Prospective Evaluation

What Is the Role of Epidural Steroid Injections in Lumbar Spinal Disease with Moderate Disability?

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Epidural steroid injections have been gaining popularity as an alternative to surgical treatment of radicular pain with associated spinal derangement. To determine the effectiveness and indications of lumbar epidural steroid injections in patients with or without surgery, we performed a prospective observational study.

We gathered data from 262 degenerative short-segment spinal disease patients (affected at one or 2 levels) with greater than 12 weeks of medication-resistant radicular pain without neurological deficits but with moderate disability (visual analog scale < 6.5; Oswestry Disability Index < 35). All patients received initial fluoroscopically guided transforaminal epidural steroid injections of the affected vertebral level(s) corresponding to their symptoms. Those with inadequate responses or who wanted subsequently surgery underwent decompression surgery. Clinical and demographic characteristics were assessed to compare the differences between the groups.

Results: Of the 262 patients who received epidural steroid injections, 204 did not have operations for up to one year. However, 58 patients experienced inadequate relief of pain or wanted operations and therefore underwent surgery. At baseline, the 2 groups had similar mean disability indices and pain scores, as well as gender ratios, ages, and durations of symptoms ($P > 0.05$). In the patients who underwent surgery, the mean disability and pain scores were not significantly decreased after injection compared to those in the injection-alone group, although the scores for the injection plus surgery patients decreased significantly after surgery ($P < 0.05$). In contrast, patients who underwent epidural steroid injection alone experienced a significant decrease in disability and pain after injection, and that persisted up to one year of follow-up ($P < 0.05$).

Epidural steroid injection can decrease the pain and disability in the majority of a moderate disability group for up to one year, although a significant number of patients underwent surgery regardless of injection. We recommend epidural steroid injection as a first-line treatment in patients with moderate disability that can be converted to surgery without significant delay.

Key words: Epidural steroid injection, spinal surgery, lumbar spinal disease, lumbar radiculopathy, lumbar radicular pain

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Lumbar epidural steroid injection (ESI) is a common interventional procedure for managing radicular pain and axial pain resulting from spinal derangement. In some patients, ESI improves symptoms and is often the best treatment method (1-5). Despite a large number of clinical trials evaluating ESI for sciatica, the indication and long-standing effectiveness of this treatment remain unclear. Although several studies have compared ESI to placebos with favorable outcomes, randomized controlled trials are needed to conclusively identify those patients most likely to benefit from ESI (6-8). Recently, Radcliff et al (9,10) reported the outcomes of the Spine Patient Outcomes Research Trial (SPORT), describing no significant

effects of ESI compared to surgery, suggesting that there are limitations to the applicability of ESI. In the present study, we assumed that the patients who will receive the most potential benefits from ESI are those with mild or moderate disability. Thus, we compared the outcomes of ESI alone with those of ESI plus spinal surgery in patients with moderate disability in order to determine the effectiveness of ESI.

Methods

Patients

Between 2010 and 2012, we gathered data on 262 consecutive patients with single-level or 2-level lumbar degenerative disease (herniated nucleus pulposus, spondylolisthesis, or spinal stenosis) without trauma and with moderate disability [3.5 < initial visual analog scale (VAS) < 6.5, 15 < Oswestry Disability Index (ODI) < 35], who complained of more than 12 weeks of radicular pain or claudication despite medication. Other causes of lumbar foraminal stenosis such as traumatic fracture or compression from neoplasm were excluded from our study. Of the 342 patients initially included in the study, we excluded 54 who had severe disability or neurological deficit (e.g., intractable pain with significant compressive neuropathy, myelopathy, or progressive motor weakness) that required direct surgery. We also excluded 26 patients who did not return after treatment for every follow-up point. All of the remaining 262 patients received fluoroscopically guided transforaminal ESIs targeting the affected nerve root according to patient symptoms. In addition, the patients were followed-up for one year.

All patients provided informed consent, and the institutional ethics committee of our institute approved the study (IRB.AS13104).

Transforaminal Epidural Steroid Injection Technique

All procedures were carried out by a pain management specialist (JYH). Each patient was positioned prone on a fluoroscopy table, and the patient's back was prepped and draped with chlorhexidine and sterile drapes. A 22-g spinal needle was then advanced through the skin toward the superior and anterior aspects of the intended foramen under fluoroscopic guidance. Once the needle was in the correct tissue plane, negative aspiration for blood and cerebrospinal fluid was confirmed, and 1 mL of radiopaque contrast dye was injected under fluoroscopy to confirm appropriate spread along the nerve root. Then, the patient received a mixture of 2 mL of lidocaine 0.5% and 20 mg/level of triamcinolone (mean 3 injections over the course of 3 months).

Outcome Assessment

From all of the patients, we collected demographic data including gender, age, duration of symptoms, disease entity, disease level, and body mass index (BMI). For outcome measurements, the VAS and ODI were used to assess pain and disability, respectively. Serial scores were addressed at each time point up to one year after ESI (3, 6, 9, and 12 months), whether or not the patients underwent surgery. If symptoms persisted or recurred after ESI, the patient was transferred into the surgical group. These surgery group patients were advised to undergo surgery, which the majority of them did. In the surgical group, microscopic minimally invasive decompressive surgery of the affected nerve root was performed by a single surgeon (HJY) with or without fusion of spinal segments. Clinical and demographic characteristics were assessed to compare the differences between groups.

Statistical Analyses

Statistical analysis (Student's t-test and Chi-square test) was performed to determine the significant differences and correlations between groups. We employed SPSS version 13 (SPSS, Chicago, Illinois) for all statistical analyses.

Results

Of the 262 patients that underwent ESI, 204 (78%) experienced decreased pain and did not undergo an operation during the one-year follow-up period. However, 58 patients (22%) underwent surgery at a mean 3.7 months after ESI (Fig. 1).

In comparison of the ESI-only and ESI plus surgery groups, the groups showed similar gender ratios, ages, symptom durations before ESI, numbers of ESIs, and disease levels ($P > 0.05$; Table 1). In addition, initial disability indices and pain scores were similar in the 2 groups (27.26 and 5.18, respectively, vs. 30.05 and 5.85; $P > 0.05$). However, there was a significant difference in outcome scores after ESI between the ESI-only and ESI plus surgery groups. The ESI-only group showed persistently decreased disability and pain scores up to one year ($P < 0.05$; Table 2), although the scores did show a tendency to increase until the final follow-up, where the difference was not statistically significant

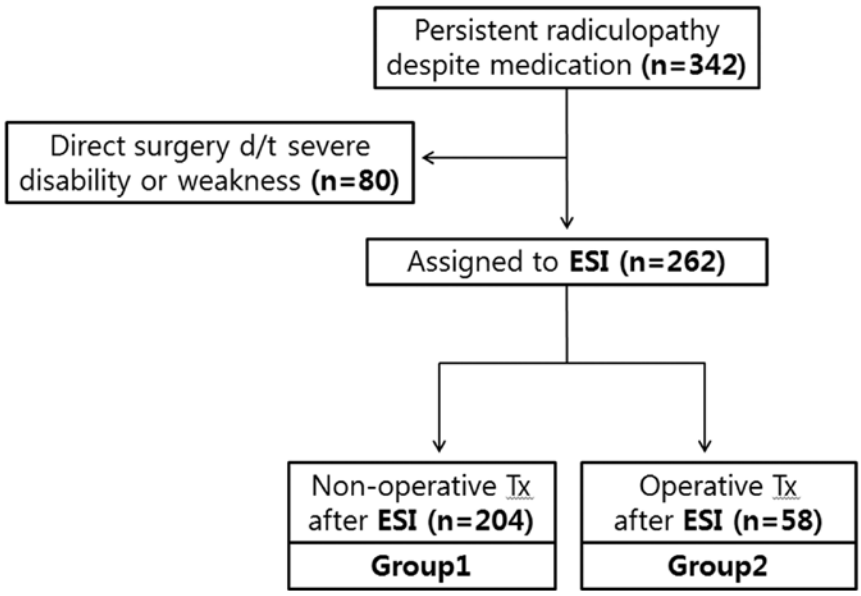

Fig. 1. *Study patients*.

Table 1. *Comparison of parameters between groups*.

	ESI-only	ESI plus Surgery	*P*-value
Number of Subjects	204	58	
Gender (M:F)	75:129	24:34	0.627
Age (Yr)	56.78±15.26	57.28±14.14	0.812
BMI (Kg/m2)	23.7±1.9	24.1±1.6	0.536
Pain duration (Mo)	7.22±4.22	6.51±3.28	0.113
Number of ESI	2.98±1.18	2.60±1.44	0.075
Time to surgery (Mo)		3.70±4.55	
Disease Level L1-2	2	2	0.651
L2-3	8	4	
L3-4	19	8	
L4-5	118	35	
L5-S1	76	25	

ESI: Epidural steroid injection, BMI: Body mass index
T-test and chi-square test were used to determine the difference between 2 groups.
There exist no significant differences between two groups (P>0.05).

(P > 0.05). However, the ESI plus surgery group did not show a decrease in disability or pain scores or a rebound of the scores over several months (P > 0.05). In contrast, disability and pain were significantly decreased after surgery in the ESI plus surgery group (P < 0.05; Figs. 2 and 3). However, according to analysis of risk factors between the ESI only and ESI plus surgery groups, no significant differences in disease entities, levels, or ages existed between the groups (P > 0.05).

Discussion

Radicular pain is defined as pain perceived as arising in a limb or the trunk caused by ectopic activation of nociceptive afferent fibers in a spinal nerve or its

Table 2. *Comparisons of outcomes*.

	ESI-only	ESI plus Surgery	*P*-value
Initial ODI	27.26 ± 9.05	30.05 ± 12.17	0.063
Initial VAS	5.18 ± 1.89	5.85 ± 2.88	0.107
Mid-term ODI (3Mo)	20.48 ± 9.45	29.63 ± 9.09	*<0.0001
Mid-term VAS (3Mo)	3.23 ± 2.07	5.00 ± 2.16	*<0.0001
Final ODI (1Yr)	21.94 ± 8.87	22.76 ± 12.96	0.779
Final VAS (1Yr)	3.73 ± 2.03	4.40 ± 2.96	0.316

ESI: Epidural steroid injection, ODI: Oswestry disability index, VAS: Visual analogue scale T-test was used to determine the difference between 2 groups. Mid-term VAS and ODI scores were significantly different between 2 groups ($P < 0.05$).

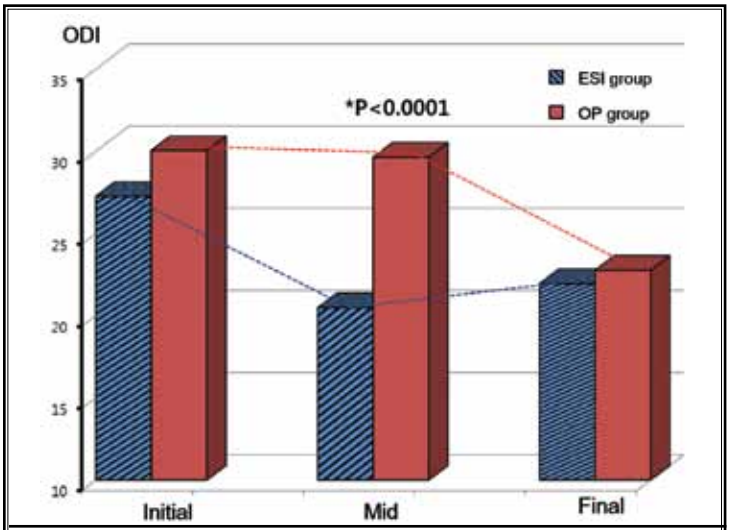

Fig. 2. *Comparison of ODI scores between groups*.

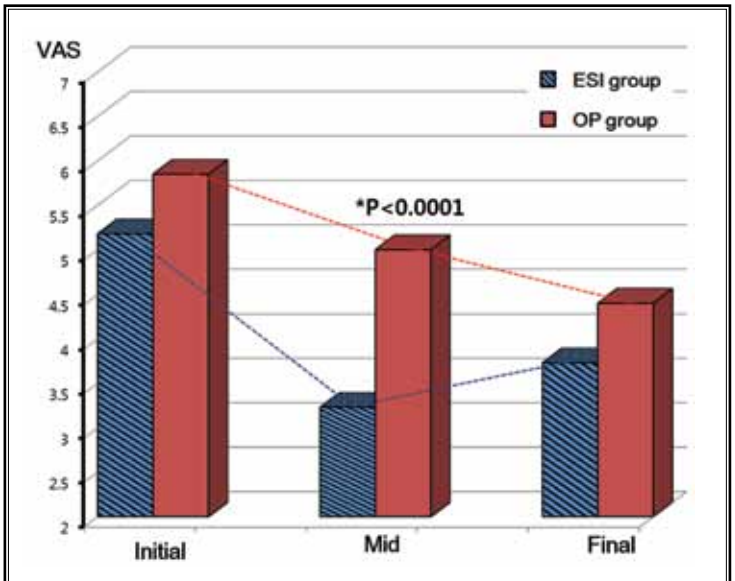

Fig. 3. *Comparison of VAS scores between groups*.

roots or other neuropathic mechanisms (11). The role of ESI in the treatment of sciatica has generated much discussion and debate over the last 50 years, with studies producing highly variable results. The hypothesis that sciatic neuralgia arises from a combination of inflammatory, immunological, and mechanical factors leading to nerve root edema suggests that corticosteroids act effectively by reducing swelling and nerve root inflammation (1-8,12-20). Despite the theoretical basis and common use of ESI for sciatica, its effectiveness remains unclear. Carette et al (6) reported unfavorable results in 158 patients; they found that the benefits of ESI evident after 3 and 6 weeks had disappeared by 3 months and did not decrease the incidence of subsequent spinal surgery. In contrast, Vad et al (7) found significant improvement after ESI during an extended follow-up period of 16 months in a randomized study. Radcliff et al (9) reported that, despite equivalent baseline statuses, ESI was associated with significantly less improvement at 4 years among all patients with spinal stenosis in their SPORT study. Furthermore, they reported that ESI was associated with longer duration of surgery and longer hospital stay. In addition, there was no improvement in outcome with ESI whether patients were treated surgically or nonsurgically. Accordingly, the role or indication of ESI has become diminished due to the negative outcomes of large-scale prospective studies. Consequently, it is important to properly define the role and indication of ESI rather than to compare its priority and effectiveness with those of surgery. We should determine the indications

of when or to whom ESI should be offered so that the most favorable results can be achieved.

In this study, to determine the effectiveness of ESI in patients with borderline surgical indications, we collected data on patients with moderate disability from one- or 2-segment lumbar spinal disease. Of the 262 patients treated with ESI, 58 (22%) required further surgical intervention, while 204 patients (78%) enjoyed relief from symptoms during the one-year follow-up period. Our results suggest that ESI can relieve pain in the majority of patients with moderate disability due to short-segment degenerative lumbar disease for up to one year. Similarly, Riew et al (8) reported a randomized clinical trial using selective nerve root injections with favorable results. They concluded that selective nerve root injections should be considered for patients with lumbar radicular pain at one or 2 levels before the consideration of surgery, which was similar to the conclusion of our study. However, Radcliff et al (9,10) reported that, in a large prospective study, patients with lumbar disc herniation treated with ESI demonstrated no improvement in short- or long-term outcome (up to 4 years) compared with patients who were not treated with ESI. Traditionally, the theoretical benefits of ESI might alter the vicious cycle of neuropathic pain, possibly improving the natural course of lumbar degenerative disease and therefore allowing patients to avoid surgery (1-8,12-20). However, we found that significant numbers of patients underwent surgery despite ESI in this study, even in the moderate short-segment disability group. Accordingly, these results might decrease the indication and effectiveness of ESI, which has been performed as a powerful treatment alternative to surgery. Nevertheless, considering the convenience and cost effectiveness of ESI, it can be a good first-line treatment option in patients with moderate disability. However, we cannot compare its effectiveness with that of surgical treatment due to the lack of data on long-term outcomes and failures in a severe disability group.

In this study, the majority of patients (78%) enjoyed symptom relief during the one-year follow-up period after ESI. However, we could not find significant differences in disease level, initial pain severity, or duration between the ESI-only and ESI plus surgery groups. This means that the ESI results might not depend on preoperative pain severity or duration, disc level, or gender or age of the patient. We cannot predict the effectiveness of ESI based on pre-injection demographics. It appears that significant numbers of patients with moderate disability can enjoy symptom relief for up to one year regardless of the affected disc level and symptom duration. However, several patients underwent surgery despite ESI, which suggests a limited role of ESI. In our study, patients with inadequate responses underwent surgery after 2.98 ESIs at a 3.7-month interval. This shows that several rounds of ESI in a short timeframe might determine the effectiveness of ESI treatment. Several large prospective studies have shown the negative long-term outcomes of ESI and the superiority of surgical treatment. However, we recommend several ESI trials in moderate disability patients prior to surgical treatment, which might broaden the treatment options for the disease. If we consider that the main strong points of ESI are its convenience and flexible conversion to surgery, an initial ESI trial might be helpful for such patients without significant delay of surgical treatment.

Our study has several limitations. The follow-up period was limited to one year, which might decrease the value of this study. In addition, the VAS and ODI showed a tendency to increase until the final follow-up, which might limit the significance of the study. In addition, our study design might have allowed biases caused by factors such as ethnic and regional differences among patients. In particular, patients with inadequate response after ESI were able to decline operative treatment or be moved to another hospital, thus being excluded from the study and potentially introducing additional bias. In addition, consensus as to what constitutes a properly performed ESI has yet to be determined, and injection parameters must be defined. In this study, we determined the "moderate disability" group using the VAS and ODI, but standard outcome measures with both subjective and objective scales are needed, and measurements must assess quality-of-life parameters during the initial recovery and over the longer term (9). Despite these limitations, we believe that the results of our prospective cohort study add to the body of knowledge regarding outcomes after ESI in a moderate disability group.

Conclusion

In conclusion, an ESI might be a good option when urgent surgical treatment is not needed. We recommend ESI as a first-line treatment in patients with moderate disability due to one- or 2-segment lumbar degenerative spinal disease, considering its cost effectiveness and flexible conversion to surgery. However, a long-term randomized trial is needed to confirm the effectiveness of ESI in patients with moderate disability.

Disclaimer

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