Original Article

Outcomes of Fluoroscopically Guided Lumbar Interlaminar Epidural Steroid Injections in Degenerative Lumbar Scoliosis with Spinal Stenosis Patients

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Objective: Fluoroscopically guided lumbar epidural steroid injection has been widely used for the treatment of lumbosacral radicular pain. The objectives of this prospective cohort study were to report the short- and long-term outcomes of fluoroscopically guided lumbar interlaminar epidural steroid injection (IESI) in degenerative lumbar scoliosis with spinal stenosis (DLSS) patients.

Materials and Methods: The DLSS patients received fluoroscopically guided lumbar IESI with 80 mg of methylprednisolone and 3 ml of 1% lidocaine hydrochloride. Patients were evaluated by an independent observer before the initial injection and at 2-week, 6-week, 3-month, and 12-month after the injections. Visual analog scale (VAS), Roland 5-point pain scale, standing tolerance, walking tolerance, and patient satisfaction scale were evaluated for the outcome measurements.

Results: Between February 2010 and January 2012, 35 DLSS patients treated with fluoroscopically guided lumbar IESI were completely followed up for inclusion in the present study. The average number of injections per patient was 1.6 (range from 1 to 3 injections per patient). Significant improvements in VAS and Roland 5-point pain scale were observed over the follow-up period from 2 weeks to 12 months ($p<0.05$). The standing tolerances were not significantly improved at any of the follow-up time periods post injection ($p>0.05$). The walking tolerances were significantly improved at 2-week and 6-week for the leg pain predominant (LP) group and at 3-month for the back pain predominant (BP) group ($p<0.05$). When compared between groups, the walking tolerance of the LP group was more significantly improved than walking tolerance in the BP group ($p=0.004$).

Conclusion: Fluoroscopically guided lumbar IESI improved short- and long-term VAS and Roland 5-point pain scale in DLSS patients. The walking tolerance of the LP group was more significantly improved than walking tolerance in the BP group.

Keywords: Degenerative lumbar, Scoliosis, Fluoroscopic, Epidural injection, Steroid, Outcome

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Degenerative lumbar scoliosis or de novo scoliosis develops during adulthood due to the degeneration of spine motion segment[1]. The clinical syndrome associated with this deformity is not well documented. The pathology of degenerative lumbar scoliosis with spinal stenosis (DLSS) is overall problems of asymmetric disc degeneration, facets arthrosis, and spinal canal stenosis with instability of ligaments and muscles. Vertebral rotation and lateral subluxation of spine are coupled phenomena. Common radiograph findings include degenerative change of L5 to S1, rotary subluxation or lateral translation at L3 to L4, and obliquity at L4 to L5. Patients may present with progressive back pain, radiculopathy, or neurogenic claudication[2].

Epidural steroid injections have been used in the treatment of low back pain and radiculopathy[3-5]. There are many techniques of epidural steroid injection that have demonstrated different results. Transforaminal approach and interlaminar approach have been reported as effective treatments in lumbar degenerative related pain[6-9]. When compared with each other, there was no statistically significant difference between transforaminal epidural steroid injection (TFESI) and interlaminar epidural steroid

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injection (IESI) in short-term pain improvement in spinal stenosis patients[10].

Few publications studied the outcomes of fluoroscopically guided lumbar epidural steroid injection in DLSS patients. All of them reported fluoroscopically guided transforaminal technique[7-11]. They showed significant clinical improvements of DLSS patients in short-term. Due to multiple degenerative pathologies and multiple levels of involvement in DLSS patients, IESI, which is widely and generally delivered medication, should be an effective non-operative treatment in DLSS patients. To the authors knowledge based on MEDLINE literature review, there has been no study that has evaluated the effectiveness of IESI in patients with DLSS.

The objectives of this study were to report the short- and long-term outcomes of fluoroscopically guided lumbar IESI in DLSS patients.

Materials and Methods

Sample size was calculated based on study of Nam and Park[11], alpha error 0.05, power of the study 0.9, mean visual analog scale (VAS) score at 3-month follow-up in the control group and the clinical improvement of VAS score of 1.2 mean VAS score at 3-month in the study group. The estimated sample size from Stata software was 34. After approval from the authors' Institutional Review Board, 35 DLSS patients that underwent fluoroscopically guided lumbar IESI between February 2010 and January 2012 were enrolled. There were 10 men and 25 women with an average age of 68 years (range 55 to 81 years). All the patients provided informed consent before enrolling in the present study. Inclusion criteria were the patients diagnosed with degenerative scoliosis of lumbar spine, Cobb's angle more than 10 degrees, age over 50 years, history of chronic low back pain and leg pain for at least three months, evidence of lumbar spinal stenosis from magnetic resonance imaging (MRI), and failure to improve with conservative treatment that includes medication, bed rest, physical therapy, and exercises for at least six weeks. All fluoroscopically guided lumbar IESIs were administered by the first author. Exclusion criteria were history of lumbar spine surgery, history of epidural steroid injection, allergy to contrast media, gross neurological deficit, cauda equina syndrome, fresh vertebral compression fracture, inflammatory joint disease, uncontrolled psychiatric disorders, or any conditions that could interfere with the interpretation of the outcome assessments.

The patients were evaluated by an independent observer before the initial injection (pre-injection), and at two weeks, at six weeks, at three months, and at one year after the injections. The back pain, leg pain, and neurological deficit of the patients were recorded. If the patient complained that the back pain was more severe than leg pain, the patients were classified as the back pain predominant (BP) group. In contrast, if the patient complained that the leg pain was more severe than back pain, the patients were classified as the leg pain predominant (LP) group.

Table 1. Five outcome measurements[6]

Visual analogue scale: 0 to 10
Roland 5-point pain scale
0=Absence of pain
1=Little pain
2=Moderate pain
3=Bad pain
4=Very bad pain
5=Almost unbearable pain
Standing tolerance test (minute)
0=0 to 5
1=5 to 10
2=10 to 30
3=30 to 60
4=More than 60
Walking tolerance test (feet)
0=0 to 50
1=51 to 200
2=201 to 500
3=501 to 0.5 mile
4=More than 0.5 mile
Patient satisfaction scale
4=Completely better
3=Somewhat better
2=Same
1=Slightly worse
0=Worse

The VAS, Roland 5-point pain scale, standing tolerance, walking tolerance, and patient satisfaction scale were evaluated for the outcome measurements according to Botwin et al[6] (Table 1). At follow-up after injection if the pain persisted or a new episode of pain was reported, the patient could be treated with reinjection.

Procedure description

The patient was put prone position on a radiolucent operating table with a pillow underneath the abdomen to partially correct lumbar lordosis and opening

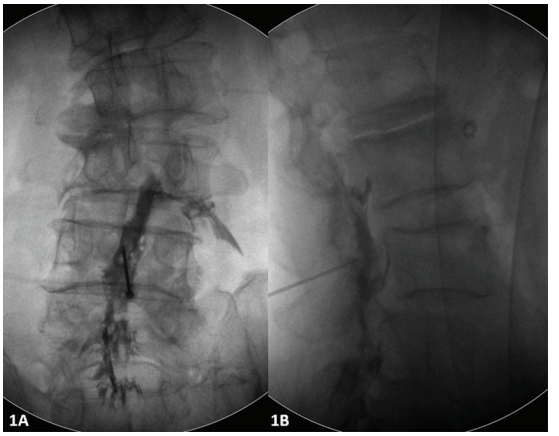

Figure 1. Anteroposterior (1A) and lateral (1B) fluoroscopic projection of IESI in DLSS patient showed contrast media spreading into epidural space. Dye was spread from L3 vertebral body to S1.

interlaminar spaces. Then the C-arm fluoroscope was positioned to identify the level of spine and the interlaminar space of the target level was clearly viewed. The IESI was performed at the level of severe stenosis from MRI. Local anesthetic (1% lidocaine HCL (Xylocaine®, AstraZeneca)) was then injected to the skin, subcutaneous tissue and muscles where needle would be placed. An 18-gauge, Tuohy needle was advanced into the epidural space, using the loss of resistance technique. Once the epidural space was entered, a lateral fluoroscopic view was obtained to ensure that the needle tip rested in posterior epidural space. Contrast media (Iopamiro®, Bracco Industria Chemica S.p.A., Milan, Italy) was injected to confirm the epidural spreading (Figure 1). After that Depo-Medral® (Pharmacia & Upjohn Company, NY, NY) 2 ml (80 mg) with 1% lidocaine hydrochloride 3 ml were slowly injected. In patients with plica mediana dorsalis, IESI was performed on both sides, and half of the medications were injected each side. Finally, the patient was observed in the recovery room under standard protocol. If the patient was free from any complications the patient was then discharged.

Statistical analysis

A repeated-measures analysis of variance was used to evaluate variables that repeated on times. Post-hoc analysis was performed using Scheffe's test for multiple comparisons.

Two-way analysis of variance was used to compare variables between groups according to times. All statistical analyses were done using Stata 12.0 (StataCorp, College Station, Texas, USA). The difference was considered significant if p-value was lower than 0.05.

Results

Thirty-five DLSS patients underwent fluoroscopically guided lumbar IESI. The average number of injections per patient was 1.6 (range 1 to 3 injections per patient). There was no reported major complication after the injection procedures in any patients. The 35 patients completed follow-up at 1-year and their data were collected for analysis.

Fourteen patients were classified in the BP group and 21 patients were classified in the LP group. The apex of the curve was more common on right side (23 patients/66%) than on the left side (12 patients/34%). The average of Cobb's angle was 30 degrees (range from 15 to 38 degrees). The apex of curve was found at L3 in 20 patients (57%) and at L2 in 15 patients (43%), respectively. Twenty-eight patients (80%) had back pain or leg pain on the same side of the apex of curve. At 1-year follow-up, 10 patients (29%) could not tolerate conservative treatment and were scheduled for surgical treatment.

Comparison of pre-injection and post-injection

The four outcome measurements were the VAS, Roland 5-point pain scale, standing tolerance, and walking tolerance. They compared the pre-injection with the post-injection at 2-week, 6-week, 3-month, and 1-year. Meanwhile, the patient satisfaction scale of 2-week post-injection was compared with the 6-week, 3-month, and 1-year post-injection as shown in Table 2.

There were significant decreased in VAS score between pre-injection and post-injection at 2-week, 6-week, 3-month, and 1-year ($p<0.001$). The Roland 5-point pain scale between pre-injection and post-injection were significantly improved at 2-week, 6-week, 3-month, and 1-year ($p<0.05$).

There was no significant improvement of the standing tolerance ($p>0.05$) between pre-injection and post-injection at 2-week, 6-week, 3-month, and 1-year.

For the walking tolerance, the significant difference was found between pre-injection and post-injection at 2-week ($p=0.03$ in the LP group and $p=0.003$ in the BP group) and at 6-week of the LP group ($p=0.033$) and at 3-month of the BP group ($p=0.04$).

For the patient satisfaction scale, there was no significant difference in satisfaction between post-injection at 2-week and at 6-week, 3-month, and 1-year ($p>0.05$).

Table 2. Outcomes of IESI in DLSS patients when compared between leg pain predominant group and back pain predominant group at pre-injection, 2 weeks, 6 weeks, 3 months, and 12 months follow-up

Variables	Type of predominant pain	Time					p-value between leg pain and back pain[a]
		Pre-injection	2 weeks	6 weeks	3 months	12 months	
VAS	Leg pain	6.90±0.56	2.90±0.54	3.15±0.83	3.70±0.55	4.41±0.12	0.360
p-value comparing with pre-injection			<0.001*	<0.001*	<0.001*	<0.001*	
	Back pain	6.86±0.75	3.34±0.87	4.12±1.71	3.66±0.81	4.44±1.10	
p-value comparing with pre-injection			<0.001*	<0.001*	<0.001*	<0.001*	
Roland	Leg pain	2.96±0.44	1.53±0.25	1.89±0.62	1.98±0.35	2.18±0.63	0.590
p-value comparing with pre-injection			<0.004*	<0.007*	0.008*	0.035*	
	Back pain	3.15±0.55	1.64±0.45	2.04±0.66	2.10±0.65	2.26±0.45	
p-value comparing with pre-injection			<0.001*	0.001*	<0.001*	0.003*	
Standing	Leg pain	1.91±0.60	2.53±0.42	2.38±0.44	2.31±0.56	1.98±0.25	0.550
p-value comparing with pre-injection			0.089	0.541	0.656	1.120	
	Back pain	2.21±0.58	2.72±0.50	2.17±0.62	1.98±0.70	1.94±0.77	
p-value comparing with pre-injection			0.166	1.112	0.999	0.999	
Walking	Leg pain	1.53±0.55	2.44±0.52	2.44±0.52	1.90±0.00	1.79±0.66	0.004*
p-value comparing with pre-injection			0.033*	0.033*	0.653	0.999	
	Back pain	1.21±0.70	2.07±0.62	1.89±0.53	1.78±0.56	1.62±0.57	
p-value comparing with pre-injection			0.003*	0.097	0.040*	0.205	
Satisfaction	Leg pain	-	3.35±0.55	3.23±0.54	2.66±0.48	2.68±0.42	0.550
p-value comparing with 2 weeks				0.990	0.507	0.337	
	Back pain	-	3.24±0.66	2.69±0.54	2.87±0.53	2.50±0.54	
p-value comparing with 2 weeks				0.272	0.442	0.188	

VAS=visual analogue scale

[a] p-value from one-way analysis of variance

* Significant value (p<0.05)

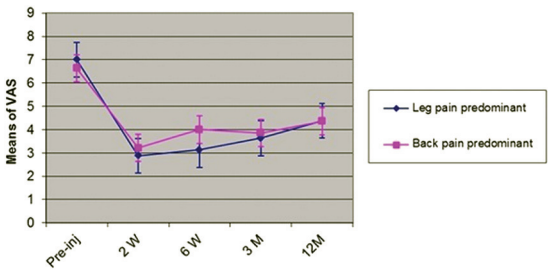

Figure 2. Line graph showing the VAS of the LP group DLSS patients with the BP group DLSS patients over time. There was no significant difference (p=0.36) between these two groups.

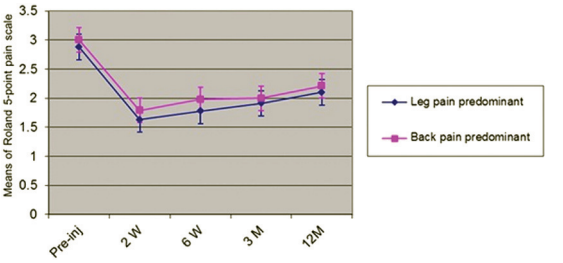

Figure 3. Line graph showing the Roland 5-point pain scale of the LP group DLSS patients with the BP group DLSS patients over time. There was no significant difference (p=0.59) between these two groups.

Comparison of the LP group with the BP group

When comparing VAS of the LP group with VAS of the BP group, there was no significant difference of the VAS between the groups (p=0.36), as shown in Figure 2.

When comparing Roland 5-point pain scale of the LP group with Roland 5-point pain scale of the BP group, there was no significant difference of the VAS between both groups (p=0.59), as shown in Figure 3.

When comparing the standing tolerance of the LP group with the standing tolerance of the BP group, there was no significant difference of the VAS between both groups (p=0.55), as shown in Figure 4.

When comparing between walking tolerance of the LP group and walking tolerance of the BP group, there was a significant improvement of the walking

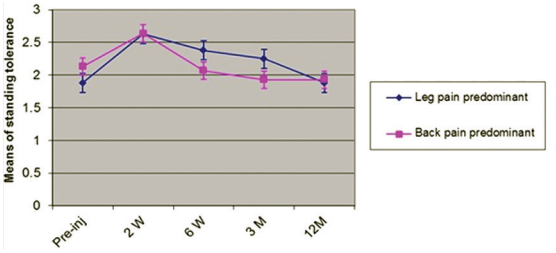

Figure 4. Line graph showing standing tolerance of the LP group DLSS patients with the BP group DLSS patients over time. There was no significant difference (p=0.55) between these two groups.

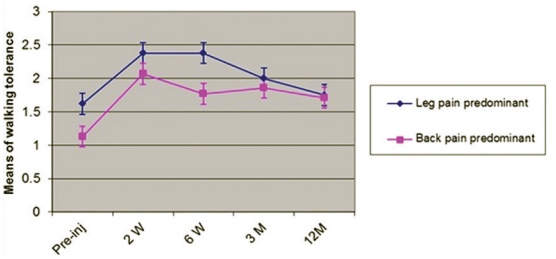

Figure 5. Line graph showing walking tolerance of the LP group DLSS patients with the BP group DLSS patients over time. There was a significant difference (p=0.004) between these two groups.

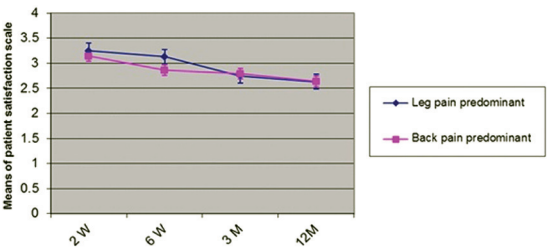

Figure 6. Line graph showing the patient satisfaction scale of the LP group DLSS patients with the BP group DLSS patients over time. There was no significant difference (p=0.55) between these two groups.

tolerance in the LP groups over the walking tolerance in the BP groups (p=0.004), as shown in Figure 5.

When comparing the patient satisfaction scale of the LP group with the patient satisfaction scale of the BP group, there was no significant difference of the patient satisfaction scale between both groups (p=0.55), as shown in Figure 6.

Discussion

DLSS is a result of degenerative change of the spine leading to complex deformities and wide range of clinical presentations. The patients may complain of low back pain, buttock and leg pain, and neurogenic claudication. Surgery is considered as an effective and reasonable treatment for treatment of DLSS patients. However, from the systematic review of Liang et al[12], the overall complication rate of surgical treatment in DLSS was 49.0%. Furthermore, the 10-year survival rate of primary scoliosis surgery in adult patients is 61%[13]. Intervention for postponing of surgery should be helpful in DLSS patients. The epidural steroid injections have been effectively used in treatment of DLSS patients, but few publications have reported the outcome[7,11,14]. Cooper et al[7] studied the effectiveness of TFESI in DLSS patients. They reported only 9.6% of their patients did not experience any transient relief of their symptoms. At 2-year post-injection, 27.3% of DLSS patients were still defined as a successful outcome. Nam and Park[11] reported about a prospective randomized control study on the effects of TFESI in DLSS patients comparing between the steroid group and the lidocaine group. The results showed a significantly greater improvement in the steroid group compared to the lidocaine group. In the present study, to evaluate the results of fluoroscopically guided lumbar IESI in DLSS patients, the authors used five outcome measurements[6]. The outcomes in the present study demonstrated that fluoroscopically guided lumbar IESI provided significant pain relief in both back pain predominant DLSS patients and leg pain predominant DLSS patients. Both VAS and Roland 5-point pain scale significantly decreased post injection. Standing tolerance test did not significantly improve post injection at any point of time. Meanwhile, walking tolerance test significantly improved in the short-term (6-week post-injection). These results showed that fluoroscopically guided lumbar IESI helped pain relief better than it helped symptoms of neurogenic claudication. Both methylprednisolone and lidocaine reduce pain in different mechanisms. Corticosteroid may have direct anesthetic effect by blocking the nociceptive c-fiber conduction and inhibit phospholipase A2 activity, which is found in injured nerve[15,16]. Lidocaine shows a variety of effects, including modulation of different types of ion channels and catalytic enzymes. Lidocaine not only works by easily binding and blocking the fast voltage gated sodium (Na+) channels but also inhibits voltage-gated Ca++ and K+ channels[17,18] and suppresses inflammatory responses of nerves by induced abrogation of T cell proliferation and cytokine secretion independent of cell death[19]. Persistent inflammatory reactions of the nerve trunk can

induce neuropathic pain[20]. Several studies reported lidocaine could suppress the important mediators that cause neuropathic pain[21,22]. A randomized, double-blind, active controlled trial of Manchikanti et al showed comparable results of lumbar IESI with local anesthetic only and IESI with local anesthetic combined with steroid[23]. Therefore, it could reduce inflammatory pain, which explained the reduction of the VAS and the Roland 5-point pain scale.

Neurogenic claudication may result from nerve ischemia caused by compression of microcirculation of nerves[24]. This mechanical compression can be well alleviated with surgical decompression. Fukusaki et al studied the therapeutic effects of epidural steroid injection on pseudoclaudication in patients with lumbar degenerative spinal canal stenosis. They found epidural local anesthetic block showed a short-term ability to improve the pseudoclaudication in lumbar degenerative spinal canal stenosis, whereas the addition of epidural steroid had no beneficial effect on the symptoms[4]. This could explain the fair improvement of standing tolerance and walking tolerance in the authors' study.

The authors compared the outcomes of the leg pain predominant DLSS patients with the back pain predominant DLSS patients. The walking tolerances of DLSS patients in the LP group after IESI were significantly better than those in the BP group. These outcomes showed that IESI in patients with DLSS improved the radicular pain better than axial back pain. Axial back pain is caused by disc degeneration and end plate inflammatory or dural and posterior longitudinal ligamentous irritation. Radicular pain is a result of mechanical compression or chemical irritation of nerve roots[25]. From previous systematic reviews, epidural steroid injection either TFESI or IESI effectively reduced radicular pain especially in the short-term[26-28]. In contrast, systematic reviews have shown fair evidence for treating axial low back pain with caudal and IESI, whereas the evidence was poor for TFESI[29].

There were some limitations of the present study. First, the sample size was small. The authors recruited only DLSS patients with spinal stenosis. Second, the numbers of injection in each patient depended on the clinical condition and tolerance of the patients. Then, the number of injections might not be equal in each patient. Some of patients had repeated procedures in-between. The follow-up time was counted from the first epidural injection. The average scores then were confounded with the second or third epidural injection. However, the average scores still represented the average outcomes at each period.

Conclusion

Fluoroscopically guided lumbar IESI improved short- and long-term VAS and Roland 5-point pain scale in DLSS patients. The walking tolerance of the LP group was more significantly improved than walking tolerance in the BP group. In summary, IESI in patients with DLSS improved pain especially the radicular pain better than walking tolerance and standing tolerance.

What is already known on this topic?

Degenerative lumbar scoliosis is one of the common conditions that is caused by degenerative change of lumbar spine. Epidural steroid injection is well established in short-term treatment of some conditions of degenerative change of lumbar spine such as herniated nuclease pulposus, spinal stenosis, and spondylolisthesis. However, few studies have been done on the outcomes of epidural steroid injection in degenerative lumbar scoliosis patients. All of them reported outcomes of fluoroscopically guided transforaminal technique. This report showed the outcomes of fluoroscopically guided interlaminar technique in degenerative lumbar scoliosis patients.

What this study adds?

Fluoroscopically guided lumbar IESI provides significant pain relief in both back pain and leg pain of degenerative lumbar scoliosis patients. Both VAS and Roland 5-point pain scale significantly decreased post injection. However, functional improvement in term of standing tolerance and walking tolerance were limited.

Conflicts of interest

The authors declare no conflict of interest.

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