Retrospective Study

Clinical Effectiveness of Percutaneous Adhesiolysis Using Navicath for the Management of Chronic Pain Due to Lumbosacral Disc Herniation

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Background: Epidural steroid injection has been frequently performed to treat chronic pain due to lumbosacral disc herniation (L-HIVD). However, a considerable number of patients do not achieve pain relief using this method because perineural or epidural adhesions prevent the spread of injectate into the epidural space. Percutaneous adhesiolysis (PA) is thought to be a useful method because it can eliminate the deleterious effects of adhesion.

Objectives: This study aimed to evaluate the effectiveness of PA in managing chronic pain due to L-HIVD and the clinical and radiological predictive factors for the effectiveness of PA using NaviCath®.

Study design: Retrospective study

Setting: Spine hospital

Methods: From a group of patients diagnosed with L-HIVD, we selected the 86 patients who underwent PA with NaviCath who had experienced chronic lower back or leg pain for at least 3 months and had failed to respond to anti-inflammatory medications or physical therapy of at least 1 month's duration and fluoroscopy guided transforaminal epidural injection. We recorded the Numeric Rating Scale for back pain (NRS back) and leg pain (NRS leg) and the Oswestry Disability Index (ODI) at pretreatment, 2 weeks, and 3 months after treatment. Clinical data and magnetic resonance imaging (MRI) findings were obtained to assess the possible predictive factors for PA efficacy.

Limitations: Retrospective chart review without a control group.

Results: At 2 weeks after PA, significant improvement was observed in NRS back, NRS leg, and ODI compared with pretreatment. This improvement was maintained until 3 months after treatment. Among 86 patients, 61 (70.9%), 53 (61.6%) and 61 patients (70.9%) showed successful outcomes in NRS back, NRS leg, and ODI at 2 weeks, respectively. Among 74 patients who were followed up at 3 months, 47 (63.5%), 44 patients (59.5%), and 50 patients (67.6%) showed successful results in NRS back, NRS leg, and ODI at 3 months, respectively.

A significantly higher proportion of patients with a history of previous lumbar surgery showed unsuccessful results on NRS back, NRS leg, and ODI scores at 2 weeks and 3 months. Co-existence of spinal stenosis was associated with a significantly higher proportion of unsuccessful results in NRS back and ODI at 2 weeks and 3 months, as well as NRS leg at 3 months. Patients with spondylolisthesis also showed a significantly higher proportion of unsuccessful results in NRS and ODI at 2 weeks.

Conclusion: PA with NaviCath showed clinical effectiveness in the treatment of chronic pain due to L-HIVD that was not responsive to transforaminal epidural injection. Previous surgery and the presence of spinal stenosis or spondylolisthesis were poor prognostic predictors. This procedure may enable the physician to place the catheter tip and deliver medicine more precisely.

Key words: Percutaneous adhesiolysis, lumbosacral disc herniation, Numeric Rating Scale, Oswetry Disability Index

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Chronic lower back or radiating leg pain from a lumbosacral herniated intervertebral disc (L-HIVD) is a common condition. Its prevalence ranges from 35% to 75% at 12 months after the initial onset of symptoms (1). Chronic lower back or leg pain was found to occur not only in response to mechanical stimuli, but also to chemical irritation around the nerve root sheath and sinuvertebral nerve (2). Leakage of the disc material into the epidural space following an annular tear leads to acute inflammation and consequent fibrocyte deposition and epidural adhesions, which result in compression of the nerve roots (3-6). While peridural or neural fibrosis in themselves are not painful, they can produce pain by trapping spinal nerves so that movement produces tension in the inflamed nerves (2,3). Generally, fluoroscopy-guided epidural injections have been used to treat chronic pain due to L-HIVD. Through their anti-inflammatory action clinical efficacy has been obtained (7,8). Transforaminal epidural injections have produced favorable results for managing lumbosacral radicular pain secondary to L-HIVD and spinal stenosis (9,10). Caudal epidural injections have provided functional improvement and pain relief for patients with chronic low back pain due to postsurgery syndrome (11,12). However, a considerable number of patients do not achieve meaningful pain relief through epidural injections. One study showed that among patients undergoing transforaminal or caudal epidural injection, only one-third obtained more than 2 months of pain relief (13). Another study revealed that epidural injection had better short-term results than interspinous or intramuscular injection, but this benefit was not maintained for up to 6 weeks in patients with L-HIVD or spinal stenosis (14). A retrospective study reported that although approximately 50% of patients with radicular symptoms may receive temporary relief, long-term relief occurs in less than 25% of patients (15). This was because the epidural space in these cases was restricted by perineural or epidural adhesions/ fibrotic tissues, and the injectate frequently failed to spread effectively into the ventral epidural space (16).

Percutaneous adhesiolysis (PA) is a minimally invasive therapy in which a catheter is placed directly into the herniated disc or scar tissue compromising the nerve root. It has potential as a useful treatment method for patients with chronic pain that is refractory to conservative treatments (17). The rationale for PA is that chronic pain is mainly caused by perineural fibrosis and that PA has the ability to eliminate the deleterious effects of adhesion, which can physically prevent the direct application of drugs around the nerves. As a result, PA ensures the delivery of high concentrations of injected drugs to the target areas (16,18-21). PA has produced clinical benefits in patients who have failed to respond to conservative treatment, including fluoroscopy-guided epidural injections (22). According to a comparative study between PA and caudal steroid injection in postsurgery syndrome, PA obtained significantly better clinical efficacy than caudal injection (23). To the best of our knowledge, all previous literature about PA was about using a Racz catheter. Whereas the catheter and spring tip on the Racz catheter cannot be steered, NaviCath (Myelotec Inc, Roswell, GA) has a steerable catheter and an atraumatic tip. This property enables the physician to place the catheter tip and deliver pain medication more precisely around the nerve root sheath and perform mechanical lysis. In this study, we intended to evaluate the clinical efficacy of PA with NaviCath in a clinical setting. Epidural injection is more often performed than PA since epidural injection is a simpler and less expensive procedure. However, PA is considered for the patient who is refractory to epidural injection. We thought the study, which was clinically informative and applicable, would be more implicative. Therefore, we aimed to evaluate PA efficacy in patients who were unresponsive to transforaminal epidural injections, instead of comparing the clinical efficacy between PA and epidural injection.

The purpose of this study was to evaluate the effectiveness of PA with NaviCath for managing chronic lower back and leg pain in patients with L-HIVD for whom transforaminal epidural injections were not successful. The study also investigated the clinical and radiological factors that are related to the clinical effectiveness of PA.

Methods

Materials

Informed consent was obtained by the Institutional Review Board of Wooridul Spine Hospital. From a group of patients diagnosed with L-HIVD, we selected the patients who underwent PA with NaviCath. These patients had experienced chronic lower back or leg pain for at least 3 months and had failed to respond to anti-inflammatory medications or physical therapy of at least one month and fluoroscopy-guided transforaminal epidural injection. We defined the failure of transforaminal epidural injection as the absence of

a 50% or more reduction of the Numeric Rating Scale (NRS) compared to preinjection, when at least 2 injections had been administered over 2 months. Finally, 86 patient charts were reviewed.

Methods

Data collection

We obtained clinical data such as age, sex, duration of symptoms in months, predominant symptom (axial back pain versus radiating leg pain) and a history of previous lumbar surgery. Magnetic resonance imaging (MRI) findings that were recorded included the type and location of the herniated disc, number of lesion levels (single versus multiple levels), grade of nerve root compression, and the co-existence of spinal stenosis. The type of herniated disc was classified as bulging, protrusion, extrusion, or sequestration. The location of the herniated disc was classified as central, subarticular, foraminal, or extraforaminal disc herniation (24).

Clinical evaluation

The NRS for back pain (NRS back) and leg pain (NRS leg) as well as the Korean version of the Oswestry Disability Index (ODI) were used to evaluate the clinical effectiveness in terms of pain reduction and functional improvement at pretreatment, 2 weeks, and 3 months after treatment (25). The NRS represented no pain with 0 and the worst pain imaginable with 10 (26). All patients were asked to give their answers considering the average severity of their symptoms over the last one-week period (27). The Korean version of ODI was utilized for functional assessment that ranged from 0 to 50. The value and validity of the NRS and Korean version of ODI have been reported previously (20,25,28). Successful pain relief was described as a 50% or more reduction of the NRS, and successful functional improvement was defined as a 40% or more reduction of the ODI (23).

Percutaneous adhesiolysis

PA was performed under fluoroscopy in a sterile operating room with monitoring equipment for blood pressure, pulse rate, and pulse oximetry. The fluoroscopy was adjusted over the lumbosacral area such that the caudal approach could be used in both the anteroposterior and lateral views. After the appropriate positioning of fluoroscopy, the needle insertion area was determined around the sacral hiatus and was injected 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 to 5 mL of contrast media to confirm that the needle was placed in the epidural space and to avoid intravascular or subarachnoid needle placement. A NaviCath was passed through the introducer after removal of the Tuohy needle under fluoroscopic visualization, and at least 5 mL of contrast media were injected to identify the 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 the suspected pain area, some patients indicated that they felt pain similar to what they had been suffering from. After adhesiolysis, approximately 3 mL of contrast media were 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 mL of 1% lidocaine and 40 mg of triamcinolone was slowly injected. We succeeded in passing the NaviCath into the area of interest in all patients except 4 who had undergone previous surgery. When the procedure was over a sterile dressing was applied around the sacral hiatus. Subsequently, the patient was turned to 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

A Wilcoxon ranking 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 among the clinical parameters and MRI findings, we compared patients' ages using a Mann-Whitney U test as well as sex distribution, duration of symptoms, predominant symptom between back and leg pain, and presence of previous operation history, type and location of herniated disc, number of lesion levels, grade of nerve root compression, and the co-existence of spinal stenosis using Chi-squared test with Fisher's exact tests between successful and unsuccessful results for NRS and ODI. All statistical analyses were performed using the SPSS Version 12.0 statistical package (IBM Corporation, Armonk, NY). Results were considered statistically significant if $P < 0.05$.

Results

At 2 weeks after PA, significant improvement was observed in NRS back, NRS leg, and ODI compared with pretreatment, and was maintained until 3 months after treatment (Table 1). At pretreatment, there were no significant differences in age, sex ratio, NRS back, NRS leg, and ODI between successful and unsuccessful results (Table 2).

Among the 86 patients, successful outcomes at 2 weeks were obtained for the following: NRS back, 61

Table 1. *Comparison of NRS and ODI between pretreatment and post treatment.*

NRS back	Pretreatment- 2 weeks Pretreatment-3 months	5.43±2.11 5.53±2.02	2.48±1.89 2.91±2.12	$P<0.001$
NRS leg	Pretreatment-2 weeks Pretreatment-3 months	5.88±2.66 5.82±2.58	3.12±2.48 2.91±2.41	$P<0.001$
ODI (%)	Pretreatment-2 weeks Pretreatment-3 months	57.6±19.4 56.9±19.3	30.2±20.9 29.3±20.4	$P<0.001$

NRS back: Back pain score of Numeric rating scale
NRS leg: Leg pain score of Numeric rating scale
ODI: Oswestry disability score

Table 2. *Comparison of clinical and MRI findings between patients with successful and unsuccessful results in NRS back.*

		NRS back at 2 weeks			NRS back at 3 months		
		Successful (N=61)	Unsuccessful (N=25)	*p*	Successful (N=47)	Unsuccessful (N=27)	*P*
Age		42.7±16.3	48.3±11.3	0.164	42.4±15.6	48.0±15.0	0.110
Gender ratio	Male	33	12	0.641	27	12	0.337
	Female	28	13		20	15	
Score at pretreatment		5.9±2.0	5.4±2.0	0.633	5.6±2.2	5.4±1.8	0.772
Spondylolisthesis	Absent	52	16	0.041*	40	19	0.145
	Present	9	9		7	8	
Duration	3-6 months	34	12	0.635	28	12	0.234
	>6 months	27	13		19	15	
Number of lesions	1	34	11	0.351	23	14	1
	>1	27	14		24	13	
Previous surgery	Absent	56	15	0.001*	47	16	<0.001*
	Present	5	10		0	11	
Predominant symptom	Axial pain	26	6	0.142	18	9	0.803
	Radiating pain	35	19		29	18	
HIVD type	Bulging	22	7	0.197	16	9	0.412
	Protrusion	20	12		15	11	
	Extrusion	19	6		16	7	
HIVD location	Central	31	12	0.704	25	15	0.763
	Subarticular	26	10		19	9	
	Foraminal	4	3		3	3	
Root compression	Abutment	16	5	0.781	13	8	0.181
	Displacement	29	12		20	16	
	Compression	16	8		14	3	
Spinal stenosis	Absent	44	9	0.002*	35	12	0.01*
	Present	17	16		12	15	

NRS back : Back pain score of Numeric rating scale
HIVD : herniaition of intervertebral disc.
Successful pain relief was described as 50% or more reduction of NRS.

patients (70.9%); NRS leg, 53 patients (61.6%); and ODI, 61 patients (70.9%). Nine patients with persistent pain after PA underwent back surgery and another 3 patients were lost during follow-up. Among the 74 patients followed up at 3 months, successful results were obtained for the following: NRS back, 47 patients (63.5%); NRS leg, 44 patients (59.5%); and ODI, 50 patients (67.6%).

A significantly higher proportion of patients with a history of previous lumbar surgery showed unsuccessful results on NRS back, NRS leg, and ODI scores at 2 weeks and 3 months. Co-existence of spinal stenosis was associated with a significantly higher proportion of unsuccessful results in NRS back and ODI at 2 weeks and 3 months as well as NRS leg at 3 months. Patients with spondylolisthesis also showed a significantly higher proportion of unsuccessful results on their NRS and ODI scores at 2 weeks (Tables 2-4).

Ten of 86 patients complained of transient local pain in the lower back and needle insertion area. This pain was well controlled by analgesics. Only one pa-

Table 3. *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=53)	Unsuccessful (N=33)	*p*	Successful (N=44)	Unsuccessful (N=30)	*p*
Age		44.9±15.2	43.3±15.3	0.683	44.1±14.9	44.9±16.6	0.881
Gender ratio	Male	30	15	0.377	26	13	0.237
	Female	23	18		18	17	
Score at pretreatment		6.1±2.5	5.8±2.9	0.599	5.9±2.3	5.7±2.9	0.897
Spondylolisthesis	Absent	45	23	0.108	37	22	0.258
	Present	8	10		7	8	
Duration	3-6 months	30	16	0.51	27	13	0.157
	>6 months	23	17		17	17	
Number of lesions	1	29	16	0.659	24	13	0.478
	>1	24	17		20	17	
Previous surgery	Absent	48	23	0.019*	42	21	0.004*
	Present	5	10		2	9	
Predominant symptom	Axial pain	19	13	0.82	15	12	0.631
	Radiating pain	34	20		29	18	
HIVD type	Bulging	18	11	0.257	15	10	0.237
	Protrusion	16	16		13	13	
	Extrusion	19	6		16	7	
HIVD location	Central	26	17	0.947	22	18	0.175
	Subarticular	23	13		20	8	
	Foraminal	4	3		2	4	
Root compression	Abutment	15	6	0.344	11	10	0.549
	Displacement	26	15		21	15	
	Compression	12	12		12	5	
Spinal stenosis	Absent	35	18	0.287	32	15	0.046*
	Present	18	15		12	15	

NRS leg : Leg pain score of Numeric rating scale
HIVD : herniaition of intervertebral disc.
Successful pain relief was described as 50% or more reduction of NRS.

Table 4. *Comparison of clinical and MRI findings between patients with successful and unsuccessful results in ODI.*

		ODI 2 weeks			ODI 3 months		
		Successful (N=61)	Unsuccessful (N=25)	*P*	Successful (N=50)	Unsuccessful (N=24)	*P*
Age		43.1±15.7	47.4±13.5	0.159	43.0±15.3	47.0±16.3	0.342
Gender ratio	Male	33	12	0.641	27	12	0.807
	Female	28	13		23	12	
Score at pretreatment		56.0±18.7	61.3±20.9	0.269	56.4±19.4	58.1±19.6	0.923
Spondylolisthesis	Absent	52	16	0.041*	43	16	0.068
	Present	9	9		7	8	
Duration	3-6 months	36	10	0.153	31	15	0.867
	>6 months	25	15		19	9	
Number of lesions	1	30	15	0.477	24	13	0.804
	>1	31	10		26	11	
Previous surgery	Absent	56	15	0.001*	49	14	<0.001*
	Present	5	10		1	10	
Predominant symptom	Axial pain	24	8	0.626	21	6	0.201
	Radiating pain	37	17		29	18	
HIVD type	Bulging	21	8	0.141	17	8	0.322
	Protrusion	20	12		16	10	
	Extrusion	20	5		17	6	
HIVD location	Central	33	10	0.181	27	13	0.17
	Subarticular	25	11		21	7	
	Foraminal	3	4		2	4	
Root compression	Abutment	19	9	0.276	17	4	0.227
	Displacement	28	10		21	15	
	Compression	14	6		12	5	
Spinal stenosis	Absent	44	9	0.003*	38	9	0.002*
	Present	17	16		12	15	

ODI : Oswestry disability score
HIVD : herniaition of intervertebral disc.
Successful functional improvement of ODI was defined as 40% or more reduction of ODI.

tient experienced a relatively severe complication of headache and transient seizure-like motions after the procedure. These symptoms disappeared without any specific treatment. This patient had a previous history of several episodes of generalized seizures and had taken antiepileptic drugs for 5 years. Among the 9 patients who underwent surgery within the 3-month follow-up period, only one patient underwent interbody fusion surgery and 8 patients underwent microscopic open discectomy. All of them showed satisfactory results in pain reduction and functional improvement after surgery.

Discussion

PA has been used for the treatment of chronic pain that is intractable to other conservative management and has been shown to have good clinical efficacy (18). PA demonstrates superior effectiveness compared to not only physical therapy, (29) but also caudal epidural steroid injections for the treatment of chronic lower

back and leg pain (23,30). This is because PA is able to eliminate adhesions or fibrous tissue that might prevent the spread of injected medications into the specific lesion site, and allows placement of the catheter tip within the target areas. Consequently, this enables the application of an adequate concentration of the steroid or other solution to the appropriate target area (31).

Previous reports regarding the efficacy of PA used the Racz catheter. Our study used NaviCath with normal saline. NaviCath has a steerable catheter and an atraumatic tip, and is different from the Racz catheter that has a catheter and spring tip that cannot be steered. This property of NaviCath enables the physician to place the catheter tip near the nerve root sheath and deliver pain medication more precisely. This might lead to performing mechanical adhesiolysis more easily.

Manchikanti et al (22) compared the clinical efficacy among 3 different treatment groups: Group I consisted of a control group not undergoing adhesiolysis with normal saline; Group II consisted of patients undergoing adhesiolysis with normal saline; and Group III consisted of patients undergoing adhesiolysis with 10% hypertonic saline. Approximately 70% of patients in Group III , 60% of patients in Group II, and 0 % of patients in Group I showed significant improvement in the Visual Analog Scale (VAS) and ODI at 12-months follow-up. Another comparative study showed that most patients achieved significant reduction of the VAS after PA and the percentage of patients with VAS improvement did not differ whether the injectate included hypertonic saline or normal saline (32). These studies suggested that appropriate mechanical adhesiolysis with normal saline could also be an effective treatment and obtained comparable results to adhesiolysis with hypertonic saline in chronic refractory back pain. Thus, it was assumed that precise placement of the catheter tip by NaviCath, which would allow for appropriate adhesiolysis, did not require hypertonic saline, which could cause serious adverse effects (16,33).

Studies on the clinical efficacy of PA have reported that PA shows more significant pain reduction and better functional outcomes than do medication, physical therapy, and an exercise program (29,32,34). In one study, about 49% of the patients that failed to achieve clinical improvement by other conservative treatments showed a significant reduction of their pain score at 3 months, while 43% achieved pain reduction at 6 months, and 49% at 12 months (32). Few studies have compared the efficacy of PA with that of epidural steroid injection. Two reports have identified that clinical outcomes of PA are better than caudal epidural injections in patients with spinal stenosis and lumbar postsurgery syndrome (23,30). But among 3 epidural injection techniques such as caudal, interlaminar, or transforaminal approach, the transforaminal approach offered better clinical effectiveness than the caudal or interlaminar approaches because it allowed the injectate to spread directly into the ventral epidural space (35-37). The implication of our study was that about 60-70% at 2 weeks and 55-60% at 3 months of the patients refractory to transforaminal epidural injection, assumed to be the most effective among epidural injection methods, could achieve significant clinical results.

In a clinical setting, PA is usually performed for patients who fail to improve clinically after an epidural steroid injection and is rarely performed for patients who have not first received an epidural injection. We assumed that PA was not required for patients who were responsive to an epidural injection since epidural injection is a simpler and less expensive procedure than PA. Therefore, we aimed to evaluate PA efficacy in patients who were unresponsive to transforaminal epidural injection, instead of comparing the clinical efficacy between PA and epidural injection.

To the best of our knowledge, no studies have assessed the clinical or laboratory factors related to the efficacy of PA. In our study, a significant relationship was not found between MRI characteristics of L-HIVD and the clinical efficacy of PA. However, the co-existence of spinal stenosis, spondylolisthesis, or previous surgical history was related to poorer outcomes. It has been reported that patients with spinal stenosis or postsurgery syndrome showed a worse response to epidural steroid injection than do L-HIVD patients (32,38). Spinal stenosis and postsurgery syndrome were associated with irreversible changes such as epidural fibrosis, scarring, and hypertrophied lateral recess and ligament, which might render the nerve root refractory to management by the local application of steroids (31,36,38). These features were assumed to be more severe and irreversible than L-HIVD and were often associated with scar formation or bony hypertrophy, which interfered with advancement of the catheter or injectates into the ventral epidural space. Spondylolisthesis also leads to not only segmental instability but also a diminished cross-sectional area of the vertebral canal, apparent thickening and buckling of the ligamentum flavum, or hypertrophy of adjacent facet joints, thus contributing to spinal stenosis (39). These structural characteristics could explain why patients with spinal stenosis, spondylolisthesis, or

postsurgery syndrome showed poorer outcomes than those without.

PA may cause epidural hematoma, infection, excessive intraspinal and intracranial pressures, and increased intraocular pressures with resultant visual deficiency. The most troubling complications are mainly related to dural puncture, spinal cord compression, intravascular injection, and administration of high volumes of fluids, potentially resulting in excessive epidural hydrostatic pressures, death, and brain damage(18,19,32,40). In our patient group, one patient who was receiving antiepileptic treatment experienced the serious complication of transient seizure-like motions. An elevated intraspinal pressure or intrathecal administration of injectate might have triggered generalized seizure in this high risk patient.

There were several limitations in this study. First, the follow-up period was relatively short. This might weaken the power of this study. Second, this study was retrospective in design. Despite these limitations, we suggested the important clinical points. We performed the PA for patients refractory to transforaminal epidural injection and showed the positive results. In the clinical setting, many patients refractory to epidural injection were regarded as failures of conservative management and consequently, underwent the surgical procedure. This study could suggest the ability of PA to be another treatment strategy for patients who could not accomplish successful results by epidural injections and might negate the need for lumbar surgery.

Conclusion

PA was effective for pain reduction and functional improvement in patients with chronic lower back or leg pain due to L-HIVD who did not respond to other conservative treatments including transforaminal epidural injection. A history of previous surgery and the co-existence of spinal stenosis or spondylolisthesis were revealed to be poor prognostic predictors of PA.

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