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Effects of Traditional Korean Medicine Treatment On Lumbar Spinal Stenosis and Assessing Improvement by Radiological Criteria: An Observational Study

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ABSTRACT

Background: This study was designed to evaluate the clinical effectiveness of traditional Korean medicine treatment for lumbar spinal stenosis as assessed by radiological criteria.
Methods: This was an observational study of 122 patients who were diagnosed with lumbar spinal stenosis and admitted to Jaseng Hospital between January 2016 and June 2017. They were analyzed according to sex, age, cause of disease, disease stage, length of admission, type of stenosis, morphological grade, and dural sac cross-sectional area. All patients were treated with traditional Korean medicine. Patients were assessed with the Numeric Rating Scale (NRS), Oswestry Disability Index (ODI) and EQ-5D before and after treatment.
Results: Regarding the distribution of the factors analyzed, these were of note: more females than males (1:3.52); and highest proportions were age more than 70 years (37.70%), cause of lumbar spinal stenosis unknown (67.21%), and subacute stage (42.62%). Comparing before and after treatment, the NRS score for low back and pelvic pain decreased from 6.14 ± 1.71 to 4.28 ± 1.91 ($p < 0.001$), and the NRS score for radiating pain and numbness decreased from 6.27 ± 1.61 to 2.02 ± 1.54 ($p < 0.001$). ODI decreased from 46.86 ± 19.40 to 33.63 ± 18.66 ($p < 0.001$), and gait-related ODI decreased from 3.34 ± 1.23 to 2.80 ± 1.11 ($p < 0.001$). There were no statistically significant differences in improvement of the NRS, ODI, gait-related ODI, and EQ-5D for morphological grade and dural sac cross-sectional area.
Conclusion: Traditional Korean medicine is effective treatment for patients with lumbar spinal stenosis. Even in patients with severe radiological findings, it is possible to reduce pain and improve quality of life.

Introduction

Lumbar spinal stenosis (LSS) is a disease that causes various symptoms such as back pain, lower back pain, and intermittent claudication. It is a clinical syndrome that occurs due to narrowing of the lumbar spine canal, lateral nerve root canal and intervertebral foramen [1]. The most common symptom of LSS is neurogenic intermittent claudication, which complicates the bilateral or unilateral discomfort of the hip and lower limbs. It is exacerbated when the lumbar spine is extended, and relaxed when the lumbar curve is flexed [2]. The incidence of LSS increases with age. As the proportion of elderly in the population increases, so effective treatment for LSS is important.

LSS treatment in Western medicine can be divided into conservative treatment and surgical treatment. Conservative treatment includes stabilization, physical therapy, orthosis, oral analgesic, and steroid injection. Surgical treatment includes neuromuscular block and laminectomy [3]. In Korean medicine, bee venom pharmacopuncture, chuna, acupuncture and moxa, and herbal medicine are used. There are Korean medicine LSS studies of bee venom pharmacopuncture therapy [4], acupuncture and moxa therapy, chuna therapy [5], motion style treatment [6], acupotomy therapy [7], and diarrhea-inducing treatment by gamsui-mal [8]. There are also studies on the correlation between

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bone mineral density and LSS [9], cross-sectional area of lumbar paraspinal muscles and walking ability in LSS patients [10], and clinical and radiological correlation between lumbar lordotic angle, lumbar intervertebral disc angle and LSS [11].

However, there are insufficient studies on the relationship between morphological grade and treatment of LSS patients. In this study, LSS patients treated with traditional Korean medicine were studied. The effects of such treatment on LSS and the differences in treatment effect according to morphological grade and dural sac cross-sectional area (DSCA) were assessed by radiological criteria.

Materials and Methods

This was an observational study of patients who were diagnosed with LSS and hospitalized and treated at Jaseng Hospital between January 1, 2016 and June 30, 2017. Patients were diagnosed with LSS on the basis of clinical symptoms, physical examination and magnetic resonance imaging (MRI).

Exclusion criteria were: serious diseases that can cause back pain (e.g., cancer, spinal infection); chronic diseases that may interfere with the interpretation of therapeutic outcomes or effectiveness of treatment (e.g., significant cardiovascular disease, diabetic neuropathy, fibromyalgia); progressive neurological deficit or severe neurological symptoms; inappropriate or unsafe conditions for acupuncture treatment (e.g., bleeding disorders, hemostatic disorders); currently taking immunosuppressants or psychosomatic drugs; pregnancy; resistance to X-ray, MRI or treatment diet; patients not followed-up; patients who did not meet the radiological diagnostic criteria for LSS (DSCA > 100 mm2, morphological grade < A4, anteroposterior diameter of spinal canal > 12 mm, and no canal or foraminal stenosis).

This study was approved by Jaseng Hospital's institutional review board on July 5, 2017 (approval no. Jaseng 2017-07-004) as a retrospective statistical analytical study that did not record patients' individual identifying information. At the time of admission, patients gave their consent for their academic data to be used in this study.

Data on the following were extracted from the collected medical records: sex; age; cause of disease (motivation for onset); disease stage; length of admission (days); number, type and location of stenoses; MRI findings (DSCA, morphological grade); location and intensity of pain; comorbidities; Numeric Rating Scale (NRS), Oswestry Disability Index (ODI) and EQ-5D Index before and after treatment.

Of the 159 LSS inpatients, 122 patients were selected for study inclusion (Fig. 1).

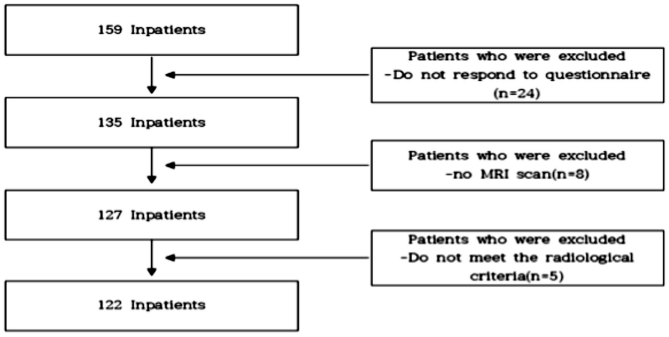

Fig. 1. Flowchart showing how patients were selected for inclusion.

Treatments

Patients were treated with acupuncture, pharmacopuncture, chuna therapy, herbal medicine therapy, and physical therapy.

Acupuncture treatment

The needles used for acupuncture were disposable stainless steel (0.30 × 40 mm; Dong Bang Medical Co. Ltd., Daecheon, Korea). Needles were inserted at the EX-B2 (Hwata Hyeopcheok) points [12], BL 23 (Shinsu) points, and Ashi points of the lumbar, pelvis, and lower limbs for 15 minutes twice a day. The depth of needle insertion was 20 mm or more. Acupuncture was combined with the use of an infra-red ray apparatus. Two Korean medicine doctors conducted the acupuncture treatment once each morning and afternoon from the day of admission.

Pharmacopuncture treatment

Based on physical examination and radiological imaging, 1 ml of Shinbaro pharmacopuncture was injected into the left EX-B2 and 1 ml was injected into the right EX-B2 (Hwata Hyeopcheok) points, at the most severe spinal level. Pharmacopuncture (from Jaseng Pharmacopuncture Medicinal Research Institute) was extracted by adding and removing medicines of Cheongpa-jeon [13], which has the efficacies of improving blood circulation, removing wind energy, and pain control (活血去風止痛), controlling dampness and eliminating swelling (化濕消腫), and strengthening muscle and bone (强筋骨). Before treatment, the area to be injected was disinfected with povidone (10% povidone-iodine) solution to prevent infection. Pharmacopuncture was then injected directly into the skin at a depth of about 3 cm using a disposable syringe (1 ml, 26G × 1.5 syringe; CPL Co. Ltd., Gyeonggi-do, Korea). Pharmacopuncture treatment was conducted once every 2 days from the day of admission.

Chuna therapy

We performed the flexion–distraction technique, lumbar extension technique, lateral extension rotation technique, and lateral lumbar correction technique five to seven times a week from the day of admission.

Herbal medicine therapy

Herbal medicines (Jaseng Hospital prescriptions) were administered to patients with LSS. Cheongpa-jeon [13] and Cheongshinbaro-hwan were taken three times a day, 30 minutes after each meal, from the day of admission.

Physical therapy

Muscle meridian medium frequency therapy (interference current therapy), muscle meridian low frequency therapy (transcutaneous electrical nerve stimulation), microwave therapy, hot pack, traction therapy or manipulation were chosen according to patients' conditions and performed five to seven times a week from the day of admission.

Disease stage classification

The stage of the disease was determined according to Kim et al's method [14]. LSS was classified as: most acute stage, within 1 week of onset; acute stage, from 1 week to 1 month of onset; subacute stage, from 1 month to 6 months of onset; and chronic stage, 6 months or more from onset. Onset was based on the most recent incident of back, hip or leg pain.

Stenosis type classification

Canal stenosis

Canal stenosis is the narrowing of the central canal due to degenerative disc disease, and thickening and break away of the ligamentum flavum and facet joints. It mainly presents with bilateral pain without limited localization. Neurogenic intermittent claudication is mainly caused by cauda equina pressure due to canal stenosis.

Foraminal stenosis

This is stenosis caused by compression of the lateral recess or neural foraminal. One or more nerve roots are stimulated to localize the pain in the region. There are many cases of localized pain in the region, as well as leg pain, numbness and weakness in the lower extremities. Neuromuscular pressure is mainly applied to the nerve roots, and symptoms appear in the form of sciatica; neurogenic intermittent claudication may also occur [15].

Radiological criteria

DSCA

We used a medical imaging storage system (STARPACS; INFINITT Healthcare Co. Ltd., Seoul, Korea) to measure DSCA on axial T1-enhanced MRI at disc level, the most severe LSS (Fig. 2). To reduce error in measurement, the average of two measurements by two Korean medical doctors (each doctor made 1 measurement each) was taken. Patients with DSCA ≥ 100 mm^2 were categorized into the mild–normal group. Those with DSCA more than 75 mm^2 but less than 100 mm^2 were categorized into the moderate group. Those with DSCA ≤ 75 mm^2 were categorized into the severe group [16].

Morphological grade

Using the same medical imaging storage system (STARPACS; INFINITT Healthcare Co. Ltd. Seoul, Korea), we confirmed the morphological grade of the dural sac on axial T2-enhanced MRI at disc level, the most severe LSS (Fig. 3). Morphological grade was measured according to Schizas et al's classification [17], summarized briefly below.

Grade A: No or only mild spinal LSS. On axial T2-enhanced MRI, cerebrospinal fluid is clearly shown in the dural sac. Can be classified into four stages: A1 to A4. Stage A1 is when the rootlets are arranged in the dorsal spinal cord and take possession of less than half of the dural sac. Stage A2 is when the rootlets are arranged in the dorsal spinal cord; the rootlets touch the dura and spread in the form of a horseshoe. Stage A3 is when the rootlets are arranged in the dorsal side of the dural sac over half of the dural sac. Stage A4 is when the rootlets are arranged in the center and take possession of the majority of the dural sac.

Grade B: Moderate stage of LSS. The rootlets take possession of the whole of the dural sac, but the rootlets are still independent. Some cerebrospinal fluid is shown. Grainy granules can be seen in the dural sac.

Grade C: Severe stage of LSS. There are no visible rootlets and no visible cerebrospinal fluid signal. There is a gray signal in the dural sac. Posterior epidural fat can be identified.

Grade D: Most severe (extreme) stage of LSS. Epidural fat (as observed in Grade C) and rootlets cannot be seen.

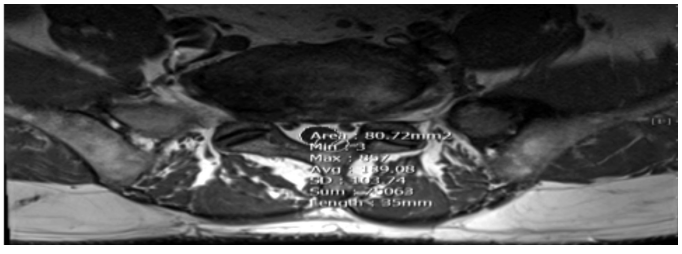

Fig. 2. Measurement of dural sac cross-sectional area.

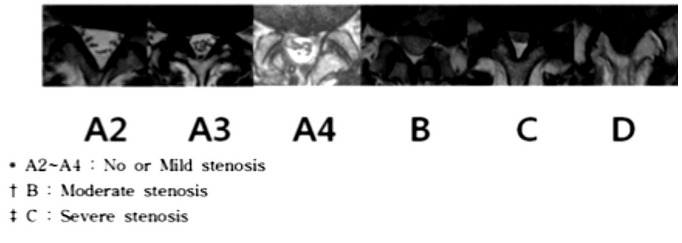

Fig. 3. Classification of morphological grade.

Numeric Rating Scale (NRS)

Of the different pain assessment methods available that express the degree of pain on a scale of 0 to 10, we chose the NRS to evaluate the degree of pain in our patients. Although it is a subjective indicator, the NRS is easy and simple to use. Zero stands for "painless", 10 stands for "the most severe pain the patient can imagine". The Visual Analog Scale is similar, but NRS does not require vision or mobility. Patients completed the NRS on both days of admission and discharge.

Oswestry Disability Index (ODI)

The ODI has 10 questions that are designed to measure the degree of disability in the daily life of patients with back pain. The score for each item ranges from 0 to 5. The total score is calculated as twice the sum of the item scores [18]. We used the Korean version of the ODI, the reliability and validity of which has been verified [19]. Patients completed the ODI on both days of admission and discharge. We collected data on the fourth item on walking condition separately due to its relation with claudication—the main symptom of LSS.

EQ-5D

The EQ-5D is a questionnaire that was developed in 1990 by the EuroQol group as a tool to assess five aspects of general health status: morbidity, self-care, usual activity, pain/discomfort, and anxiety/depression. The answer options for each question are: "There are no problems at all", "There are some problems", and "There are important problems". As a result, we can define 35;243 possible health conditions. If you add two more states of death and loss of consciousness, then 245 health levels are possible [20]. The EQ-5D-5L version, which assesses health status at five levels, is published on the EuroQol website. In this study, we used the three-level scale (EQ-5D-3L); it has quality weightings for domestic (Korean) application, and it was used in the Korea National Health and Nutrition Examination Survey until 2013. The weighting formula used in the analysis was calculated based on the quality-weight estimation research report of the quality-of-life survey tool presented in the 2007 guidelines of the Korea Centers for Disease Control and Prevention for the use of primitive data [20].

EQ-5D index = 1 – (0.050 + 0.096 × M2 + 0.418 × M3 + 0.046 × SC2 + 0.136 × SC3 + 0.051 × UA2 + 0.208 × UA3 + 0.037 × PD2 +

0.151 × PD3 + 0.043 × AD2 + 0.158 × AD3 + 0.050 × N3)

if LQ_1EQL = 1 & LQ_2EQL = 1 & LQ_3EQL = 1 & LQ_4EQL = 1 & LQ_5EQL = 1

then EQ-5D = 1,

where M refers to athletic ability, SC to self-management, UA to everyday life, PD to pain/discomfort, and AD to anxiety/depression. The number 2 (i.e., M2, SC2, UA2, PD2, AD2) means "There is a little problem", the number 3 (i.e., M3, SC3, UA3, PD3, AD3) means "There is a serious problem". If it is applicable, then it substitutes 1. If it is not applicable, then it substitutes 0. N3 means to substitute 1 if there is more than one "serious problem". In the Korean version of the EQ-5D, convergence and discriminant validity were confirmed in a validity and reliability study of the general population in Korea. The overall percent agreement between test–retest was 76–97%. The kappa coefficient was 0.24–0.59, indicating that it has adequate reliability [21].

Statistical analyses

All statistical analyses were performed with IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA). Data are expressed as mean ± standard deviation and p values. Sex and age were included in the initial statistical analysis. Changes in NRS, ODI, gait-related ODI, and EQ-5D after treatment as compared to before were analyzed using paired t-test and Wilcoxon signed-rank test. Kruskal-Wallis test and one-way ANOVA were performed according to data after Shapiro-Wilk test as needed. A p value < 0.05 was considered statistically significant.

Results

Most of the patients were females (77.87%); mean age was 66.79 ± 10.32 years. The youngest patient was 39 years old and the oldest was 90 years old. The majority of patients (59.02%) were elderly aged ≥ 65 years (Table 1).

In about two-thirds of patients, the reason for LSS was unknown (67.21%); the next most frequent causes were lumbar strain (9.01%) and overwork (7.38%) (Table 2).

Most patients had subacute (52/122, 42.62%) or chronic (40/122, 32.79%) LSS (Table 3).

Length of admission ranged from a minimum of 2 days to a maximum of 71 days; mean hospitalization period was 20.44 ± 15.19 days (Table 4).

The number of stenoses in patients ranged from one to five. LSS type was determined by considering MRI images and clinical symptoms. The number of patients who had canal stenosis and foraminal stenosis was the same (113/122, 92.62%). Nine patients (7.38%) had only canal stenosis and another nine patients (7.38%) had only foraminal stenosis, while 104 (85.25%) had both canal and foraminal stenoses. Among the patients with foraminal stenosis, most (81.97%) had both left and right foraminal stenoses. The majority of patients (73.77%) had LSS in L4/5 (Table 5).

With regard to morphological grade, no patients were in Stage A1. About a quarter of patients (25.41%) were in Stages A2–A4, while half (50.00%) already had Grade C LSS. Almost three-quarters of patients (72.13%) had DSCA ≤ 75 mm2, which indicates the most severe LSS. The narrowest DSCA was 25.16 mm2 and the widest was 176.36 mm2; mean DSCA was 66.68 ± 27.07 mm2 (Table 6).

The areas where patients experienced pain and numbness are shown in Table 7. Many had pain in more than one area, with most

Table 1. Distribution of Sex and Age

		N	%
Sex	Male	27	22.13
	Female	95	77.87
Age	20~29	0	0.00
	30~39	1	0.82
	40~49	3	2.46
	50~59	35	28.69
	60~69	37	30.33
	70~	46	37.70
	<65	50	40.98
	≥65	72	59.02
Total		122	100

Table 2. Distribution of Causes of LSS

	N	%
Reason unknown	82	67.21
Lumbar strain	11	9.01
Same motion in long period	5	4.10
Overwork	9	7.38
Trauma	5	4.10
Postoperative sequela	5	4.10
Etc	5	4.10
Total	122	100

Table 3. Distribution of LSS Disease Stage

	N	%
Most acute stage	14	11.48
Acute stage	16	13.11
Subacute stage	52	42.62
Chronic stage	40	32.79
Total	122	100

In this study, LSS was classified as:
- most acute stage, within 1 week of onset;
- acute stage, from 1 week to 1 month of onset;
- subacute stage, from 1 month to 6 months of onset;
- chronic stage, 6 months or more from onset.

Table 4. Distribution of Length of Admission

No. of days	N	%
0~5	17	13.93
6~10	17	13.93
11~15	21	17.21
16~20	15	12.30
21~25	18	14.75
26~30	11	9.02
31~35	9	7.38
36~40	3	2.46
41~45	3	2.46
46~50	1	0.82
51~	7	5.74
Total	122	100

Table 5. Distribution of Number, Type and Location of Stenoses

		N	%
Number of stenoses	1	31	25.41
	2	44	36.07
	3	27	22.13
	4	16	13.11
	5	4	3.28
	Total	122	100.00
Type	Canal stenosis(only canal type)	113(9)	92.62(7.38)
	Foraminal stenosis - both left & right	100	81.97
	Foraminal stenosis – only left	11	9.02
	Foraminal stenosis – only right	2	1.64
Location	L1/2	10	8.20
	L2/3	38	31.15
	L3/4	51	41.80
	L4/5	90	73.77
	L5/S1	57	46.72
	L5/L6	2	1.64

reporting pain in the lumbar and pelvic regions.

Eight patients (6.56%) had no comorbidities, while almost two-thirds (62.30%) had herniated intervertebral disc. A small number of patients (2.46%) had stenosis in the cervical or thoracic spine (Table 8).

The Shapiro-Wilk test was conducted on NRS scores for lumbar and pelvic pain, and radiating pain and numbness, ODI, gait-related ODI, and EQ-5D before and after treatment. The changes in each of these according to morphological grade and DSCA were tested for normality (Tables 9 & 10). These analyses included groups that had fewer than 30 patients, and should be considered carefully for this study purpose. After that, to evaluate treatment efficacy, data were analyzed using the paired t-test and Wilcoxon signed-rank test according to normality (Tables 11–15). Also according to normality, Kruskal-Wallis test and one-way ANOVA were used to evaluate the differences according to morphological grade and DSCA (Table 16).

Evaluation of treatment

NRS

To evaluate the progress and significance of treatment, changes in mean NRS scores for back pain, pelvic pain and lower extremity pain and numbness were separately measured before and after treatment.

We found that NRS score for low back and pelvic pain in the whole group of patients significantly decreased from 6.14 ± 1.71 before treatment to 4.28 ± 1.91 after treatment ($p < 0.001$). In addition, when analyzed according to sex, age, disease stage, and radiological criteria, significant decreases in NRS score were still seen ($p < 0.001$), except for morphological grade D where the improvement was not significant ($p = 0.071$) (Table 11).

For radiating pain and numbness to the lower extremities, NRS score in the whole patient group decreased from 6.27 ± 1.61 before treatment to 4.24 ± 1.76 after treatment ($p < 0.001$). Again, when

Table 6. Distribution of Morphological Grade and Dural Sac Cross-sectional Area (DSCA)

		N	%
Morphological grade	A2~A4	31	25.41
	B	26	21.31
	C	61	50.00
	D	4	3.28
	Total	122	100.00
DSCA	≤ 75mm^2	88	72.13
	> 75 mm^2 and < 100 mm^2	20	16.39
	≥ 100mm^2	14	11.48
	Total	122	100.00

Table 7. Distribution of Pain and Numbness

	N	%
Lumbar pain	110	90.16
Pelvic pain	97	79.51
Thigh pain and numbness	81	66.39
Calf pain and numbness	81	66.39
Foot pain and numbness	36	29.51

Table 8. Distribution of Comorbidities

	N	%
None	8	6.56
Herniated intervertebral disc	76	62.30
C- or T-Spine stenosis	3	2.46
Spondylolisthesis	4	3.28
Other musculoskeletal disorders	44	36.07
Other comorbidities (non-musculoskeletal disorders)	74	60.66

Table 9. Test of Normality by Morphological Grade

	Morphological Grade	N	Admission	Discharge	Improvement
				p-value*	
NRS(lumbar & pelvic pain)	A2~A4	31	0.065	0.004	0.014
	B	26	0.011	0.061	0.007
	C	59	0.061	0.041	0.000
	D	4	0.272	0.161	0.406
NRS(radiating pain & numbness)	A2~A4	25	0.091	0.057	0.033
	B	20	0.224	0.035	0.006
	C	50	0.072	0.086	0.001
	D	3	0.000	†	0.000
ODI	A2~A4	31	0.629	0.271	0.144
	B	26	0.735	0.011	0.121
	C	61	0.544	0.000	0.182
	D	4	0.724	0.387	0.491
Gait-related ODI	A2~A4	31	0.021	0.009	0.010
	B	26	0.005	0.016	0.004
	C	61	0.001	0.000	0.000
	D	4	0.161	0.406	0.272
EQ-5D	A2~A4	31	0.138	0.000	0.052
	B	26	0.000	0.000	0.021
	C	61	0.000	0.000	0.000
	D	4	0.096	0.040	0.300

*Using Shapiro-Wilk test. †3 patient's NRS scores were equal. so they had been omitted.

Table 10. Test of Normality by Dural Sac Cross-sectional Area (DSCA)

	DSCA	N	Admission	Discharge	Improvement
				p-value*	
NRS(lumbar & pelvic pain)	≤ 75mm^2	86	0.004	0.000	0.000
	> 75 mm^2 and < 100 mm^2	20	0.107	0.059	0.161
	≥ 100mm^2	14	0.019	0.006	0.355
NRS(radiating pain & numbness)	≤ 75mm^2	73	0.036	0.021	0.000
	> 75 mm^2 and < 100 mm^2	15	0.068	0.592	0.071
	≥ 100mm^2	10	0.025	0.108	0.445
ODI	≤ 75mm^2	88	0.391	0.000	0.296
	> 75 mm^2 and < 100 mm^2	20	0.528	0.916	0.726
	≥ 100mm^2	14	0.893	0.389	0.768
Gait-related ODI	≤ 75mm^2	88	0.000	0.000	0.000
	> 75 mm^2 and < 100 mm^2	20	0.015	0.001	0.048
	≥ 100mm^2	14	0.003	0.058	0.529
EQ-5D	≤ 75mm^2	88	0.000	0.000	0.000
	> 75 mm^2 and < 100 mm^2	20	0.013	0.085	0.009
	≥ 100mm^2	14	0.355	0.035	0.065

*Using Shapiro-Wilk test.

Table 11. Differences in Lumbar and Pelvic Pain Numeric Rating Scale (NRS) Before and After Treatment

		N	NRS			p-value
			Admission	Discharge	Improvement	
Sex	Male	26	5.81±2.08	3.81±2.25	2.00±1.37	p<0.001*
	Female	94	6.23±1.59	4.40±1.80	1.83±1.44	p<0.001*
Age	<65	50	5.84±1.66	3.74±1.56	2.10±1.68	p<0.001*
	≥65	70	6.36±1.72	4.66±2.06	1.70±1.44	p<0.001*
Disease stage	Acute stage(Most acute&acute)	30	6.17±1.58	4.17±2.23	2.00±1.51	p<0.001*
	Subacute stage	51	6.06±1.78	4.12±1.85	1.94±1.67	p<0.001*
	Chronic stage	39	6.23±1.74	4.56±1.74	1.67±1.44	p<0.001*
Morphological grade	A2~A4	31	6.42±1.80	4.13±1.86	2.29±1.81	p<0.001†
	B	26	6.35±1.70	4.50±2.53	1.85±1.43	p<0.001†
	C	59	5.90±1.70	4.20±1.67	1.70±1.45	p<0.001†
	D	4	6.25±0.96	5.00±1.41	1.25±1.26	p=0.071*
DSCA	≤ 75mm^2	86	6.19±1.71	4.44±2.00	1.74±1.50	p<0.001†
	> 75 mm^2 and < 100 mm^2	20	6.10±1.92	3.90±1.80	2.20±1.74	p<0.001*
	≥ 100mm^2	14	5.93±1.39	3.79±1.48	2.14±1.56	p<0.001†
Total		120	6.14±1.71	4.28±1.91	1.87±1.55	p<0.001*

Average NRS values are means ± standard deviation.
* paired t-test before and after NRS; significance at p<0.05.
† Wilcoxon signed-rank test before and after NRS; significance at p<0.05.

analyzed according to sex, age, disease stage, and radiological criteria, significant decreases in NRS score were still seen ($p < 0.001$), except for morphological grade D where the improvement was not significant ($p = 0.065$) and DSCA ≥ 100 mm2 where the improvement was borderline significant ($p < 0.05$) (Table 12).

The non-significant results for morphological grade D were likely due to the small number of patients.

ODI and gait-related ODI

To assess the degree of treatment progression and its significance, changes in mean ODI score after treatment as compared to before treatment (including for ODI Item 4) were analyzed. However, item 4 of the ODI was also separately analyzed due to its relation to claudication—the main symptom of LSS (Tables 13 & 14).

We found that ODI score in the whole group of patients significantly decreased from 46.86 ± 19.40 before treatment to 33.63 ± 18.66 after treatment ($p < 0.001$). ODI Item 4, which represents walking disorder, also significantly decreased from 3.34 ± 1.23 to 2.80 ± 1.11 in the whole patient group ($p < 0.001$). When analyzed according to sex, age, disease stage, and radiological criteria, the decreases were still significant, except for morphological grade D (due to the small number of patients).

EQ-5D

Change in quality of life before and after treatment was assessed by analyzing EQ-5D index values (Table 15).

There was only a slight increase from 0.648 ± 0.589 before treatment to 0.763 ± 0.579 after treatment observed in the whole patient group, which was not statistically significant ($p = 0.055$).

However, males ($p < 0.05$), elderly aged ≥ 65 years ($p < 0.05$), and those with acute-stage LSS ($p < 0.001$) showed significant improvements. When analyzed according to radiological criteria,

Table 12. Differences in Radiating Pain and Numbness Numeric Rating Scale (NRS) Before and After Treatment

		N	NRS			p-value
			Admission	Discharge	Improvement	
Sex	Male	22	6.14±1.28	4.09±1.63	2.05±1.89	p<0.001*
	Female	76	6.30±1.70	4.29±1.80	2.01±1.44	p<0.001*
Age	<65	38	6.13±1.63	3.87±1.63	2.26±1.61	p<0.001*
	≥65	60	6.35±1.60	4.48±1.81	1.87±1.50	p<0.001*
Disease stage	Acute stage(Most acute&acute)	22	5.86±1.64	4.00±1.85	1.86±1.39	p<0.001*
	Subacute stage	43	6.28±1.68	4.14±1.95	2.14±1.73	p<0.001*
	Chronic stage	33	6.52±1.48	4.55±1.42	1.97±1.40	p<0.001*
Morphological grade	A2~A4	25	6.36±1.60	4.12±1.76	2.24±1.67	p<0.001*
	B	20	5.90±1.74	3.95±2.28	1.95±1.61	p<0.001†
	C	50	6.40±1.60	4.44±1.58	1.96±1.50	p<0.001*
	D	3	5.67±1.16	4.00±0.00	1.67±1.16	p=0.065*
DSCA	≤ 75mm^2	73	6.32±1.60	4.32±1.78	2.00±1.51	p<0.001†
	> 75 mm^2 and < 100 mm^2	15	6.73±1.83	4.33±1.99	2.40±1.84	p<0.001*
	≥ 100mm^2	10	5.20±0.79	3.60±1.17	1.60±1.27	p<0.05†
Total		98	6.27±1.61	4.24±1.76	2.02±1.54	p<0.001*

Average NRS values are means ± standard deviation.
* paired t-test before and after NRS; significance at p<0.05.
† Wilcoxon signed-rank test before and after NRS; significance at p<0.05.

Table 13. Differences in Oswestry Disability Index (ODI) Before and After Treatment

		N	ODI			p-value
			Admission	Discharge	Improvement	
Sex	Male	27	42.82±21.88	26.17±18.44	16.65±17.67	p<0.05*
	Female	95	48.01±18.60	35.75±18.26	12.26±13.49	p<0.001*
Age	<65	50	42.86±18.37	29.99±15.95	12.87±14.51	p<0.001*
	≥65	72	49.64±19.73	36.16±20.05	13.48±14.68	p<0.001*
Disease stage	Acute stage(Most acute&acute)	30	53.79±22.24	34.89±20.51	18.90±18.32	p<0.001*
	Subacute stage	52	42.82±19.64	32.05±18.53	10.76±13.61	p<0.001*
	Chronic stage	40	46.93±15.39	34.74±17.67	12.19±11.47	p<0.001*
Morphological grade	A2~A4	31	51.51±19.90	35.90±19.25	15.61±20.91	p<0.001*
	B	26	47.56±22.44	34.99±19.46	12.56±13.33	p<0.001†
	C	61	43.54±17.36	31.05±17.40	12.49±11.11	p<0.001†
	D	4	57.11±20.12	46.61±26.29	10.50±11.97	p=0.089*
DSCA	≤ 75mm^2	88	46.50±19.28	34.77±20.03	11.72±12.09	p<0.001†
	> 75 mm^2 and < 100 mm^2	20	45.94±20.17	31.56±14.09	14.38±11.82	p<0.001*
	≥ 100mm^2	14	50.48±20.11	29.41±15.15	21.06±26.58	p<0.05†
Total		122	46.86±19.40	33.63±18.66	13.23±14.56	p<0.001*

ODI values are means ± standard deviation.
* paired t-test before and after ODI; significance at p<0.05.
† Wilcoxon signed-rank test before and after ODI; significance at p<0.05.

Table 14. Differences in Gait-related Oswestry Disability Index (ODI) (Item No. 4) Before and After Treatment

		N	Gait-related ODI			p-value
			Admission	Discharge	Improvement	
Sex	Male	27	3.11±1.45	2.56±1.09	0.56±1.25	p<0.05*
	Female	95	3.41±1.15	2.86±1.11	0.55±0.95	p<0.001*
Age	<65	50	2.98±1.17	2.62±1.05	0.36±1.08	p<0.05*
	≥65	72	3.60±1.20	2.92±1.14	0.68±0.96	p<0.001*
Disease stage	Acute stage(Most acute&acute)	30	3.63±1.27	2.83±1.12	0.80±1.03	p<0.001*
	Subacute stage	52	3.02±1.18	2.77±1.08	0.25±0.93	p<0.05*
	Chronic stage	40	3.55±1.18	2.80±1.16	0.75±1.06	p<0.001*
Morphological grade	A2~A4	31	3.52±1.21	2.84±1.10	0.68±1.42	p<0.05†
	B	26	3.42±1.36	2.85±1.12	0.58±0.86	p<0.05†
	C	61	3.18±1.16	2.72±1.11	0.46±0.85	p<0.001†
	D	4	4.00±1.41	3.25±1.26	0.75±0.96	p=0.108*
DSCA	≤ 75mm^2	88	3.27±1.26	2.83±1.18	0.44±0.83	p<0.001†
	> 75 mm^2 and < 100 mm^2	20	3.45±1.15	2.80±0.77	0.65±1.04	p<0.05†
	≥ 100mm^2	14	3.64±1.15	2.57±1.15	1.07±1.77	p<0.05†
Total		122	3.34±1.23	2.80±1.11	0.55±0.09	p<0.001*

ODI (Item No. 4) values are means ± standard deviation.
* paired t-test before and after ODI (Item No. 4); significance at p<0.05.
† Wilcoxon signed-rank test before and after ODI (Item No. 4); significance at p<0.05.

Table 15. Differences in EQ-5D Before and After Treatment

		N	EQ-5D			p-value
			Admission	Discharge	Improvement	
Sex	Male	27	0.630±0.191	0.735±0.182	0.104±0.180	p<0.05*
	Female	95	0.652±0.660	0.770±0.650	0.118±0.892	p=0.10*
Age	<65	50	0.742±0.889	0.749±0.151	0.007±0.875	p=0.478*
	≥65	72	0.582±0.188	0.772±0.745	0.190±0.724	p<0.05*
Disease stage	Acute stage(Most acute&acute)	30	0.503±0.243	0.677±0.260	0.174±0.247	p<0.001*
	Subacute stage	52	0.758±0.865	0.744±0.142	-0.014±0.851	p=0.453*
	Chronic stage	40	0.613±0.143	0.853±0.974	0.240±0.953	p=0.060*
Morphological grade	A2~A4	31	0.528±0.214	0.664±0.244	0.136±0.219	p<0.05†
	B	20	0.605±0.213	0.695±0.225	0.090±0.205	p<0.05†
	C	61	0.729±0.800	0.849±0.779	0.120±1.104	p<0.001†
	D	4	0.607±0.203	0.657±0.236	0.050±0.054	p=0.125†
DSCA	≤ 75mm^2	88	0.681±0.680	0.776±0.677	0.094±0.925	p<0.001†
	> 75 mm^2 and < 100 mm^2	20	0.577±0.228	0.734±0.130	0.156±0.197	p<0.05†
	≥ 100mm^2	14	0.533±0.168	0.723±0.148	0.190±0.174	p<0.001†
Total		122	0.648±0.589	0.763±0.579	0.115±0.072	p=0.055*

EQ-5D index values are means ± standard deviation.
* paired t-test before and after EQ-5D; significance at p<0.05.
† Wilcoxon signed-rank test before and after EQ-5D; significance at p<0.05.

Table 16. Differences in Treatment Effect According to Radiological Criteria

	Morphological Grade	DSCA
	p-value	
NRS(lumbar & pelvic pain)	0.452*	0.425*
NRS(radiating pain & numbness)	0.900*	0.490*
ODI	0.762†	0.076†
Gait-related ODI	0.890*	0.229*
EQ-5D	0.546*	0.288*

* Kruskal-Wallis test. † One-way ANOVA.

significant increases were observed in each group except for morphological grade D (due to the small number of patients).

Differences in treatment effects according to radiological criteria

Differences in NRS scores (for lumbar and pelvic pain, and radiating pain and numbness), ODI and gait-related ODI scores, and EQ-5D values after treatment compared to before treatment were analyzed according to morphological grade and DSCA (Table 16). There were no statistically significant differences.

Discussion

LSS is a degenerative disease. Its prevalence increases with age. In one study [22], 47% of those aged 60–69 years had radiological signs of LSS. Effective management and treatment of LSS will become increasingly important as the proportion of elderly in populations increase as a result of aging. Neurogenic intermittent claudication, which is a typical and the most common symptom of LSS, and which occurs during walking, has a great influence on the quality of life of the elderly [23]. According to the 2016 Health Insurance Review and Assessment frequency morbidity statistics, other spondylopathies (M48, International Classification of Disease), including LSS, presenting at the time of admission ranked eighth. By age, they ranked fourth in those aged 60–69 years and fifth in those aged 70–79 years [24].

In Korean medicine, LSS is viewed as belonging to muscle and bone Bijeung (筋骨痺症), lumbar and leg pain (腰腿痛). It is thought that when the body is in a weak state, long-term invasion of Sa qi (邪氣), or trauma or fatigue can cause LSS [25]. Chronic degeneration after middle age and decline in kidney qi (腎氣) are the main causes of LSS [26].

Diagnosis of LSS is based on clinical symptoms and radiological findings. At present, although there are no standard radiological diagnostic criteria for LSS [27], there are studies on the anteroposterior diameter of the spinal canal [28], area of the spinal canal, DSCA [29], and morphological grade [17]. A recent report describes a method for diagnosing LSS by measuring the total cross-sectional area of the ligamentum flavum [30].

There are only a few studies on LSS and radiological diagnostic criteria in traditional Korean medicine. In particular, there are no papers on morphological grade (which is closely related to LSS severity) and the radiological signs that indicate that LSS surgery is necessary [31]. The objective of this study was to determine if LSS treatment using traditional Korean medicine led to any significant improvements as assessed by radiological criteria.

The male to female ratio in our study population was 1 to 3.52, which is quite different from the 1 to 1.63 ratio reported in the 2016 Health Insurance Review and Assessment morbidity subclass statistics [32]. The distribution of our study patients across the age categories is also consistent with the fact that LSS is a degenerative disease that increases in prevalence with age. We had the greatest number of patients in the group aged ≥ 70 years, and the least in the group aged 30–39 years, with none in the 20–29 years group (Table 1).

Almost three-quarters of our patients (73.77%) had LSS in L4/5 (Table 5), which is consistent with previous reports of it being a frequent site of LSS [33].

There is a tendency for patients admitted to hospital to have severe LSS according to radiological criteria. This was observed in our study as well: 50% of patients had morphological grade C; 72% had DSCA ≤ 75 mm2 (severe group) (Table 6).

The way to represent before and after treatment states in numbers is the strongest objective way [34]. In this study, NRS, ODI and gait-related ODI before and after treatment were measured in order to evaluate the efficacy of Korean medical treatment on pain and function. EQ-5D index was assessed before and after treatment to evaluate the effect of the therapy on quality of life.

NRS scores for low back and pelvic pain and radiating pain and numbness improved significantly (both $p < 0.001$) after treatment. The improvements remained significant even when analyzed according to sex, age, disease stage, and radiological criteria (except for morphological grade D). The results of this study indicate that traditional Korean medicine has a significant effect on lumbar pain, pelvic pain, radiating pain and numbness (which are the main symptoms of LSS) in the whole patient group as well as the subgroups analyzed in this study (Tables 11 & 12).

ODI and ODI Item 4 (which assesses gait disorder) scores also improved significantly after treatment (both $p < 0.001$). Again, the improvements remained significant even when analyzed according to sex, age, disease stage, and radiological criteria (except for morphological grade D). (Tables 13 & 14). The results show that traditional Korean medical treatment of LSS can relieve dysfunction due to back pain and improve pain. The improvement in gait-related ODI also indicates that Korean medicine not only improves simple pain but also overall quality of life.

However, when we look at the EQ-5D index of the whole patient group before and after treatment to determine if treatment had any significant effect on quality of life, we found no statistically significant difference. This may be due to the presence of a number of comorbidities in our patients. It is to be expected that improvement in quality of life may not necessarily result from treatment of a single disease (LSS) only. Nevertheless, subgroup analyses revealed significant increases in EQ-5D index values for males, elderly aged ≥ 65 years, and patients with acute stage LSS. Analyses according to radiological criteria also revealed significant increases (except for the morphological grade D group). Treatment of LSS with Korean medicine may reduce pain and improve physical and mental quality of life (Table 15).

When the changes between pre- and post-treatment NRS, ODI, gait-related ODI, and EQ-5D were analyzed by morphological grade and DSCA, there were no statistically significant differences (Table 16). This means that symptom improvement as a result of traditional Korean medical treatment in radiologically severe LSS may be as good as that in mild LSS. Therefore, in patients with severe LSS who have been recommended to undergo surgery based on radiological signs (though they may not have absolute indications for surgery), traditional Korean medical treatment may be recommended before surgery. Furthermore, as noted in a recent Cochrane review [35], it is difficult to say if surgery is superior to conservative therapy in LSS treatment. Thus, traditional Korean medicine can be a viable alternative treatment for LSS.

This study had a few limitations. First, as the study was an observational one, there is lack of evidence to show the complete correlation between traditional Korean medicine treatment and pain and quality of life in LSS patients. In addition, patients could not be compared under the same conditions due to differences in treatment period (based on length of hospitalization) and different therapists who administered the treatments. The main indicators were only measured on admission and at discharge, which is not sufficient to demonstrate long-term efficacy. Accurate comparison was also difficult because of the different numbers of patients by radiological criteria, though this situation may be meaningful in that it is more reflective of the actual clinical environment. It is hoped that future research will address these points.

Conclusion

The results of this study suggest that traditional Korean medicine is effective treatment for LSS patients by reducing pain and improving quality of life, even in those with severe radiological findings.

Conflicts of Interest

All authors have no conflicts of interest to declare.

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