spine, they state that epidural and perineural injections are indicated primarily for the treatment of radicular pain with MRI or CT showing a compressive lesion correlating with the patient symptom complex and following an appropriate course of conservative care. They state that injections are contraindicated for non-specific neck pain without radicular pain and in patients who have failed 1-2 prior injections for a given episode of pain. They state that injections are also contraindicated in patients with clinical evidence of compressive myelopathy. Moderate or severe cord compression on MRI or CT should also be considered a relative contraindication to an interlaminar injection, particularly if signal abnormalities are present in the cord. The clinical signs of myelopathy can be somewhat subtle and may not be apparent on cursory physical examination.

In the lumbar spine, NASS again states that injections are not indicated for back pain without radicular pain except with a high-level athlete during a competitive season, or for a pregnant woman with intractable pain.

Exceptions to the requirement for a course (4 weeks) of conservative care include, but are not limited to:

1. At least moderate pain with significant loss of function at home or work;
2. Uncontrolled pain;
3. Inability to tolerate non-surgical non-invasive care;
4. Prior successful ESI for the same condition.

The NASS appropriateness documents list numerous *procedural requirements and restrictions,* several of which are listed below:

1. For transforaminal ESIs, live contrast-enhanced fluoroscopy or digital subtraction angiography is preferred, although contrast-enhanced CT guidance may be performed with the understanding that this form of visualization might not detect intravascular flow leading to potential complications, especially if particulate steroids are used.

2. Films documenting the final needle position and contrast flow must be retained for documentation.

3. Exceptions to the use of contrast are considered in patients who have a significant history and/or are at high risk for an adverse event if contrast material is used (e.g. contrast allergy).

    a) In these cases, physicians should consider using a test-dose injection (of lidocaine) prior to injecting any particulate steroids and/or use only non-particulate steroid solutions.*
    b) The reasons for not using contrast *(or using MRI contrast)* should be documented in the procedure report.

4. The indications for injections are based on the patients' symptoms and response to previous injections, i.e. good or excellent response to a previous injection with the return of moderate or severe pain. (No routine series of 3 injections.)

5. If a prior lumbar ESI provided no relief, a second ESI is allowed following reassessment of the patient, injection technique and/or medication used.

6. For each session (including all injections performed on a given day), no more than 80mg of triamcinolone, 80 mg of methylprednisolone, 12 mg of betamethasone, 15 mg of dexamethasone or equivalent corticosteroid dosing should be used.

7. Given the recent RCT evidence (Kennedy et al, Pain Medicine, 2014; El-Yahchouchi et al, Pain Medicine, 2014) for the therapeutic equivalency of dexamethasone to particulate steroid, particulate-free steroid, such as dexamethasone, should be used as the first line drug in all transforaminal ESIs.

8. Particulate steroid should be used only after failure of particulate-free steroid and with appropriate patient counseling and safeguards, such as digital subtraction imaging.

We have included links to these documents for your convenience.[5, 6]

**(Note that MRI contrast can also be used in these patients however its effectiveness in detecting vascular flow has not been assessed.)*

Medicare Regulations for Lumbar Epidural Steroid Injections – (NGS L35338 for MA & MN[7] and Noridian L34117/L33836 for WA & AZ[8])

Effective for services performed on or after 12/16/2014, NGS (Medicare) has issued the following requirements or restrictions for the states in their coverage area including Massachusetts and Maine:

Indications for Lumbar ESI:

1. Pain associated with
    a. Herpes Zoster and/or,
    b. Radicular pain,
    c. Neurogenic claudication,
    d. Low Back Pain with
        i. NPRS ≥ 3/10,
        ii. Significant impairment of activities and either
        iii. Substantial imaging abnormalities such as a central disc herniation, severe degenerative disc disease or central canal stenosis.
2. Failure of four weeks of conservative therapy including oral medications and PT to the extent tolerated with the exception of
    a. Herpes Zoster,
    b. At least moderate pain with significant dysfunction at home or work,
    c. Uncontrolled pain,
    d. Inability to tolerate conservative care,

e. Prior successful injections for the same condition with relief of at least 3 months duration.

Procedural requirements include (additional listed in LCD):

1. Plain films to rule out red flag conditions may be appropriate if potential issues of trauma, osteomyelitis or malignancy are a concern.

2. *Real-time* imaging guidance, fluoroscopy or computed tomography, with the use of injectable radio-opaque contrast material is required for all steroid injections and all transforaminal injections. Its use is urged, but not required, for other epidural injections.

3. Contrast medium should be injected during epidural injection procedures unless patient has contraindication to the contrast. The reasons for not using contrast must be documented in the procedure report.

4. Films** that adequately document final needle position and injectate flow must be retained and made available upon request.

5. For each session, no more than 80mg of triamcinolone, 80 mg of methylprednisolone, 12 mg of betamethasone, 15 mg of dexamethasone or equivalent corticosteroid dosing may be used.

Provider Qualifications:

"Patient safety and quality of care mandate that healthcare professionals who perform Epidural Steroid Injections are appropriately trained and/or credentialed by a formal residency/fellowship program and/or are certified by either an accredited and nationally recognized organization or by a post-graduate training course accredited by an established national accrediting body or accredited professional training program. A practitioner who works in a hospital or ASC facility at any time should be credentialed by the facility for any procedure also performed in an office setting. (At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics as well as proficiency in diagnosis and management of disease, the technical performance of the procedure and utilization of the required associated imaging modalities)."

Selected Limitations (additional listed in LCD):

1. For a patient with low back pain only, a simple disc bulge or annular tear/fissure is insufficient to justify performance of an epidural.*

2. The patient must not have major risk factors for spinal cancer (e.g., LBP with fever or weight loss) or, if cancer is present, the pain must be clearly unrelated to the cancer and secondary to one of the indications previously listed.

3. A co-existing medical or other condition that precludes the safe performance of the procedure precludes coverage of the procedure, e.g., new onset of LBP with fever, active

spine infection, pain secondary to cancer in the spine, cauda equina syndrome, rapidly progressing (or other) neurological deficits, coagulopathy.

4. Numbness and/or weakness without paresthesiae/dysesthesiae or pain preclude coverage.

*(*Several physicians at CDI have responded that they have had patients with high signal intensity annular fissures that have responded well to epidural injections. There is little data to support one position over the other position in this regard; however this is the language in the LCD. The overriding theme is that for medical necessity purposes, patients undergoing epidural injections for axial pain should have a significant MRI abnormality (e.g. central disc herniation, central canal stenosis, significant disc degeneration, or disc degeneration with moderate or marked discogenic marrow edema) and that the abnormality should be documented in the procedure notes.)*

***Presumably electronic images would suffice.*

Medicare Regulations for Lumbar Epidural Steroid Injections –

(Palmetto GBA L34336 for VA[9], Cahaba GBA L32112 for TN[10], and First Coast Services Options L29165 for FL[11])

The LCD for Virginia (L34336) provides a more thorough consideration of the indications and contraindications for ESIs.[9] The procedural requirements are more limited and include plain x-rays to rule out fracture, infection or cancer; image guidance; contrast; image documentation; and maximum cortisone doses as stated above.

The procedural requirements for epidural steroid injections in the LCDs for Tennessee (L32112) and Florida (L29165) are even more limited requiring only image guidance.[10, 11]

Medicare Regulations for Lumbar Epidural Steroid Injections –

(WI Physician Service Insurance Corp for IN[12])

The LCD for Indiana is less restrictive with respect to the indications for epidural injections in general, and includes each of the following:

- Acute obstetric, post traumatic and postoperative pain;
- Advanced cancer pain, primary or metastatic;
- Acute/subacute and chronic pain syndrome including cervical, thoracic and lumbar pain with radiculopathy and intervertebral disc disease (with neuritis or radiculitis) with or without myelopathy that has failed to respond to adequate conservative management;
- Nerve root injuries and neuropathic pain and post traumatic including post laminectomy syndrome (failed back syndrome);
- Spinal cord myelopathy;
- Complex regional pain syndrome;
- Epidural scarring from prior infection, hemorrhage and/or surgery;
- Multiple rib fractures;

- Vertebral compression fractures;
- Post herpetic neuralgia and herpes zoster; and
- Phantom limb pain.

The specific indications for transforaminal injections are:

- Radicular pain resistant to more conservative measures or when surgery is contraindicated;
- Post-decompressive radiculitis or post-surgical scarring;
- Monoradicular pain, confirmed by diagnostic block in which a surgically correctible lesion cannot be identified; and
- Treatment of acute herpes zoster or post herpetic neuralgia.

The requirements for repeat injections are:

- Significant improvement in the patient's symptoms from a prior injection,
- Carefully documented technical reasons that it is appropriate to repeat the procedure, or
- Patients with persistent pain in whom the imaging findings suggest that the pathology should respond to a corticosteroid injection.

Notwithstanding a compelling reason, a procedure should not be repeated a third time if two previous injections have not worked.

The procedural restrictions in Indiana are limited and require only image guidance.

We could not find an LCD for epidural steroid injections for Texas.

References

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