Fluoroscopic Transforaminal Lumbar Epidural Steroids: An Outcome Study

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OBJECTIVES: To determine the therapeutic value and long-term effects of fluoroscopic transformaminal epidural steroid injections in patients with refractory radicular leg pain.

BACKGROUND DATA: Although numerous studies have evaluated the efficacy of traditional transsacral (caudal) or translaminar (lumbar) administration of epidural steroids, to our knowledge no studies have assessed specifically the therapeutic value of fluoroscopic transformaminal epidural steroids.

STUDY DESIGN: A prospective case series that investigated the outcome of patients with lumbar herniated nucleus pulposus and radiculopathy who received fluoroscopic transformaminal epidural steroid injections.

METHODS: Patients who met our inclusion criteria received fluoroscopically guided, contrast-enhanced transformaminal epidural administration of anesthetic and steroid directly at the level and side of their documented pathology. Patients were evaluated by an independent observer and received sequential questionnaires before and after injection, documenting pain level, activity level, and patient satisfaction.

RESULTS: Sixty-nine patients met our inclusion criteria and were followed for an average period of 80 weeks (range, 28 to 144 weeks); 75.4% of patients had a successful long-term outcome, reporting at least a >50% reduction between preinjection and postinjection pain scores, as well as an ability to return to or near their previous levels of functioning after only 1.8 injections per patient (range, 1 to 4 injections). Of our patients, 78.3% were satisfied with their final outcomes.

CONCLUSIONS: Fluoroscopic transformaminal epidural steroids are an effective nonsurgical treatment option for patients with lumbar herniated nucleus pulposus and radiculopathy in whom more conservative treatments are not effective and should be considered before surgical intervention.

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THE FIRST REPORT of therapeutic spinal injections to treat low back pain and sciatica was published in 1901 and reported on the use of cocaine. In 1925, Viner administered epidural injections of procaine, Ringer's solution, and saline to treat intractable sciatica. Robecchi and Capra in 1952 were the first to advocate corticosteroid injections into the lumbar epidural space for the treatment of low back pain. These injections are now widely used to treat low back and leg pain.

More than 40 papers have described clinicians' experiences with epidural steroid injections. The success rates reported have varied from 20% to 100%, with an average success rate of 67%. Usually the therapeutic effect is short-lived (less than 3 months) and diminishes with time. Of the five recent controlled clinical trials,6,10 two6,7 have had favorable and three8,10 have had unfavorable results.

The two major criticisms of these previous studies are (1) that the majority of the studies had a mixed patient population (ie, disc herniations, spinal stenosis, spondylolisthesis, postsurgical); and (2) that the techniques used to administer the epidural steroids were not target specific (techniques used were the traditional translumbar or transsacral techniques, not transformaminal at the level and side of their symptoms). Furthermore, none of the studies used fluoroscopic guidance with preinjection contrast to document the epidurogram and proper flow to the target tissue. There have been reports that even in experienced hands, the epidural injectate may be misplaced in up to 30% of the cases.5,11 This has led to recent emphasis on the use of fluoroscopically guided epidural steroid injections.12

Recent studies13,15 have indicated that pain factors such as substance P, calcitonin gene-related peptide, and c-fos and immune responses in abnormal quantities after disc herniation, causing a chemical radiculitis.16 Corticosteroids have been shown to inhibit prostaglandin synthesis and impair the cell-mediated and humoral immune responses in addition to blocking nociceptive C fiber conduction.10 Based on this, it makes intuitive sense to deliver the highest concentration of steroid injectate to the perceived target site of pathology. If we perceive that target as the posterior annulus and ventral aspect of the nerve root sleeve, it would seem incongruous that delivery of adequate concentrations of medication would be achieved with the traditional transsacral or translaminar approaches. For these reasons, Derby and colleagues14,15 developed the fluoroscopically guided transformaminal injection techniques for diagnostic and therapeutic purposes to allow precise delivery of high concentrations of the injectate directly at the ventral aspect of the nerve root sleeve and posterior annulus.

To our knowledge no studies have evaluated the efficacy of fluoroscopically guided transformaminal epidural steroid injections for the treatment of refractory radicular leg pain. The purpose of this study was to prospectively evaluate the therapeutic efficacy of fluoroscopically guided transformaminal epidural steroid injections in a series of patients with lumbar herniated nucleus pulposus (HNP) and radiculopathy in whom more conservative treatment measures had not been effective.

METHODS

We prospectively followed 69 patients (average age, 43.5 years; range, 22 to 77 years; 54% men, 46% women) with lumbar HNP and radiculopathy for an average follow-up of 80 weeks (range, 28 to 144 weeks). Patients were recruited from the private practices of two of the authors (G.E.L., R.J.W.) in a consecutive manner, and all parameters were defined in this.
prospective clinical case series before the study. Of the subjects recruited, 21 of 69 (32%) had either a workman’s compensation case or litigation pending. Every patient in our case series had documented magnetic resonance imaging (MRI) findings that showed disc herniation with nerve root compression at the level and side of the clinical symptoms and signs. Inclusion criteria were as follows: (1) chief complaint of primarily leg pain that did not respond to at least a 4-week trial of conservative treatment with a combination of an oral nonsteroidal antiinflammatory medication and an oral narcotic for severe pain; an initial period of 2 days of bedrest, followed by a 2- to 3-week physical therapy program consisting of therapeutic modalities and extension-biased exercises 3 times a week; (2) history, physical examination, and pain drawing consistent with lumbar radiculopathy; and (3) MRI results documenting a herniated lumbar nucleus pulposus.

Exclusion criteria were prior spinal surgery at the same level, an MRI-documented large HNP with associated severe spinal stenosis, progressive neurologic deficits, or recent lumbar or caudal epidural steroid injections. Data collection was performed preinjection; postinjection at 1 week and 1 month; and then every 3 to 6 months by an independent observer with serial questionnaires and telephone follow-up. If the patient’s pain level at follow-up was a 4 or greater on a visual numerical pain scale (0, no pain; 10, severe pain) they were reinjected at an interval of approximately 2 weeks. The pain data were reported as averages of pretreatment and posttreatment visual numerical scale pain scores. The pain data were also reported as 75th, 50th, and 25th percentiles before and after treatment. Statistical evaluation of preinjection and postinjection visual numeric pain scores was performed using paired Wilcoxon signed rank, as well as demographics of responders and nonresponders performed by \( \chi^2 \) analysis (significance defined as \( p < .05 \)).

Once adequate pain control was established, an individualized goal-directed functional restoration program consisting mainly of therapeutic exercise and education emphasizing lumbar stabilization training was prescribed for a period of 6 to 12 weeks. Patients were asked to rate their functional level as follows: (1) excellent, able to return to work and athletic activities; (2) good, able to return to work and limited athletic activities, (3) fair, able to return to work part-time with no athletic activity; and (4) poor, unable to return to work.

For lumbar HNP at or above the L4-5 level, a double-needle paramedian technique was used. All injections were performed under fluoroscopy by one of the authors (G.E.L.). After the usual sterile preparation, drape, and local anesthesia, a 20-gauge 3.5-inch spinal needle was advanced into the so-called “safe triangle” area. The “safe triangle” is composed of a roof made up by the pedicle, a tangential base that corresponds to the exiting nerve root, and a side that is made by the lateral border of the vertebral body. Adapted and reprinted with permission.

RESULTS

A successful outcome was reported by 52 of the 69 patients (75.4%) at an average follow-up of 80 weeks (range, 28 to 144 weeks). Our follow-up rate was 100%. Seventy-eight percent of the patients were satisfied with their final outcome. Only 2 patients with less than a 50% reduction in pain scores were able to report good or excellent function and satisfaction with their outcomes. To achieve a successful outcome, only 1.8 injections per patient were required (range, 1 to 4 injections per patient). Of the patients who had successful outcomes, 40% (21 of 52) required only 1 injection, 40% (21 of 52) required 2 injections, 18% (9 of 52) required 3 injections, and only 2% (1 of 52) required 4 injections. There were no reported complications of dural puncture, nerve root injury, or infection after a total of 94 injection procedures.

The average duration of symptoms preinjection was approximately 22 weeks (range, 4 to 52 weeks). The average preinjection pain score was 8.06 (range, 4 to 10). The preinjection scores were 8.8, 7.4, and 6.4 at the 75th, 50th, and 25th percentiles, respectively. The average postinjection pain score was 2.61 (range, 0 to 10). The postinjection pain scores, expressed as percentiles, were 4.5, 2.7, and 1.4 at 75th, 50th, and 25th percentiles, respectively. In our patient population, 42% of the treated pathology was at the L5 level, 40% was at the S1 level, 14% at the L4 level, and 4% was at the L3 level. The difference between average preinjection and postinjection pain scores was determined to be statistically significant.

\[ \chi^2 \]
Patients with a preinjection symptom duration of less than 36 weeks (n = 35) had 78.8% successful outcome. Patients with a preinjection symptom duration of more than 36 weeks (n = 17) had 64.7% successful outcome.

Seventeen of 69 patients (24.6%) did not report successful outcome. Eleven of 17 patients in whom injection therapy was not effective required surgical intervention. Ten of 11 patients underwent a single-level microdiscectomy, and 1 patient required a single-level fusion with instrumentation. Nine of the 11 (81.8%) had successful outcomes using the same criteria. Six of 17 in whom treatment failed did not have surgical intervention.

(p < .05, Wilcoxon signed rank). There was no significant difference between responders and nonresponders in age, sex, level of disc herniation, or preinjection pain level (p > .05, χ² test). There was, however, a significant difference (p < .05, χ² test) between those patients with a preinjection symptom duration of less than 36 weeks and those with duration longer than 36 weeks.
DISCUSSION

In this prospective case series, we studied the response and long-term outcome of patients with lumbar HNP and severe disabling radicular leg pain to fluoroscopic transforaminal epidural steroid injections. We studied a discrete population of patients with subacute or chronic radicular pain in whom at least 4 weeks of trial of oral medications, rehabilitative interventions (therapeutic modalities and exercise), and activity modulation had been ineffective. Clearly, higher success rates with nonoperative treatment of lumbar HNP could have been attained if we had included patients in whom just oral medications and rehabilitative interventions had been effective. In many patients, however, these interventions are not effective, and the patients are then considered possible surgical candidates. We focused our therapeutic intervention on this patient subgroup and achieved a long-term success rate of 75.4%.

A major criticism of this study is that there was no control group. This is a prospective case series describing our clinical experience with what we believe is a relatively new, safe, and effective technique for administering epidural steroids. Prospective, double-blind, controlled, randomized studies comparing different injection techniques, medications, and doses, as well as different patient populations, are needed to further validate the results of this study. Although we acknowledge the lack of a control group, our study does in fact verify that significant radicular pain relief can be achieved by fluoroscopically guided, contrast-enhanced, target-specific application of a relatively small aliquot of corticosteroid directly at the site of radicular pain.

If we compare our results with other authors’ experiences using the more traditional transsacral (caudal) or translaminar (lumbar) epidural steroid injection techniques, two trends become noticeable. First, our 75.4% success rate compares favorably with those of other reported studies; however, our average follow-up of 20 months (range, 6 months to 3 years) was much longer than in previous studies. Our results are also in contrast to those of studies that reported unfavorable outcomes. Second, we needed only an average of 1.8 injections per patient (range, 1 to 4) to achieve a therapeutic effect. This is much less than the standard 3 to 4 injections per patient that are traditionally prescribed.

We believe there are several explanations for our long-term successful outcome. Caudal or lumbar epidural steroid injections typically use 6 to 10 cc volume, thus diluting the potential therapeutic effect of the corticosteroid necessary to treat the chemical radiculitis. In contrast, using a transforaminal technique, the volume of injectate was only 3 cc (1 cc betamethasone acetate and 1.5 cc 2% xylocaine). Without fluoroscopic guidance, there may be up to a 30% chance of misplacing the steroid, even in experienced hands. The caudal and lumbar techniques are also dependent on normal epidural anatomy to reach the target tissue. If there is stenosis, epidural scarring, or a midline raphe, the medication may not even reach the target site. The success of the injection depends on precise delivery of high concentrations of medication directly to the interface between the HNP and the ventral aspect of the nerve root sleeve or dura. This can only be done on a reliable basis by using a fluoroscopically guided transforaminal approach directly at the side and level of involvement with preinjection contrast documenting flow to the target tissue. To achieve this, needle placement was often modified.

An additional advantage of the fluoroscopically guided transforaminal technique is that it can be used for diagnostic purposes to confirm the level of pathology by recording pain responses during the injection phase and then recording the degree of pain reduction during the anesthetic phase. There also appears to be a decreased risk for intravascular injection or dural puncture compared with traditional techniques without fluoroscopy. In this study, we had no reported complications of dural puncture, intravascular injection, infection, or nerve root injury.

One criticism of epidural steroid injections is that their benefit is short-lived. Ridley and associates reported that the therapeutic benefits disappeared within 6 months of treatment. We, however, had a long-term success rate of 75.4% at an average follow-up of 20 months. One reason for this may be that in addition to precise delivery of the injectate to the site of pathology, we combined our treatment program with goal-directed functional restoration program that emphasized active exercise and education. Injection of epidural steroids has role in pain control in the early stages, but this should be followed by progressive lumbar stabilization training to treat the underlying segmental microinstability resulting from disc disease.

It appears from this study, as well as from other studies, that patients with concomitant moderate to severe lateral recess stenosis respond less favorably and are more likely to require surgical intervention to decompress the area of stenosis. It appears that an injection of epidural steroids will do little to relieve the effects of chronic mechanical nerve root compression on the basis of severe bony lateral recess stenosis. Perhaps this patient population should be selected earlier for surgical intervention to minimize their period of disability. In addition, patients with a preinjection symptom duration of more than 24 weeks did not respond as favorably as with those with a preinjection symptom duration of less than 24 weeks. Irreversible neurophysiologic changes may take place with chronic neural compression and inflammation that become refractory to management with the local application of steroids after a period. This suggests that in treating patients with radiculopathy, we should be more cognizant and aggressive in the use of these treatments that may ultimately change a patient’s long-term outcome.

We conclude that fluoroscopic transforaminal epidural steroids are an effective nonsurgical treatment option for patients with lumbar HNP and refractory radicular leg pain and should be considered before surgical intervention. It is only after adequate pain control has been established that rehabilitation can be effective and function restored. Lower success rates are seen in patients with a preinjection symptom duration longer than 24 weeks; therefore, earlier use of this technique may improve long-term outcome.

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References


