Retrospective Evaluation

Evaluation of Prognostic Predictors of Percutaneous Adhesiolysis Using a Racz Catheter for Post Lumbar Surgery Syndrome or Spinal Stenosis

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Background: Percutaneous adhesiolysis (PA) is considered to be a reasonable nonoperative treatment for herniation of intervertebral disc (HIVD), spinal stenosis, and post-lumbar-surgery syndrome (PLSS). The success of PA depends on the removal of epidural fibrosis and drug delivery to the target region. However, prognostic predictors of the effects of PA are not well known.

Objective: The aim of this study was to evaluate prognostic predictors of PA using a Racz catheter for patients with PLSS or spinal stenosis.

Study Design: Retrospective assessment.

Methods: PA using a Racz catheter was performed on 78 patients. We assessed the effectiveness of PA at pretreatment, 2 weeks, 3 months, and 6 months following the procedure. Effectiveness was defined as a 50% or more reduction of the Numeric Rating Scale (NRS) for back and leg pain or a 40% or more reduction of the Oswestry Disability Index (ODI) following the procedure. Data collected for each patient included age, gender, BMI, grade and location of stenosis in magnetic resonance imaging (MRI), symptom durations, and history of previous lumbar surgery. The adjusted odds ratios (OR) and 95% confidence intervals (CI) for each variable were analyzed by logistic regression.

Results: PA using a Racz catheter was more effective in patients with no previous lumbar surgery (OR, 7.426; 95% CI, 1.820–30.302; $P = 0.005$) or root compression with HIVD or foraminal stenosis (OR, 5.479; 95% CI, 1.137–26.391; $P = 0.036$). Other included factors were not related to PA effectiveness.

Limitations: The number of patients examined in this study was relatively small.

Conclusion: Good prognostic predictors were identified as no previous lumbar surgery or root compression with HIVD or foraminal stenosis. These results are expected to contribute to the establishment of indications for PA.

Key words: Percutaneous adhesiolysis, post lumbar surgery syndrome, spinal stenosis

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The causes of persistent low back pain include degenerative lumbar spinal stenosis and herniation of intervertebral discs, post-lumbar-surgery syndrome (PLSS), facet disease, and undefined causes (1-3). Many nonsurgical treatments, including medication and physical therapy, have been applied. One nonsurgical method, epidural steroid injection (ESI), is known to reduce pain and improve function in degenerative spinal stenosis and PLSS (1,3,4). Among the multiple approaches of epidural injection

(caudal, interlaminar, and transforaminal), caudal ESI has been reported to offer long-term effectiveness in central canal stenosis (2,4). However, some controversy regarding the effectiveness of caudal ESI remains, and evidence of a treatment response in patients with spinal stenosis is moderate (5,6). The limitation of caudal injection is considered to be incorrect drug delivery in some patients due to epidural fibrosis. The primary purpose of percutaneous adhesiolysis (PA) is the removal of epidural fibrosis and the delivery of injected drugs (hypertonic saline, steroid, and local anesthetics) through placement of a catheter in the target lesion. Also, the effect of PA in patients with spinal stenosis was demonstrated to be superior to caudal steroid injection in a previous study (7).

However, in recent systemic reviews, evaluations of PA were divided. In 2009, Epter et al (8) reported that PA showed strong evidence for the treatment of PLSS. That same year, Chou et al (9) pointed out insufficient evidence of PA. In 2011, Chou et al (10) commented that the quality of studies of nonsurgical interventional therapies had some problems. The latest systemic review published in 2012 by the U.S. Preventative Services Task Force reported that the effectiveness of PA in PLSS and spinal stenosis was "fair" (11,12). The source of such controversies regarding the effectiveness of PA may be the lack of established guidelines. PLSS and spinal stenosis have multiple causes and patients have various conditions (i.e., location of stenosis or fibrosis, severity of disease, periods of morbidity). However, the indications for PA are nonspecific PLSS or spinal stenosis. Therefore, identification of clinically significant prognostic predictors of PA will clarify the standard indications. To our knowledge, no studies have reported the prognostic factors related to better long-term outcomes of PA using a Racz catheter. The purpose of this study was to investigate potential prognostic predictors of the effectiveness of PA using a Racz catheter.

Methods

Patients

This study was approved by the Institutional Review Board (IRB). Among the patients diagnosed with lumbar spinal stenosis or PLSS from August 2010 to December 2011, we identified those over the age of 18 years who underwent PA using a Racz catheter. All patients underwent magnetic resonance imaging (MRI) prior to PA. In the MRI, pathology suspected as the source of persistent pain of the low back or leg was confirmed. All patients had received standard treatments before undergoing PA, which included physical therapy, medication, and caudal or transforaminal epidural injections. The inclusion criteria included 1) low back pain with/without radicular pain due to PLSS or spinal stenosis for at least 3 months; 2) persistent pain (absence or a 50% or more reduction compared to baseline pain) despite the standard 2 months of treatment; and 3) if the patient had undergone surgery, it was performed more than 6 months prior to the PA. The final study group consisted of 78 patients.

Percutaneous Adhesiolysis with Racz Procedure

All procedures were performed by 2 pain specialists with > 3 years of experience. Before the procedure, intravenous access and antibiotic administration were conducted. PA using a Racz catheter was performed under sterile conditions using fluoroscopy with monitoring of vital signs (blood pressure, pulse oximeter, and electrocardiogram). Upon confirmation of the location of pathology by MRI, local anesthetics were injected around the sacral hiatus with the patient in the prone position. A 15-gauge RK needle (Epimed International, Inc., Gloversville, NY) was inserted into the epidural space and a 19-gauge Racz catheter was advanced through the needle up to 3rd sacral vertebra. An epidurogram was then obtained by injection of 5 mL of Omnipaque 300 contrast media (iohexol, 300-mg iodine per mL; GE Healthcare, Piscataway, NJ) and filling defects were identified. The needle was repositioned if intravascular or subarachnoid injection was detected. The tip of the Racz catheter was positioned at the pathologic change identified by MRI or by filling defects. Mechanical adhesiolysis was carried out with normal saline after confirmation of the location of the tip of the anterolateral epidural aspect of the vertebral foramen. When the mechanical adhesiolysis was performed in the area of the pathologic change, some patients expressed a feeling similar to that from which they had been suffering. After adhesiolysis, sufficient filling of the target nerve roots and epidural space was confirmed without intravascular, subarachnoid, or extra epidural injections. Thereafter, the final tip position was determined, and 5 mL of 0.25% ropivacaine containing 1500 units of hyaluronidase was slowly injected. The catheter was fixed with bio-occlusive dressing. In the recovery room, patients were monitored for any potential complications, including motor weakness. After confirmation of no complications, 6 mL of 10% so-

dium chloride solution was injected at a rate of one mL every 30 minutes for 2.5 hours. Next, a mixture of 2 mL of 0.9% sodium chloride solution containing 40 mg of triamcinolone was injected. Following the last injection, the patient was monitored closely in the recovery room for any complications. The catheter was then removed and the patient was discharged.

Clinical Effectiveness

The 78 patients were categorized into effective and noneffective PA groups. The standards for effectiveness evaluation were pain reduction and functional improvement. Back and leg pain were measured using the Numeric Rating Scale (NRS, ranging from 0 = no pain to 10 = absolutely intolerable pain) and functional improvement was measured using the Korean version of the Oswestry Disability Index (KODI, ranging from 0 to 50) (13) at pretreatment, 2 weeks, 3 months, and 6 months following the procedure. Effectiveness was defined as a 50% or more reduction in the NRS for back and leg pain, or a 40% or more reduction in the KODI following the procedure (14). Also, the "effective PA group" was defined as those showing effectiveness at 6 months after the procedure.

Data Collection and Statistical Analysis

We collected the following data for logistic regression analysis: age, gender, BMI, grade and location (central, foraminal) of stenosis in MRI, history of previous lumbar surgery, and symptom durations. The grade of central stenosis was based on a recent grading system (15). Mild central canal stenosis was characterized by obliteration of the cerebrospinal fluid (CSF) space in front of the cauda equina, but clear separation of all intrathecal nerve roots; moderate stenosis showed aggregation of some of the cauda equina; and severe stenosis showed no separation of the cauda equina. The grade of foraminal stenosis was also based on a 3-stage system (16). Mild foraminal stenosis showed perineural fat obliteration around the nerve root in either the transverse or vertical direction; moderate grade showed obliteration in both directions; and severe grade showed nerve root collapse or deformity. Root compression with herniation of intervertebral disc (HIVD) or foraminal stenosis was defined as displacement or compression of the nerve root.

The adjusted odds ratios (OR) and 95% confidence intervals (CI) were estimated using logistic regression analysis. The history of previous lumbar surgery was used as the primary independent variable (X), and the effectiveness of PA was the primary outcome (Y). The sample size was calculated as described previously (17), using the G*power version 3.1.0 software with the following conditions: 1) expected OR for the primary outcome = 3.5; 2) R^2 (squared multiple correlation coefficient when the predictor of interest was regressed on the other predictors) = 0; 3) probability (Y = 1 X = 1) under the null hypothesis = 0.3, and 4) the binomial distribution of X (central stenosis versus central and foraminal stenosis) with a probability 0.5, $\alpha = 0.05$, $\beta = 0.2$ for a one-tailed test. The sample size was 69 patients. The PASW version 18.0 software (SPSS, Chicago, IL) was used for statistical analyses. Results are expressed as means ± SD. A value of $P < 0.05$ was taken to indicate statistical significance.

Results

All 78 patients were treated with PA using a Racz catheter without complications. Demographic data of the patients are listed in Table 1. Of the 78 patients, 27 (34.6 %) had undergone lumbar surgery. The number of patients with central canal and foraminal stenosis (30 patients, 39.5%) was greater than the number of patients with central canal stenosis (21 patients, 27.6%). Moderate spinal stenosis represented the highest number of patients (42 patients, 53.8%), followed

Table 1. *Patient demographics*.

Characteristic	Value
Age (years)	61.97 ± 9.42
Gender (male/female)	35/43
Body mass index (kg/m2)	24.43 ± 3.00
Previous lumbar surgery	
Yes, n (%)	27 (34.6)
No, n (%)	51 (65.4)
Location of spinal stenosis	
Central, n (%)	21 (27.6)
Foraminal, n (%)	25 (32.9)
Central and foraminal, n (%)	30 (39.5)
Grade spinal stenosis	
Mild, n (%)	26 (33.3)
Moderate, n (%)	42 (53.8)
Severe, n (%)	10 (12.8)
Root compression	
Yes, n (%)	36 (46.2)
No, n (%)	42 (53.8)
Symptom duration (month)	17.37 ± 14.65

by mild (26 patients, 33.3%) and severe (10 patients, 12.8%) stenosis. The proportions of patients in the effective and noneffective PA groups at each measurement time (2 weeks, 3 months, and 6 months) are listed in Table 2. Of the 51 patients who had effect at 2 weeks, 18 (35%) patients had undergone lumbar surgery. Among the 51 patients in the effective PA group at 2 weeks, 13 (25.4%) changed to the noneffective PA group at 6 months. Table 3 presents the adjusted ORs with 95% CIs of each variable for the effective PA group at 6 months. PA using a Racz catheter was more effective in patients with the following factors: 1) no history of previous lumbar surgery (OR, 7.426; 95% CI, 1.820–30.302; P = 0.005), or 2) root compression with HIVD (OR, 5.479; 95% CI, 1.137–26.391; P = 0.036). Of the 51 patients with no history of lumbar surgery, 31 (60.7%) were included in the effective PA group at 6 months. In addition, of the 36 patients who showed root compression on MRI, 23 (63.8%) were in the effective PA group at 6 months. Patient age, BMI, location of stenosis, and symptom duration were not correlated with effective PA at 6 months.

Table 2. *Changes in patient pain and function following PA*

Group	Frequency, n (%)		
	2 week	3 month	6 month
Effective PA[a]	51 (65.4%)	45 (51.1%)	38 (48.7%)
Noneffective PA	27 (34.6%)	33 (37.5%)	40 (51.3%)

[a] Effective PA was defined as a 50% or more reduction in VNRS or a 40% or more reduction in the KODI

Table 3. *Odds ratios (OR) and 95% confidence intervals (CI) for each variable.*

Variable	*P* value	OR	95% CI
Age (years)			
> 60	-	1.00	-
≤ 60	0.737	0.082	0.222–2.899
Body mass index (kg/m2)			
> 23	-	1.00	-
≤ 23	0.182	0.392	0.099–1.550
Previous lumbar surgery			
Yes	-	1.00	-
No	0.005	7.426	1.820–30.302
Location of stenosis			
Central	-	1.00	-
Foraminal	0.353	0.478	0.101–2.266
Central and foraminal	0.523	0.625	0.148–2.644
Grade of stenosis			
Mild	-	1.00	-
Moderate	0.058	5.474	0.946–31.665
Severe	0.567	1.531	0.356–6.582
Root compression			
No	-	1.00	-
Yes	0.036	5.479	1.137–26.391
Symptom duration (month)			
> 12	-	1.00	-
≤ 12	0.989	1.009	0.296–3.436

Discussion

Approximately 49% of our patients showed pain reduction and improvement of function for up to 6 months. Also, no previous history of lumbar surgery and root compression were correlated with the effectiveness of PA using a Racz catheter after 6 months. Many studies have reported the clinical advantages of PA compared with other nonsurgical methods (especially caudal epidural steroids injection) for spinal stenosis and PLSS. Among the several randomized controlled trials (RCT) comparing the effectiveness of PA with caudal epidural steroids injection (ESI), one dealt with PLSS (14) and the other with spinal stenosis (7). These 2 studies demonstrated that PA was superior to caudal ESI during follow-up periods of up to 12 months; however, they did not report prognostic factors of PA using a Racz catheter.

The key to successful PA is considered to be effective drug delivery to the target area after the removal of fibrosis. If removal of fibrosis failed, good results of PA are unlikely. Of the multiple causes of PLSS, epidural fibrosis can explain 20 to 36% of all cases (8). The most common cause of epidural fibrosis in PLSS is accepted to be post-operative scar tissue. One previous study reported that more extensive epidural scarring provoked 3.2-fold more radicular pain (18). Also, PA or epiduroscopic adhesiolysis for the removal of epidural fibrosis demonstrate superior symptom and function improvement compared to conservative therapy (11,19). However, in the current study, a lack of previous lumbar surgery was correlated with good effectiveness of PA using a Racz catheter. This result was shown in the regression analysis and does not indicate that PA was ineffective for PLSS. Of the 27 patients who had a history of lumbar surgery, 13 (48%) were included in the effective PA group at 3 months. Takeshima and colleagues (20) reported re-adhesion in patients with PLSS following epiduroscopic adhesiolysis.

They suspected that the cause of re-adhesion might involve the removal of ligament around the dura during previous lumbar surgery. Removal of ligament around the dura is made more difficult by adhesion onto adjacent tissue. Therefore, re-adhesion can be a cause of remaining or worsened pain in some patients with PLSS following PA. In addition, the pathophysiology of PLSS not only varies, but also overlaps (i.e., recurrent disc herniation, facet or sacroiliac joint pain, degenerative disc, neuropathic pain). Because each patient with PLSS could have several causes of pain, the present analysis may not be sufficient, although PA was shown to be effective for PLSS.

Caudal or transforaminal ESIs are reported to be effective nonsurgical treatments for spinal stenosis or HIVD (2,21). The steroid effect of ESI is known to reduce the local inflammatory reaction of compressed nerve roots by inhibiting the synthesis of pro-inflammatory mediators (prostaglandin) (21,22). In the current study, although all 78 patients had caudal or transforaminal ESIs performed prior to PA, these procedures did not result in improvements in symptoms. On the other hand, the compression of nerve roots with HIVD or foraminal stenosis was correlated with good results after PA. This implies that PA has significant clinical value. Intermittent or continuous compression of nerve roots caused by HIVD or foraminal stenosis could lead to edema, hyperemia, and leakage of inflammatory mediators around nerve roots (2), which could lead to perineural fibrosis (23). The effectiveness of PA in patients whose response to caudal or transforaminal ESI treatment was unsatisfactory could be explained by the successful removal of perineural fibrosis. Hypertonic saline and hyaluronidase play a role in disruption of epidural fibrosis. In particular, hyaluronidase destroys proteoglycans, accelerating epidural adhesiolysis (24). Therefore, PA may be accepted as the next step following ESI not only for nonresponsive patients receiving conservative therapy, but also for those at high-risk for spinal surgery or patients who refuse surgery.

The degree of severity in radiologic findings of spinal stenosis is known to not be proportional to symptom severity (25,26). Park and colleagues (27) reported no correlation between the dural sac cross-sectional area (DSCSA) and efficacy of PA in spinal stenosis patients. These results are similar to the current findings, in which the grade of spinal stenosis was not correlated with the effectiveness of PA.

We expected to find a significant correlation between the location of spinal stenosis and the effectiveness of PA. Caudal ESI is used to treat central canal stenosis patients at the low lumbar level because the drug tends to be delivered to the ventral aspect of the epidural space (28); in contrast, the transforaminal approach offers drug delivery into the ventrolateral epidural space (29). Therefore, PA with a Racz catheter through a caudal approach was expected to show better clinical effectiveness in patients with central spinal stenosis compared with those with foraminal stenosis, but the location of the spinal stenosis was not a significant factor in the prognosis of PA. In a recent study, percutaneous transforaminal adhesiolysis in patients with lumbar neuroforaminal spinal stenosis was reportedly an effective treatment (30). If both caudal and transforaminal approaches are used for PA, the results regarding the correlation between the location of spinal stenosis and the effectiveness may change.

A previous study reported prognostic factors for a poor outcome after PA using NaviCath for HIVD patients (23). The factors prognostic for a poor outcome of PA using Navicath were previous lumbar surgery and the co-existence of spinal stenosis or spondylolisthesis. However, no studies of the prognosis of PA using a Racz catheter in patients with spinal stenosis or PLSS have been conducted. Thus, this is the first report of prognostic factors for the success of PA using a Racz catheter in patients with spinal stenosis or PLSS.

This study has some limitations. First, the population was relatively small. No previous history of lumbar surgery and root compression showed good correlations with PA effectiveness after 6 months. However, moderate-grade spinal stenosis showed an OR of 5.474 (95% CI, 0.946–31.665), which is considered to indicate a tendency to effective PA. Because the sample size was small, the 95% CI was wide. Second, the follow-up period was 6 months, whereas other RCTs of PA included 12-month follow-ups (7,14).

Conclusion

No previous history of lumbar surgery and root compression were identified to be good prognostic predictors of the results of PA using a Racz catheter. These results are expected to facilitate the establishment of indications for PA.

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