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Randomized Trial

Effects of Transforaminal Balloon Treatment in Patients with Lumbar Foraminal Stenosis: A Randomized, Controlled, Double-Blind Trial

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Background: Lumbar spinal stenosis is a common condition in the elderly. Although balloon treatment is a well-known therapeutic method in specific pain conditions, applying the balloon treatment in patients with lumbar spinal stenosis is not yet well established.

Objectives: We tested the therapeutic effect of transforaminal balloon treatment with a Fogarty balloon catheter on body pain and functional performance in patients with severe lumbar spinal stenosis.

Study Design: Prospective, randomized, double-blinded, active control trial.

Setting: A tertiary, interventional pain management practice, specialty referral center.

Methods: Sixty-two patients with refractory unilateral radiculopathy aggravated by walking were enrolled and randomly assigned to receive transforaminal steroid injection after transforaminal balloon treatment using a 3 Fr balloon catheter (n = 32) or the same procedure without balloon treatment (n = 30). The patients were prohibited from making any alterations to their medications during the 12 weeks of their follow-up period. After the first 12 weeks, the patients who had persistent symptoms or unbearable pain were allowed to increase the dose of analgesics or to receive additional interventional treatment.

Outcome Assessment: Visual analogue scale (VAS) pain scores for the leg and lower back, Oswestry disability index (ODI), and claudication distance were measured at 2, 4, 8, and 12 weeks post procedure. During the 52 weeks of the overall follow-up period, the patients achieving ≥ 50% leg pain relief without additional treatment or increasing the dose of analgesics were evaluated.

Results: Significant improvement occurred compared to baseline in VAS ($P < 0.001$), ODI ($P < 0.001$), and claudication distance ($P < 0.001$) in the balloon group during the overall follow-up period, whereas the improvement in ODI ($P < 0.05$) and claudication distance ($P < 0.05$) in the control group persisted for 8 weeks. The balloon group showed better improvement in leg VAS ($P < 0.05$), ODI ($P < 0.05$), and claudication distance ($P < 0.05$) than the control group at all post-procedure assessment points. Kaplan-Meier analysis of the duration of the patients achieving ≥ 50% leg pain relief without additional treatment or increasing the dose of analgesics showed a significant intergroup difference between the balloon and control ($P = 0.003$) groups. Six patients (18.8%) in balloon group maintained > 50% pain relief for 52 weeks whereas no patient (0%) did in control group.

Limitations: Our study is an active-controlled randomized design with a relatively small number of patients.

Conclusion: Transforaminal balloon treatment leads to both significant pain relief and functional improvement in a subset of patients with refractory spinal stenosis.

Institutional Review: This study was approved by the Institutional Review Board of the Asan Medical Center.

Key words: Neurogenic claudication, lumbar foraminal stenosis, transforaminal balloon treatment, Fogarty catheter

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Lumbar spinal stenosis is a common condition in the elderly that causes pain in the lower back and extremities, impaired walking, and various forms of disability. The majority of symptomatic patients managed conservatively report no substantial change over the course of one year (1,2). Although there are ample studies that demonstrate efficacy with lumbar epidural steroid injections in managing chronic low back and lower extremity pain (3-14), epidural steroid injections in managing spinal stenosis are occasionally not effective in leg pain and have no beneficial effect on claudication distance (15-213). This is because the symptoms of spinal stenosis reflect a combination of pathological processes due to space-occupying lesions or perineural fibrosis, including interruption of blood flow, ischemia, venous congestion, intraneural fibrosis, and decreased nutrient transport (22-25). Although surgery may be recommended for patients who do not respond to non-operative treatments, older individuals with various comorbidities are not always surgical candidates due to their limited physical status.

Percutaneous lysis of adhesions or interspinous distraction is regarded as a non-surgical modality that reduces radicular pain in patients with degenerative spinal stenosis who are unresponsive to conservative care (26-33). Recently, Raffaeli et al (34) showed that the Fogarty balloon is useful for the removal of fat, mild fibrosis, and adhesions occluding the spinal canal. Using the Fogarty catheter with a transforaminal approach, we previously reported the successful treatment of several patients with severe lumbar foraminal stenosis who had persistent symptoms despite repeated conventional steroid injections (35). Until now, there have been no randomized controlled trials on transforaminal balloon treatment in selected patients with spinal stenosis. We examined the therapeutic effect of transforaminal balloon treatment using the Fogarty balloon on body pain, functional performance, and claudication distance in patients with lumbar foraminal stenosis who were refractory to conventional treatment.

Methods

Patients

This randomized, double-blind, active-controlled study was conducted at the Asan Medical Center, Seoul, Korea. The study protocol was approved by the Institutional Review Board of our institution, and written informed consent was obtained from all patients. Between July 2010 and August 2011, patients 45 - 85 years of age with leg pain were examined to ascertain their eligibility. After clinical and radiological assessment, the study participants included patients with unilateral radicular pain with positive provocation factors that were not relieved by routine conservative treatments consisting of physiotherapy, exercise, analgesic medications, and epidural steroid injection for at least 6 months. Positive provocation factors included leg symptoms elicited or aggravated by walking but relieved by sitting down. A thorough history and physical examination was performed to rule out the confounding diagnosis of vascular disease or other origins. All eligible patients received diagnostic conventional fluoroscopically guided transforaminal epidural blockade with local anesthetic and steroid before enrollment, and the patients who showed no or minimal response in pain reduction (< 50%) to the epidural blockade that did not exceed one month were enrolled in this study. The exclusion criteria included acute back or leg pain; patients who developed signs of progressive neurologic deficits, including muscle atrophy and abnormal tendon reflexes; and patients with a history of prior spine surgery, allergic response to steroid or contrast dye, and bleeding diathesis or overt coagulopathy. Patients with bilateral radiculopathy or spinal stenosis at more than 3 levels were also excluded.

Technique of Balloon Treatment

The patients were randomly assigned to one of 2 groups: balloon group (n = 32) receiving transforaminal steroid injection after transforaminal balloon treatment using a 3 Fr balloon catheter and the control group (n = 30) receiving the same procedure without balloon treatment. The computer-generated randomization sequence was concealed throughout the study from both the participants and the investigator.

No premedication or sedatives were used. The patient was placed in the prone position on an operating table, and a pillow was placed under the abdomen to minimize lumbar lordosis. After sterile preparation of the surgical field, the skin and soft tissue were anesthetized with 1 mL 1% lidocaine. An 18-gauge R-K needle (Epimed International, Gloversville, USA) was introduced into the affected intervertebral foramen relevant to each patient. During the procedure, fluoroscopy was used to visualize the target region, and the needle tip was confirmed to be in the anterior epidural space. Proper positioning of the needle tip

was confirmed by injection of a contrast medium (Omnipaque, Nycomed Imaging, Oslo, Norway) through the needle. A 3-French Fogarty catheter (Edward Lifescience, Irvine, CA) was gently introduced into the epidural space of the relevant intervertebral foramen and advanced into the medial portion of the stenotic area under fluoroscopic guidance (Fig. 1). If introduction of the catheter to the appropriate portion of the epidural space could not be obtained, the patient was dropped from the study. To avoid damaging or tearing the balloon catheter with the sharp edge of the bevel, the R-K needle was slightly withdrawn so that the needle tip was positioned just outside the foraminal inlet. Sequential repeated inflation and deflation of the balloon were performed throughout the affected region, in specific, at least 5 consecutive points from the medial side of the lateral recess to the outlet of the neural foramen, with each balloon session lasting less than 5 seconds and repeated 3 times per each session (26). The catheter was pre-filled with contrast media, and the maximal inflated balloon diameter was determined within 6 mm by injecting 0.13 mL of contrast media. The extent of balloon inflation volume was adjusted by degree of pain; if moderate to severe pain during the balloon inflation was noted, no further attempt at treatment was made due to safety reasons. After removing the Fogarty catheter carefully, the R-K needle was reinserted. Under fluoroscopy, the tip position at the anterior epidural space was confirmed, and then 3 mL of a mixture of 0.8% lidocaine, 20 mg of triamcinolone acetate, and 1,500 IU of hyaluronidase was administered.

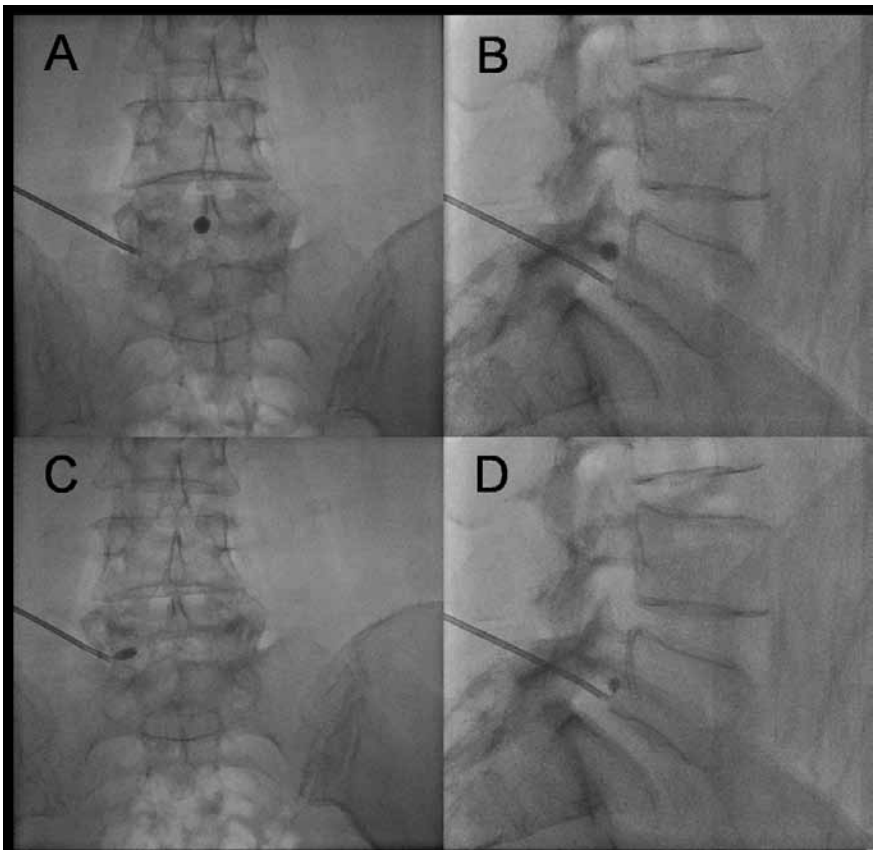

Fig. 1. *A serial fluoroscopic image of anteroposterior (A, C) and lateral views (B, D) of the lumbar spine during balloon decompressive foraminoplasty using a 3 Fr Fogarty catheter filled with contrast dye (0.13 mL). Balloon treatment was performed from the medial side of the intervertebral foramen (upper) to the lateral recess (bottom). Note the squeezed balloon shadow at the foraminal inlet (C), which suggests intervertebral foraminal stenosis.*

Measured Variables and Follow-up

All outcome assessments were conducted by an independent physician who was blinded to the nature of the study design and assigned treatment group. To obtain the baseline characteristics, each patient underwent a standard history and physical examination. Outcome measures were well validated, and accepted standards of functional status and walking ability were assessed according to hospital visits at baseline and at 2, 4, 8, and 12 weeks after the procedure. Prior to the procedure, all patients were instructed in the use of a 100-mm visual analogue scale (VAS, no pain to unbearable pain 100) and Oswestry disability index (ODI) to obtain a baseline value. ODI, consisting of a 10-item self-administered questionnaire, is considered a useful evaluating tool for low back functional outcomes (36). To assess neurogenic claudication distance, the actual claudication distance was measured using a treadmill test, which was a modification of the protocol described by Tomkins et al (37). Each patient was asked to walk on a treadmill at a self-selected speed until they had to stop due to their symptoms, or until a time limit of one hour had been reached. At 2, 4, 8, and 12 weeks post procedure, patients revisited our clinic and completed these measurements.

The primary outcomes were the mean differences from baseline pain as measured by VAS at 2, 4, 8, and 12 weeks and the number of patients achieving ≥ 50% leg pain relief during 52 weeks without additional treatment or increasing the dose of analgesics. Secondary outcomes were changes in ODI and claudication distance, patient satisfaction with treatment, and incidence of adverse events. Patients were asked to report any adverse events to the physician at each visit. They also could report by telephone at any other time for further management or advice. All adverse events including paresthesia, neuralgia, numbness, and motor weakness were recorded. All procedures were performed by a single operator. After the procedure, all participants were advised to continue medications that had been previously prescribed for all kinds of degenerative diseases. These patients were prohibited from making any alterations to their medications during the 12 weeks of their follow-up period. After the first 12 weeks, the patients who had persistent symptoms or unbearable pain were allowed to increase the dose of analgesics or to receive additional interventional treatment, and during 40 weeks of further follow-up period, the patients achieving at least 50% leg pain relief without additional treatment or increasing the dose of analgesics were evaluated.

Statistical Analysis

Statistical analyses were performed using the statistical package SPSS 12.0 for windows (SPSS Inc., Chicago, IL). Demographic data within the groups were compared by using the chi-square test or the Fisher's exact test or unpaired t-test. Two-way repeated measures of analysis of variance with Bonferroni tests for multiple comparisons were used to compare the changes from baseline values of each variable post procedure, and at 2, 4, 8, and 12 weeks. The Kaplan-Meier method was used to determine the duration of the patient's achieving at least 50% leg pain relief without additional treatment in both groups; the curves were compared using the log rank test (Mantel-Cox). Values were estimated as mean ± SD. A value of $P < 0.05$ was considered statistically significant.

Results

Study Population

Of 198 patients with lumbar spinal stenosis screened, 72 patients entered the protocol and were randomized (Fig. 2). Two patients from the balloon group and 2 patients from the control group did not receive allocated intervention because of insertion failure of the balloon catheter. Two patients from the balloon group and 3 patients in the control group were lost to follow-up. Data from one patient in the control group were not used because of incomplete data collection. Thus, data from 62 participants (32 balloon and 30 control) were analyzed for the study. There were no differences between the groups in the demographic data and other medical conditions (Table 1).

Primary Outcome

For leg pain, there was a significant interaction between the groups and time for the mean changes in VAS scores ($P < 0.001$). In the balloon group, VAS scores were lower at all post-procedure assessment points compared with baseline ($P < 0.001$). In the control group, VAS scores improved at all assessment points compared with baseline ($P < 0.001$) except at 12 weeks ($P = 0.004$) (Fig. 3). When comparing leg pain improvement to baseline, the balloon group showed better improvement compared with the control group at all post-procedure assessment points ($P < 0.05$) (Table 2). For back pain, there was a statistically significant interaction between the group and time for the mean

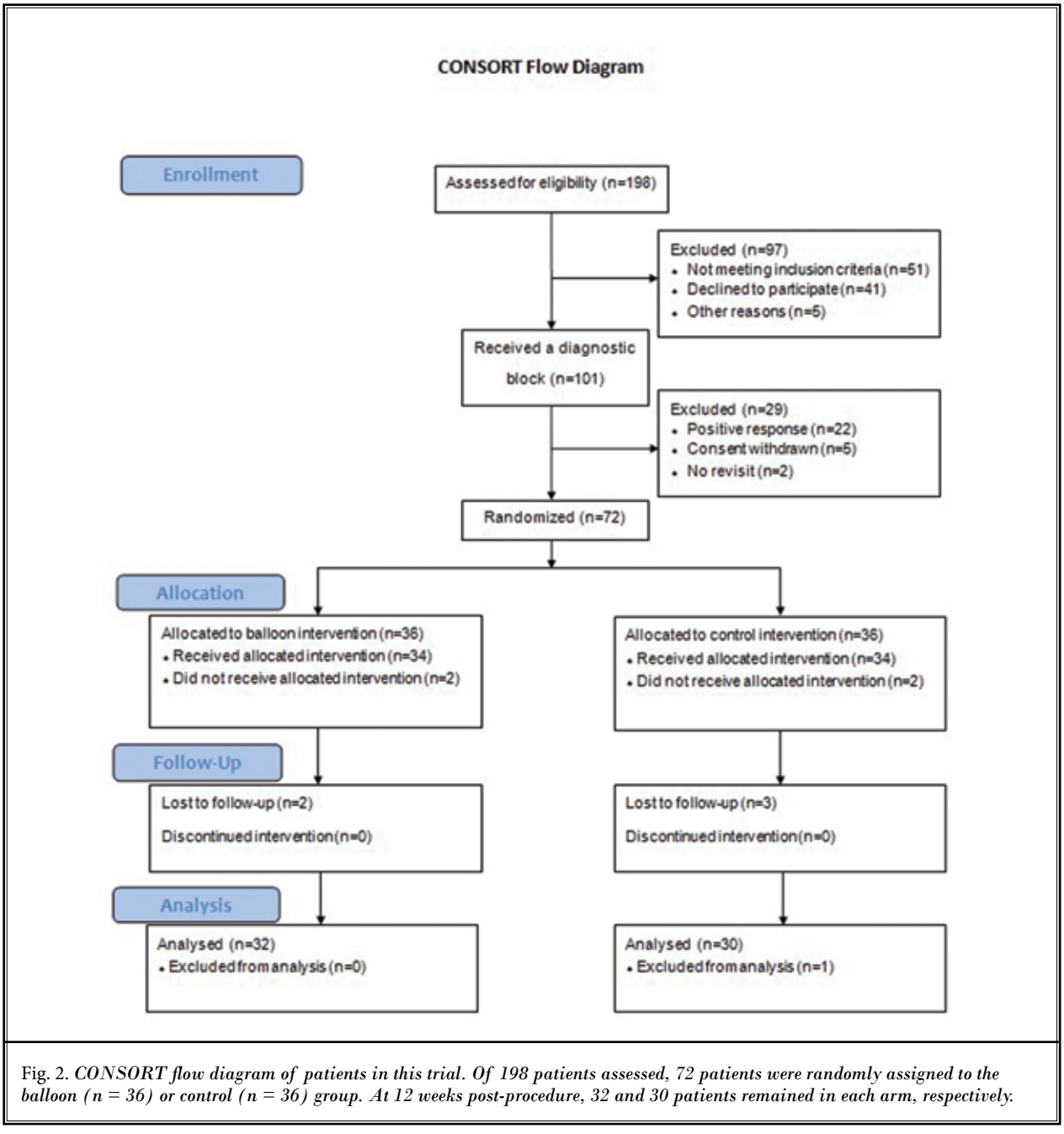

Fig. 2. *CONSORT flow diagram of patients in this trial. Of 198 patients assessed, 72 patients were randomly assigned to the balloon (n = 36) or control (n = 36) group. At 12 weeks post-procedure, 32 and 30 patients remained in each arm, respectively.*

changes in VAS scores (P = 0.024). In both groups, VAS scores were lower at all post-procedure assessment points compared with baseline (P < 0.05). However, there was no significant difference between the groups during the follow-up period. Kaplan-Meier analysis of the duration of the patient's achieving ≥ 50% leg pain relief without additional treatment or increasing the dose of analgesics showed a significant intergroup difference between the balloon and control (P = 0.003) groups (Fig. 4). Six patients (18.8%) in balloon group maintained > 50% pain relief for 52 weeks whereas no patient (0%) did in control group.

Secondary Outcome

Table 1. *Characteristics of the patients*

	Sham group (n= 30)	Balloon group (n= 32)	*P*-value
Age (yr)	64.5 ± 7.9	65.3 ± 11.1	0.950
Gender (M/F)	17/13	17/15	
Height (cm)	155.0 ± 6.0	157.9 ± 7.3	0.105
Weight (kg)	57.4 ± 9.1	62.2 ± 6.6	0.084
Body mass index (kg/m2)	23.5 ± 3.3	24.5 ± 2.3	0.458
Duration of symptom (mon)	26.2 ± 17.5	26.6 ± 26.2	0.490
Score on the visual analogue scale on pain			
Leg (mm)	68.4 ± 13.3	71.4 ± 13.4	0.489
Lower back (mm)	53.4 ± 22.4	57.1 ± 20.3	0.459
Oswestry disability index (%)	42.5 ± 14.1	40.7 ± 14.3	0.604
Caludication distance (m)	384.6 ± 272.3	372.8 ± 290.9	0.955
Previous trial of ESI before enrollment (n)	5.1 ± 4.6	5.8 ± 5.3	0.582
Involved level			
L4-5 (n)	7	10	0.657
L5-S1 (n)	23	22	
Underlying disease			
Diabetes mellitus (n)	7	5	0.068
Hypertension (n)	20	19	1.000
Osteoporosis (n)*	8	7	0.090

* T-score -2.5 or less
Data are presented as mean ± SD or number.
ESI = epidural steroid injection

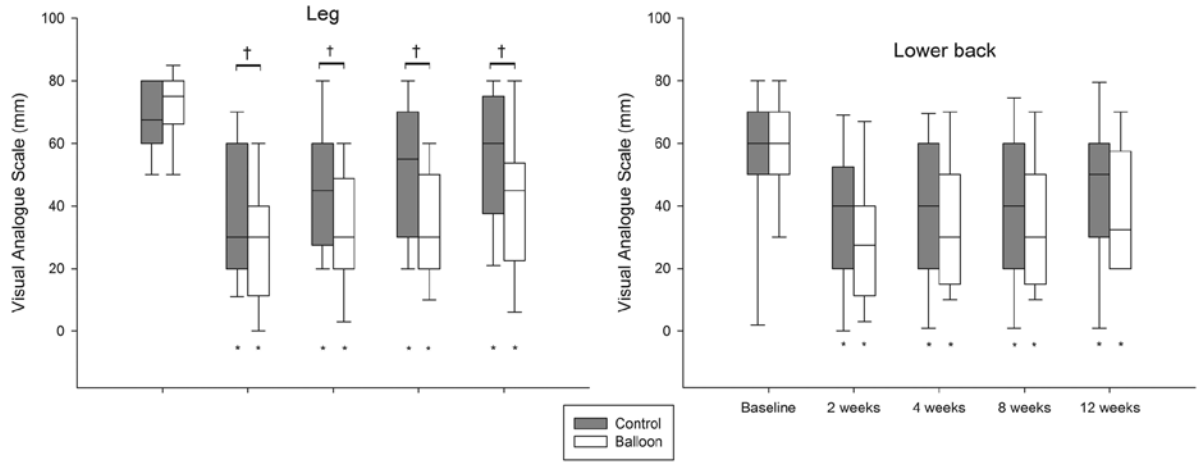

Fig. 3. *Visual analogue scale pain scores for the leg and lower back in patients receiving transforaminal balloon treatment or control operation. Data are shown in a box plot with range (whiskers), interquantile range (boxes), and median (solid line). *P < 0.05 vs baseline. †P < 0.05 vs control.*

Table 2. *Clinical and functional outcome after transforaminal balloon decompression and changes from baseline values.*

Post-procedure time	Sham (n= 30)	Balloon (n= 32)	*P*-value	Changes from baseline		*P*-value
				Sham	Balloon	
Leg VAS (0-100 mm)						
baseline	68.4 ± 13.3	71.7 ± 13.4	0.489			
2 weeks	37.7 ± 21.9	29.4 ± 21.5	0.041	30.7 ± 21.4	42.3 ± 22.3	0.054
4 weeks	46.2 ± 22.6	32.2 ± 20.3	0.003	22.2 ± 25.0	39.5 ± 21.5	0.005
8 weeks	52.7 ± 21.8	34.7 ± 20.9	<0.001	15.7 ± 24.3	37.0 ± 20.6	<0.001
12 weeks	56.8 ± 20.8	41.6 ± 22.7	0.002	11.6 ± 22.8	30.2 ± 23.7	0.002
ODI (0-100%)						
baseline	42.5 ± 14.1	40.7 ± 14.3	0.604			
2 weeks	32.2 ± 16.5	21.2 ± 13.3	0.020	10.3 ± 14.4	19.5 ± 15.0	0.027
4 weeks	35.1 ± 18.3	24.8 ± 16.4	0.019	7.4 ± 14.5	15.9 ± 16.2	0.044
8 weeks	36.1 ± 19.7	25.1 ± 16.8	0.011	6.4 ± 15.6	15.6 ± 17.2	0.068
12 weeks	39.1 ± 21.4	28.9 ± 18.4	0.017	3.4 ± 14.9	11.8 ± 17.3	0.080
Claudication distance (m)						
baseline	384.6 ± 272.3	372.8 ± 290.9	0.955			
2 weeks	683.4 ± 608.4	1222.5 ± 901.7	0.003	298.8 ± 19.1	849.7 ± 856.0	0.003
4 weeks	715.7 ± 585.9	1285.8 ± 930.8	0.002	331.1 ± 28.2	913.0 ± 852.4	0.002
8 weeks	682.7 ± 689.0	1210.3 ± 914.0	0.004	298.1 ± 76.3	837.5 ± 54.8	0.002
12 weeks	606.0 ± 634.4	1098.1 ± 932.0	0.007	221.4 ± 86.4	725.3 ± 944.1	0.005

Data are presented as mean ± SD or number. VAS = visual analogue scale, ODI = Oswetry disability index

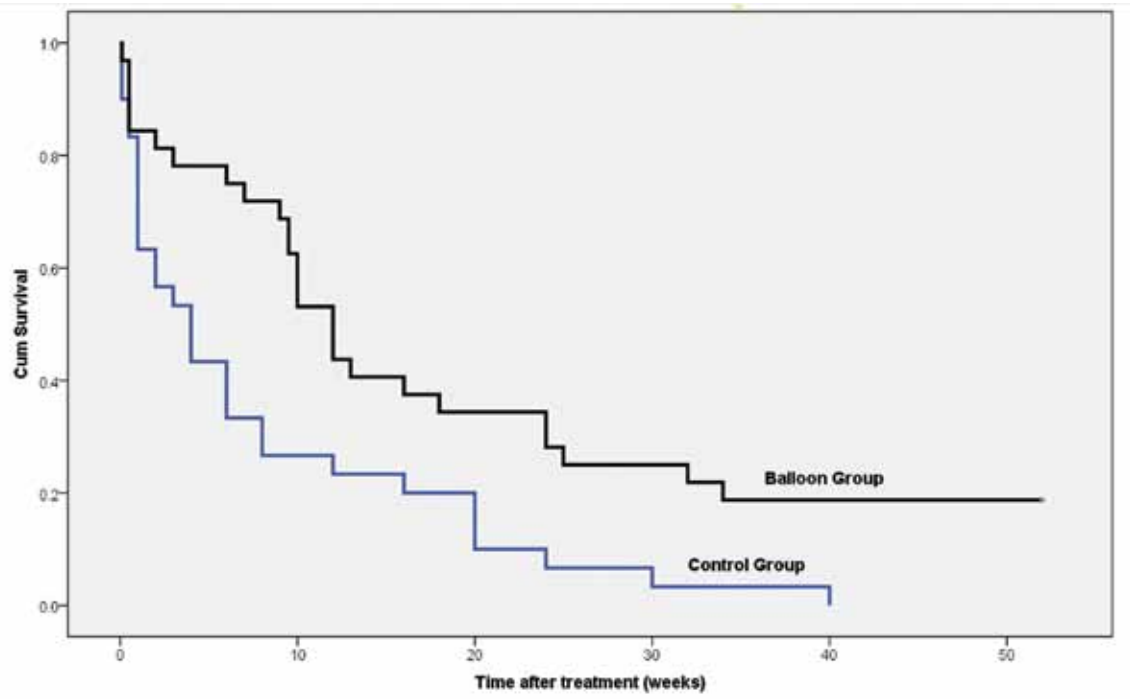

Fig 4. *Kaplan-Meier analysis of the duration of the patients achieving at least 50% leg pain relief without additional treatment or increasing analgesics showed a significant intergroup difference between the balloon and control groups (P = 0.003).*

There was a significant interaction between the groups and time for the mean changes in ODI scores (P = 0.013). In the balloon group, ODI scores improved at all assessment points compared to baseline (P < 0.001). In the control group, ODI scores improved at all assessment points compared with baseline (P < 0.05) except 12 weeks (P = 0.425) (Fig. 5A). The balloon group ODI scores were significantly lower than the control group scores at all post-procedure assessment points (P < 0.05).

There was a significant interaction between the groups and time for the mean changes of claudication distance (P < 0.001). In the balloon group, claudication distances improved at all assessment points compared with baseline (P < 0.001). In the control group, claudication distances improved at all assessment points compared with baseline (P < 0.05) except 12 weeks (P = 0.222) (Fig. 5B). When comparing changes in claudication distances from baseline, the balloon group showed better improvement compared with the control group at all assessment points (P < 0.05).

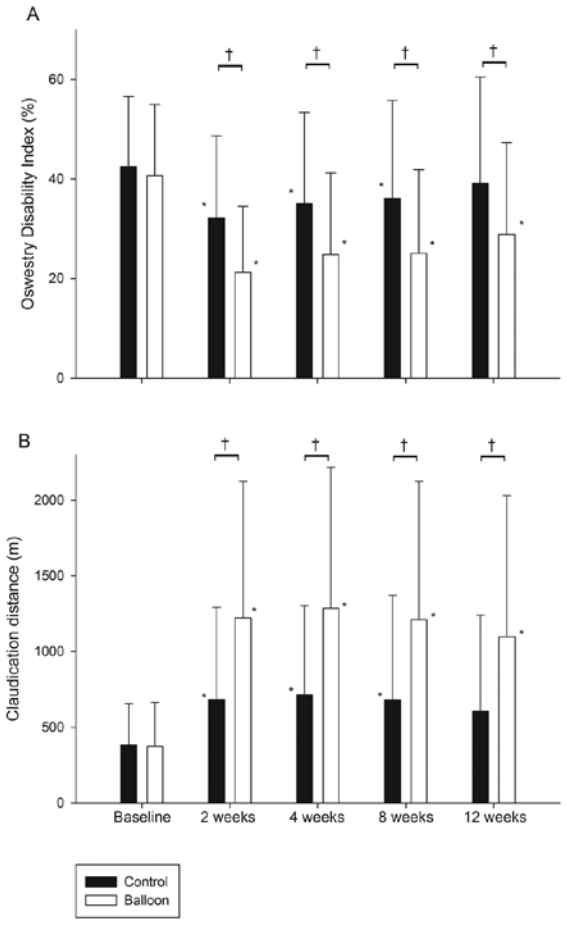

Fig. 5. *Oswestry disability index (A) and claudication distance (B) in patients receiving transforaminal balloon treatment or control operation. Data are shown as the mean and SD. *P < 0.05 vs baseline. †P < 0.05 vs control.*

Adverse Events

Despite the fact that several patients experienced temporary pain during catheter insertion or balloon inflation (24 in the balloon group and 6 in the control group), the pain was tolerable and no additional pain killer or sedatives were required. There was no case of dural puncture during the procedure in either group. Several patients in both groups complained of 2 - 3 days of remaining pain during the post-procedural period (18 in the balloon group and 5 in the control group); however, the transient pain aggravation was mostly insignificant and relieved without any neurological sequelae in all cases. Otherwise, no participants reported adverse events, including deterioration of motor or sensory deficits during the follow-up period.

Discussion

The present study is the first randomized trial showing the clinical efficacy of transforaminal balloon treatment for lumbar foraminal stenosis. We found that transforaminal balloon treatment provided sufficient pain relief in patients who were refractory to conventional epidural steroid injection, and > 50% improvement of pain was maintained for 52 weeks in 18.8% of the patients. These patients also experienced significant functional improvement after balloon treatment, especially in ODI and claudication distance. Considering that ODI and walking ability are not commonly improved by conventional epidural steroid injections, our results suggest that transforaminal balloon treatment may have beneficial effects for refractory spinal stenosis patients with functional impairment.

The genesis of neurogenic intermittent claudication in lumbar spinal stenosis is greatly affected by the variation of the dynamic mechanical stress on the spinal nerve roots, rather than the static mechanical stress (38). The dorsal root ganglion in the lumbar spine is in close proximity to the lumbar nerve foramen and thus would be affected in foraminal stenosis (39). In our study, the balloon group showed superior improvement in leg pain, VAS, ODI, and claudication distance compared with the control group at all post-procedure

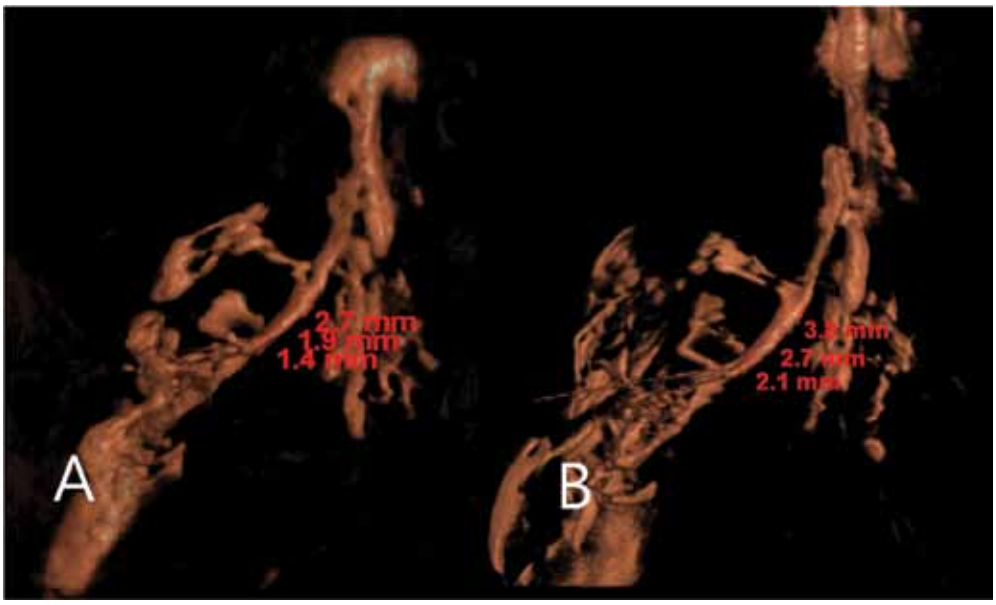

Fig 6. *Three-dimensional reconstructed images of the epidural space, identified by retained contrast medium within tissue, were obtained with the volume rendering technique. Rotational angiography was used to visualize the target before (A) and after the balloon procedure (B), and images were then transferred to the syngo InSpace 3D high-contrast imaging Workplace (Siemens AG) for post processing. As shown in this representative patient, the diameter of the epidural space was measured in the region of the intervertebral foramen at 3 different points.*

assessment points, although there was no significant difference in back pain reduction between the groups. The discrepancy in the balloon treatment between back and leg pain may be attributable to target sites of the balloon treatment, mainly lateral foraminal stenosis, not central adhesion.

This study is novel in that the balloon treatment was introduced to treat patients with lumbar spinal stenosis, which is a new possible indication in a common pathological condition. There are several factors which could be responsible for effective pain relief and functional improvement after balloon treatment. First, distension of the epidural space by transforaminal balloon inflation/deflation may lead to effective mechanical detachment of a perineural adhesion, which would play a role in long-lasting symptom relief and functional improvement. In the epidural space, fibrosis and adhesions may develop due to inflammation around the involved neural tissue (40), and such factors cause radiculopathy by interfering with the mobility of the dural sleeve of nerve roots (41). We suggest that mobility of the nerve roots may be restored to some extent after transforaminal balloon treatment and may contribute to long-term symptom relief, exceeding the intrinsic effective duration of epidural injections. Second, mechanical ballooning of the stenotic intervertebral foramen may lead to reduced venous congestion and mechanical irritation. Venous congestion has been suggested as the essential factor precipitating circulatory disturbance, thus inducing neurogenic claudication (42). Perineural fibrosis is closely related to venous obstruction and may further impede nutrient transfer and predisposition to nerve stretch injury (43). Such pathology, at least in part, is supposed to be resolved by balloon treatment. Lastly, initial improvement of symptoms after decompressive procedures may reflect local anesthetics and steroids reaching the area causing these symptoms. Balloon dilatation and adhesiolysis may contribute to more efficient delivery of epidural injections to the involved region of spinal stenosis and the preganglionic area; therefore, further improvement in the drug effect at the target lesion was possible. This may lead to effective decreases in perineural and neurogenic inflammation. Co-administration of hyaluronidase also plays a role in enhancing the effect of lysis of epidural adhesions (44-46).

Our results also imply that the control operation, which had minimal adhesiolysis using the Fogarty catheter but with no balloon treatment, had modest clinical efficacy in patients who showed poor improve-

ment with conventional epidural steroid injection. The mechanism of control operation may be similar to that of Racz's method (23,27), which leads to reduced mechanical barriers prohibiting medications from reaching areas of pathology in the epidural space with this catheter. As the epidural adhesiolysis has been proven to be effective in patients with epidural adhesion (23,47,48), the control operation in our study may have superior therapeutic effect compared with conventional epidural steroid injection due to minimal adhesiolysis effect by the catheter, but have inferior effect compared with balloon treatment. Establishing the control group as an active treatment would confirm the pure effect of balloon treatment itself on the therapeutic efficacy. In addition, as we included the patients who had not achieved sufficient symptom relief and showed short-lived improvement after the conventional epidural injection of steroids and local anesthetics, we had to set the control group as an active treatment for ethical reasons.

To demonstrate changes in the intervertebral foramen after balloon treatment, three-dimensional reconstructed images of the epidural space, identified by retained contrast medium within tissue, were obtained with the volume rendering technique (Fig. 6). Rotational angiography (AXIOM Artis system, Siemens AG, Berlin, Germany) was used to visualize the target before and after the balloon procedure. After the complete session of transforaminal balloon treatment in representative patients (n = 4), the measured diameter of the epidural space in the region of the intervertebral foramen at 3 different points was increased by 10.5% - 31.8% (median 28.0%), and the average of the measured lumbar foraminal canal volume was increased approximately 98%. It supports the therapeutic mechanism of our newly introduced procedure and provides evidence of successful epidural decompression.

Patient safety should be mentioned because acute compression on spinal nerves and surrounding vascular structures could occur during the study protocol. As the Fogarty catheter was originally intended to remove soft emboli and thrombi from the vascular system, its pliable distal tip is designed to minimize trauma to the venous valves. Thus, such structures enable relatively safe treatment procedures by manipulating around perineural structures. In the paucity of definitive research, however, increasing the pressure and lengthening the duration has been found to induce more pronounced effects including intraneural edema, decreased conduction velocity, and pathological changes in nerves such as periaxonal swelling (24,49,50). We confined the maximal duration of each ballooning session to less than 5 seconds and adjusted each session according to the patient pain response. In our study, no participant reported adverse events such as deterioration of motor or sensory deficits during the follow-up period, and no participants withdrew from the study owing to an adverse event. However, we acknowledged that transforaminal balloon treatment is a more invasive procedure compared to conventional transforaminal blockade, and thus the procedure should be selectively performed for patients refractory to conventional treatment. Further multicenter studies on the safety of the balloon techinique will be warranted.

The present study has several potential limitations. First, to be eligible for participation, a patient's foraminal stenosis was confirmed by physical examination and radiologic reading, but the severity of stenosis on imaging, which may be attributable to the response, was not quantified. Although radiologic findings may not always correspond to the symptoms of spinal stenosis and the response to treatment (17,51-53), our inclusion criteria included patients who were randomly distributed to either the balloon or control group regardless of the degree of disease severity, and this may have affected the results. Second, our study was an active-controlled randomized design with a relatively small number of patients to draw a definitive conclusion. Future trials with larger sample sizes for regression analysis are warranted to establish proper selection criteria indicated for this method or factors predicting a favored therapeutic effect. In addition, further trials are needed to determine whether our transforaminal balloon treatment decreases surgery rates over the long-term follow-up period.

Conclusion

In summary, transforaminal balloon treatment leads to significant pain reduction and functional improvement in a subset of patients with lumbar foraminal stenosis, and this may be an effective treatment in such cases. Our results provide therapeutic clues that suggest transforaminal treatment using a balloon catheter has potential as a non-surgical treatment by modifying the underlying pathophysiology of segmental stenosis.

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