Retrospective Study

Effectiveness of Epidural Balloon Neuroplasty in Patients With Chronic Spinal Stenosis Accompanied by Redundant Nerve Roots: A Longitudinal Cohort Study

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Background: Symptomatic patients with chronic lumbar spinal stenosis (LSS) accompanied by redundant nerve roots (RNR) have poor treatment outcomes. Recently, epidural balloon neuroplasty has been shown to be effective in patients with chronic LSS.

Objective: To evaluate the effectiveness of epidural balloon neuroplasty in patients with chronic LSS accompanied by RNR.

Study Design: Retrospective cohort study.

Setting: A single pain clinic of a tertiary medical center in Seoul, Republic of Korea.

Methods: Patients with chronic LSS were divided into groups with (RNR group) and without RNR (non-RNR group). The generalized estimating equations (GEE) model was used to evaluate the effectiveness of epidural balloon neuroplasty in both groups based on Numeric Rating Scale (NRS-11) score for pain intensity, Medication Quantification Scale III (MQS III), and proportion of functional improvement at one, 3, and 6 months postprocedure.

Results: GEE analyses showed a significant reduction of pain intensity in NRS-11 and functional improvement compared to baseline throughout the 6-month follow-up period in both groups ($P < 0.001$), without differences between groups. After adjusting for potential confounding variables, the NRS-11 of leg pain one month after the procedure in the RNR group was reduced less than that in the non-RNR group ($P = 0.016$), although we did not find a significant time and group interaction. After adjustment, less functional improvement was observed 3 months after the procedures in the RNR group than in the non-RNR group ($P = 0.001$), with a significant interaction between time and group ($P = 0.003$). The estimated mean MQS III values were unchanged at 6 months regardless of adjustment in both groups.

Limitations: Retrospective design and a lack of information on adjuvant nonpharmacologic therapies.

Conclusion: Epidural balloon neuroplasty may be an effective option for reducing pain in patients with chronic LSS accompanied by RNR.

Key words: Back pain, balloon, epidural space, lumbar vertebrae, neuroplasty, radicular pain, redundant nerve root, spinal stenosis

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Redundant nerve root (RNR) syndrome is a phenomenon characterized by a tortuosity of enlarged and elongated nerve roots in patients with lumbar spinal stenosis (LSS) (1-4). RNR was first reported by Verbiest in 1954 (5) and is considered a rare congenital anomaly. Although the mechanism remains unknown, in chronic spinal stenosis, a portion of the nerve root is tightened or fixed, limiting its normal movement and stretching during spinal flexion and extension, resulting in excessive lengthening redundancy (3,6,7). Although some studies have reported on the treatment and prognosis of patients with chronic LSS accompanied by RNR (8-12), there is no consensus on the treatment of RNR in patients with chronic LSS. Moreover, the treatment outcomes for symptomatic patients with chronic LSS accompanied by RNR are poor (8,9,11).

Recently, percutaneous epidural balloon neuroplasty (combined epidural adhesiolysis and balloon decompression) was developed to mechanically remove light adhesions of surrounding tissues or alleviate lumbar stenosis, which is effective for pain reduction and functional improvement in patients with chronic LSS refractory to conventional management therapies, including epidural steroid injection (13,14). Choi and colleagues (15) reported significant pain reduction and improved function for one year after combined balloon decompression and adhesiolysis (balloon neuroplasty) in patients with chronic lumbar stenosis. Moreover, a recent multicenter prospective study reported that the higher the success rate of balloon inflation for multiple target sites, the more decreased the pain intensity and improved functional status for at least for 6 months in patients with chronic refractory LSS (16). However, there are currently no studies on the effect of epidural balloon neuroplasty in patients with chronic LSS accompanied by RNR.

Therefore, in this longitudinal cohort study, we evaluated the effectiveness of epidural balloon neuroplasty in patients with chronic LSS accompanied by RNR.

Methods

Study Design and Population

This study was conducted at the pain clinic of our center and was approved by our institutional review board (2020-0876), which waived the requirement for written informed consent due to the retrospective design. We reviewed all patients with radicular leg pain and/or low back pain who underwent epidural balloon neuroplasty from January 2014 through December 2018. All patients who underwent epidural balloon neuroplasty did not respond to conservative management therapies, such as exercise therapy, physical therapy, analgesic medications, epidural blocks, or percutaneous epidural neuroplasty using a balloonless catheter (Racz or NaviCath).

This study included patients aged 20 years and older with LSS who were found to have a macroscopically distinct conus medullaris and cauda equina on lumbar magnetic resonance imaging (MRI), and who were morphologically classified as having a moderate or higher grade of LSS. The exclusion criteria were patients with a history of lumbar spinal surgery or interventional procedures within the previous 6 months; those who had a severe deformation and diseases of the lumbar spine that could alter the effect of epidural balloon neuroplasty except for spinal stenosis and herniated intervertebral disc (17,18); those in whom the procedure was not properly performed due to dural puncture; those with incomplete or missing data; those without MRI images; and those who were untreated or lost to follow-up after the procedure. For each patient, the date of the epidural balloon neuroplasty after MRI for examination was considered the start of the study.

Epidural Balloon Neuroplasty

After sterile preparation, one-percent lidocaine was infiltrated into the skin and soft tissue. A 10G guide needle was then advanced through the sacral hiatus under fluoroscopic image guidance and the epidural space was identified by injecting diluted contrast medium. After target areas were appropriately identified by epidurogram, an epidural balloon catheter (ZiNeu®, JUVENUI) was advanced through the guide needle to the area of the filling defect or the pathology site, as determined by both symptomatology and MRI findings. Epidural balloon neuroplasty with a ZiNeu catheter was performed to target sites such as the central canal, lateral recess, and intervertebral foramen (Fig. 1). The balloon was gently filled with 0.13 mL of contrast medium using a one mL Luer-Lock syringe (BD Medical), with each ballooning process limited to 5 seconds (16-19). If the patient complained of moderate to severe pain during balloon inflation, no further decompression (ballooning) was attempted, and the balloon catheter was only moved in the deflated state to avoid severe pain or damage. After adhesiolysis and decompression, a total of 6-8 mL of one-percent lidocaine mixed with

5 mg dexamethasone and 1500 IU hyaluronidase was injected at each target site after exclusion of subarachnoid or intravascular filling with contrast medium. At the end of the procedure, a Perifix® epidural catheter (B. Braun) was inserted at the main target site through the ZiNeu catheter and 4 mL 10% hypertonic saline was injected via the Perifix catheter in the recovery room.

Demographic Data and Outcome Assessments

Baseline characteristics, including age, gender, body mass index (BMI), diabetes, hypertension, pain intensity, medications, and pain duration were retrieved from electronic medical records. The location and grade of the LSS and spondylolisthesis were recorded

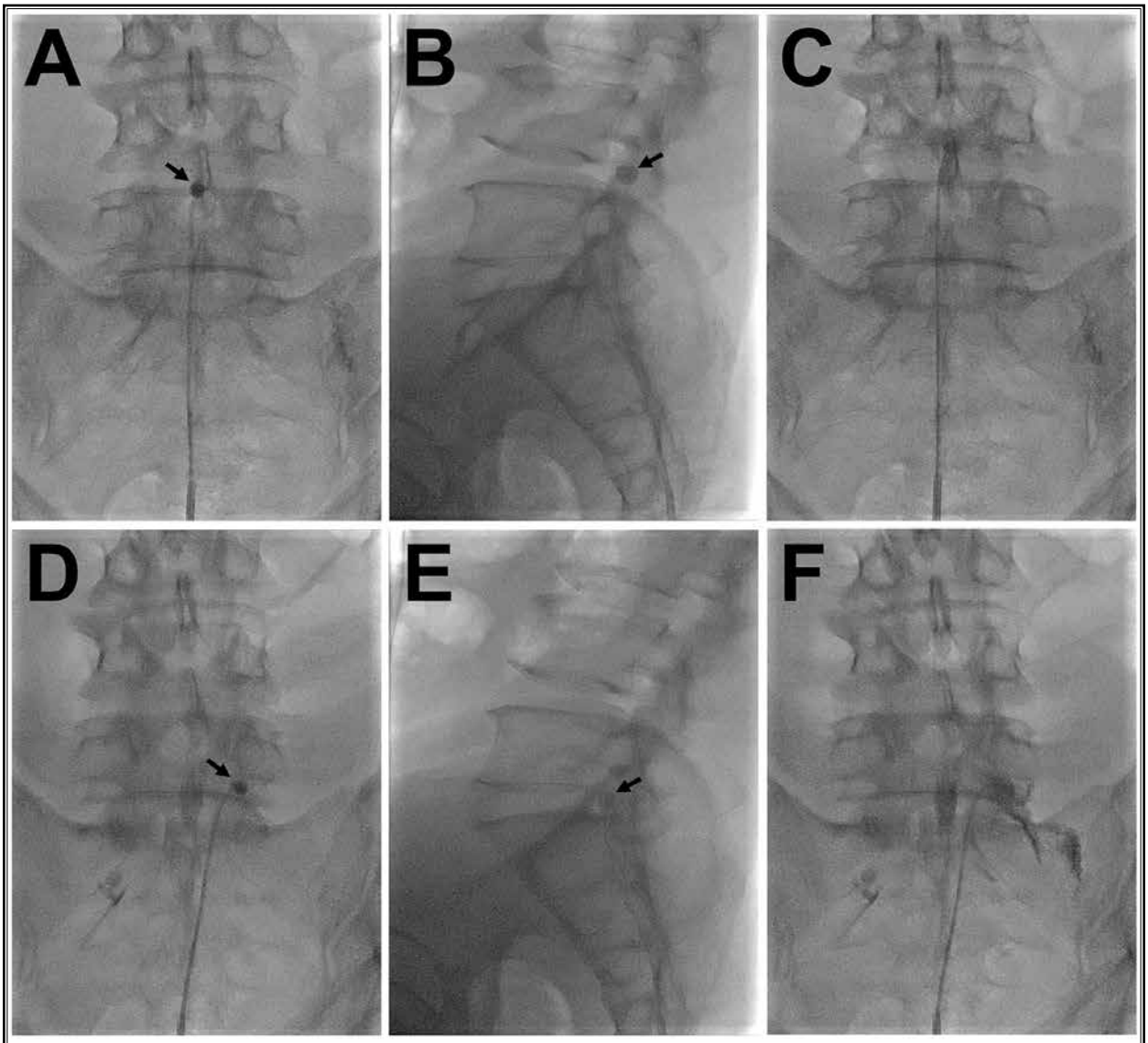

Fig 1. *Serial fluoroscopic images of epidural balloon neuroplasty. (A) Anteroposterior view showing the epidural balloon neuroplasty catheter placed in the L4-L5 intervertebral space. (B) Lateral view showing the epidural balloon neuroplasty catheter placed in the L4-L5 intervertebral space. (C) Fluoroscopic view showing the central diffusion of contrast medium at the L4-5 epidural space after epidural balloon neuroplasty. (D) Anteroposterior view showing the epidural balloon neuroplasty catheter placed in the right L5 intervertebral foramen. (E) Lateral view showing the epidural balloon neuroplasty catheter placed in the right L5 intervertebral foramen. (F) Fluoroscopic view showing the foraminal diffusion of contrast medium at the right L5 intervertebral foramen after epidural balloon neuroplasty.*

from MRI images. Intervention characteristics, including target level and complications, were also recorded.

The study population was divided into 2 groups according to lumbar MRI findings: patients with LSS accompanied by RNR (RNR group) and those with LSS without RNR (non-RNR group). To evaluate the effectiveness of the epidural balloon neuroplasty in the groups with and without RNR, the study outcomes were based on improvement in pain intensity, change in medication profiles for pain control and symptom management, and improved physical functional status at one, 3, and 6 months postprocedure. An 11-point Numeric Rating Scale (NRS-11) was used to assess the intensity of pain (0 for no pain to 10 for the worst possible pain) (20). The changes in medication for pain control were measured using the Medication Quantification Scale III (MQS III) (21). Improvement in physical functional status was defined as an amelioration of walking distance and activities of daily living (22).

Additionally, we compared the postprocedure adverse effects between the 2 groups. After the balloon neuroplasty, patients were advised to continue their formerly prescribed analgesic medications but to adjust their doses according to the patient's remnant pain intensity at each follow-up visit. Also, nonpharmacologic management therapies, such as exercise and physical therapy, and additional interventions were allowed if the patient wanted them or they were available.

Radiological Evaluation

We analyzed MRI images using a photo archiving and communication system (PetaVision, Version 2.1). The grades, locations, and total numbers of LSS were measured on T2-weighted images. The presence of RNR was measured on midsagittal images of the lumbar column, and analysis was performed by consensus among the 3 investigators (2 pain physicians and one radiologist each with more than 10 years of clinical experience).

Statistical Analysis

In the analysis of the baseline data of the study cohort, continuous variables were presented as mean ± standard deviation or medians with the interquartile range if skewed. Categorical variables were presented as frequencies and percentages. To assess baseline differences between the 2 groups, continuous variables were compared using Student's t test or the Mann–Whitney U test, as appropriate. Categorical variables were compared, as appropriate, using Pearson's r,χ^2,or Fisher's exact test to assess the differences between the 2 groups.

To replace missing data resulting from the 6-month follow-up, a generalized estimating equations (GEE) model was used. Data manipulation and statistical analyses were conducted using IBM SPSS Statistics for Windows, version 22.0 (IBM Corp.) and Stata Version 13.1 (StataCorp LP). All reported *P* values are 2-sided, and $P < 0.05$ was considered statistically significant.

Results

Study Population

During the study period, 1,218 patients who underwent epidural balloon neuroplasty were enrolled in the entire cohort, 425 of whom were excluded based on the study criteria. Finally, this study included a total of 793 patients, who were divided into either the RNR or non-RNR group (Fig. 2). Of the study patients, 572 (72.1%) had RNR. The determination of RNR showed high consistency among this study's 3 investigators (Fleiss' kappa value = 0.912). Table 1 shows the baseline and intervention characteristics of the study population. The median NRS-11score of pain intensity was 7.0 (6.0–8.0) for both back and leg pain. The median value of MQS III was 6.8 and the median value of pain duration was 24 months.

Study Outcomes

The unadjusted estimation of values and differences between the non-RNR and RNR groups from baseline for the NRS-11 score of pain and MQS III score over the 6-month follow-up period are shown in Table 2. In both groups, GEE analyses revealed a significant improvement in the estimated mean NRS-11 score of pain intensities compared to that at baseline throughout the study period ($P < 0.001$). Comparison of back and leg pain NRS-11 scores between the 2 groups using a GEE model showed no significant differences that affected the changes in NRS-11 scores throughout the study period except for the leg pain score at one month ($P = 0.002$). Neither group showed significant improvement in mean MQS III score compared to that at baseline throughout the study period. Comparisons of the MQS III scores between the 2 groups using a GEE model showed no significant differences that affected the changes in MQS III scores throughout the study period. The *P* values of the interactions between the groups and times for back pain, leg pain, and MQS III

score were 0.680, 0.089, and 0.657, respectively (Table 2).

The adjusted estimation of values and differences between the 2 groups from baseline for the NRS-11 score of pain and MQS III score over the 6-month follow-up period is shown in Table 3. Age, gender, BMI, diabetes, hypertension, central stenosis grading, foraminal stenosis grading, and spondylolisthesis were included to adjust for demographic differences. In both groups, GEE analyses also revealed a significant improvement in the adjusted estimation of the mean NRS-11 score compared to that at baseline throughout the study period ($P < 0.001$). Comparison of the back and leg pain scores between the 2 groups showed no significant differences that affected the changes in NRS-11 scores throughout the study period except for the leg pain score at one month. The NRS-11 score of leg pain at one month after the procedures in the RNR group was reduced less than that in the non-RNR group ($P = 0.016$). Neither group showed significant improvement in the mean MQS III score compared to that at baseline throughout the study period. Comparisons of MQS III scores between the 2 groups showed no significant differences that affected the changes in MQS III scores throughout the study period. The *P* values of the interactions between the groups and times for back pain, leg pain, and MQS III were 0.678, 0.097, and 0.594, respectively (Table 3).

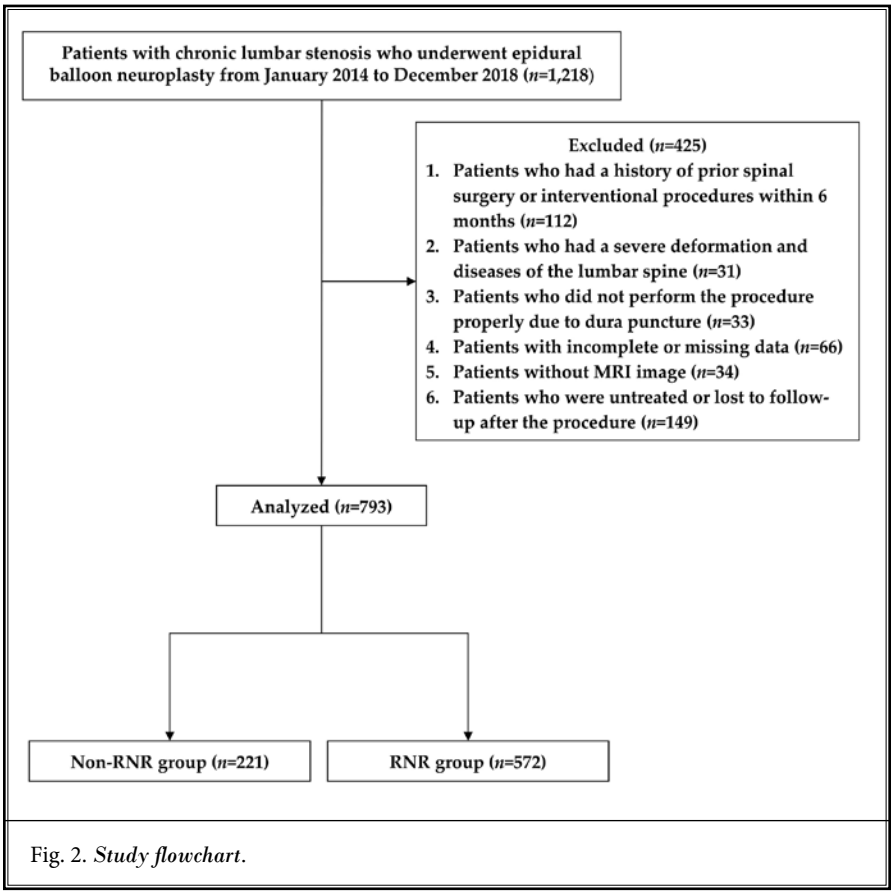

Fig. 2. *Study flowchart.*

The estimated proportions of improved physical function over the 6-month period after epidural balloon neuroplasty in both groups are shown in Table 4. Comparisons of physical functional status between the 2 groups showed that the estimated proportion of improved function was less at 3 months after the procedure in the RNR group than that in the non-RNR group ($P = 0.001$), whereas the differences at one and 6 months were not significant. The adjusted *P* value of the interaction between the groups and time for physical functional status was 0.003 (Table 4).

Among the 793 patients, a total of 15 patients (1.9%) had a complication. In the RNR group, 2 patients had vascular injections, 3 patients showed transient motor weakness, and 6 patients showed transient hypotension. In comparison, in the non-RNR group, only 4 patients showed transient hypotension. There were no significant differences between the 2 groups. During the follow-up period of 6 months after the epidural balloon neuroplasty, a total of 337 patients (42.5%) underwent an additional interventional procedure. However, there was no significant difference between the 2 groups (Table 5).

Discussion

The results of this study demonstrate that epidural balloon neuroplasty decreased pain intensity and improved physical functional status for at least 6 months in patients with chronic LSS with and without RNR. The functional improvement after the balloon neuroplasty may be less in patients with chronic LSS accompanied by RNR than in those without RNR.

Table 1. *Baseline characteristics of the study population.*

Variables	Total (n = 793)	Non-RNR group (n = 221)	RNR group (n = 572)	*P* value
Age, years	66.8 ± 10.4	60.8 ± 11.7	69.2 ± 8.8	< 0.001
Gender, male	389 (49.1%)	113 (51.1%)	276 (48.3%)	0.467
BMI, kg/m^2	24.9 ± 3.1	24.3 ± 2.9	25.1 ± 3.1	< 0.001
Diabetes	150 (18.9%)	31 (14.0%)	119 (20.8%)	0.029
Hypertension	346 (43.6%)	84 (38.0%)	262 (45.8%)	0.047
Pain intensity (NRS-11)				
Back pain	7.0 (6.0 – 8.0)	7.0 (6.0 – 8.0)	7.0 (6.0 – 8.0)	0.078
Leg pain	7.0 (6.0 – 8.0)	7.0 (6.0 – 8.0)	7.0 (6.0 – 8.0)	0.338
MQS III	6.8 (4.1 – 12.0)	6.3 (4.1 – 11.7)	6.8 (4.1 – 12.2)	0.105
Pain duration, months	24.0 (20.0 – 24.0)	20.0 (15.0 – 24.0)	24.0 (21.0 – 25.0)	0.359
Pain location				
Back/ leg/ both	59 (7.4%)/228 (28.8%)/ 506 (63.8%)	14 (6.3%)/ 67 (30.3%)/ 140 (63.3%)	45 (7.9%)/161 (28.1%)/ 366 (64.0%)	0.657
Central stenosis grading				
Mild/ Moderate/ Severe	237 (29.9%)/ 152 (19.2%)/ 372 (46.9%)	118 (53.4%)/ 38 (17.2%)/ 44 (19.9%)	119 (20.8%)/ 114 (19.9%)/ 328 (57.3%)	< 0.001
Foraminal stenosis grading				
Mild/ Moderate/ Severe	257 (32.4%)/ 206 (26.0%)/ 210 (26.5%)	83 (37.6%)/ 48 (21.7%)/ 45 (20.4%)	174 (30.4%)/ 158 (27.6%)/ 165 (28.8%)	0.016
Spondylolisthesis	414 (52.2%)	89 (40.3%)	325 (56.8%)	< 0.001
Target level				0.152
1 level	378 (47.7%)	118 (53.4%)	260 (45.5%)	
2 levels	332 (41.9%)	86 (38.9%)	246 (43.0%)	
3 levels	75 (9.5%)	16 (7.2%)	59 (10.3%)	
> 4 levels	8 (1.0%)	1 (0.5%)	7 (1.2%)	

Study population were divided into two groups according to lumbar magnetic resonance imaging: patients with lumbar spinal stenosis accompanied by redundant nerve roots (RNR group) and those with lumbar spinal stenosis without redundant nerve roots (non-RNR group). Values are expressed as means ± standard deviations, medians (interquartile ranges), or numbers (percentages). BMI, body mass index; NRS-11, numeric rating scale; MQS III, medication quantification scale; RNR, redundant nerve roots.

Several recent studies reported poor surgical outcomes in patients with chronic low back pain with RNR (8,9). A study on nonsurgical treatment reported that lumbar epidural steroid injection was also significantly less effective in patients with RNR than those without RNR (11). Previous studies have suggested that the lack of effective surgical and nonsurgical treatment in patients with RNR can partially be explained by histological changes in nerve roots (9,11). Histological biopsy in RNR has shown decreased nerve fiber density in nerve tissue. This reduction occurs due to the disarrangement and degenerative changes of nerve fibers, including their demyelination and endoneural fibrosis, as well as from Schwann cell proliferation (3,23,24).

Based on these histological changes, RNR can be classified into either type 1 or type 2(3,25). Type 1 can be sufficiently treated with decompressive laminectomy alone, whereas type 2, in which histologic degeneration is irreversible, has shown poor surgical outcomes. Therefore, it might be important to perform decompression by surgical or nonsurgical methods in early-stage RNR to prevent the irreversible histological changes that occur during the progression from type 1 to type 2.

Epidural neuroplasty using an inflatable balloon catheter is newly developed for safe and successful epidural decompression and adhesiolysis (15,16,26) and has shown an excellent therapeutic effect in patients with intractable lumbar radicular and back pain (15,16). Epidural balloon neuroplasty provides significant pain reduction and functional improvement compared to conventional neuroplasty with Racz-type catheters in patients with chronic LSS (13,27). However, to our knowledge, no studies have reported the effectiveness

Table 2. *Changes in the estimated pain and medication quantification scores after epidural balloon neuroplasty in patients with chronic lumbar spinal stenosis with and without accompanying redundant nerve roots.*

Variables	Time	Estimated pain score (95% CI)		Estimated difference (95% CI)*	*P* value
		Non-RNR group (n = 221)	RNR group (n = 572)		
Back pain (NRS-11)	Baseline	6.4 (6.1 to 6.8)	6.8 (6.6 to 7.0)	0.4 (0.0 to 0.7)	0.068
	One month	4.5 (4.1 to 4.8)†	4.8 (4.6 to 5.1)†	0.4 (0.0 to0.8)	0.057
	3 months	4.4 (4.0 to 4.9)†	4.7 (4.4 to 4.9)†	0.2 (-0.3 to 0.8)	0.420
	6 months	4.5 (3.9 to 5.1)†	4.4 (4.1 to 4.8)†	0.0 (-0.7 to 0.7)	0.911
Leg pain (NRS-11)	Baseline	7.0 (6.7 to 7.3)	7.1 (7.0 to 7.3)	0.1 (-0.2 to 0.5)	0.424
	One month	4.4 (4.1 to 4.7)†	5.0 (4.8 to 5.2)†	0.6 (0.2 to 0.9)	0.002
	3 months	4.5 (4.1 to 4.9)†	4.7 (4.4 to 4.9)†	0.1 (-0.3 to 0.6)	0.574
	6 months	4.6 (4.1 to 5.1)†	4.6 (4.3 to 4.9)†	0.0 (-0.6 to 0.6)	0.962
MQS III	Baseline	7.9 (7.0 to 8.8)	8.7 (8.1 to 9.2)	0.8 (-0.3 to 1.9)	0.164
	One month	8.4 (7.5 to 9.4)	9.1 (8.5 to 9.6)	0.6 (-0.4 to 1.7)	0.252
	3 months	8.7 (7.8 to 9.7)	9.0 (8.4 to 9.6)	0.3 (-0.9 to 1.4)	0.647
	6 months	8.1 (7.0 to 9.1)	8.2 (7.5 to 8.8)	0.1 (-1.2 to 1.3)	0.917

The study population was divided into 2 groups according to lumbar magnetic resonance imaging: patients with lumbar spinal stenosis accompanied by redundant nerve roots (RNR group) and those with lumbar spinal stenosis without redundant nerve roots (non-RNR group). A numerical rating scale (NRS-11) was used to assess the intensity of both lower back and leg pain. A generalized estimating equation model was used in the statistical analysis. Data are presented as the estimated mean with 95% confidence interval (CI). The *P* values of the interactions between the groups and times were 0.680, 0.089, and 0.657 for back pain, leg pain, and MQS III, respectively. *Estimated difference in values between groups. †$P < 0.001$ compared to baseline in each group. MQS III, medication quantification scale; RNR, redundant nerve roots.

Table 3. *Adjusted changes in the estimated pain and medication quantification scores after epidural balloon neuroplasty in patients with chronic lumbar spinal stenosis with and without accompanying redundant nerve roots.*

Variables	Time	Estimated pain score (95% CI)		Estimated difference (95% CI)*	Adjusted *P* value
		Non-RNR group (n = 221)	RNR group (n = 572)		
Back pain (NRS-11)	Baseline	6.5 (6.1 to 6.8)	6.8 (6.6 to 7.0)	0.3 (-0.1 to 0.8)	0.108
	One month	4.5 (4.1 to 4.8)†	4.8 (4.6 to 5.0)†	0.4 (-0.1 to 0.8)	0.093
	3 months	4.5 (4.0 to 4.9)†	4.7 (4.4 to 4.9)†	0.2 (-0.4 to 0.8)	0.484
	6 months	4.5 (3.9 to 5.1)†	4.4 (4.1 to 4.8)†	0.0 (-0.8 to 0.7)	0.892
Leg pain (NRS-11)	Baseline	7.0 (6.7 to 7.4)	7.1 (6.9 to 7.3)	0.1 (-0.3 to 0.5)	0.721
	One month	4.5 (4.2 to 4.8)†	5.0 (4.8 to 5.2)†	0.5 (0.1 to 0.9)	0.016
	3 months	4.6 (4.2 to 5.0)†	4.6 (4.4 to 4.9)†	0.1 (-0.4 to 0.6)	0.784
	6 months	4.6 (4.1 to 5.1)†	4.5 (4.2 to 4.9)†	-0.1 (-0.7 to 0.5)	0.800
MQS III	Baseline	7.5 (6.5 to 8.5)	8.8 (8.2 to 9.4)	1.3 (0.1 to 2.5)	0.036
	One month	8.1 (7.1 to 9.1)	9.2 (8.6 to 9.7)	1.1 (-0.1 to 2.3)	0.076
	3 months	8.4 (7.4 to 9.4)	9.1 (8.5 to 9.7)	0.7 (-0.5 to 2.0)	0.254
	6 months	7.8 (6.7 to 8.9)	8.3 (7.6 to 8.9)	0.5 (-0.8 to 1.8)	0.470

The study population was divided into 2 groups according to lumbar magnetic resonance imaging: patients with lumbar spinal stenosis accompanied by redundant nerve roots (RNR group) and those with lumbar spinal stenosis without redundant nerve roots (non-RNR group). A numerical rating scale (NRS-11) was used to assess the intensity of both lower back and leg pain. A generalized estimating equation model was used in the statistical analysis. Age, gender, body mass index, diabetes, hypertension, central stenosis grading, foraminal stenosis grading, and spondylolisthesis were included to adjust for demographic differences. Data are presented as estimated means with 95% confidence intervals (CIs). The *P* values of the interactions between the groups and times were 0.678, 0.097, and 0.594 for back pain, leg pain, and MQS III, respectively. *Estimated difference in values between groups. †$P < 0.001$ compared to baseline in each group. MQS III, medication quantification scale; RNR, redundant nerve roots.

Table 4. *Estimated proportions of improved function after epidural balloon neuroplasty in patients with chronic lumbar spinal stenosis with and without accompanying redundant nerve roots.*

Variables	Time	Estimated proportion (95% CI)		Estimated difference (95% CI)*	*P* value	Adjusted P†
		Non-RNR group (n = 221)	RNR group (n = 572)			
Function	One month	0.7 (0.6 to 0.7)	0.7 (0.6 to 0.7)	-0.1 (-0.5 to 0.3)	0.612	0.680
	3 months	0.8 (0.7 to 0.8)	0.6 (0.6 to 0.7)	-0.8 (-1.2 to -0.3)	0.001	0.001
	6 months	0.6 (0.5 to 0.7)	0.6 (0.6 to 0.7)	0.0 (-0.5 to 0.4)	0.827	0.777

The study population was divided into 2 groups according to lumbar magnetic resonance imaging: patients with lumbar spinal stenosis accompanied by redundant nerve roots (RNR group) and those with lumbar spinal stenosis without redundant nerve roots (non-RNR group). Data are presented as the estimated proportions with 95% confidence intervals (CIs). A generalized estimating equation model was used in the statistical analysis. *Estimated difference in values between groups. †Adjusted *P* values considering age, gender, body mass index, diabetes, hypertension, central stenosis grading, foraminal stenosis grading, and spondylolisthesis as covariates. The adjusted *P* value of the interaction between the group and time was 0.003. RNR, redundant nerve roots.

Table 5. *Additional interventional procedures in the 6-month follow-up period for the study population.*

Additional procedures	Non-RNR group (n = 221)	RNR group (n = 572)	*P* value
Epidural block	61 (27.6%)	185 (32.3%)	0.200
Epidural balloon neuroplasty	8 (3.6%)	24 (4.2%)	0.842
Neuroplasty without balloon	1 (0.5%)	6 (1.0%)	0.680
Pulsed radiofrequency	4 (1.8%)	17 (3.0%)	0.464
Others*	7 (3.2%)	24 (4.2%)	0.683

Data are expressed as numbers (%). During the 6-month follow-up period after the epidural balloon neuroplasty, 337 (42.5%) patients underwent additional interventional procedures. *Others included lumbar sympathetic block, lumbar medial branch block, percutaneous endoscopic lumbar decompression, prolotherapy, and trigger point injections. Note that one patient in the non-RNR group received pulsed radiofrequency after epidural block, and another patient in the RNR group received one more epidural balloon neuroplasty after pulsed radiofrequency during the follow-up period. RNR, redundant nerve roots.

of epidural balloon neuroplasty in patients with LSS accompanied by RNR.

Our results show that epidural balloon neuroplasty effectively decreased pain intensity and improved physical function status during one, 3, and 6 months of follow-up in patients with chronic LSS accompanied by RNR. Although not fully understood, the following mechanisms may provide evidence for the effectiveness of epidural balloon neuroplasty.

The effect of epidural balloon neuroplasty in decreasing pain intensity of patients with LSS accompanied by RNR may result from the advantages of epidural balloon neuroplasty, which offers a combination of physical effects such as adhesion removal and decompression, as well as chemical effects through the use of local anesthetics, steroids, and hypertonic saline. In patients with chronic LSS accompanied by RNR, accurate drug injection may be difficult due to severe adhesions to the lesion site. However, epidural balloon neuroplasty involves removal of adhesions and insertion of a catheter into the lesion site, enabling the accurate and repeated injection of drugs such as local anesthetics, steroids, and hypertonic saline (15,16). In addition, local anesthetics stabilize the sensitized nerves and decrease the excitability of the sympathetic nerve fibers (28), while steroids have anti-inflammatory actions (29). Finally, hypertonic saline reduces neural activity and cell edema and has an analgesic effect by expressing a hyperosmolar effect through the semipermeable membrane of the nerve root (30).

The results of this study show significant differences between the 2 groups in the improvement of leg pain at one month. However, this difference was temporary and we observed no significant difference in the reduction of pain intensity between the 2 groups at 3 months and 6 months, as well as the overall 6-month follow-up period. We also observed a significant difference in the physical functional status improvement between the 2 groups during the overall follow-up period of 6 months: analysis by period showed no significant difference between the 2 groups at one and 6 months, while the difference was significant at 3 months. This partially supports the existing general argument that treatment and functional improvement after balloon neuroplasty may have limited effectiveness in patients with LSS accompanied by RNR.

Our research has some limitations. First, the main limitations of this study were those inherent to its retrospective design, including the possibility of reporting

undocumented factors or biases. However, we tried to reduce the effect of confounding factors by using GEE to adjust for variables that could affect the outcome. Second, this study lacked information on adjuvant nonpharmacologic therapies, such as exercise therapy and physical therapy in individual patients. Finally, definitions of the improvement in physical functional status vary. A different definition may have affected our results. However, based on previous reports (16,22), we carefully designated the response criteria to reflect the clinically meaningful functional status of patients.

Conclusion

In conclusion, epidural balloon neuroplasty may be an alternative treatment option to reduce pain intensity in patients with chronic LSS, even those accompanied by RNR. However, functional improvement after balloon neuroplasty may be limited in these patients.

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