

Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 13: injection therapies, low-back pain, and lumbar fusion

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Therapeutic Recommendations

Standards. Facet injections are not recommended as long-term treatment for chronic low-back pain.

Guidelines. There is insufficient evidence to recommend a treatment guideline.

Options. The use of lumbar epidural injections or TPIs is not recommended as a treatment option for long-term relief of chronic low-back pain. The use of lumbar epidural injections, facet injections, or TPIs is recommended as a treatment option to provide temporary, symptomatic relief in selected patients with chronic low-back pain.

Diagnostic Recommendations

Standards. There is insufficient evidence to recommend a diagnostic standard.

Guidelines. There is insufficient evidence to recommend a diagnostic guideline.

Options. The use of lumbar facet injections is recommended as a diagnostic tool for predicting the response to

lumbar facet RF ablation. The use of lumbar facet injections is not recommended as a diagnostic tool to predict the response to lumbar fusion surgery.

Rationale

Several injection techniques, using an anesthetic agent, typically in combination with another agent such as a steroid, are used in the treatment of patients with chronic low-back pain due to degenerative disease of the lumbar spine. An analysis of the literature regarding these treatments was performed in an attempt to answer three questions. 1) Are lumbar ESIs effective for improving the outcomes of patients with chronic low-back pain resulting from degenerative disease of the lumbar spine? 2) Are lumbar facet injections effective for improving the outcomes of patients with chronic low-back pain resulting from degenerative disease of the lumbar spine? 3) Are lumbar TPIs effective for improving the outcomes of patients with chronic low-back pain resulting from degenerative disease of the lumbar spine?

Search Criteria

A computerized search of the database of the National Library of Medicine was conducted for the period of 1996 to July 2003 using the terms “epidural steroid injections or blocks,” “caudal injections or blocks,” “selective nerve root

Abbreviations used in this paper: ESI = epidural steroid injection; MPQ = McGill Pain Questionnaire; ODI = Oswestry Disability Index; RCT = randomized controlled trial; RF = radiofrequency; ROM = range of motion; TP = trigger point; TPI = TP injection; VAS = visual analog scale.

injections or blocks,” “transforaminal injections or blocks,” “facet injections or blocks,” “median nerve blocks,” and “trigger point injections.” The search was limited to publications in the English language. Review papers were also a source of references and any new titles identified were added to the search results yielding a total of 1486 papers. Papers not concerned with lumbar ESIs, lumbar facet injections, or lumbar TPIs were discarded. Papers restricted to the evaluation of the role of injections for the management of radiculopathy or acute back pain were also rejected. Fifty papers were identified as providing relevant medical evidence concerning the use of lumbar ESIs, 48 papers for lumbar facet injections, and 17 papers for lumbar TPIs. All papers providing Class II or better evidence and selected papers providing Class III evidence regarding the use of injections in the treatment of chronic low-back pain are recorded by injection type in Tables 1 to 3. Significant supportive data from Class III studies and review articles are provided by the references listed in the bibliography.

Scientific Foundation

The Use of Lumbar ESIs (Epidural Injections, Caudal Injections, Transforaminal Injections) in the Treatment of Chronic Low-Back Pain due to Degenerative Disease of the Lumbar Spine

Epidural injections have been used for the treatment of spinal disorders for more than 50 years.^{8,35,55,69} One encounters several difficulties when interpreting the literature regarding the use of these techniques for the treatment of chronic (here defined as > 3 months) low-back pain. Recent studies have indicated that the application of ESIs without radiographic confirmation is associated with a needle malposition rate as high as 40%.^{27,32,51,72} Because needle malposition may be responsible for treatment failure and because the needle malposition rate in studies performed without confirmatory fluoroscopic imaging are not known, the results of such studies must be interpreted with caution.^{20,27,31,51,69,71} In most reports published before 2000 fluoroscopic imaging and contrast administration to confirm needle placement were not consistently used.

Another difficulty encountered in the literature is related to mixed patient populations. Many studies mixed patients with primary radicular complaints with patients who had primary low-back pain complaints.^{4,26,28,33,35,46,54,55,58,59,68,71} There are several randomized studies that report beneficial effects of ESI on radicular complaints.^{21,54,69} The use of ESIs in the treatment of acute low-back pain (rather than radiculopathy) has not been subjected to the same scientific scrutiny. The results of several of these studies do not support ESIs for the treatment of acute low-back pain alone.^{13,33,35,39,58,68} The ability to discern the effect of ESI on acute low-back pain is confounded by the inclusion of patients with radiculopathy. It is generally not possible to separate out the treatment effect of ESI on the two conditions because of the manner in which the data are presented.

Nelemans and colleagues^{47,48} published a Cochrane Review regarding the use of injection therapy for subacute and chronic benign low-back pain. In their review the authors cite nine randomized clinical trials in which ESIs in the treatment of chronic low-back pain were investigat-

ed.^{3,6,7,10,12,13,24,44,57} The authors of this review state that no significant evidence could be derived from these trials to support the use of ESIs as an effective treatment for chronic low-back pain. A close evaluation of the trials cited reveals that six of the nine trials evaluated the effectiveness of epidural injections for the treatment of subacute and chronic sciatica, not back pain.^{3,7,10,12,44,57} A total of four randomized clinical trials in which epidural injections were performed in the treatment of chronic low-back pain without significant sciatica have been identified.

Brievik, et al.,⁶ reported on 35 patients with incapacitating chronic low-back pain treated with epidural injections. Between one and three injections were given at weekly intervals. One treatment group of 16 patients received injections containing 20 ml of bupivacaine 0.25% and 80 mg of depomethylprednisolone. The other treatment group (19 patients) received injections containing 20 ml bupivacaine 0.25% followed by 100 ml saline. They reported no difference in the degree of pain relief or changes in physical examination between the two groups. Unfortunately, saline in this volume, especially if forcefully injected, has been suggested as therapeutic in and of itself.^{45,53} This study provides Class III medical evidence suggesting that ESIs may be an effective treatment for chronic low-back pain because there was no true control group.

Dallas and colleagues¹³ also compared two ESI treatments in a small group of patients with chronic postoperative low-back pain. They used a randomized, double-blind, cross-over design. In their study, 10 patients received an epidural injection of 8 mg morphine and 10 patients received an epidural injection of 10 ml saline. All patients then received an injection of 80 mg of methylprednisolone 1 hour later. After 8 weeks, the groups crossed over and the treatment was repeated. Outcomes (a VAS and changes in physical examination) were gathered at 30 minutes, 2 hours, 16 hours, weekly for 1 month, biweekly for a 2nd month, and again at 6 months. The only significant difference identified between groups occurred at 6 weeks. At this time point, the morphine plus steroid group had superior pain relief compared with the saline plus steroid group. Rocco, et al.,⁵⁶ published a randomized, double-blind study in which 22 patients with chronic low-back pain resulting from postlaminectomy syndrome were examined. In their study, all patients received 50 mg lidocaine epidurally and were randomly assigned to receive 75 mg triamcinolone diacetate, 8 mg morphine, or both, in addition to the lidocaine. Pain VAS as well as ODI and Waddell disability scores were used in follow-up study. The study was terminated due to marked respiratory depression in the groups that received morphine. Only one patient in the entire study achieved lasting pain relief. This paper provides Class III medical evidence suggesting that ESIs do not provide long-term relief of pain in patients with chronic low-back pain due to postlaminectomy syndrome. This study also suggests that respiratory depression is a common and significant side effect of morphine injection into the epidural space.

Epidural steroid injections were compared with intrathecal injections of midazolam in a study by Serrao, et al.⁶¹ Theirs was a prospective, double-blind trial involving 28 patients. All patients had chronic low-back pain, and all other attempts at conservative care had failed. Outcomes were assessed by the MPQ, VAS score, and a record of pain medication requirements prior to and at 2 weeks and 2