

MEDICAL POLICY

EPIDURAL STEROID INJECTION

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POLICY

- Recommended as a possible option for short-term treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy). The purpose of an ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, reduction of medication use and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.

Criteria for the use of Epidural steroid injections:

1. Radiculopathy must be documented. Objective findings on examination need to be present. Radiculopathy must be corroborated by imaging studies and/or electrodiagnostic testing.
2. Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).
3. Injections should be performed using fluoroscopy (live x-ray) and injection of contrast for guidance.
4. *Diagnostic Phase:* At the time of initial use of an ESI (formally referred to as the “diagnostic phase” as initial injections indicate whether success will be obtained with this treatment intervention), a maximum of one to two injections should be performed. A repeat block is not recommended if there is inadequate response to the first block (< 30% is a standard placebo response). A second block is also not indicated if the first block is accurately placed unless: (a) there is a question of the pain generator; (b) there was possibility of inaccurate placement; or (c) there is evidence of multilevel pathology. In these cases a different level or approach might be proposed. There should be an interval of at least one to two weeks between injections.
5. No more than two nerve root levels should be injected using transforaminal blocks.
6. No more than one interlaminar level should be injected at one session.

7. *Therapeutic phase:* If after the initial block/blocks are given (see “Diagnostic Phase” above) and found to produce pain relief of at least 50-70% pain relief for at least 6-8 weeks, additional blocks may be supported. This is generally referred to as the “therapeutic phase.” Indications for repeat blocks include acute exacerbation of pain, or new onset of radicular symptoms. The general consensus recommendation is for no more than 4 blocks per region per year.

8. Repeat injections should be based on continued objective documented pain relief, decreased need for pain medications, and functional response.

9. Current research does not support a routine use of a “series-of-three” injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections for the initial phase and rarely more than 2 for therapeutic treatment.

10. It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or sacroiliac blocks or lumbar sympathetic blocks or trigger point injections as this may lead to improper diagnosis or unnecessary treatment.

11. Cervical and lumbar epidural steroid injection should not be performed on the same day. (Doing both injections on the same day could result in an excessive dose of steroids, which can be dangerous, and not worth the risk for a treatment that has no long-term benefit.)

SUPPORTING DOCUMENTATION

ODG:

Recommended as a possible option for short-term treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy) with use in conjunction with active rehab efforts. See specific criteria for use below. Radiculopathy symptoms are generally due to herniated nucleus pulposus or spinal stenosis, although ESIs have not been found to be as beneficial a treatment for the latter condition. In fact, according to SPORT, ESIs are associated with less improvement in spinal stenosis. ([Radcliff, 2013](#))

Short-term symptoms: The American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months. ([Armon, 2007](#)) Epidural steroid injection can offer short-term pain relief and use should be in conjunction with other rehab efforts, including continuing a home exercise program. There is little information on improved function or return to work. There is no high-level evidence to support the use of epidural injections of steroids, local anesthetics, and/or opioids as a treatment for acute low back pain without radiculopathy. ([Benzon, 1986](#)) ([ISIS, 1999](#)) ([DePalma, 2005](#)) ([Molloy, 2005](#)) ([Wilson-MacDonald, 2005](#)) A recent RCT of 29 patients divided into three groups addressed the use of ESIs for treatment of spinal stenosis. A control group with no treatment was compared to a group receiving passive physical therapy for two weeks and another receiving an interlaminar ESI at the stenotic level. At two weeks the group that received the ESI had significantly better pain relief than the other two groups. When the three groups were compared there was no statistical difference except in pain intensity and Roland Morris Disability Index and this was at two weeks only. The authors stated that improvement only appeared to be in the early phase of treatment. ([Koc, 2009](#))

Use for chronic pain: Chronic duration of symptoms (> 6 months) has also been found to decrease success rates with a threefold decrease found in patients with symptom duration > 24 months. The ideal time of either when to initiate treatment or when treatment is no longer thought to be effective has not been determined. ([Hopwood, 1993](#)) ([Cyteval, 2006](#)) Indications for repeating ESIs in patients with chronic pain at a level previously injected (> 24 months) include a symptom-free interval or indication of a new clinical presentation at the level.

Transforaminal approach: Some groups suggest that there may be a preference for a transforaminal approach as the technique allows for delivery of medication at the target tissue site, and an advantage for transforaminal injections in herniated nucleus pulposus over translaminar or caudal injections has been suggested in the best available studies. (Riew, 2000) (Vad, 2002) (Young, 2007) This approach may be particularly helpful in patients with large disc herniations, foraminal stenosis, and lateral disc herniations. (Colorado, 2001) (ICSI, 2004) (McLain, 2005) (Wilson-MacDonald, 2005) Two recent RCTs of caudal injections had different conclusions. This study concluded that caudal injections demonstrated 50% pain relief in 70% of the patients, but required an average of 3-4 procedures per year. (Manchikanti, 2011) This higher quality study concluded that caudal injections are not recommended for chronic lumbar radiculopathy. (Iversen, 2011)

Fluoroscopic guidance: Fluoroscopic guidance with use of contrast is recommended for all approaches as needle misplacement may be a cause of treatment failure. (Manchikanti, 1999) (Colorado, 2001) (ICSI, 2004) (Molloy, 2005) (Young, 2007)

Factors that decrease success: Decreased success rates have been found in patients who are unemployed due to pain, who smoke, have had previous back surgery, have pain that is not decreased by medication, and/or evidence of substance abuse, disability or litigation. (Jamison, 1991) (Abram, 1999) Research reporting effectiveness of ESIs in the past has been contradictory, but these discrepancies are felt to have been, in part, secondary to numerous methodological flaws in the early studies, including the lack of imaging and contrast administration. Success rates also may depend on the technical skill of the interventionalist. (Carette, 1997) (Bigos, 1999) (Rozenberg, 1999) (Botwin, 2002) (Manchikanti, 2003) (CMS, 2004) (Delpont, 2004) (Khot, 2004) (Buttermann, 2004) (Buttermann2, 2004) (Samanta, 2004) (Cigna, 2004) (Benzon, 2005) (Dashfield, 2005) (Arden, 2005) (Price, 2005) (Resnick, 2005) (Abdi, 2007) (Boswell, 2007) (Buenaventura, 2009) Also see Epidural steroid injections, “series of three” and Epidural steroid injections, diagnostic. ESIs may be helpful with radicular symptoms not responsive to 2 to 6 weeks of conservative therapy. (Kinkade, 2007) Epidural steroid injections are an option for short-term pain relief of persistent radiculopathy, although not for nonspecific low back pain or spinal stenosis. (Chou, 2008) As noted above, injections are recommended if they can facilitate a return to functionality (via activity & exercise). If post-injection physical therapy visits are required for instruction in these active self-performed exercise programs, these visits should be included within the overall recommendations under Physical therapy, or at least not require more than 2 additional visits to reinforce the home exercise program.

With discectomy: Epidural steroid administration during lumbar discectomy may reduce early neurologic impairment, pain, and convalescence and enhance recovery without increasing risks of complications. (Rasmussen, 2008)

Patient selection: ESIs are more often successful in patients without significant compression of the nerve root and, therefore, in whom an inflammatory basis for radicular pain is most likely. In such patients, a success rate of 75% renders ESI an attractive temporary alternative to surgery, but in patients with significant compression of the nerve root, the likelihood of benefiting from ESI is low (26%). This success rate may be no more than that of a placebo effect, and surgery may be a more appropriate consideration. (Ghahreman, 2011)

MRIs: According to this RCT, the use of MRI before ESIs does not improve patient outcomes and has a minimal effect on decision making, but the use of MRI might have reduced the total number of injections required and may have improved outcomes in a subset of patients. Given these potential benefits as well as concerns related to missing important rare contraindications to epidural steroid injection, plus the small benefits of ESIs themselves, ODG continues to recommend that radiculopathy be corroborated by imaging studies and/or electrodiagnostic testing. (Cohen, 2012)

Fracture risk: Lumbar ESIs are associated with an increased risk for spinal fracture. Each single additional ESI increased the risk for fracture by 21%, with an increasing number of ESIs associated with

an increasing likelihood of fracture. Use of ESIs seems to promote deterioration of skeletal quality. This definable fracture risk should be balanced with the best available evidence regarding the long-term efficacy of ESIs, which is limited. Clinicians should consider these findings before prescribing ESIs for elderly patients. (Mandel, 2013)

Recent research: An updated Cochrane review of injection therapies (ESIs, facets, trigger points) for low back pain concluded that there is no strong evidence for or against the use of any type of injection therapy, but it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy. (Staal-Cochrane, 2009) Recent studies document a 629% increase in expenditures for ESIs, without demonstrated improvements in patient outcomes or disability rates. (Deyo, 2009) There is fair evidence that epidural steroid injection is moderately effective for short-term (but not long-term) symptom relief. (Chou3, 2009) This RCT concluded that caudal epidural injections containing steroids demonstrated better and faster efficacy than placebo. (Sayegh, 2009) In this RCT there were no statistically significant differences between any of the three groups at any time points. This study had some limitations: only one type of steroid in one dose was tested; the approach used was caudal and transforaminal injections might provide superior results. (Weiner, 2012) Effects are short-term and minimal. At follow-up of up to 3 months, epidural steroids were associated with statistically significant reductions in mean leg pain and mean disability score, but neither of these short-term improvements reached the threshold for clinical significance. There were no significant differences in either leg pain or disability at 12 months follow-up. (Pinto, 2012)

ACOEM:

- Recommended for Acute and Sub-Acute Radicular Pain Syndromes (Insufficient Evidence (I))
- Recommended for Acute Spinal Stenosis (Insufficient Evidence (I))
- Not Recommended for Acute, Sub-Acute and Chronic Low Back Pain (Limited Evidence (C))

Background

Epidural glucocorticosteroid injections are performed in an attempt to deliver the active medication as close to the target tissue as possible, whether most commonly a herniated disc or spinal stenosis. (abdi 07, cannon 00, delpont 04) The three approaches most commonly used are caudal, interlaminar, and transforaminal. (abdi 07, manchikanti 03, boswell 07; Gordon 80) This is performed as an interlaminar epidural injection in which the injection is placed immediately adjacent to the dural sac in the posterior spinal column with subsequent diffusion to the herniated disc or other offending structure. Fluoroscopic guidance has been shown to improve the accuracy of injection placement, as blind targeting has been shown to be 77% accurate. (manchikanti pain phy 04) It is the least technical of these procedures. Complications occur, are rare, but in rare cases may be serious. These include infection (meningitis, epidural abscess, etc.) and hemorrhage related to penetration of an anatomical variant artery. A resulting epidural hematoma may compress the nerve or spinal cord (abdi 07) and generally requires emergency surgery. Suppression of the pituitary-adrenal axis does occur. (kay 94)

Transforaminal injections most closely target the usual sites of pathology and inflammation and use the least volume of agent. Transforaminal epidural injections (aka selective nerve root plus injections) accomplish the same task, except the needle is placed along the nerve root in closer proximity to the herniated disc or impinged neurologic structure. (abdi 07, botwin 02;697) These are technically more difficult. Transforaminal injections are generally performed under fluoroscopic or CT guidance. (lutze 97) Transforaminal injections also necessitate better diagnostic precision to ensure the closest proximity to the affected level via the injection. (manchikanti 03;6(1):3-81) A technique has been described using electrical stimulation to assist

with nerve root identification. (haynsworth 03) As these injections are most frequently performed as a combination of a glucocorticoid with an anesthetic, they are considered to be both diagnostic and therapeutic. (samanta 04) The technical performance of these injections, including the precision of placement of medication using fluoroscopic guidance, is reportedly a significant aspect related to the efficacy of these injections. (cannon 00) Uncontrolled data suggest psychological factors may be associated with treatment failure, (hopwood 93) but that is not a universal finding. There are radiation exposure concerns for fluoroscope operators and patients that should be addressed. (botwin 02) Serious complications are rare in the RCTs reviewed, but have occurred and include intraspinal abscesses and meningitis. (butler 05, gaul 05)

Rationale

Systematic reviews have arrived at contradictory conclusions. Those with the highest standards for evidence have generally not found glucocorticosteroid injections to be a cost effective treatment. Most of the RCTs have studied blind interlaminar epidural injection. Fluoroscopic guidance may improve results; however, that theory has not been directly tested.

Glucocorticosteroid injections have been evaluated in moderate to high-quality studies. All four high-quality studies that evaluated patients in the 4 to 6 week timeframe demonstrated that these injections are helpful to reduce short-term leg and back pain ratings for those with herniated intervertebral discs. (arden 05, karppinen spine 01, price 05, carette 97) Data also appear to mostly show that benefits of a single injection disappear by approximately 6 weeks. The available quality evidence suggests there are no long-term benefits. The evidence does not suggest that these injections change function or the need for surgery. Importantly, there is good evidence that it is the natural history of symptoms from a herniated disc to trend towards resolution over time. (price 05, Gibson 07) Thus, it should be recognized that the purpose of these injections for acute radicular pain syndromes is perhaps best stated as “buying time” through a period of natural recovery that decreases the patient’s pain while shrinkage or resorption of the herniated disc occurs.

Since the relief from epidural steroid injections is brief, and since by definition chronic non-specific back pain and chronic radicular pain with or without prior back surgery are chronic problems, epidural steroid injections are not recommended as a transient treatment for these long-term problems. There also is no quality evidence that accomplishing these injections earlier in the course of the syndrome results in any improvement in the condition. On the contrary, there is some evidence inferred from the published studies suggesting it may make no difference. (price 05) There is also limited evidence in two moderate-quality RCTs that these injections help symptoms of spinal stenosis, (Wilson-macdonald 05, fukusaki 98) though again on a short-term basis. Therefore, epidural glucocorticosteroid injections are an option as a second-line treatment for acute flare-ups of spinal stenosis, although the evidence is less robust than it is for herniated discs.

Technique may be important as well as the anatomical approach chosen. (cannon 00) However, there is insufficient evidence presently to recommend one technique over the other for an initial approach (caudal vs. interlaminar vs. transforaminal), other than to note that there is evidence that endoscopy for steroid injection has not been shown to be beneficial. (dashfield 05) Although it is suspected that fluoroscopic or CT guidance for these injections is helpful, there is not sufficient evidence for guidance on that topic.

Although three studies used a series of up to 3 injections over 6 weeks, (arden 05, price 05, carette 97) there is no quality study that performed 3 injections without an assessment after each injection to determine whether an additional injection was appropriate and recommended. Most studies utilized one injection. Thus, there is no quality evidence to support or require a series of 3 injections. There is no evidence that there is a limit of 3 in a year or lifetime, although if there is no clear benefit, then repeated injections are not recommended.

Current practice in the U.S. is generally to obtain an MRI or CT prior to an epidural injection. However, there is evidence that this is not necessary, and at least three of the trials appeared to solely rely on the clinical examination to address the level targeted with subsequent epidural glucocorticosteroid injection. (arden 05, price 05, buttermann 02) Additional studies may be needed to determine whether imaging is required or not, as if it is not necessary, it can be eliminated and markedly reduce the cost of this intervention.

Epidural glucocorticoid injections are invasive, have a low risk of adverse effects, (price 05) and are costly. The number needed to achieve partial pain relief at 3 weeks was 11.4, but there was no benefit from weeks 6 to 52. (price 05) These injections are an option in acute radiculopathy, but as a second-line treatment after prior treatment with NSAIDs, possibly a short course of an oral corticosteroid and a suggested waiting period of at least 3 weeks.

REFERENCES

Official Disability Guidelines, Low Back Chapter, 2013
ACOEM Practice Guidelines, Low Back Chapter, 2013