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Fluoroscopically Guided Transforaminal Epidural Steroid Injections for Lumbar Radicular Pain

Prepared under the direction of the
Technology Assessment Committee
(TAC Sponsor: Thomas Elliot, M.D.)
by Peter Lynch, MPH, Staff

Description of Treatment/Procedure

Approximately 5% of Americans suffer from chronic disabling lumbar radicular pain. About 90% of patients with acute low back pain will have improvements in pain and disability within 6 weeks with conservative therapy although recurrence of painful symptoms is common. Those patients unresponsive to conservative therapy within 3 months may develop chronic lumbar radicular pain and consider other more invasive treatments, including surgery. The anatomic cause of radicular pain is often a herniated nucleus pulposus or a lateral spinal stenosis. Neurogenic inflammation may contribute to axial and radicular pain and prevent adequate healing. Thus, corticosteroids, known anti-inflammatory agents, may help reduce radiculopathy.

There are 3 main steroid injection approaches: transforaminal, interlaminar, and caudal. The transforaminal approach seems to be the most specific and effective route. Among the other injection variables, fluoroscopy seems to be a major determining factor in whether or not steroids can be effective for back pain. Before 2000, there were few published studies that utilized fluoroscopically guided needle placement with contrast confirmation. This report focuses on studies that have used fluoroscopic guidance and contrast confirmation of needle placement with a transforaminal approach.

Potential Uses

Fluoroscopically guided steroid injections targeted to the site of pathology are indicated for intraspinal inflammation causing axial spine or radicular pain. Epidural steroid injections may be helpful in the management of acute, subacute, or chronic axial spine and radicular pain that is refractory to more conservative care such as rest, analgesics, and physical therapy.

Contraindications

Contraindications include local infection at injection site; anticoagulation with warfarin, heparin compounds and certain anti-platelet drugs; bleeding diathesis; uncontrolled congestive heart failure; and uncontrolled diabetes mellitus.

Efficacy of Treatment/Procedure

Two randomized controlled trials, 1 non-randomized trial, and 2 case series have reported results of patients receiving steroid injections under fluoroscopic guidance. In a randomized trial of surgical candidates, 20 of 28 patients injected with steroids (71%) as compared with 9 of 27 controls (33%) chose not to have surgery during 13 to 28 months of follow-up (p<0.004). The second randomized trial showed reduced leg pain, improved leg raising, and improved lumbar flexion for the steroid injection group at 2 weeks post-injection but no pain-related or functional benefits at 4 weeks or 1 year. At 4 weeks, the costs associated with therapy visits and medications were lower in the steroid group. The other studies reported reduced pain, especially short-term, with less consistent results for long-term pain relief. In those studies, most patients were satisfied with their outcomes but, in the absence of a control group, it is not possible to conclude whether the results were due to the steroid injections or other factors.

Committee Summary

With regard to fluoroscopically guided epidural steroid injections for lumbar radicular back pain, the ICSI Technology Assessment Committee finds:

1. Fluoroscopically guided epidural steroid injections are generally safe when performed by an experienced physician in a controlled setting. Epidural steroid injections should not be done without fluoroscopic guidance. Commonly used corticosteroids include methylprednisolone and betamethasone.
2. Based on limited data, the results appear promising. However, at this time, there is insufficient evidence to comment on the efficacy of epidural steroid injections. Ongoing studies may allow for more definitive statements in the future. (Conclusion Grade III)

Fluoroscopically Guided Transforaminal Epidural Steroid Injections for Lumbar Radicular Pain

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Prepared under the direction of the
Technology Assessment Committee

(TAC Sponsor: Thomas Elliot, M.D.)

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*See Potential Conflict of Interest Disclosure at the end of the report

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ICSI Technology Assessment Report Process

- A topic is selected by the Technology Assessment Committee (TAC) based on its relevance to ICSI member organizations or ICSI sponsoring health plans.
- A work group of 4 to 6 physicians and other health care professionals who are experts in the topic area is identified (with a formally designated leader). A TAC sponsor is also identified. Prospective work group members are asked to disclose any potential conflicts of interest relevant to the topic of the report; disclosure forms are reviewed for unacceptable conflicts.
- The literature search is completed using MEDLINE; in addition, bibliographies of articles obtained from the literature search are examined to identify articles that may have been missed and work group members are asked to provide key references.
- The ICSI staff person gets direction on the scope of the report from the work group leader and prepares a draft report based on the available literature. The evidence is graded according to the system described in the References section of the report.
- The work group meets to review the draft report and direct the ICSI staff person in revising the report.
- After approval of the draft report by the work group and the TAC sponsor, the work group leader presents the report to the TAC. Committee members review the report to determine whether the conclusions are supported by the evidence cited. The draft report is concurrently distributed to ICSI member organizations and content experts nationwide for their review.
- All comments received are shared with the work group leader and revisions to the report are made, if necessary.
- With work group and TAC sponsor approval of the revisions, the TAC makes the final decision regarding approval of the report for distribution. Newly approved reports are posted at www.icsi.org.
- Reports are reviewed bi-annually and revised, if warranted.

Description of Technology/Procedure

Approximately 5% of Americans suffer from chronic disabling lumbar radicular pain. Spine pain is a major health related problem for providers and patients. About 90% of patients with acute low back pain will have improvements in pain and disability within 6 weeks with conservative therapy including analgesics, antiinflammatory agents, physical therapy, and/or activity modification. Recurrence of painful symptoms is likely. Those patients unresponsive to conservative therapy within 3 months may develop chronic lumbar radicular pain and consider other more invasive treatments including surgery (Lippert & McGraw, 2002; Chen, Derby, Kim, & Lee, 2003, Pengel, Herbert, Maher, & Refshauge, 2003).

Compression and/or chemical irritation of nerve roots in the spine may cause radicular pain (Chen et al., 2003, Pengel et al., 2003). The anatomic cause of radicular pain is often a herniated nucleus pulposus (HNP) or a lateral spinal stenosis. The pathology of lumbar axial pain is not diagnosed as easily. Finding the correct anatomic cause of radicular pain is valuable because well selected surgical candidates generally have better outcomes (Derby et al., 1992; Weinstein & Herring, 2001; Chen et al., 2003).

Neurogenic inflammation may contribute to axial and radicular pain. This inflammation can prevent adequate healing and the end result of chronic inflammation may be fibrosis. Corticosteroids have been used for decades to reduce discogenic low back pain and radicular pain. Corticosteroids may have anesthetic-like properties as well as anti-inflammatory properties (Cannon & Aprill, 2000; Weinstein & Herring, 2001; Chen et al., 2003). It has been suggested that if inflammation and pain can be controlled, dysfunction and disability may improve as well (Weinstein & Herring, 2001). Commonly used corticosteroids include methylprednisolone and betamethasone (Manchikanti et al., 2003).

Injections of corticosteroids increase the target site concentration more than oral administration. The first injections of corticosteroids for relieving back pain were done in the early 1950s (Weinstein & Herring, 2001). There are 3 main approaches for steroid injection: transforaminal, interlaminar, and caudal.

Most studies of epidural steroid injections published before 2000 evaluated "blind epidural injection," (i.e., injection without fluoroscopic guidance). "Success" rates of 18% to 90% were reported for those studies (Chen et al., 2003). Recently, the trend has been toward the use of fluoroscopy to document intraspinal placement of medication. Fluoroscopically guided transforaminal injections are the focus of this report as they appear to be the most specific and effective route for delivering medication to the primary site of the pathology (Chen et al., 2003; Manchikanti et al., 2003).

Identifying the epidural space with a needle can be difficult. Epidural injections, particularly if done without fluoroscopy, have the potential risk for intraneural injection, neural trauma, technical difficulty in the presence of spinal fusion or hardware, intravascular injection, and spinal cord trauma. Between 19% and 53% of blind injections (without fluoroscopy and without contrast confirmation of correct needle placement), done by experienced physicians using a loss-of-resistance technique, have been shown to be misplaced. In the absence of contrast confirmation of needle placement, proper epidural location cannot be confirmed. Other injection variables that can affect target site concentration include the presence of epidural plica or scarring, the volume of injectant, and the rate or pressure of injection (Cannon & Aprill, 2000; Weinstein & Herring, 2001; Boswell, Hansen, Trescot, & Hirsch, 2003; Manchikanti et al., 2003; Windsor, Storm, & Sugar, 2003; Chen et al., 2003).

The American Society of Interventional Pain Physicians (Manchikanti et al., 2003) recommends that injections be done at intervals of 2 weeks provided the procedure was regarded as medically necessary. A maximum of 6 injections per body region per year was suggested. All regions should be treated at the same time, if feasible.

Potential Uses

Fluoroscopically guided epidural steroid injections targeted to the site of the pathology are indicated for intraspinal inflammation causing axial spine or radicular pain. Epidural steroid injections may be helpful in the management of acute, subacute, or chronic axial spine and radicular pain that is refractory to more conservative care such as rest, analgesics, and physical therapy.

Contraindications

Contraindications include local infection at injection site; anticoagulation with warfarin, heparin compounds and certain anti-platelet drugs; bleeding diathesis; uncontrolled congestive heart failure; and uncontrolled diabetes mellitus.

Efficacy of Treatment or Procedure

Randomized Trials

In a randomized controlled trial by Riew et al. (2000), 55 operative candidates (radiographically confirmed diagnosis of HNP or spinal stenosis with radicular pain) received either fluoroscopically guided steroid injections or injections with saline. The patients had completed a course of nonoperative management (antiinflammatory medication, physical therapy, and activity modification) for 6 weeks without benefit (except for patients with intractable pain despite a maximum dose of antiinflammatory medication, narcotic pain medication, and activity modification). Patients who experienced acute trauma, cauda equina syndrome, a progressive neurological deficit, a motor deficit, or a pathological or infectious etiology, or who were non-operative candidates, were involved in a worker's compensation claim, had a history of adverse reaction to corticosteroids or local anesthetic, or needed injections at 3 or more levels to alleviate symptoms were excluded. The study included 27 men and 28 women all of whom were more than 21 years old. Patients indicated their pain level on a scale of 0 to 100 by filling out a nerve-root-injection questionnaire prior to injection. A nurse also administered a North American Spine Society low back pain outcome questionnaire including questions regarding medical history, expectations, and outcomes. Further details of the 2 questionnaires were not provided. Although the authors reported nerve-root injections, the description of the injection technique was basically that of a transforaminal epidural injection procedure. Fluoroscopic control was used to verify that contrast material and injected medication, 1 mL of 0.25% bupivacaine (control) or 1 mL of 0.25% bupivacaine with 6 milligrams of betamethasone (treatment), were reaching the correct area. Throughout the study, both the patient and the treating spine surgeon were unaware to which treatment group the patient was randomized. Patients were allowed to choose to receive up to 4 injections (with the same injectant as the first injection) during the follow-up period. There were 28 patients in the treatment group and 27 in the control group. Both groups were similar at baseline with regard to age, gender, number of levels of disease, diagnosis, number of previous operations, and North American Spine Society outcome measurements. At a mean follow-up of 23 months (range 13 to 28 months), 9 of 27 patients (33%) in the control group and 20 of 28 patients (71%) in the treatment group chose not to have surgery ($p < 0.01$). Nineteen of the 55 patients (35%) had more than 1 injection (10 patients had 2 injections, 6 patients had 3 injections, and 3 patients had 4 injections). Of the 19 patients with multiple injections, 13 avoided surgery and 6 had surgery. Intervals between injections ranged from 6 days to 10.5 months. In patients who had a stenosis and who avoided surgical treatment, there was a significant decrease in neurological symptoms ($p < 0.03$) and significant relief of low-back pain ($p < 0.01$) from baseline to final follow-up based on answers to questionnaires. For both patients with a stenosis ($p < 0.01$) and patients with an HNP ($p < 0.001$) who avoided surgery, significant improvements were observed in scores for treatment expectations over the course of the study. In the treatment group, patients with a stenosis who avoided surgery had significant relief of low back pain ($p < 0.05$). This study has several limitations. Although the main outcome measurement was avoidance of surgery in patients with disc herniations who were planning to undergo surgery, the authors did not report other outcome measures including functional status (i.e., return to work or normal activity) or patient satisfaction and pain relief for all patients randomized. In addition, the sample size was small (28 patients in the treatment group). Although the study had good internal validity, external validity (or generalizability) is limited as is the case for all randomized, controlled trials.

Karppinen et al. (2001a) enrolled 160 patients with sciatica in a randomized controlled trial comparing periradicular corticosteroid injection with saline injection. The mean age of the patients was 44 years; 61% were men. All patients had unilateral pain lasting for 3 to 28 weeks and radiating from the back to the knee. Leg pain intensity was similar to back pain intensity. Patients with prior back operations, clinical depression, prior injections (within the past 3 months), allergies to treatments, synovial cysts, or nonregenerative spondylolisthesis or who were pregnant were excluded from the study. A clinical exam that included tests for straight leg raising, lumbar flexion, tendon reflexes, sensibility, and motor function was performed on all patients. Magnetic resonance imaging (MRI) and electroneuromyography were performed prior to randomization. Patients received either 40 mg/mL of

methylprednisolone and 5 mg/mL of bupivacaine (treatment) (n=80) or isotonic (0.9%) sodium chloride solution (control) (n=80) with 2 mL of injectant used for L4 and L5 blocks and 3 mL used for S1. All injections were done under fluoroscopic guidance using a transforaminal approach. Patients and physicians were blinded to the patients' treatment assignments. Each patient received one injection. Patients also received back school instructions from a physical therapist at 2 weeks post-injection. If symptoms persisted, patients could receive pain medication and traditional physiotherapy or, in severe cases, be referred for discectomy evaluation. All patients completed a 100-point visual analog scale of leg and back pain, the Oswestry Low Back Disability Questionnaire, and the Nottingham Health Profile (NHP) at baseline and at 2 weeks, 1 month, 3 months, 6 months, and 1-year post-injection (except NHP was not done at 2 weeks). Information was obtained for at least 99% of patients at each follow-up. At baseline, the only significant differences between the 2 groups pertained to the affected disc (L4-L5 more often affected in treatment group and L5-S1 more often affected in the control group, $p=0.03$) and the number of days patients were on sick leave before the intervention (mean higher in control group, $p=0.03$). The authors adjusted for these differences in the analyses. Immediately after the injections, there was a greater decrease in leg pain intensity (using a visual analog scale) in the treatment group compared with the control group (61% vs 44%, respectively, $p=0.02$) but changes in back pain were similar between the 2 groups. At 2 weeks, treatment group patients reported significantly less leg pain (39 vs 54 mm on a 100 mm scale, $p=0.02$) and significantly better improvements in leg raising (73 degrees vs 70 degrees, $p=0.03$) and lumbar flexion (4.9 cm vs 4.8 cm, $p=0.05$) compared with the control group patients. There were no significant differences in pain-related or functional outcomes between the 2 groups at 4 weeks. However, at 4 weeks, the costs associated with therapy visits and medications were significantly lower (both $p<0.05$) for the treatment group. At 3 months, patients in the control group reported significantly less back pain (23 vs 26 mm, $p=0.03$) compared with the treatment group. At 6 months, patients in the control group reported significantly less leg pain (22 vs 31 mm, $p=0.003$) and back pain (20 vs 23 mm, $p=0.02$) compared with the treatment group. One year after the injections, there were no significant differences in treatment outcomes between the 2 groups. Eighteen patients in the treatment group and 15 patients in the control group had undergone surgical treatment at 1 year. However, most of the patients in the study were not surgical candidates prior to injection. There was one complication, a retroperitoneal hematoma in a steroid group patient who was on anticoagulant therapy. The authors did not report the number of vertebral levels affected. It is important to note that in this study, only one injection was given and this injection involved a relatively low dose of methylprednisolone. Since there were no differences between groups beyond 4 weeks post-treatment, the results are inconclusive beyond that point regarding potential benefits or harms associated with epidural steroid injections.

A subsequent publication (Karppinen et al., 2001b) looked at the efficacy and cost effectiveness of epidural steroids in subgroups of patients. Subgroups were defined according to the MRI classification: bulges (18 treatment patients, 11 control patients), contained herniations (24 treatment, 26 control), or extrusions (38 treatment, 43 control) and also by disc level: L3-4/L4-5 (51 treatment, 36 control) or L5-S1 (29 treatment, 44 control). For patients with bulges, no differences were observed between groups in either outcome measures or costs. For patients with contained herniations, leg pain (visual analog scale) at 2 weeks and 4 weeks was significantly less in the treatment group; by 6 months, pain was less in the control group (all $p<0.05$). The treatment group also reported greater disability and poorer pain-related quality of life at 6 months (both $p<0.05$). For patients with extrusions, the only significant difference between groups was less leg pain in the control group at 6 months ($p<0.05$). Patients with lesions at L3-L4/L4-L5 and who were in the treatment group had better outcomes for leg pain, disability, and straight leg raising at 2 weeks and at 4 weeks compared with the control group (all $p<0.05$). There were no differences between groups after 4 weeks. None of the outcome measures favored the treatment group among patients with L5-S1 lesions. Cost data indicated a significantly greater savings in need for home care at 4 weeks and total costs at 6 months with steroid injections for patients with contained herniation (both $p<0.05$). Among patient with contained herniation, 42% of the control group and 20% of the treatment group underwent surgery by 1 year of follow-up. For patients with extrusions, the cost of therapy visits at 4 weeks was less in the treatment group ($p=0.001$). Total costs did not differ between groups at any point in the follow-up. In patients with extrusions, 13% of the control group and 32% of the steroid group underwent surgery by 1 year ($p=0.05$). By disc level, 4 week therapy costs were lower in the L3-L4/L4-L5 group that received treatment group compared with the L5-S1 group ($p=0.01$). There were no differences in total costs or rates of operation. Steroid injections were considered cost-effective for contained herniations (\$12,666 more required to achieve a

pain-free patient in the control group) but counter-effective for extrusions (\$4,445 more required to achieve a pain-free patient in the treatment group).

Other Studies

Weiner and Fraser (1997) presented results of responses to fluoroscopically guided foraminal injections from a case series of 30 patients (18 males and 12 females with mean age 54 years; range 30-81 years). All had lateral lumbar disc herniation (confirmed with computed tomography) and severe lumbar radiculopathy. The patients had received a variety of treatments, including epidural injections but no surgery, prior to the study injection of local anesthetic (2 mL of 1% lidocaine) and 2 mL of 11.4 mg betamethasone. Patient satisfaction was assessed as complete, moderate, minimal, or none. At 3 weeks post-injection, 27 of 30 patients had reported at least moderate relief of symptoms. Patients were contacted at follow-up via telephone by an independent observer. The mean follow-up was 3.4 years (range 1 to 10 years). Two patients were lost to follow-up; both had reported complete relief of symptoms at 6 weeks post-injection. At most recent follow-up, 22 of the 28 available patients reported lasting relief of symptoms (14 had returned to usual activities with no pain, 7 had returned to most activities with moderate pain, and 1 had minimal relief but symptoms were tolerable). Of the 17 patients working before symptoms, 13 had returned to the same job and 2 had returned to another job with decreased workload. The mean Low Back Outcome Score was 54 after injection (out of a maximum of 75) as compared with 24 before injection. Among patients who reported relief of symptoms, the mean score was 61.

A prospective case series of 69 consecutive patients (mean age 44 years [range 22 to 77 years]; 54% men) receiving transforaminal lumbar steroid injections was studied by Lutz, Vad, and Wisneski (1998). All patients had lumbar HNP with radiculopathy (confirmed by MRI) that had not responded to at least 4 weeks of conservative treatment (oral nonsteroidal antiinflammatory medication and an oral narcotic, 2 days of bedrest, and 2-3 weeks of physical therapy). None of the patients had prior spinal surgery at the same level or recent epidural steroid injections. Injections of 9 mg of betamethasone acetate and 1.5 cc of 2% xylocaine were done under fluoroscopic guidance. An independent observer collected information via questionnaires and telephone interviews prior to injection, at 1 week and 1 month following injection, and every 3 to 6 months thereafter. Repeat injections were given at 2-week intervals for patients whose pain scores were 4 or more on a 10-point scale. Once pain was controlled, patients continued with 6 to 12 weeks of therapeutic exercise and education on lumbar stabilization training. A successful outcome was identified as a greater than 50% reduction in pain scores after injection sustained throughout follow-up and the ability to return to near previous levels of functioning. Seventy-five percent of patients reported a successful outcome at an average follow-up of 80 weeks (range 28 to 144 weeks). No patients were lost to follow-up. Patients were satisfied with their outcome in 78% of cases. An average of 1.8 injections (range 1 to 4) were performed in patients with a successful outcome. The mean pain score prior to injection was 8.1 (on a scale of 10) and the mean pain score post-injection was 2.6 ($p < 0.05$). No injection-related complications were reported.

A trial reported by Vad, Bhat, Lutz, and Cammisa (2002) evaluated 50 consecutive patients who received a transforaminal epidural steroid injection or a trigger point injection of saline. All patients were greater than 18 years of age, had leg pain greater than back pain with symptoms persisting longer than 6 weeks, and MRI-documented HNP. Patients with prior lumbar surgery, prior epidural steroid injections, allergies to local anesthetics or corticosteroids, or large HNP with severe spinal stenosis were excluded. Patients were "randomized by patient choice" to receive either fluoroscopically guided transforaminal epidural steroid injections (TFESI; 1.5 mL each of betamethasone acetate [9 mg] and 2% preservative-free xylocaine) or trigger point saline injections (TPI, 3 mL normal saline) done without fluoroscopy. The 25 patients in the TFESI group had a mean age of 41.3 years, received a mean of 1.7 injections, and were followed for a mean of 1.4 years. The 23 patients in the TPI group had a mean age of 42.1 years, received a mean of 1.6 injections, and were also followed for a mean of 1.4 years. Patients in both groups were given a program of lumbar stabilization exercises (to be done at home) and a back cryobrace (to be worn for 15 minutes each night). Outcomes were assessed before and after treatment and at 3 weeks, 6 weeks, 3 months, 6 months, and 12 months. For the TFESI group, improvements were seen at the end of the study period in the Roland-Morris low back pain score (an increase from 8.8 to 22.1 where a higher score indicates less pain), a visual numeric score (a decrease from 8.8 to 1.6 on a 0 [no pain] to 10 [severe pain] scale), a test of hip flexion (a decrease in finger-to-floor distance of 69.6 to 20.3 cm), and the patient satisfaction score (an increase from 0.8 to 2.9 on a 0 [poor] to 4 [excellent] scale) (all $p < 0.05$). Maximal improvement was obtained within 6 weeks of treatment. A successful

outcome (defined as a patient satisfaction score of 2 [good] or 3 [very good], improvement on the Roland-Morris score of 5 or more, and pain reduction greater than 50% at least 1 year after treatment) was reported by 84% of the patients. For the TPI group, improvements were seen at the end of the study period in the Roland-Morris low back pain score (an increase from 9.6 to 18.3), a visual numeric score (a decrease from 9.4 to 3.6), a test of hip flexion (a decrease in finger-to-floor distance of 64.8 to 24.4 cm), and the patient satisfaction score (an increase from 0.8 to 1.9) (all $p < 0.05$). Maximal improvement was obtained within 12 weeks of treatment. A successful outcome was reported by 48% of the patients ($p < 0.005$ vs. TFESI group). There were no cases with dural puncture, excessive bleeding, headache, or infection. It should be noted that the patients were not blinded to the treatment (although the outcome assessment was done by a nurse blinded to the treatment protocol) and the analysis was not by intention to treat (of 50 patients randomized, 2 were lost to follow-up). In an accompanying editorial, Riew (2002) commented that it was not possible to determine if differences between the two groups were due to the treatment (corticosteroids or local anesthetic), the disappointment of being assigned to a "control" group, or other unknown effects.

Boswell et al. (2003) reported a systematic review of evidence pertaining to the effectiveness of epidural injections for the treatment of chronic (defined in the review as at least 3 months) spinal pain. The review was based on studies published between January 1966 and March 2003 along with peer-reviewed abstracts for the two years prior to the review. Both randomized and non-randomized trials were included. For transforaminal injections, 7 randomized trials were identified but only 3 met the criteria for inclusion in the review (including the Riew et al. [2000] and Karpinnen et al. [2001] studies cited above). The authors concluded that all 3 studies showed the effectiveness (more effective than the reference treatment) of transforaminal epidural steroids in managing back pain. There were also 3 prospective non-randomized trials and 4 retrospective non-randomized trials (including the studies by Weiner and Fraser [1997], Vad [2002], and Lutz [1998] cited above). These trials also showed positive (effective) long-term (greater than 3 months) and short-term relief. There were no major complications or side effects reported in any of the studies included in the review. Overall, the authors concluded that there was "strong" evidence (Level II on a scale of I to V with I representing "conclusive" evidence and V representing "indeterminate" evidence) for the effectiveness of transforaminal epidural steroid injections in managing lumbar nerve root pain. No quantitative analyses were done.

Safety of Treatment or Procedure

The evidence (or lack thereof), as cited in the literature, pertaining to:

- a. morbidity rate (side effects)-*vaso-vagal reaction during the procedure is possible; rare adverse effects include dural puncture, infection, spinal cord trauma, hematoma or abscess formation, pneumothorax, allergic reactions, cerebrovascular or pulmonary embolus, myopathy, nerve root injury, paraplegia or transient paralysis; adverse reactions post-procedure include nausea, facial flushing, insomnia, fever, nonpositional headache, and transient increased pain; Johnson, Schellhas, and Pollei (1999) reported 4 complications requiring either an emergency department visit or hospitalization in a series of 5,334 patients treated with epidural injections (approximately 87% of which were lumbar injections [either transforaminal, caudal, or interlaminar] done with contrast epidurography and fluoroscopy)*
- b. mortality rate-*no deaths been reported directly from epidural steroid injections; there may be associated mortality if used with local anesthetic or opioids*
- c. training and experience required to perform the procedure safely-*injections should be done or supervised by a board certified or board eligible physician with special training in spinal injections*
- d. where the procedure should be performed (e.g., volume of procedures, skilled support team, location/ need for follow-up visits, etc.)-*injections should be done in hospital outpatient settings, ambulatory surgery centers, or office-based pain clinics meeting the criteria to perform surgical procedures*
- e. co-morbidities that increase the risk associated with the procedure-*immunocompromised patients, patients with previous back surgery, and any patients with chronic disease including congestive heart failure, diabetes mellitus, severe spine degeneration, or spinal stenosis*
- f. potential for inappropriate use of the technology-*patients who have failed multiple attempts at pain reduction with high quality, fluoroscopically guided steroid injections targeted to the appropriate pain generator should not receive the procedure; the International Spinal Injection Society has recommended that epidural steroid injection series be limited to no more than 4 injections at intervals of at least 7 to 14 days within a 6 month period; the American Society of Interventional Pain Physicians guidelines call for no more*

than 6 injections in one year (at least 2 weeks apart) unless the patient is being treated for reflex sympathetic dystrophy, post-herpetic neuralgia, or pain related to malignancy.

Alternative Forms of Treatment

A patient may choose to have no treatment for lumbar radicular pain. Other alternative treatments include other medications or injections, physical therapy, acupuncture, and finally surgery.

Epidemiology and Costs

The 2004 Medicare reimbursement rate for injection of a steroid at a single lumbar or sacral level, in a non-facility (i.e., clinic) setting and using a transforaminal epidural approach is estimated at \$357. For each additional level, the reimbursement rate is estimated to be \$157 (AAOS, 2004). These rates represent professional costs associated with the procedure. Costs associated with fluoroscopic guidance and any facility fees are not included.

Summary

With regard to fluoroscopically guided epidural steroid injections for lumbar radicular back pain, the ICSI Technology Assessment Committee finds:

1. Fluoroscopically guided epidural steroid injections are generally safe when performed by an experienced physician in a controlled setting. Epidural steroid injections should not be done without fluoroscopic guidance. Commonly used corticosteroids include methylprednisolone and betamethasone.
2. Based on limited data, the results appear promising. However, at this time, there is insufficient evidence to comment on the efficacy of epidural steroid injections. Ongoing studies may allow for more definitive statements in the future. (Conclusion Grade III based on Class A evidence, see Appendix).

Potential Conflict of Interest Disclosure

In the interest of full disclosure, ICSI has adopted the policy of revealing relationships work group members have with companies that sell products or services that are relevant to this technology assessment report topic. The reader should not assume that these financial interests will have an adverse impact on the content of the technology assessment report, but they are noted here to fully inform readers. Readers of the technology assessment report may assume that only work group members listed below have potential conflicts of interest to disclose.

No work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's Web site at www.icsi.org.

References

Evidence is classed and graded as described below.

I. CLASSES OF RESEARCH REPORTS

A. Primary Reports of New Data Collection:

- | | |
|----------|--|
| Class A: | Randomized, controlled trial |
| Class B: | Cohort study |
| Class C: | Non-randomized trial with concurrent or historical controls
Case-control study
Study of sensitivity and specificity of a diagnostic test
Population-based descriptive study |
| Class D: | Cross-sectional study
Case series
Case report |

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M: Meta-analysis
Systematic review
Decision analysis
Cost-effectiveness analysis

Class R: Consensus statement
Consensus report
Narrative review

Class X: Medical opinion

II. CONCLUSION GRADES

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system defined in Section I, above, and are assigned a designator of +, -, or \emptyset to reflect the study quality. Conclusion grades are determined by the work group based on the following definitions:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

The symbols +, -, \emptyset , and N/A found on the conclusion grading worksheets are used to designate the quality of the primary research reports and systematic reviews:

+ indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis;

- indicates that these issues have not been adequately addressed;

\emptyset indicates that the report or review is neither exceptionally strong or exceptionally weak;

N/A indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

American Academy of Orthopaedic Surgeons (AAOS). 2004 Medicare reimbursement rates for 50 orthopaedic procedures performed in the non-facility setting. Available at <http://www.aaos.org/wordhtml/nonfacilitycodes.htm>. Accessed June 15, 2004. (Class not assignable)

Boswell MV, Hansen HC, Trescot AM, Hirsch JA. Epidural steroids in the management of chronic spinal pain and radiculopathy. *Pain Physician* 2003;6:319-334. (Class M)

- Cannon DT, Aprill CN. Lumbosacral epidural steroid injections. *Arch Phys Med Rehabil* 2000;81:S87-98. (Class R)
- Chen Y, Derby R, Kim B, Sang-Heon L. Epidural steroid injections: past, present, and future. *Spine*, 2003. (Class R)
- Derby R, Kine G, Saal JA, et al. Response to steroid and duration of radicular pain as predictors of surgical outcome. *Spine* 1992;17:S176-183. (Class C)
- Johnson BA, Schellhas KP, Pollei SR. Epidurography and therapeutic epidural injections: technical considerations and experience with 5,334 cases. *AJNR Am J Neuroradiol* 1999;20:697-705. (Class D)
- Karppinen J, Malmivaara A, Kurunlahti M, et al. Periradicular infiltration for sciatica: a randomized controlled trial. *Spine* 2001a;26:1059-1067. (Class A)
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- Lutz GE, Vad VB, Wisneski RJ. Fluoroscopic transforaminal lumbar epidural steroids: an outcome study. *Arch Phys Med Rehabil* 1998;79:1362-1366. (Class D)
- Manchikanti L, Staats PS, Singh V, et al. Evidence-based practice guidelines for interventional techniques in the management of chronic spinal pain. *Pain Physician* 2003;6:3-81. (Class R)
- Pengel LH, Herbert RD, Maher CG, Refshauge KM. Acute low back pain: systematic review of its prognosis. *BMJ* 2003;327:323. (Class M)
- Riew KD. Point of View. *Spine* 2002;27:16. (Class X)
- Riew KD, Yin Y, Gilula L, et al. The effect of nerve-root injections on the need for operative treatment of lumbar radicular pain. A prospective, randomized, controlled, double-blind study. *J Bone Joint Surg Am* 2000;82-A:1589-1593. (Class A)
- Vad VB, Bhat AL, Lutz GE, Cammisa F. Transforaminal epidural steroid injections in lumbosacral radiculopathy: a prospective randomized study. *Spine* 2002;27:11-16. (Class C)
- Weiner BK, Fraser RD. Foraminal injection for lateral lumbar disc herniation. *J Bone Joint Surg Br* 1997;79:804-807. (Class D)
- Weinstein SM, Herring SA. Lumbar epidural steroid injections. *North American Spine Society Contemporary Concepts In Spine Care*, 2001. (Class R)
- Windsor RE, Strom S, Sugar R. Prevention and management of complications resulting from common spinal injections. *Pain Physician* 2003;6:473-483. (Class R)

Appendix

See next pages

Appendix - Conclusion Grading Worksheet

Work Group's Conclusion: Based on limited data, the results appear promising. However, at this time there, is insufficient evidence to comment on the efficacy of epidural steroid injections. Ongoing studies may allow for more definitive statements in the future.

Conclusion Grade: III

Author/Year	Design Type	Class	Quality +,-,0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ <i>Work Group's Comments</i> (italicized)
Riew et al. (2000)	RCT	A	+	<p>-55 operative candidates randomized to receive fluoroscopically guided steroid injections or injections with saline</p> <p>-patient inclusion/exclusion (see report)</p> <p>-patient and treating spine surgeon blinded to treatment group</p> <p>-patients allowed to choose to receive up to 4 injections</p> <p>-follow-up included: a complication survey at 2 weeks, an evaluation by surgeons at 1-4 weeks, questionnaires via mail at 8 weeks, an evaluation in person or by telephone which included the 2 questionnaires at 1 year, and final calls at mean of 23 months to determine if any patients had surgery</p>	<p>-28 patients injected with bupivacaine and betamethasone and 27 patients injected with only bupivacaine</p> <p>-9 of 27 (33%) patients in the control group (bupivacaine) as compared with 20 of 28 (71%) patients in the treatment group (bupivacaine and betamethasone) chose not to have surgery during mean follow-up 23 months (p<0.001)</p> <p>-19 of 55 patients (35%) had more than 1 injection; of 19 patients with multiple injections, 13 avoided surgery and 6 had surgery; intervals between injections ranged from 6 days to 10.5 months</p> <p>-patients with a stenosis and who avoided surgery had significant decrease in neurological symptoms and significant relief of low-back pain (both p<0.05)</p> <p>-patients with a stenosis or a herniated nucleus pulposus and who avoided surgery had significant improvements in scores for treatment expectations (both p<0.001)</p> <p>-treatment group patients with a stenosis and who avoided surgery had significant relief of low back pain (p<0.05)</p>	<p>-These finding suggest that patients who have lumbar radicular pain at one or two levels should be considered for treatment with selective nerve-root injections of corticosteroids prior to being considered for operative intervention.</p> <p><i>-Work Group's Comments: Inclusion and exclusion criteria well defined; clinically significant treatment effect, and blinding of participants was used</i></p>

Appendix - Conclusion Grading Worksheet (cont)

Author/Year	Design Type	Class	Quality +, -, 0	Population Studied/Sample Size	Primary Outcome Measure(s)/Results (e.g., p-value, confidence interval, relative risk, odds ratio, likelihood ratio, number needed to treat)	Authors' Conclusions/ <i>Work Group's Comments (italicized)</i>
Karppinen et al. (2001)	RCT	A	0	<p>-160 patients (mean age 44 years; 61% men) with sciatica randomized to single transforaminal injection under fluoroscopic guidance with 40 mg/mL methylprednisolone and 5 mg/mL bupivacaine or isotonic sodium chloride solution</p> <p>-patient inclusion/exclusion (see report)</p> <p>-patients received back school instructions from a physical therapist at 2 weeks post-injection</p> <p>-patients could receive pain medication and traditional physiotherapy or be referred for discectomy evaluation in severe cases</p> <p>-100-point visual analog scale of leg and back pain, the Oswestry Low Back Disability Questionnaire, and the Nottingham Health Profile (NHP) were used</p> <p>-patients and physicians were blinded to the patients' treatment assignments</p>	<p>-of the 160 patients included in the study, 80 received saline and 80 received treatment with methylprednisolone and bupivacaine</p> <p>-immediately after injections, leg pain decreased significantly more in treatment group compared with saline group (61% vs 44%, respectively, p=0.02); changes in back pain similar between 2 groups</p> <p>-at 2 weeks, treatment group patients reported significantly less leg pain (39 mm vs 54 mm, p=0.02) and significantly better improvements in leg raising (73 degrees vs 70 degrees, p=0.03) and lumbar flexion (4.9 cm vs 4.8 cm, p=0.05) compared with saline group</p> <p>-no significant differences in pain or function measures between 2 groups at 4 weeks; lower costs associated with therapy visits and medications in the treatment group</p> <p>-at 3 months, saline group patients reported significantly less back pain (23 mm vs 26 mm, respectively, p=0.03) compared with treatment group</p> <p>-at 6 months, saline group patients reported significantly less leg pain (22 vs 31, p=0.003) and back pain (20 vs 23, p=0.02) compared with treatment group</p> <p>-1 year after injections, no significant differences in treatment outcomes between groups; 18 patients in treatment group and 15 patients in saline group had undergone surgical treatment</p>	<p>-Improvement during the follow-up period was found in both the methylprednisolone and saline groups. The combination of methylprednisolone and bupivacaine seems to have a short-term effect, but at 3 and 6 months, the steroid group seems to experience a "rebound" phenomenon.</p>