

SPINE SECTION

Original Research Article

Clinical Effectiveness of Percutaneous Adhesiolysis and Predictive Factors of Treatment Efficacy in Patients with Lumbosacral Spinal Stenosis

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Abstract

Objective. Patients with lumbosacral spinal stenosis (LSS) do not always obtain satisfactory pain relief from transforaminal epidural steroid injection (TFESI) because perineural/epidural adhesions prevent the spread of injectate into the epidural space. Percutaneous adhesiolysis (PA) can eliminate the deleterious effects of adhesion. This study was to evaluate the effectiveness of PA among patients with LSS refractory to TFESI and to ascertain the prognostic factors determining PA efficacy.

Design. Retrospective study.

Setting. Spine hospital.

Subjects. Sixty-five patients with LSS refractory to TFESI who underwent PA with NaviCath® were reviewed.

Methods. We recorded Numeric Rating Scale for back pain (NRS back) and leg pain (NRS leg), and Oswestry Disability Index (ODI), at pretreatment, 2 weeks, and 3 months after treatment. Successful pain relief and functional improvement were

described as a 50% and 40% or more reduction in NRS and ODI, respectively. Clinical data and radiological findings were obtained to assess the possible predictive factors for PA efficacy.

Results. Among the 65 patients, 45 (69.2%), 40 (61.5%), and 39 (60.0%) patients showed successful outcomes in NRS back, NRS leg, and ODI at 2 weeks, respectively. Among 63 patients who were followed up at 3 months, 34 (54.0%), 32 (50.8%), and 30 (47.6%) patients showed successful results, respectively. Spondylolisthesis, previous lumbar surgery, and foraminal stenosis were associated with a significantly higher proportion of unsuccessful result in NRS and ODI (%).

Conclusion. PA may be a useful treatment in patients with LSS refractory to TFESI and reduce the surgical requirement. Previous surgery, spondylolisthesis, and foraminal stenosis may be associated with poor prognosis.

Key Words. Percutaneous Adhesiolysis; Lumbosacral Spinal Stenosis; Numeric Rating Scale; Oswestry Disability Index

Introduction

Lumbosacral spinal stenosis (LSS) is defined as the narrowing of the spinal canal, subarticular area, or intervertebral neural foramen due to progressive hypertrophy of bony or ligamentous structures, arthritic changes of facet joints, or intervertebral disc bulging, and may result in neurogenic or vascular compression of the contents of the spinal canal at one or more levels. The clinical manifestations of LSS include neurogenic claudication, lower back pain, and referred lower extremity pain.

Various types of conservative treatments have been used for patients with LSS. Fluoroscopic-guided epidural injection shows clinical benefits, and especially transforaminal epidural injection produces more favorable results in LSS because it enables more accurate delivery of injectates into the ventral epidural space [1]. However, epidural steroid injections, including those administered using the

transforaminal technique, had lower effectiveness in LSS than in disc herniation and showed only fair grade of evidence [1]. One study revealed that epidural injection had better short-term results than those of interspinous or intramuscular injection, but this benefit was not maintained for up to 6 weeks in patients with LSS [2]. Another study showed that among patients undergoing transforaminal or caudal epidural injection, only one third obtained more than 2 months of pain relief [3]. The epidural/perineural fibrosis or anatomical barriers associated with LSS may reduce the efficacy of epidural injection by preventing the injectate from spreading into the ventral epidural space effectively [4–6].

Percutaneous adhesiolysis (PA) is a minimally invasive therapy, in which a catheter is placed directly into the ventral epidural space or around the nerve root sheath. It has potential as a useful treatment method for patients with chronic pain refractory to conservative treatments [7]. The rationale for PA is that chronic pain is primarily caused by perineural or epidural fibrosis, and that PA has the ability to eliminate the deleterious effects of adhesion, which can physically prevent the spread of drugs around the nerves. The catheter used for PA can be inserted into ventral epidural spaces and remove the adhesion of ventral epidural spaces mechanically. In addition, the catheter tip can be placed near the nerve root sheath or ventral epidural spaces, ensure the delivery of medication to the target area more precisely and accurately, and thus overcome the limitation of epidural injection [8–11]. PA ensures the delivery of high concentrations of injected drugs to the target area, and this property of PA provides clinical benefits among patients failing to respond to conservative treatment, including epidural injections [9]. In comparative study on PA and caudal steroid injection in post-surgery syndrome, PA provided significantly better clinical efficacy than did caudal injection [12].

PA was also effective in patients with LSS [10,13]. However, our previous study assessing the clinical efficacy of PA in disc herniation revealed that the presence of LSS associated with lumbar disc herniation reduced the clinical effectiveness of PA [11]. A review article also provided a fair grade of evidence about PA efficacy in relieving low back or leg pain secondary to LSS [14].

The purpose of this study was to evaluate the effectiveness of PA with NaviCath® (Myelotec Inc., Roswell, GA, USA) in managing chronic lower back or leg pain among patients with LSS for whom transforaminal epidural injection was not successful. This study also investigated the factors influencing the clinical efficacy of PA in treating patients with LSS.

Methods

Subjects

This study was a retrospective study that was approved by the institutional review board of Wooridul Spine Hospital. From a group of patients diagnosed with LSS, we

selected patients who underwent PA using NaviCath® from September 2011 until September 2012. These patients had chronic lower back or leg pain for at least 3 months after failing to respond to anti-inflammatory medications or physical therapy of at least 1 month duration, and fluoroscopy-guided transforaminal epidural injection. The diagnosis of LSS was determined by clinical and radiological evaluation, including magnetic resonance imaging (MRI). We defined failure of transforaminal epidural injection as the absence of 50% or more reduction in pain on Numeric Rating Scale (NRS) compared with pre-injection pain, with at least two injections administered over 2 months. Finally, 65 patients' charts were selected and reviewed.

Data Collection

We obtained clinical data, such as age, gender, duration of symptoms in months, predominant symptom (axial back pain vs radiating leg pain), and history of previous lumbar surgery. Radiological findings from simple radiography and MRI were assessed, including the presence of spondylolisthesis, the severity and location of LSS, and the number of lesion levels (single vs multiple levels).

Radiological Classification of LSS by MRI

The location of LSS included central, subarticular, and foraminal stenosis, and the severity was rated as mild, moderate, or severe grade. The subarticular area was defined as extending from the medial edge of the articular facet to the edge of the neuroforamen. Mild stenosis represented a compromise of the area less than one third of its normal size, moderate stenosis was a compromise between one third and two thirds of normal size, and severe stenosis was a compromise of two thirds or more of normal size. Central and subarticular zone stenoses were rated on axial T2-weighted images, and foraminal stenoses on sagittal T1-weighted images. For patients with multilevel spinal stenosis, the level with the greatest stenosis was selected for analysis.

Clinical Evaluation

The NRS for back pain (NRS back) and leg pain (NRS leg), as well as the Korean version of Oswestry Disability Index (ODI), were used to evaluate the clinical effectiveness in terms of pain reduction and functional improvement at pretreatment, 2 weeks after treatment, and 3 months after treatment. All patients were asked to report the average severity of their symptoms over the previous 1 week period. On the NRS, a score of 0 represents no pain, and a score of 10 represents the worst pain imaginable. The Korean version of ODI, ranging from 0 to 50, was used for functional assessment. ODI (%) was calculated using the scores provided by each patient. For example, if the total score from 10 sections for one patient was 16, the score of that patient would be 32% ($16/50$ [maximal possible score] $\times 100$). The value and validity of the NRS and the Korean version of ODI have been reported previously [15]. Successful pain relief was described as a 50% or more

reduction in NRS, and successful functional improvement was defined as a 40% or more reduction in ODI [12].

PA

PA was performed under fluoroscopy in a sterile operating room with monitoring equipment for blood pressure, pulse rate, and pulse oximetry. The fluoroscope was adjusted over the lumbosacral area such that the caudal approach could be used in both the anteroposterior and lateral views. After appropriate positioning of the fluoroscope, the needle insertion area was determined around the sacral hiatus and infiltrated with local anesthetics. A tiny incision was made at the needle insertion area, and a 15-gauge Tuohy needle with an introducer was inserted into the epidural space through the sacral hiatus. An epidurogram was obtained after injecting approximately 2–5 cc of contrast media to confirm that the needle was placed in the epidural space and to avoid intravascular or subarachnoid needle placement. The NaviCath® was passed through the introducer after the removal of the Tuohy needle under fluoroscopic visualization, and at least 5 cc of contrast media was injected to identify filling defects by examining the contrast flow into the nerve roots. The catheter was positioned near the filling defect and the suspected pain source area. Subsequently, adhesiolysis and decompression were carried out by distension with normal saline and by mechanical means using the catheter. When the catheter was placed in an area suspected to be the source of pain, some patients indicated that they felt pain similar to that they had been experiencing. After adhesiolysis, approximately 3 cc of contrast media was injected in order to confirm that satisfactory filling was obtained epidurally and at the targeted nerve root without subarachnoid or intravascular flow. Then, a mixture of 4 cc of 1% lidocaine and 40 mg of triamcinolone was slowly injected. After completion of the procedure, a sterile dressing was applied to the sacral hiatus. Subsequently, the patient was placed in the supine position and transferred to the recovery room. In the recovery room, the patient was monitored very closely for any potential complications or side effects.

Statistical Analysis

The Wilcoxon rank test was used to assess the clinical improvement in the NRS back, NRS leg, and ODI (%) at 2 weeks and 3 months after PA. To determine prognostic

predictors of PA, the following characteristics were compared between patients with successful and unsuccessful treatment outcomes on NRS and ODI (%) using chi-square with Fisher's exact tests: gender distribution, duration of symptoms (3–6 months vs >6 months), number of lesion (1 vs ≥ 2 lesions) predominant symptom (back pain vs leg pain), presence of spondylolisthesis, previous surgical history, and severity and location of LSS. Age was also compared with student *t*-test between successful and unsuccessful NRS and ODI. All statistical analyses were performed using the SPSS version 12.0 statistical package (SPSS Inc., Chicago, IL, USA). The results were considered statistically significant if the *P* value was less than 0.05.

Results

Among the 65 patients, the number of male and female patients was 28 and 37, respectively. A comparison of the scores at pretreatment with those at 2 weeks or 3 months after PA showed significant improvement in NRS back, NRS leg, and ODI (%) at 2 weeks compared with pretreatment, which was maintained until 3 months (Table 1). Table 2 demonstrated the proportions of patients with successful and unsuccessful results, as well as the different grades of improvement among successful results in terms of NRS back, NRS leg, and ODI (%) at 2 weeks and 3 months. Among the 65 patients, 45 (69.2%), 40 (61.5%), and 39 (60.0%) patients showed successful treatment outcomes on NRS back, NRS leg, and ODI at 2 weeks, respectively. Two patients were lost during follow-up. Among the 63 patients who were followed up at 3 months, 34 (54.0%), 32 (50.8%), and 30 (47.6%) patients showed successful results on NRS back, NRS leg, and ODI at 3 months, respectively.

At pretreatment, there were no significant differences in gender ratio, NRS back, NRS leg, and ODI (%) between successful and unsuccessful results. The lesion levels were L3-4 in five cases, L4-5 in 44 cases, and L5-S1 in 16 cases. There was no significant relationship between lesion levels and successful pain reduction or functional improvement. Spondylolisthesis was associated with a significantly higher proportion of unsuccessful outcome on NRS back and ODI (%) at 3 months, as well as NRS leg at 2 weeks and 3 months. Patients who had undergone previous lumbar surgery obtained worse results on NRS back, NRS leg, and ODI (%) at 3 months. In terms of LSS

Table 1 Comparisons of back pain, leg pain, and functional disability between pre- and posttreatment

	Pretreatment (N = 65)	2 Weeks (N = 65)	3 Months (N = 63)	<i>P</i>
NRS back	6 (5, 7)	2 (2, 4)	3 (2, 4)	<0.001*
NRS leg	7 (5.5, 8)	3 (2, 5)	4 (2, 5)	<0.001*
ODI (%)	40.0 (26.5, 54.8)	21.0 (10.5, 34.0)	24 (12, 35)	<0.001*

* Significant difference was found between pretreatment and 2 weeks, as well as pretreatment and 3 months.

NRS back = back pain score of Numeric Rating Scale; NRS leg = leg pain score of Numeric Rating Scale; ODI = Oswestry Disability Index.

Table 2 The proportion of patients according to different grades of improvement

	Grades of Improvement	NRS Back 2 Weeks	NRS Back 3 Months	NRS Leg 2 Weeks	NRS Leg 3 Months
Unsuccessful	<50%	25	29	25	31
Successful	≥50% and <75%	24	22	24	23
	≥75% and <100%	14	11	14	9
	100%	2	1	2	0
	Total	65	63	65	63

	Grades of Improvement	ODI 2 Weeks	ODI 3 Months
Unsuccessful	<40%	26	33
Successful	≥40% and <70%	16	15
	≥70% and <100%	23	15
	100%	0	0
	Total	65	63

NRS back = back pain score of Numeric Rating Scale; NRS leg = leg pain score of Numeric Rating Scale; ODI = Oswestry Disability Index.

location, foraminal stenosis was significantly related to poorer outcomes on NRS leg and ODI (%) at 3 months, and also had trends toward poorer outcomes in NRS back at 3 months. One patient had foraminal stenosis and

previous surgical history at the same time. Four patients had foraminal stenosis and spondylolisthesis, and 10 patients had previous surgical history and spondylolisthesis simultaneously. The patients who had at least two poor

Table 3 Comparison of clinical and MRI findings between patients with successful and unsuccessful results in NRS back

		NRS Back 2 Weeks			NRS Back 3 Months		
		Successful (N = 45)	Unsuccessful (N = 20)	P	Successful (N = 34)	Unsuccessful (N = 29)	P
Age		59.4 ± 10.4	57.9 ± 9.85	0.587	57.1 ± 10.3	60.7 ± 9.61	0.159
Gender ratio	Male	19	9	0.835	13	14	0.422
	Female	26	11		21	15	
Score at pretreatment		5.45 ± 1.79	6.02 ± 1.49	0.220	5.69 ± 1.51	5.94 ± 1.71	0.541
Spondylolisthesis	Absent	33	10	0.067	30	12	<0.001*
	Present	12	10		4	17	
Duration	3–6 months	18	6	0.441	14	10	0.586
	>6 months	27	14		20	19	
Number of lesions	1	18	9	0.706	15	11	0.619
	>1	27	11		19	18	
Previous surgery	Absent	33	11	0.145	30	13	<0.001*
	Present	12	9		4	16	
Predominant symptom	Axial pain	15	7	0.896	10	10	0.666
	Radiating pain	30	13		24	19	
LSS location	Central	22	10	0.511	17	13	0.153
	Subarticular	20	7		16	11	
	Foraminal	3	3		1	5	
LSS severity	Mild	11	4	0.857	9	4	0.322
	Moderate	19	8		15	12	
	Severe	15	8		10	13	

Successful pain relief was described as 50% or more reduction of NRS.

LSS = lumbosacral spinal stenosis; NRS back = back pain score of Numeric Rating Scale; MRI = magnetic resonance imaging.

* $P < 0.05$.

Table 4 Comparison of clinical and MRI findings between patients with successful and unsuccessful results in NRS leg

		NRS Leg 2 Weeks			NRS Leg 3 Months		
		Successful (N = 40)	Unsuccessful (N = 25)	P	Successful (N = 32)	Unsuccessful (N = 31)	P
Age		57.4 ± 10.5	61.2 ± 9.53	0.144	56.8 ± 10.1	60.7 ± 9.8	0.135
Gender ratio	Male	19	9	0.362	13	14	0.716
	Female	21	16		19	17	
Score at pretreatment		6.76 ± 2.20	6.63 ± 1.82	0.790	6.74 ± 1.86	6.63 ± 1.95	0.808
Spondylolisthesis	Absent	31	12	0.014*	28	14	<0.001*
	Present	9	13		4	17	
Duration	3–6 months	17	7	0.239	12	12	0.921
	>6 months	23	18		20	19	
Number of lesions	1	15	12	0.403	16	10	0.153
	>1	25	13		16	21	
Previous surgery	Absent	29	15	0.294	27	16	0.005*
	Present	11	10		5	15	
Predominant symptom	Axial pain	14	8	0.804	10	10	0.932
	Radiating pain	26	17		22	21	
LSS location	Central	17	15	0.214	16	14	0.030*
	Subarticular	20	7		16	11	
	Foraminal	3	3		0	6	
LSS severity	Mild	10	5	0.891	9	4	0.112
	Moderate	16	11		15	12	
	Severe	14	9		8	15	

Successful pain relief was described as 50% or more reduction of NRS.

LSS = lumbosacral spinal stenosis; NRS leg = leg pain score of Numeric Rating Scale; MRI = magnetic resonance imaging.

* $P < 0.05$.

prognostic factors at the same time showed poorer outcomes on NRS back, NRS leg, and ODI (%) at 3 months. Five patients reported vague discomfort in the lower back and the needle insertion area, which resolved without any specific treatment or analgesics use. The severity, duration, pain distributions (back or leg pain), age, gender proportion, and the number of lesions had no significant relationship with NRS back, NRS leg, and ODI(%) at any time (Tables 3–5).

Discussion

In clinical setting, PA is usually performed for patients who fail to improve clinically after epidural steroid injection and is rarely performed for patients who have not received epidural injection because epidural injection is a simpler and less expensive procedure. We thought a study that was clinically informative and applicable would be more implicative. Therefore, we aimed to evaluate PA efficacy for patients with LSS who were non-responsive to transforaminal epidural injection, instead of comparing the clinical efficacy between PA and epidural injection.

In our study, we used NaviCath® with normal saline. NaviCath® has a steerable catheter and an atraumatic tip, and is different from Racz catheter, which has a non-steerable and spring tip. This property of NaviCath®

enables the physician to place the catheter tip near the nerve root sheath, deliver pain medication more precisely, and perform mechanical adhesiolysis more easily, which consequently reduces the necessity of hypertonic saline that can cause serious adverse effect [16]. Two comparative studies indicated that adhesiolysis with normal saline fulfilled compatible results as those with hypertonic saline [9,17].

Overall, we observed significant improvement in NRS and ODI (%) at 2 weeks and 3 months after treatment. Approximately 60% and 50% of patients obtained successful results in terms of NRS and ODI (%) at 2 weeks and 3 months. Compared with our previous study demonstrating approximately 70% and 60% of success in patients with disc herniation at the same follow-up periods [11], the current study showed moderate effectiveness, especially at 3 months. This previous report also showed that the combination of LSS was poor predictive factors of PA efficacy in patients with disc herniation. But considering that PA was performed only in patients with LSS refractory to transforaminal steroid injection, which offered the better clinical effectiveness than caudal or interlaminar approach because it allowed injectate to spread directly into the ventral epidural space [1], our result can suggest that PA could achieve meaningful clinical results and can be a useful treatment for LSS. When patients were treated

Table 5 Comparison of clinical and MRI findings between patients with successful and unsuccessful results in ODI

		ODI 2 Weeks			ODI 3 Months		
		Successful (N = 39)	Unsuccessful (N = 26)	P	Successful (N = 30)	Unsuccessful (N = 33)	P
Age		59.1 ± 10.8	58.6 ± 9.50	0.841	57.0 ± 9.98	60.3 ± 10.1	0.200
Gender ratio	Male	15	13	0.357	10	17	0.145
	Female	24	13		20	16	
Score at pretreatment		44.7 ± 15.4	45.5 ± 21.2	0.830	41.5 ± 19.7	41.6 ± 20.3	0.980
Spondylolisthesis	Absent	28	15	0.239	25	17	0.007*
	Present	11	11		5	16	
Duration	3–6 months	17	7	0.173	12	12	0.767
	>6 months	22	19		18	21	
Number of lesions	1	14	13	0.258	12	14	0.845
	>1	25	13		18	19	
Previous surgery	Absent	29	15	0.159	26	17	0.003*
	Present	10	11		4	16	
Predominant symptom	Axial pain	13	9	0.915	11	9	0.424
	Radiating pain	26	17		19	24	
LSS location	Central	16	16	0.149	14	16	0.031*
	Subarticular	20	7		16	11	
	Foraminal	3	3		0	6	
LSS severity	Mild	9	6	0.993	8	5	0.256
	Moderate	16	11		14	13	
	Severe	14	9		8	15	

Successful functional improvement of ODI was defined as 40% or more reduction of ODI.

LSS = lumbosacral spinal stenosis; ODI = Oswestry Disability Index; MRI = magnetic resonance imaging.

* $P < 0.05$.

with epidural steroid injection, those with LSS were worse responders than those with disc herniation [17,18]. This response was attributable to the high association of LSS with irreversible changes such as epidural scar, and hypertrophy of bony structures and ligament; such changes may render the nerve root refractory to management by the local application of steroids [1,18,19]. This property of LSS also interfered with advancement of the catheter or injectates into the ventral epidural space and contributed to relatively poorer outcomes of PA.

Studies have investigated the efficacy of PA in LSS. One study reported that 76% of patients who underwent PA obtained significant pain relief at 12 months, whereas only 12% of those with caudal block obtained pain relief. This study demonstrated better clinical efficacy than that observed in our study despite a long-term follow-up period of 12 months. But in this study, an average of 3.5 sessions of PA were performed per year, and patients who had a history of lumbar surgery, central spinal stenosis without radicular pain, and foraminal stenosis were excluded [10]. A retrospective study showed that 89% of patients with moderate or severe LSS had significant pain relief at 3 months. But they also performed repetitive procedures [20]. A prospective observational study also reported better outcomes than those of our study, reporting successful results in approximately 74% of patients at

2 weeks and 67% of patients at 6 months after PA based on a 5-point patient satisfaction index in LSS [13]. But the scale used for clinical evaluation in their study was different from that of our study. They evaluated clinical outcomes with a 5-point satisfaction index, and included “no pain,” “much improved,” and “slightly improved” in an improvement group, which could be more generous than our study. If they had included only “no pain” and “much improved” in improvement group, about 50% of patients would have been included in improvement group.

Spondylolisthesis and previous surgical history had a poor influence on PA efficacy. Spondylolisthesis also lead to segmental instability, as well as diminished cross-sectional area of vertebral canal, apparent thickening and buckling of the ligamentum flavum, or hypertrophy of adjacent facet joints [21]. Post-lumbar surgery syndrome was also associated with epidural and perineural scarring and nerve root adherence to the underlying disc and pedicle [12]. These structural characteristics of both could produce more severe and irreversible barriers that hamper catheter advancement and effective adhesiolysis, which explained why patients with spondylolisthesis or post-surgery syndrome showed poorer outcomes than those without.

Unexpectedly, PA efficacy in treatment of LSS was not influenced by severity of LSS. Clinical efficacy of

transforaminal epidural injection did not correlate with the degree of stenosis noted in the MRI in patients with LSS [22]. The degree of LSS of patients with improvement after epidural injection was not significantly different from that of patients without improvement [23]. The literature evaluating LSS severity and degree of pain relief after PA in LSS showed that the dural sac cross-sectional area (DSCSA) did not differ between participants with and without improvement, and that there was no correlation between pain relief and DSCSA in patients with central LSS [13]. These results indicated that clinical outcomes after treatment in patients with LSS were not correlated with static anatomical aspect, even with MRI [24].

Instead, PA efficacy was influenced by location of LSS. Foraminal stenosis notably showed poor outcomes at 3 months. First, the number of patients with foraminal stenosis was so small that there could be statistical bias. Second, among the six patients with foraminal stenosis, two had moderate stenosis and four had severe stenosis. The diameter of the neural foramen is smaller than the subarticular area or central canal. Although the central canal or subarticular area was narrowed by stenosis, it could provide adequate space for the catheter to be advanced or placed at target sites because of its relatively larger size compared with neural foramen. However, even a one-third reduction of normal foraminal diameter could seriously block the catheter advancement, and consequently effective elimination of adhesion.

There were several limitations in this study. First, the follow-up period was relatively short. This may have weakened the power of this study. Second, this study was retrospective in design. Third, the study population of 65 patients was insufficient to conduct multivariate analysis of predictors of unsuccessful results. Therefore, we could not analyze the clinical efficacy of PA with nine groups divided by a combination of severity and location, for example, mild, moderate, and severe degree of central, subarticular, and foraminal stenosis. Despite these limitations, we demonstrated important clinical points. This study suggest that PA is effective for pain reduction and functional improvement in patients with LSS who do not respond to other conservative treatments, including transforaminal epidural injection, and can reduce the necessity of surgical treatment. Previous surgery, spondylolisthesis, and foraminal stenosis may be associated with poor prognosis of PA.

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