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Research paper

Clinical outcomes according to Modic changes of lumbar sprain due to traffic accidents following treatment with Korean Medicine

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ABSTRACT

Introduction: Traffic accidents are increasing in modern society and demand for Korean Medicine for the treatment of symptoms associated with them are also increasing in Korea. In this study, we analyzed the clinical outcomes, according to Modic changes (MCs) on MRI, of Korean Medicine treatment in patients with lumbar sprain following a traffic accident.

Methods: This retrospective observational review was conducted with 268 patients with lumbar sprain following a traffic accident who had been admitted to Bucheon Jaseng Korean Hospital from January 2015 to May 2018. Changes in the numerical rating scale (NRS) for pain severity, Oswestry disablity index (ODI) for disability, and EuroQol-5 dimension (EQ-5D) for the quality of life were compared between groups of different MC types.

Results: The difference in NRS, ODI and EQ-5D between admission and discharge showed statistical significance ($p < 0.05$). Changes in the NRS were significantly different among the different MC types ($p < 0.05$). ODI and EQ-5D did not show statistical significance according to the MC type ($p > 0.05$).

Conclusion: We ascertained that the lesser the degree of MCs present, the better the outcome of the NRS after treatment with Korean Medicine in patients with lumbar sprain following a traffic accident, but not in ODI and EQ-5D.

1. Introduction

Traffic accidents (TAs) continue to increase as the use of cars in modern society continues to rise, and is becoming a major factor causing human injuries [1]. Injuries due to TAs present with various symptoms which include both physical and mental complaints [2].

In 2017, the medical expenses of Korean Medicine (KM) covered by the auto insurance industry amounted to 554.5 billion Korean Won, which was about 55% higher than the 357.6 billion won in 2015. This figure shows that the demand for KM to treat injuries caused by TAs is sharply increasing [3]. Not only are the number of TA patients who prefer to be treated with KM increasing [4] but the satisfaction levels of patients making use of KM is quite high [1]. Many studies have been published on the topic of KM since 1993 with a particular increase in publications after 1999 [5]. Do et al. [6] analyzed clinical data from patients who experienced TAs and treated with KM, whereas Kim et al. [7] reported the effectiveness of KM in patients with lumbar sprain caused by TAs.

Modic changes (MCs) refer to changes in the vertebral endplates and bone marrow and are used as an important tool to grade spinal degeneration [8]. They are known to play a role in back pain in a variety of clinical conditions [9]. MCs are classified into three types: MC type I is associated with the inflammatory changes seen in degenerative disc diseases; MC type II represents the fatty degenerative stage of disc degeneration, which is considered a more stable condition, and is related to chronicity; and MC type III represents the hardening stage of degenerative disc diseases [10–12]. Herlin C et al. [13] reviewed the relationship between low back pain, activity limitation, outcomes such as disc levels and sex, and MCs. Romero-Muñoz LM et al. [14] studied the relationship between surgical procedures for low back pain and MCs,

Abbreviations: EQ-5D, EuroQol-5 dimension; IRB, Institutional Review Board; KM, Korean Medicine; KMDs, Korean Medicine doctors; MCs, Modic changes; MRI, magnetic resonance image; NRS, numerical rating scale; ODI, Oswestry disability index; TAs, traffic accidents

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only showing negative results. Kim et al. [15] reported an association between MC type II and facet joint arthrosis. However, a study using MCs to assess the treatment outcomes of low back pain from TAs using KM has not been published so far.

For this reason, this study was designed to evaluate the clinical outcomes of KM in patients with lumbar sprain caused by a TA according to MC types, in conjunction with other measurements of low back pain, including pain intensity, level of dysfunction and quality of life.

2. Methods

2.1. Participants

A retrospective analysis was done of the data of patients with the primary diagnosis of sprain and strain of the lumbar spine (ICD-10 code S33.5) admitted to Bucheon Jaseng Korean Medicine Hospital from the 1st of January 2015 to the 31st of May 2018. This study was approved by the Institutional Review Board (IRB) of the Jaseng Korean Medicine Hospital on 30th of July 2018 (IRB No. JASENG 2018-07-004). Because it was a retrospective chart review, authors requested a waiver of consent and the IRB approved it as the personal information of participants were limited and coded. The study protocol was registered with the Clinical Research Information Service (Approval No. KCT0004090). This manuscript is written according to the STROBE guidelines for reporting observational studies (see Additional file 1 for the STROBE checklist).

2.1.1. Inclusion criteria

1) admitted with the primary diagnosis of sprain and strain of the lumbar spine (ICD-10 code S33.5) caused by a traffic accident
2) above 18 years of age
3) acute stage of injury, defined as symptom onset within 7 days of the traffic accident
4) findings of MCs on magnetic resonance image (MRI) of the lumbar spine confirmed by a radiologist
5) a hospitalization period of 9–14 days

2.1.2. Exclusion criteria

1) diagnosed with lumbar disc herniation or lumbar spinal stenosis
2) presence of a fracture, spondylolisthesis or active lumbar radiculopathy
3) incomplete questionnaires

2.2. Data extraction and management

Researchers extracted the data from electronic documents, selecting patients according to the inclusion and exclusion criteria (Fig. 1). Lumbar spine MRI images of the included patients were analyzed by a radiologist and classified according to MCs. The assessor of the patients' data was blinded to the MC classification.

2.3. Treatment

2.3.1. Pharmacopuncture

During hospitalization, once a day a total of 1 cc of Shinbaro pharmacopuncture (Jaseng Pharmacopuncture Herbal dispensary facility, Namyangju, Korea) was injected into the areas surrounding the lumbar spine, intervertebral ligaments, acupoint BL23, etc. injecting 0.1-.02 cc at each point using a 31 G disposable insulin syringe (B/Braun, Germany).

2.3.2. Acupuncture

A 0.25 × 30 mm needle, made of disposable stainless steel (Dongbang, Seoul, Korea), was inserted twice daily in the painful area, BL23, BL40, SP6, GB39, etc. at a depth of 5–15 mm for 15 min for the duration of hospitalization

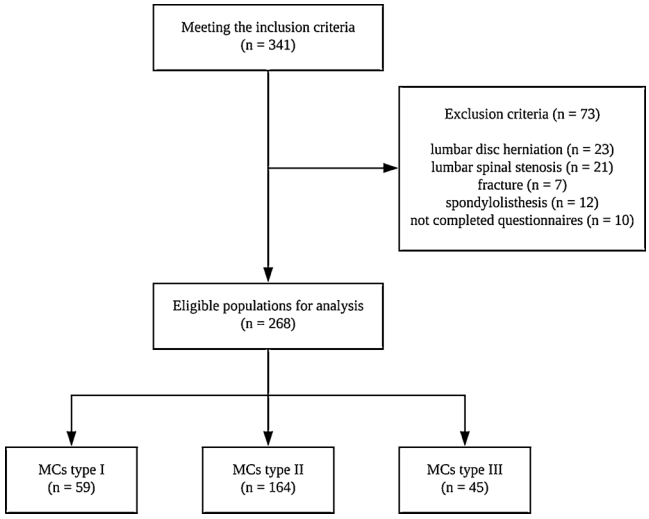

Fig. 1. Flowchart of the study.

2.3.3. Cupping therapy

Cupping was done twice a day during hospitalization. For each treatment, two cups were applied for 3 min on the tender points, identified by the practitioner, around the lumbosacral area.

2.3.4. Chuna manual therapy

The spine flexion distraction technique, sidelying lumbar spine distraction technique and prone iliac correction technique were conducted by Korean Medicine doctors (KMDs) using the Ergo Style FX Table (Chattanooga group, England) once a day.

2.3.5. Herbal medicine

Dangguisusan (consisting of *Radix Angelicae gigantis, Lignum Sappan, Radix Linderae, Radix Paeoniae Rubra, Rhizoma Cyperi, Flos Carthami, Semen Persicae, Cortex Cinnamomi* and *Radix et Rhizoma Glycyrrhizae*) were prescribed twice a day to patients.

2.4. Measurements

2.4.1. Primary outcome

2.4.1.1. Numerical rating scale (NRS). The NRS is mainly used to assess the intensity of pain. Patients were required to choose the degree of pain from 0 (no pain) to 10 (extreme pain) [17] on the day of both admission and discharge.

2.4.2. Secondary outcome

2.4.2.1. Oswestry disability index (ODI). ODI is a tool for evaluating daily dysfunction caused by low back pain. It consists of 10 items related to daily movement. Patients answer according to the severity of dysfunction, ranging from 0 (no disability) to 5 (severe disability) [18]. The question regarding sex life was removed. The remaining nine questions were given to the patients to answer on the day of admission and discharge.

2.4.2.2. EuroQol - 5 dimensions (EQ-5D). The EQ-5D was developed in 1990 by the EuroQol group as a tool for assessing overall health. The questionnaire assesses motility, self-care, usual activity, pain/discomfort and anxiety/depression. There are three types of responses: 'there is no problem at all, there is some problem, and there is an important problem'. This questionnaire was conducted on

the day of admission and discharge.

2.5. Statistics

Statistical analysis was performed using SPSS 22.0 for Windows (SPSS Inc., Chicago, IL, USA). Sex was presented in frequency and remaining measurements were expressed as mean ± standard deviation. Normality tests were performed, using the Kolmogorov-Smirnov test and the Shapiro-Wilk test, to distinguish between parametric and nonparametric test results. A homogeneity test for sex by the type of MCs was performed using the Pearson's Chi-square test. Comparisons of the NRS, ODI and EQ-5D between admission and discharge for each type of MCs were performed using the Wilcoxon signed rank test. A p-value of less than 0.05 was considered significant. The Kruskal-Wallis test, which is a nonparametric test, was used to compare the age, hospitalization period, NRS, ODI and EQ-5D for each type of MCs. A post-hoc test was performed using the Mann-Whitney U test when significant values were found. The significance level for this analysis, based on the Bonferroni's method by dividing 0.05 by 3, was 0.0167

3. Results

3.1. General characteristics of participants

Of the total 268 participants, 107 (39.93%) were men and 161 (60.07%) were women (Table 1). The number of Type I MCs were 59 (22.01%), Type II MCs were 164 (61.19%) and Type III MCs were 45 (16.79%). The higher the degree of MCs, the higher the age, however, without statistical significance. There was no statistically significant difference between gender or hospitalization period and MCs at baseline ($p > 0.05$).

3.2. Changes of NRS, ODI and EQ-5D in each MC group between admission and discharge

Regarding change in the NRS, it decreased from 5.68 ± 0.81 on admission to 2.85 ± 0.89 on discharge in patients with MC type I, from 5.80 ± 0.83 to 3.31 ± 0.78 in MC type II, and from 6.24 ± 0.67 to 3.89 ± 0.85 in MC type III. All groups showed a decrease in NRS, which were all statistically significant ($p < 0.05$) (Table 2). ODI decreased from 42.98 ± 12.38 on admission to 21.24 ± 10.97 on discharge in the MC type I group, from 47.48 ± 11.11 to 27.26 ± 6.90 in the MC type II group, and from 51.56 ± 10.67 to 32.25 ± 9.92 in the MC type III group. All groups showed a decrease in ODI and all were statistically significant ($p < 0.05$). EQ-5D increased from 0.512 ± 0.140 on admission to 0.853 ± 0.109 on discharge in MC type I patients, from 0.504 ± 0.155 to 0.842 ± 0.070 in MC type II patients, and from 0.481 ± 0.130 to 0.802 ± 0.077 in MC type III patients. EQ-5D improved in all groups with statistical significance ($p < 0.05$).

3.3. Comparison of the variation of NRS, ODI and EQ-5D between MC groups

The difference in the NRS between admission and discharge was 2.83 ± 0.92 in the MC type I group, 2.49 ± 0.83 in the MC type II group, and 2.36 ± 0.85 in the MC type III group. The difference between groups were statistically significant ($p < 0.05$) (Table 3). This was verified with the post-hoc test ($p < 0.0167$) (Table 4). The change in the ODI was 21.73 ± 9.10 in the MC type I patients, 20.22 ± 10.09 in the MC type II patients, and 19.31 ± 8.92 in the MC type III patients. There were no significance differences between the groups ($p > 0.05$). The change in EQ-5D was 0.341 ± 0.134 in the patients with MC type I, 0.338 ± 0.134 in the patients with MC type III, and 0.321 ± 0.125 in the patients with MC type III, however, these changes were not statistically significant ($p > 0.05$).

Table 1
General characteristics of each MCs type.

Characteristics		Type I	Type II	Type III	p-value
Gender (n)	Male	20	72	15	0.248
	Female	39	92	30	
Age (years)		46.89 ± 6.81	48.33 ± 9.11	48.82 ± 8.31	0.332
Hospitalization period (days)		12.47 ± 0.91	12.48 ± 0.84	12.67 ± 1.01	0.525

Abbreviations: MCs = Modic changes.

Table 2
The changes in the NRS, ODI and EQ-5D in each MCs group using the Wilcoxon signed rank test.

MCs	Measurements	On admission	On discharge	p-value
Type I	NRS	5.68 ± 0.81	2.85 ± 0.89	< 0.001*
	ODI	42.98 ± 12.38	21.24 ± 10.97	< 0.001*
	EQ-5D	0.512 ± 0.140	0.853 ± 0.109	< 0.001*
Type II	NRS	5.80 ± 0.83	3.31 ± 0.78	< 0.001*
	ODI	47.48 ± 11.11	27.26 ± 6.90	< 0.001*
	EQ-5D	0.504 ± 0.155	0.842 ± 0.070	< 0.001*
Type III	NRS	6.24 ± 0.67	3.89 ± 0.85	< 0.001*
	ODI	51.56 ± 10.67	32.25 ± 9.92	< 0.001*
	EQ-5D	0.481 ± 0.130	0.802 ± 0.077	< 0.001*

Abbreviations: NRS = Numeric rating scale; ODI = Oswestry disability index; EQ-5D = EuroQol-5 dimensions; MCs = Modic changes.
* $p < 0.05$.

Table 3
Comparison of the variation in the NRS, ODI and EQ-5D between the MCs groups using the Kruskal-Wallis test.

Measurements	MCs			p-value
	Type I	Type II	Type III	
ΔNRS	2.83 ± 0.92	2.49 ± 0.83	2.36 ± 0.85	< 0.001*
ΔODI	21.73 ± 9.10	20.22 ± 10.09	19.31 ± 8.92	0.363
ΔEQ-5D	0.341 ± 0.134	0.338 ± 0.134	0.321 ± 0.125	0.714

Abbreviations: NRS = Numeric rating scale; ODI = Oswestry disability index; EQ-5D = EuroQol-5 dimensions; MCs = Modic changes.
* $p < 0.05$.

Table 4
The results of the post-hoc test, using the Mann-Whitney U test, assessing the difference in variation of the NRS between each two MCs groups.

MCs	Z	p-value
Type I & II	−3.698	< 0.001*
Type I & III	−5.849	< 0.001*
Type II & III	−3.821	< 0.001*

Abbreviations: NRS = Numeric rating scale; MCs = Modic changes.
* $p < 0.0167$.

4. Discussion

Approximately one third of TA patients fully recover from the initial symptoms within three months, one third have mild pain and impairment lasting more than three months, and the remaining one third suffer from severe pain and disability even after three months. It is difficult to predict the prognosis objectively after TAs [2].

MCs, one of the main indicators of disc degeneration [8], is one of the factors considered when predicting the prognosis of low back pain. Mok F. P. et al. [26] reported that MCs were associated with low back pain and that patients with MC greater than 90% on MRI experienced low back pain within 1 year [27,28]. On the other hand, Herlin C [13] and Romero-Muñoz L.M [14] have studied the relationship between MCs and the pain severity of low back pain and the necessity of surgery, concluding that there is no significant correlation. Meanwhile, other studies reported that MCs were related to disc herniation of the thoracic spine [29] and spondylitis [30].

There have been reports that investigated MCs as a predictor of the clinical outcomes of interventions. Before posterior spinal fusion or laminectomy, MRIs of low back pain patients were analyzed and classified as either MC type I or II and the clinical results of the surgery were then compared between the two MC types. This comparison revealed that the type of MCs was accompanied by specific results [31]. Furthermore, another study showed that the presence of MCs in low back pain were related to poor clinical outcomes following an imaging-guided lumbar nerve block. [32]. On the other hand, a cohort study showed that MCs did not influence the clinical results of patients with low back pain after brief intervention and education [33]. Clinical outcomes associated with Korean Medicine interventions for lumbar sprain following TAs are still lacking, and this study is the first of its kind. We hypothesized that the degeneration of the intervertebral disc may affect the outcome of Korean Medicine treatment for lumbar sprain following a TA.

In order to verify this hypothesis, we analyzed patients who were hospitalized at a Korean Medicine hospital with sprain and strain of the lumbar spine (ICD-10 code S33.5) following a TA and with MRI findings of MCs.

The novel finding of this study is that the lower the degree of MCs present on MRI, the greater the reduction in pain severity after treatment. There was also a tendency of improvement in disability and quality of life, but without statistical significance. We concluded that patients with MC type I showed the best outcome, followed by MC type II and III, as a lower degree of MCs means less degenerative changes of the vertebrae. This conclusion corresponds with findings from previous studies [31,32]. This is owing to the strong relation between MCs and disc degeneration [34]. The reason for the absence of statistical significance with the ODI and EQ-5D may be due to the fact that these parameters do not change much in the short term.

There are some limitations to this study. Firstly, it is difficult to generalize the results to all patients with lumbar strain following a TA because the patient population was from only one specific hospital in Korea. Secondly, the difference in the number of patients between each type of MCs was relatively large and the total number of patients was small, therefore the results from the analysis may be misleading. Thirdly, this is a pragmatic integrative study which did not standardize the treatment given to all the patients. Although everybody had been treated with pharmacopuncture, acupuncture, cupping therapy, Chuna manual therapy and herbal medicine, the specific areas of treatments applied are a little different from person to person according to their symptoms and diagnosis of conductors. However, it is a limitation of all the retrospective chart reviews in that this design tries to reflect the real, not standardized clinical situation. Despite these limitations, this study is meaningful in that it is the first study to analyze the clinical outcomes, by MC type, of Korean Medicine in patients with lumbar sprain following a TA, and so allows for the prediction of treatment response.

In the clinical setting, if an MRI is obtained in the acute stage of lumbar sprain following a TA, the medical team can predict the likely outcome of Korean Medicine treatment based on the type of MCs observed and explain this to patients before initiating treatment. This will reduce patient misunderstanding regarding treatment outcomes and help tailor different treatment durations based on the MC type. Further studies including larger numbers of patients and making comparisons with conventional therapies will be needed in the future.

5. Conclusion

This study compared the NRS, ODI, and EQ-5D in different MC types in order to identify how the different MC types influence the outcomes of Korean Medicine treatment in patients with lumbar sprain following a TA. We found that the lower the grade of MCs, the greater the degree of improvement of pain ($p < 0.05$), but not in disability and quality of life ($p > 0.05$). Based on these results, when initiating Korean Medicine treatment in patients with lumbar sprain from a TA, the medical team can predict and explain the expected outcome to patients and decide on the length of treatment required.

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Declaration of Competing Interest

None declared.

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