



Original Article

Pain, disability, and MRI changes in lumbar disc herniation patients treated with integrative medicine: Ten-year results of an observational study



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ABSTRACT

Background: To date, a 10-year follow-up study on complementary and alternative medical treatment of lumbar intervertebral disc herniation (LDH) has never been conducted. Therefore, we aimed to perform a prospective 10-year follow-up study on the integrated treatment of LDH in Korea.

Methods: One hundred and fifty patients from the baseline study, who initially met the LDH diagnostic criteria with a chief complaint of radiating pain and received integrated treatment, were recruited for this follow-up study. The 10-year follow-up was conducted from February 2018 to March 2018 on pain, disability, satisfaction, quality of life, and changes in herniated disc, muscles, and fat through magnetic resonance imaging.

Results: Sixty-five patients were included in this follow-up study. Visual analogue scale score for lower back pain and radiating leg pain were maintained at a significantly lower level than the baseline level. Significant improvements in Oswestry disability index and quality of life were consistently present. MRI confirmed that disc herniation size was reduced over the 10-year follow-up. In total, 95.38% of the patients were either “satisfied” or “extremely satisfied” with the treatment outcomes and 89.23% of the patients claimed their condition “improved” or “highly improved” at the 10-year follow-up.

Conclusions: The reduced pain and improved disability was maintained over 10 years in patients with LDH who were treated with nonsurgical Korean medical treatment 10 years ago. Nonsurgical traditional Korean medical treatment for LDH produced beneficial long-term effects, but future large-scale randomized controlled trials for LDH are needed.

Study registration: [ClinicalTrials.gov](https://clinicaltrials.gov), NCT03426215.

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1 Introduction

Korea has accepted traditional medicine into its healthcare system. It features a dual healthcare system, where patients are diag-

nosed using modernized medical equipment and consulted about conventional medicine and traditional Korean medicine before being instituting traditional Korean medical treatment. Traditional Korean medicine primarily employs integrated treatments, including acupuncture, herbal medicine, chuna, and pharmacopuncture. Chuna is the Korean style of manual therapy aiming to restore the balance between anatomical structures and function, and is performed by Korean Medicine Doctors (KMDs). Pharmacopuncture is a relatively new acupuncture therapy combining acupuncture with herbal medicine.

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Patients in Korea actively seek traditional Korean medicine for musculoskeletal disorders, which is confirmed by the Korean health insurance claim data, where the number of claims for the use of traditional Korean medicine for dorsalgia was 3,719,415 in 2020 alone¹.

Lumbar intervertebral disc herniation (LDH) is characterized by pain, weakening, and tingling due to a displacement of disc material². Low back pain (LBP) and sciatica, the major symptoms of LDH, have a great impact on the working hours since they can cause disability³; therefore, LBP is known to have a high disease burden, as suggested by its number one ranking in years lived with a disability (YLD)⁴. Conservative treatments, such as transforaminal epidural steroid injection, pharmacological treatment, and physical therapy, as well as surgery are recommended for LDH². Many patients with LDH in Korea seek integrated traditional Korean medical treatment. This is owing to quick therapeutic effects on pain disorders, such as LBP, by acupuncture and other traditional Korean modalities and many studies have confirmed that integrated treatment can prevent surgery in acute LBP^{5, 6}. Furthermore, while conservative treatments, such as injection, and surgery have been linked to serious complications, such as failed back surgery syndrome⁷ and infection⁸, CAM such as traditional Korean medical treatments, are perceived as noninvasive and relatively safe⁹.

Disc herniation is recurrent even after the improvement of symptoms through surgery and conservative treatment. Therefore, prevention of long-term recurrences and the effect on quality of life (QOL) are crucial issues. In a study comparing the long-term effects of surgery and nonsurgical treatments, surgery led to a quick recovery in the beginning; however, its outcomes were similar to that of conservative treatment after a year¹⁰. Moreover, a 10-year follow-up study reported no differences in outcomes after 4 years¹¹. However, to date, there has been no study on whether the long-term outcomes of integrated traditional Korean medical treatment are equal to or better than that of the conventional conservative treatment. Therefore, it is necessary to examine the long-term progress of LDH after treatment with integrated complementary and alternative medicine (CAM).

We had previously performed a prospective observational study on LDH patients undergoing CAM treatment and reported the results of the 6-month, 3-year, and 5-year follow-up¹²⁻¹⁴. In the present study, we report on the nonsurgical CAM treatment of LDH patients who met the medical diagnostic criteria and prospectively observed their pain, functions, and QOL as well as changes in disc displacement, fat, and muscle mass as shown on magnetic resonance imaging (MRI) after 10 years of treatment.

2. Methods

2.1. Patients

In the baseline study, LDH patients with a chief complaint of sciatica were recruited from the Jaseng Hospital in Republic of Korea from November 2006 to April 2007¹². The Jaseng Hospital is a traditional Korean hospital specializing in spinal disorders which is acknowledged by the Ministry of Health and Welfare, and more than 900,000 patients with spinal disorders are treated at Jaseng every year through integrated traditional Korean medical treatment¹⁵. The patients included were between the ages of 18 and 60 years with LDH less than 1 year from onset and LBP and leg pain with a numeric rating scale (NRS) score ≥ 5 and received integrated traditional Korean medical treatment for disc herniation as intervention. The integrated traditional Korean medical treatment consisted of herbal medicine, acupuncture, pharmacopuncture, and chuna and the intervention was given by KMD specialists with more than 10 years of clinical experience. The treatment was

performed once a week for 24 weeks. Herbal medicine was administered twice a day for 24 weeks.

For this 10-year follow-up study, the patients who completed the baseline study were eligible. In order to encourage to participate 10-year follow-up study, the patients were contacted via phone and mail from February to March 2018 with information about the study participation. A voluntarily written informed consent was obtained from the participant, who was given a copy of his or her informed consent form.

2.2. Clinical protocol

We had previously reported the results of the 6-month, 3-year, and 5-year follow-up of this study, and the details of the study intervention are described in our previous reports¹²⁻¹⁴. The protocol of this study was registered as NCT03426215. The clinical trial protocol of the present study was approved by the Institutional Review Board (IRB) at Jaseng Hospital (JASENG 2017-12-008-002). The study was conducted in accordance to the tenets of the Declaration of Helsinki.

2.3. Outcomes

The following parameters were examined in the 10-year follow-up:

- LBP and radiating leg pain (assessed by visual analog scale (VAS)/numerical rating scale (NRS))
- Level of function (disability) (assessed by Oswestry disability index (ODI))
- Quality of life (assessed by SF-36)
- Satisfaction / perception of improvement (assessed by 5-point Likert scale)
- Disc herniation type, degeneration grade, and volume (measured by MRI)
- Number of degenerative discs (measured by MRI)
- Volume of muscle and fat (measured by MRI)
- Bone mineral density (BMD) (measured by quantitative computed tomography or dual x-ray absorptiometry)
- Current status, 10-year course and perception (assessed by questionnaire)

The questionnaire included the questions about the following. (lumbar surgery after 24 weeks treatment / pain recurrence with duration of ≥ 1 month after conclusion of treatment / currently suffers from LBP and/or leg pain (attributed LDH) for ≥ 3 months to a level that interferes with daily activities / currently receives treatment relating to LBP or leg pain / regret being treated at the traditional Korean medical hospital / superiority of long-term effects / adherence to changes in lifestyle / prophylactic treatment)

2.4. Assessments

All assessments were performed by trained physicians (traditional KMDs). Patients were followed-up at baseline, weeks 24, year 1, year 5, and at year 10. Physicians who participated in the assessment were trained over three sessions to ensure the quality control and the consistency in outcome assessment.

The assessments by a clinical specialist were analyzed without analyzing changes in the size of herniation or muscle mass. In this follow-up, we compared disc herniation, degree of degeneration, muscle mass, and subcutaneous fat mass over a 10-year period by comparing the MRIs taken at the baseline, 6 months, 1, year, 5 years, and 10 years. In patients with multiple herniated discs, the major disc herniation was measured, and herniation at the same level was measured again at 6 months, 1 year, 5 years, and 10 years. The type of disc herniation was classified as bulging,

protrusion, extrusion, migration, and sequestration as suggested by the North American Spine Society (NASS)¹⁶. The classification criteria put forth by Pfirrmann et al¹⁷, which classifies the LDH degeneration by structure, signal intensity, and disc height on MRI into 5 levels from Grades I to V, was employed. Higher grades imply greater degeneration, and generally, Grades IV and V indicate disc degeneration. Modic types were classified into 0 (no modic change), and modic types 1, 2, and 3. The location of the modic type change in the vertebral body was recorded as (i) above, (ii) below, or (iii) both above and below the LDH level, or (iv) no modic type change¹⁸. Size of herniation was measured as described by Seo et al.¹⁹, and muscle mass was measured as described by Lee et al.²⁰. BMD was measured at the baseline, 6 months, and 10 years, on the basis of which we attempted to examine the changes over 10 years. However, it was difficult to compare the direct values of BMD owing to the changes in technologies and differences in hospital equipment over the 10-year period. Thus, we did not compare the changes in the values itself but instead classified patients as being normal or having osteopenia or osteoporosis as indicated by the equipment used at the time for comparisons. To minimize error in MRI-based measurements, two physicians having agreed on the method of measurement in advance, independently assessed 30 patients, and compared their results to compute the Kappa and Intraclass Correlation Coefficient to check for agreement before measuring other participants.

2.5. Statistical analysis

All analyses were performed using the statistical package SAS version 9.4 (SAS Institute Inc, Cary, NC, USA). $P < 0.05$ was considered to be statistically significant. All continuous variables were calculated as mean and standard deviations, and categorical variables as frequency and percentages (%). Significance was analyzed using the differences and 95% confidence intervals (95% CI) in the average NRS of LBP and radiating leg pain, and ODI measured at baseline, 24 weeks, 1-year, 5-year and 10-year follow-up. The linear mixed model was employed to analyze the repeated measurement data at 24 weeks, 1 year, 5 years, and 10 years. The categorical variables were analyzed using chi-square tests.

3. Results

3.1. Participants

Sixty-five patients successfully completed the 10-year follow-up, whereas 85 were lost to follow-up or did not complete the treatment. From the 150 patients who participated baseline study, 22 did not completed 6 months of treatment, 63 could not participate in this study; 48 were lost to follow-up owing to either change in phone number or migration, and 15 refused to participate (Supplementary Figure 1). Supplementary Table 1 shows a comparison of the basic characteristics of those who were successfully followed-up and those who were lost to follow-up or did not complete the treatment.

3.2. Baseline characteristics

There were no significant differences in any of the following characteristics compared at the baseline between the 65 patients who completed follow-up and 85 who were lost to follow-up or did not complete the treatment: age, sex, smoking, severity of pain at beginning of study, recommendation of surgery, and size of disc herniation (Supplementary Table 1). There were no significant differences in the pain, ODI and SF-36 at the point of 1 year and 5 years for those who were successfully followed up and those who were not (Supplement Table 2).

3.3. Patients reported outcomes

3.3.1. LBP

Progress was compared at the baseline, 6 months, 1 year, 5 years, and 10 years (Table 1). VAS for LBP significantly decreased from 4.39 ± 2.74 at baseline to 1.07 ± 1.27 at 6 months. This effect persisted up to 1 year, and VAS scores of LBP actually decreased more at the 1-year follow-up. At the 5-year follow-up, it slightly increased to 1.25 ± 1.81 , but a significant reduction in pain continued to persist even until the 10-year follow-up (1.15 ± 1.41).

3.3.2. Radiating leg pain

The VAS scores of radiating leg pain decreased from 7.42 ± 1.36 at baseline to 1.09 ± 1.55 at 6 months and 0.75 ± 1.45 at 1 year. They slightly increased at the 5-year follow-up (0.98 ± 1.73) and 10-year follow-up (0.88 ± 1.37), but were maintained at a similar level as those at the 6-month follow-up.

3.3.3. Level of function

ODI significantly decreased from 41.36 ± 15.49 at baseline to 11.84 ± 11.18 at 6 months. They were further improved at the 1-year follow-up, and remained at a consistent level until the 5-year follow-up. At the 10-year follow-up, ODI was similar to that at the 6-month follow-up. QOL was significantly improved at the 6-month follow-up compared to that at baseline. It was further improved at the 1-year follow-up, and remained similar until the 10-year follow-up.

3.3.4. Satisfaction and perceived improvement

Satisfaction and perceived improvement were assessed among patients who participated in the 10-year follow-up (Supplementary Table 3). Thirty-one (47.69%) participants were "extremely satisfied" and 31 (47.69%) were "satisfied" with the treatment outcomes at year 10. Three (4.62%) were "slightly satisfied" and none of the participants were "dissatisfied" or "extremely dissatisfied". Regarding currently perceived improvement, 27 (41.54%) chose "highly improved" and 31 (47.69%) chose "improved." Four participants chose "no change" and three participants chose "worsened".

On surveying the recurrence lasting more than 1 month over the 10-year period and participants undergoing surgery (Supplementary Table 4), we observed that twenty-three (35.94%) participants had recurrence lasting more than 1 month, and five had surgery, all of whom only had a single surgery. Six patients currently had pain for more than 3 months, and four (6.25%) patients were currently undergoing treatment for herniated disc. Although some patients revealed that their condition had worsened, all of the patients asserted that they do not regret undergoing traditional Korean medical treatment. Furthermore, 84.38% of the patients believed that herniated discs could be treated without surgery, suggesting that they think a herniated disc can be improved using nonsurgical treatments. Regarding the superiority of the long-term therapeutic effects, 77.47% chose nonsurgical traditional Korean medical treatment, while 8.45% chose nonsurgical conventional treatment. A total of 2.81% of the patients thought that surgical and nonsurgical treatments have the same effects, and 1.41% chose surgery. In addition, 84.38% of the patients were still adhering to the changes in lifestyle recommended during treatment.

3.4. MRI & BMD outcomes

We also compared the MRIs and the BMD. Based on MRIs, we confirmed that the size of disc herniation from baseline significantly and gradually decreased over time, from the 6-month follow-up to 1-year, 5-year, and 10-year follow-ups (Table 2). As the size of herniation decreased, many patients tended to have a

Table 1
Difference in pain, function, and quality of life over 10 years compared to baseline.

	Baseline (n=150)	24 weeks (n=128)	1 year (n=108)	5 years (n=92)	10 years (n=65)
Low back pain					
VAS Mean (SD)	4.39±2.74	1.07±1.27	0.81±1.10	1.25±1.81	1.15±1.41
Mean change ^a (95% CI)	-	-3.30 (-3.66, -2.95) p<0.001	-3.52 (-3.90, -3.15) p<0.001	-3.03 (-3.42, -2.63) p<0.001	-3.18 (-3.64, -2.73) p<0.001
NRS Mean change ^a (95% CI)	4.35±2.57	1.26±1.33 (-3.47, -2.76) p<0.001	NR	1.52±1.82 (-3.21, -2.41) p<0.001	1.49±1.51 (-3.30, -2.42) p<0.001
Radiating leg pain					
VAS Mean (SD)	7.42±1.36	1.09±1.55	0.75±1.45	0.98±1.73	0.88±1.37
Mean change ^a (95% CI)	-	-6.31 (-6.63, -5.99) p<0.001	-6.62 (-6.96, -6.28) p<0.001	-6.39 (-6.75, -6.03) p<0.001	-6.47 (-6.88, -6.07) p<0.001
NRS Mean (SD)	7.21±1.30	1.23±1.53	NR	1.29±1.81	1.08±1.42
Mean change ^a (95% CI)	-	-5.95 (-6.28, -5.62) p<0.001	NR	-5.92 (-6.29, -5.55) p<0.001	-6.10 (-6.51, -5.70) p<0.001
Level of function					
Oswestry Disability Index Mean (SD)	41.36±15.49	11.84±11.18	8.06±9.47	7.61±9.82	11.26±9.24
Mean change ^a (95% CI)	-	-29.17 (-34.88, -25.92) p<0.001	-32.42 (-34.93, -29.91) p<0.001	-33.78 (-36.42, -31.13) p<0.001	-29.72 (-32.14, -26.19) p<0.001
Quality of life					
SF-36 Mean (SD)	35.62±13.69	66.46±15.75	73.69±14.09	74.74±16.06	74.09±15.53
Mean change ^a (95% CI)	-	31.32 (28.57, 34.06) p<0.001	37.53 (34.64, 40.41) p<0.001	40.66 (37.56, 43.77) p<0.001	38.72 (35.30, 42.14) p<0.001

^a Mean difference from baseline CI, confidence interval; NR, Not reported; NRS, numeric rating score; SD, standard deviation; VAS, visual analog scale.

milder disc herniation type over time; however, disc degeneration tended to worsen and modic changes increased over time.

Right and left lower back muscle mass gradually increased until year 5, and that at year 10 was slightly lower than that at year 5 but still higher than that at the baseline. Subcutaneous fat mass slightly varied across the follow-ups but tended to increase in general. BMD was not significantly altered over the 10-year period.

4. Discussion

Patients who had been recruited between 2006 and 2007 and treated using integrated Korean medical treatment were followed-up in 2018, and data from 65 patients were analyzed. At the 10-year follow-up, the VAS scores of LBP and radiating leg pain were significantly lower than those at baseline. Furthermore, ODI and QOL were also significantly improved. MRI confirmed that the size of disc herniation was smaller than that at baseline, which showed a decrease at each follow-up. Right and left lower back muscle mass gradually increased until year 5; at year 10, it was slightly lower than that at year 5 but still higher than that at baseline. Satisfaction and perceived improvement were assessed; 47.69% of participants were “extremely satisfied” and 47.69% were “satisfied” with the treatment outcomes at year 10. In addition, 89.23% of the patients said that their condition was improved or highly improved, suggesting that the improvement persisted even after 10 years from treatment. Furthermore, all patients said that they did not regret receiving integrated Korean medical treatment.

To date, there is no published long-term (10-year) follow-up study on nonsurgical traditional Korean medical treatment for LDH. In particular, this study is meaningful in that it prospectively examined patients who met the medical criteria for LDH. Moreover, it is also meaningful in that it examined objective improvements based on modern medical equipment, such as MRI. We had previously published a study on disc absorption with nonsurgical traditional Korean medical treatment²¹. However, in the present follow-

up study, we were able to confirm that disc absorption occurs not only in the early days after treatment but continues over a long period. Although additional prospective studies are needed to examine whether nonsurgical traditional Korean medical treatment induces more disc absorption compared to other conservative treatments, this study is meaningful in that it prospectively observed long-term disc absorption. It is estimated that this long-term effect has been combined with the effects of acute pain relief in acupuncture and chuna, as well as the long-term effects of neuroprotection and anti-inflammation in herbal medicine. Numerous studies have reported superior pain reduction and rapid recovery effects of acupuncture and manual therapy compared to conventional therapy^{22, 23}. Additionally, GCSB-5, the main ingredient of herbal medicine for LDH have been studied for anti-inflammatory, neuroprotection effects^{24, 25}. In addition, 83.38% of patient confirmed changes in their lifestyle, which would have had a long-term effect, since they would avoid specific movements that could worsen LDH based on their lifestyle. Lifestyle are known to play an important role in the recurrence or chronicity of back pain^{26, 27}, and it is estimated that the long-term effect could be maintained by changing their lifestyles.

LDH is known to be recurrent. In the present follow-up, we surveyed whether there were any recurrences that lasted for more than 1 month over 10 years and whether patients received surgery. Twenty-three (35.94%) had a recurrence that lasted for more than 1 month, and only five patients underwent surgery. Although there indeed have been recurrences, it seems that a large number of patients were well managed using nonsurgical treatment. Furthermore, such long-term effects may have reduced the size of disc herniation while increasing muscle mass. An increase in muscle mass may have resulted from changes in the patients' lifestyle since we encouraged patients to inculcate changes in their lifestyles during the treatment process through patient education. Therefore, education coupled with integrated traditional Korean medical treatment appears to have resulted in beneficial long-term effects.

Table 2
Difference in the volume of herniated discs, back muscle, and subcutaneous fat over 10 years compared to baseline.

	Baseline (n=143 ^a)	24 weeks (n=123 ^b)	1 year (n=104 ^b)	5 years (n=84 ^b)	10 years (n=64 ^b)
Vol. of herniated discs (mm ³)	603.52	472.85	341.08	296.11	218.43
Vol. of back muscle (Rt, mm ³)	±263.04	±249.00 **	±188.45**	±180.60**	±140.15**
Vol. of back muscle (Lt, mm ³)	2,030.86	2,057.63	2,096.59	2,156.20	2,135.97
Vol. of sub.fat (Rt, mm ³)	±422.98	±421.29*	±444.73**	±441.25**	±434.35**
Vol. of sub.fat (C, mm ³)	2,018.97	2,058.30	2,086.23	2,147.43	2,130.11
Vol. of sub.fat (Lt, mm ³)	±428.40	±422.74*	±430.36**	±437.99**	±430.08**
Vol. of sub.fat (Lt, mm ³)	8.51±4.64	9.43±4.84	8.96±4.96	9.07±4.27	10.09±5.39**
Vol. of sub.fat (C, mm ³)	13.39±5.78	14.50±6.28*	14.16±6.40	13.99±6.00	15.13±6.84**
Vol. of sub.fat (Lt, mm ³)	8.91±4.48	9.74±4.87	9.23±4.84	11.04±16.75	10.49±5.38*
Disc herniation type					
Bulging	3(2.10)	6(4.88)	8(7.69)	16(19.05)	16(25.00)
Protrusion	75(52.45)	74(60.66)	69(66.35)	47(55.95)	30(46.88)
Extrusion	50(34.97)	30(24.59)	21(20.19)	17(20.24)	16(25.00)
Migration	15(10.49)	13(10.66)	6(5.77)	4(4.76)	2(3.13)
Sequestration	-	-	-	-	-
Disc degeneration grade					
I	-	-	-	-	-
II	5(3.50)	2(1.63)	2(1.92)	-	-
III	44(30.77)	33(26.83)	19(18.27)	11(13.10)	2(3.13)
IV	74(51.75)	71(57.72)	65(62.50)	47(55.95)	15(23.44)
V	20(13.99)	17(13.82)	18(17.31)	26(30.95)	47(73.44)
Modic change type of vertebral body					
0	129(89.58)	107(86.99)	88(84.62)	58(69.05)	34(53.13)
1	-	-	-	2(2.38)	29(45.31)
2	15(10.42)	16(13.01)	16(15.38)	24(28.57)	1(1.56)
3	-	-	-	-	-
Modic change of vertebral body area					
Above	2(1.39)	2(1.63)	2(1.92)	5(5.95)	1(1.56)
Below	-	-	-	-	-
Both	13(9.03)	14(11.38)	14(13.46)	21(25.00)	29(45.31)
None	129(89.58)	107(86.99)	88(84.62)	58(69.05)	34(53.13)
BMD					
Normal	121(85.21)	104(85.25)	-	-	55(85.94)
Osteopenia	21(14.79)	18(14.75)	-	-	8(12.50)
Osteoporosis	-	-	-	-	1(1.56)

Vol, Volume; BMD, Bone Mass Density; sub, subcutaneous; Rt, Right, Lt, Left, C, Central, *, p<0.01; **, p<0.001.

a: MRI measurement in 7 out of 150 people were not measured due to differences in MRI equipment at the time.

b: Some patients who were followed by phone did not have MRI.

One of the greatest limitations of our study is that many patients were lost to follow-up over the 10-year period. In Korea, people frequently move to different regions, and many patients changed their cell phone numbers during the follow-up period. For this reason, it was impossible to contact the patient in many cases, which led to the loss to follow-up. Since it is likely that patients who had been satisfied at the time of treatment responded to the follow-up study, we cannot eliminate the possibility of overestimation in our satisfaction survey. Furthermore, due to the lack of a control group, we could not compare this intervention directly with other treatment methods. In addition, there may be a recall bias since the satisfaction or regret of the treatment, which took place 10 years ago, has now been surveyed. The objective results were confirmed through MRI and BMD, but these two modalities have developed many advancements over the decade, which can lead to changes in the imaging protocol, thereby limiting the direct comparison of the MRI from 10 years ago with the current MRI. Since the other treatment was not confined after 24 weeks of treatment, it is difficult to confirm that maintenance of pain reduction and improvement is the only effect of 10 years ago. However, there has been no long-term prospective follow-up study on integrated Korean medical treatment on patients with LDH in Korea. Hence, being a pioneer study is the greatest strength of our study. There have been several long-term follow-up studies after surgery, but long-term follow-up studies after conservative treatment were relatively lacking, with no long-term follow-up study on integrated

Korean medical treatment at all. Furthermore, the fact that we utilized objective medical equipment, such as MRI, for our follow-up is also an important factor. Our study results may be meaningful in that we examined not only subjective pain-related indices but also objective indices such as changes in herniation size based on MRI.

In the future studies, integrated Korean medical treatment should be compared with conservative treatment for patients with LDH in randomized controlled trials (RCTs), and the long-term effects should be examined. Furthermore, studies need to analyze whether the differences in long-term treatment of disc absorption affect the amount of disc absorption.

Author contributions

Conceptualization: IHH and JSS. Methodology: BCS. Investigation: MK, HWC, JYS and KCS. Data Curation: MK and YJL. Writing – Original Draft: YJL and JL. Writing – Review & Editing: YJL, HC and JL. Supervision: BCS. Project Administration: IHH and JSS.

Conflict of interest

BCS is an editorial board member of this journal but his membership had no bearing on the editorial process or decision. The authors declare that they have no other conflicts of interest.

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None

Ethical statement

This research was reviewed and approved by the institutional review board of at Jaseng Hospital (JASENG 2017-12-008-002). Informed consent was obtained from all participants.

Data availability

The datasets generated and/or analyzed during the current study are not publicly available as they are being analyzed in another study; however, they are available from the corresponding author on reasonable request.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.imr.2022.100833](https://doi.org/10.1016/j.imr.2022.100833).

References

- 2020 National Health Insurance Statistical Yearbook: Health Insurance Review & Assessment Service. *National Health Insurance Service*. 2021.
- Kreiner DS, Hwang SW, Easa JE, Resnick DK, Baisden JL, Bess S, et al. An evidence-based clinical guideline for the diagnosis and treatment of lumbar disc herniation with radiculopathy. *Spine J*. 2014;14(1):180–191.
- van Tulder MW, Koes BW, Bouter LM. A cost-of-illness study of back pain in The Netherlands. *Pain*. 1995;62(2):233–240.
- Hoy D, March L, Brooks P, Blyth F, Woolf A, Bain C, et al. The global burden of low back pain: estimates from the Global Burden of Disease 2010 study. *Annals of the rheumatic diseases*. 2014;73(6):968–974.
- Grisa MH, Baccouche H, Boubaker H, Beltaief K, Bzeouich N, Fredj N, et al. Acupuncture vs intravenous morphine in the management of acute pain in the ED. *The American journal of emergency medicine*. 2016;34(11):2112–2116.
- Koh W, Kang K, Lee YJ, Kim MR, Shin JS, Lee J, et al. Impact of acupuncture treatment on the lumbar surgery rate for low back pain in Korea: A nationwide matched retrospective cohort study. *PLoS One*. 2018;13(6):e0199042.
- Baber Z, Erdek MA. Failed back surgery syndrome: current perspectives. *Journal of pain research*. 2016;9:979–987.
- Shamliyan TA, Staal JB, Goldmann D, Sands-Lincoln M. Epidural steroid injections for radicular lumbosacral pain: a systematic review. *Physical Medicine and Rehabilitation Clinics*. 2014;25(2):471–489 e50.
- Jackman A, Mayan M, Kutt A, Vohra S. Perceptions of complementary health approaches among undergraduate healthcare professional trainees at a Canadian university. *European Journal of Integrative Medicine*. 2017;9:120–125.
- Peul WC, van den Hout WB, Brand R, Thomeer RTWM, Koes BW. Leiden-The Hague Spine Intervention Prognostic Study G. Prolonged conservative care versus early surgery in patients with sciatica caused by lumbar disc herniation: two year results of a randomised controlled trial. *BMJ*. 2008;336(7657):1355–1358.
- Weber H. Lumbar disc herniation. A controlled, prospective study with ten years of observation. *Spine*. 1983;8(2):131–140.
- Park JJ, Shin J, Choi Y, Youn Y, Lee S, Kwon SR, et al. Integrative package for low back pain with leg pain in Korea: a prospective cohort study. *Complement Ther Med*. 2010;18(2):78–86.
- Shin JS, Lee J, Kim MR, Shin BC, Lee MS, Ha IH. The long-term course of patients undergoing alternative and integrative therapy for lumbar disc herniation: 3-year results of a prospective observational study. *BMJ open*. 2014;4(9):e005801.
- Shin JS, Lee J, Lee YJ, Kim MR, Ahn YJ, Park KB, et al. Long-term course of alternative and integrative therapy for lumbar disc herniation and risk factors for surgery: a prospective observational 5-year follow-up study. *Spine*. 2016;41(16):E955–E963.
- Robinson N, Liu J. Oriental and traditional medicine—supporting the vision for integrated health. *European Journal of Integrative Medicine*. 2012;4(4):e363–ee65.
- Fardon DF, Milette PC. Nomenclature and classification of lumbar disc pathology: recommendations of the combined task forces of the North American Spine Society, American Society of Spine Radiology, and American Society of Neuroradiology. *Spine*. 2001;26(5):E93–E113.
- Pfirrmann CW, Metzendorf A, Zanetti M, Hodler J, Boos N. Magnetic resonance classification of lumbar intervertebral disc degeneration. *Spine*. 2001;26(17):1873–1878.
- Kjaer P, Korsholm L, Bendix T, Sorensen JS, Leboeuf-Yde C. Modic changes and their associations with clinical findings. *European Spine Journal*. 2006;15(9):1312–1319.
- Seo J-Y, Roh Y-H, Kim Y-H, Ha K-Y. Three-dimensional analysis of volumetric changes in herniated discs of the lumbar spine: does spontaneous resorption of herniated discs always occur? *European Spine Journal*. 2016;25(5):1393–1402.
- Lee JC, Cha JG, Kim Y, Kim YI, Shin BJ. Quantitative analysis of back muscle degeneration in the patients with the degenerative lumbar flat back using a digital image analysis: comparison with the normal controls. *Spine*. 2008;33(3):318–325.
- Lee J, Kim J, Shin JS, Lee YJ, Kim MR, Jeong SY, et al. Long-Term Course to Lumbar Disc Resorption Patients and Predictive Factors Associated with Disc Resorption. *Evid Based Complement Alternat Med*. 2017;2017:2147408.
- Santilli V, Beghi E, Finucci S. Chiropractic manipulation in the treatment of acute back pain and sciatica with disc protrusion: a randomized double-blind clinical trial of active and simulated spinal manipulations. *The Spine Journal*. 2006;6(2):131–137.
- Vas J, Aranda JM, Modesto M, Benítez-Parejo N, Herrera A, Martínez-Barquín DM, et al. Acupuncture in patients with acute low back pain: a multicentre randomised controlled clinical trial. *PAIN®*. 2012;153(9):1883–1889.
- Kim T-H, Yoon S-J, Lee W-C, Kim J-K, Shin J, Lee S, et al. Protective effect of GCSB-5, an herbal preparation, against peripheral nerve injury in rats. *Journal of Ethnopharmacology*. 2011;136(2):297–304.
- Chung H-J, Lee H-S, Shin J-S, Lee S-H, Park B-M, Youn Y-S, et al. Modulation of acute and chronic inflammatory processes by a traditional medicine preparation GCSB-5 both in vitro and in vivo animal models. *Journal of Ethnopharmacology*. 2010;130(3):450–459.
- Taimela S, Diederich C, Hubsch M, Heinrich M. The Role of Physical Exercise and Inactivity in Pain Recurrence and Absenteeism From Work After Outpatient Rehabilitation for Recurrent or Chronic Low Back Pain: A Follow-Up Study. *Spine*. 2000;25(14):1809–1816.
- Billis E, Koutsojannis C, Matzaroglou C, Gliatis J, Fousekis K, Gioftsos G, et al. Association of low back pain on physical, sociodemographic and lifestyle factors across a general population sample within Greece. *Journal of back and musculoskeletal rehabilitation*. 2017;30(2):279–290.