



## Study Protocol

## Korean medicine registry for low back pain – A study protocol for prospective observational multi-center study (KLOS)



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## ABSTRACT

**Background:** Low back pain (LBP) is a major burden in Korea. Despite its high prevalence, the government and the public health sector do not address the specific evidences of symptom control and prevention of LBP to reduce long-term healthcare costs and increase the quality of life. Thus, the Korean medicine sector encourages to collection and analysis of the medical utilization pattern of patients with LBP in Korea to provide evidences of LBP control strategy as well as political decisions.

**Methods:** KLOS, a prospective, multi-center, patient registry pilot study will collaborate with 7 traditional Korean medicine hospitals and recruit patients with LBP into the registry. A total of 150 eligible patients with new episodes of LBP, who visit a Korean hospital without any other treatment history, will be enrolled in the registry. After enrollment, we will collect the individual characteristics of each patient, such as pain intensity, LBP-related daily disability, anthropometrics, and Health-Related Quality of Life (HRQoL) at baseline and FU1 and FU2. We will also access the patients' clinical and administrative electronic records to analyze the pattern of patients' resource utilization. Overall, the aims of KLOS are to (1) explore the general characteristics of patients with new episodes of LBP and (2) evaluate the efficacy and safety of various Korean medicine treatments for LBP, based on nationwide registry outcome collecting process.

**Discussion:** The first pilot study of prospective, multi-center registry of newly diagnosed LBP patients in traditional Korean medicine hospitals. The result of this study may show the current status of LBP patients who receive Korean medicine treatments and provide evidences for reasonable decision-making on Korean medicine healthcare policy in the future.

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## 1. Introduction

Low back pain (LBP) is a major cause of non-fatal health loss that currently affects quality of life in Korea.<sup>1</sup> There is no official report on the prevalence of LBP from national medical statistics. Some epidemiological data show that lifetime prevalence of LBP in elderly rural community residents in Korea is 61.3%, and LBP is more common in women than in men.<sup>2</sup> The results of a 2012 Korean Burden of Disease Study reported that for every 100,000 citizens, 1915 disability-adjusted life years (DALYs) were lost to LBP, and 99.81% of

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these DALYs resulted from years lost due to disability (YLDs).<sup>3</sup> This relates to the current trend of high prevalence of musculoskeletal conditions in Korea.

The healthcare system in Korea has distinctive features such as medical pluralism, which means that patients can treat a particular disease or condition in both conventional and traditional Korean medicine (TKM) hospitals by various treatment methods. However, due to the burden of long-term chronic disease management, rising hospital utilization and cost, patients often turn to choose TKM care, especially in the case of musculoskeletal disorders.<sup>4</sup> Data from 2008 to 2009 Korea Health Panel showed that patients with musculoskeletal problems made more frequent visits to TKM institutions than to conventional institutions (70.0% vs. 26.6%).<sup>5</sup> A 2011 National survey of oriental (Korean) medicine utilization and herbal drug consumption also announced that treating musculoskeletal disorder is the most common reason for visiting TKM hospitals (50.2%), and LBP accounted for the highest percentage of TKM use at 6.6%.<sup>6</sup>

Previous studies<sup>7,8</sup> showed a strong association with musculoskeletal system diseases and TKM; however, there are only few statistical analysis studies on basic characteristics and utilization pattern of TKM data from the Korean population, which may not be the strong evidence of generalization. There is also a lack of systematic analysis studies on symptom, diagnosis and treatment regimen pattern of LBP patients.

The patient registry research method<sup>9</sup> is generally used for collecting organized information from real-world data on a particular disease or condition, in order to measure or improve the quality of the practice of medicine in the public health sector. It also helps to understand the course of the disease, various treatment regimens, the effectiveness and safety of the treatments, and other significant parameters. Currently, this methodology is still unfamiliar and rarely applied in the Korean medicine field.<sup>10</sup>

In this study, we plan to collect the data of newly diagnosed patients with LBP to explore the trend of patient characteristics as well as the factors that affect their risk of developing discomfort due to the pain.

## 2. Methods and analysis

### 2.1. Study design

This registry is a prospective, multi-center, observational, pilot phase low back pain patient registry in Korea. The study design is schematized in [Table 1](#).

Participating centers have been selected by performing feasibility assessments on the frequency of patients with the disease, their location, and accessibility. After a preliminary assessment, a total of 7 university-affiliated tertiary KM hospitals have been selected, which are widely distributed across the country. We included 4 metropolises (Seoul, Incheon, Daejeon, Pusan), as well as the eastern (Wonju), center (Jecheon), and western (Jeonju) regions of the peninsula. All participating hospitals serve on average 1000 patients with LBP per year, mostly drawn from the nearby communities.

### 2.2. Study population and recruitment

The study population is both inpatients and outpatients in Korean medicine hospitals with new episodes of low back pain. Each participating institution will advertise the registry by posting recruitment posters on the hospital's website or on off-line bulletin boards. If necessary, advertising on the local community newspaper will be considered as well.

### 2.3. Eligibility criteria

We will recruit 150 patients with a new episode of LBP that are eligible to the following criteria which shown in [Table 2](#).

### 2.4. Study procedures and registration

All participants will receive a full explanation of the study flow and enough time to consider the registry participation. Written informed consent will be obtained from all participants before beginning any trial procedures. Once the participant enrolls into the registry, they will be assigned a registry identification number to protect them from privacy invasion. Each participant's data will be collected at each scheduled clinic visit.

### 2.5. Data collection

We will collect the data from the two types of the sources: patient-reported outcomes and clinical and administrative electronic records. When an eligible subject first visits the clinic, a trained research coordinator collects the baseline information in person. Afterwards, we will re-collect the data on patient treatment and outcomes during every subsequent visit for outpatient and at discharge day for inpatient. Research coordinators at each site will contact the registry participants for follow-ups at 30 (Follow-up 1, FU1) and 90 (Follow-up 2, FU2) days after baseline to collect the data, either in person or by telephone with a window period of 7 days. All data will be collected using paper case report forms (CRFs) from patient-reported questionnaires and electronic medical records. The principal investigators of each site will be responsible for data entry and cleansing.

### 2.6. Baseline data

#### 2.6.1. Demographic data

General demographic information will include date of birth, gender, handedness, level of education, body size measurements (height, weight, and waist/thigh circumference). Socio-demographic information also be collected, such as type of medical insurance, employment status, occupation (including shift patterns), type of workload, average working hours, smoking status, drinking habits, exercise habits, types of hospital admission, and more.

#### 2.6.2. Medical history

Medical history obtained will include the type and duration of LBP, history of back surgery, other clinically significant diagnoses judged by the principal investigator, menstrual status, medication history, concurrent medical condition and intake of medication.

#### 2.6.3. General information of low back pain

We will obtain information on onset, location, diagnosis of pain and LBP-related examinations. We will ask participants to answer questions on the first and recent onset of the pain to analyze the duration of the LBP. Pain locations will be assessed by lower back diagram. It is a multiple answer diagram and analyses the frequency of location. The lifetime first episode of LBP, aggravating and alleviating conditions (or factors), will be assessed by collecting and analyzing each patient's own verbal description. The diagnosis on LBP will be evaluated by KCD code and TKM expert pattern identification. The TKM pattern identification contains a 2-part process, which includes a traditional LBP classification among 10 types, based on TKM classic *Dong-Eui-Bo-Gam*,<sup>11</sup> and 3 types of recently-modified LBP classification that were reorganized by TKM LBP experts<sup>12,13</sup> for assessing the common types of LBP in Korean

**Table 1**  
Study Flow Chart

	Enrollment <sup>a</sup> (baseline)	Subsequent visits <sup>b</sup>	Follow up 1 (30d ± 7d)	Follow up 2 (90d ± 7d)
Informed consent form	V			
Eligibility assessment	V			
Sociodemographic characteristics, Medical history	V			
General information of LBP	V			
Characteristic of LBP	V	V	V	V
ROM Evaluation	V			
Neurodynamic assessments	V			
Symptoms of LBP	V	V	V	V
Roland-Morris Disability Questionnaire	V	V	V	V
Numeric Rating Scale	V	V	V	V
European Quality of Life-5 dimension	V		V	V
LBP Pattern Identification Questionnaire	V		V	V
Diagnostic examination			V	V
Therapeutic procedures			V	V
Medical expense				V

<sup>a</sup> Defines as First day of hospitalization for inpatients, first visit of clinic for outpatients.

<sup>b</sup> Defines as any independent visits between registration and FU1 for outpatients and discharge day for inpatients.

**Table 2**  
Eligibility Criteria

Inclusion criteria
1. Age greater than or equal than 19
2. Patients with a new episode of low back pain in care in a Korean medicine rehabilitation center (no treatment of LBP at any medical clinic for at least 3 months)
Exclusion criteria
1. Patients with low back pain caused by other diseases (ex. lumbar herniated disc-surgery within the past 3 months, vertebral fracture, inflammatory spondylitis, spinal infection, metastatic cancer etc.)
2. Patient with musculoskeletal pain w more severe than the lower back pain
3. Patients with chronic diseases that may affect the results of the clinical trial
4. Treatment with medication for low back pain within the past 4 months
5. Participation in other low back pain clinical trials within the past month
6. Patients who are unable to communicate, such as with Alzheimer's disease or mild cognitive impairment
7. Pregnant women
8. Patients who are judged to be inappropriate for the clinical study by the researchers

population. Lumbar examination will be performed to evaluate the normal range of waist motion and to assess neurological mobility.

## 2.7. Baseline and follow-up outcome measures

### 2.7.1. Primary outcome

**2.7.1.1. Roland-Morris Disability Questionnaire.** We selected the Roland-Morris Disability Questionnaire (RMDQ),<sup>14</sup> the most responsive questionnaire that reflects the clinical changes over time, to evaluate the disability of daily life in this registry. It consists of 24 items representing general physical functions that were likely to be affected by LBP. Higher numbers on the questionnaire's scale reflect the greater levels of disability.

## 2.8. Additional outcomes

### 2.8.1. Pain Numeric Rating Scale

We will ask participants to evaluate the intensity of their pain within the past 7 days by using an 11-point scale, with 0 being no pain and 10 being the worst pain. Numeric Rating Scale (NRS) is a well-known core measure in pain clinical trials, and offers the advantage of easy administration via phone, reducing the risk of incomplete or missing data.<sup>15</sup>

### 2.8.2. European Quality of Life-5 dimension

European Quality of Life-5 dimension (EQ-5D-5L) is a validated measure of health-related quality of life that consists of 2 types of measures – the descriptive system of EQ-5D-5L and the visual analogue scale of EQ(EQ-VAS). The descriptive system contains of 5 dimensions including mobility, self-care, usual activities, pain/discomfort and anxiety/depression, and each dimension includes 5 levels of severity of discomfort to daily life. The EQ-VAS is used as a quantitative measurement of health status judged by individuals.<sup>16</sup>

## 3. Additional pre-specified data

### 3.1. Patient reported data

#### 3.1.1. LBP pattern identification questionnaire

LBP pattern identification questionnaire (LBPIQ) is a self-developed LBP pattern identification questionnaire by Korean medicine rehabilitation experts. It consists of 52 items which contain general and LBP-related discomfort questions and helps the diagnosis by Korean medicine physicians. This questionnaire originated from efficacy assessment sample questions of LBP guidelines for the clinical trial of Korean herbal drugs by the Korean ministry of food and drug safety.<sup>17</sup> It relies on a Delphi expert panel process with TKM rehabilitation experts with more than 10 years of clinical experience in the field, in order to extract and modify the original contents by filtering out irrelevant questions.<sup>12</sup>

#### 3.1.2. Characteristics of LBP

We will ask participants to report their conditions (or factors) of LBP initiation, aggravation and alleviation and we will record the patients' own verbal descriptions.

### 3.2. Electronic system collected data

We will use electronic medical records available at each site to collect general information on laboratory, diagnostic procedure, type of treatment and medication, cost of medical utilization, etc.

#### 3.2.1. Clinical laboratory tests

We will collect, only for inpatients at hospitalization and discharge day, the results of liver function tests (AST and ALT). Owing to the lack of scientific evidence to establish the safety of herbal medicine, most of TKM hospitals perform the liver function test as a routine procedure for monitoring liver function elevation within

**Table 3**  
List of LBP Specific Therapeutic Procedures

acupuncture therapy
Cupping therapy
Heating therapy
Pharmacopuncture therapy
Bee-venom acupuncture therapy
Physiotherapy
Chuna therapy
Plaster therapy
Taping therapy
Manipulation therapy
Exercise therapy (or education)
Medication (types (decoction, OTC, etc.), purpose, ingredient, amount)

a certain period of time after treatments.<sup>18</sup> Thus, these results will be used for safety analysis of inpatients.

### 3.2.2. Diagnostic procedures

We will collect the result data of magnetic resonance, computed tomography, and X-ray images of a lumbar spine, as well as KM pulse diagnosis, Ryodoraku diagnosis and heart rate variability. Collected indicators will be frequency, result and cost of each procedure.

### 3.2.3. Therapeutic procedure

The list of LBP specific therapeutic procedures from the previous study<sup>19</sup> will be used in this registry to collect the information on given procedures and medications for each visit. The list is shown in Table 3. Collected data are performance of each procedure and information on prescribed medications, such as name, type, ingredient, amount of products and cost of treatment.

### 3.2.4. Medical costs

Medical cost data associated with hospital visit includes all direct expenses incurred by the use of medical facilities and services for study period. We will collect the individuals' data from the participant's registered institution database, as well as any receipts of medical care from other medical facilities that are voluntarily provided by the participants. Included data will be the cost shared by each patient, the insurance coverage and the total expenses.

### 3.3. Withdrawal

Voluntary participation and informed consent before enrollment is mandatory for this study. All participants have the right to withdraw from the study at any time for any reason. Discontinuation of participation by investigators is possible for any of the following reasons: loss of follow-up, frequent late visits, voluntary withdrawal, pregnancy, or any other reasons that the investigator determines that justify discontinuation. All withdrawal cases will be documented in CRFs and data will be analyzed using the intention-to-treat (ITT) principle.

### 3.4. Data management

Before the initiation of the study, the research staffs will train for data collections and reporting procedure through Standard Operation Procedures (SOP) meetings. A data audit team will monitor the data collection status and management. During the study, site audit visits by third party Contract Research Organization (CRO) will occur on a regular basis to ensure adherence to study documentation. Paper CRF will be reviewed to ensure that the data are collected accurately as well. All data management and supervising procedures must be in accordance to company SOPs for Korean Good Clinical Practice (KGCP) Guidelines.

### 3.5. Data analysis

Descriptive analysis will be used to assess baseline data, diagnosis and therapeutic procedures, including mean and proportions. We will also conduct the subgroup analysis by LBP pattern identification according to the Korean medicine theory to evaluate the heterogeneity of treatment effects by each subgroup.

All efficacy analyses are using ITT, defined as all patients who have received at least one treatment. The primary outcome measure is the LBP-related disability by RMDQ at FU1 (30 days after registration), assessed by Student's *T*-test. The secondary outcome measures are similar analyses for RMDQ at FU2, as well as NRS and EQ5D at FU1 and FU2. The changes in score of each secondary outcome at a particular visit will be analyzed using repeatedly measured analysis of variance (ANOVA) method. The last observation-carried-forward approach will be used for efficacy assessment in case of missing data. The verbal description of pain obtained from each patient will be collected and directly transformed into an analytical form by analysis experts. For example, expressions describing the characteristics of pain will be reorganized and their frequency analyzed, in order to compare with other back pain-related information such as pattern identifications. In addition, we will extract meaningful contents from sentences using KoNLP,<sup>20</sup> a Korean morphological analysis package of the statistical software R. Based on the Korean medicine terminology dictionary and medical terminology dictionary database, terms related to Korean medicine, conventional medicine, and others are classified, and the bundle is handled as Bag-of-Words information. The meaningful terms will be assessed using the term frequency-inverse document frequency (TF-IDF) algorithm in consideration of the frequency and rarity of the words.<sup>21</sup> In addition, the qualitative information that is not expressed in the descriptions will be identified by the patient's treatment regimens during the study period. It will be used to explore the relationship between LBP, treatment procedures and various independent predictors. The two methods will be compared and we will examine the accuracy of the results.

### 3.6. Sample size

This patient registry is a pilot phase study to estimate the trends in treatment of patients with a new episode of low back pain in Korea. The determination of sample size in our study is mainly based on the assumption from the number of possible enrollment patients in each site.

### 3.7. Ethics and dissemination

The institutional review boards of all participating hospitals have approved the protocol of this registry: Gachon University Gil Oriental Medical Hospital (14-102), Sangji University Oriental Medical Center (SJIRB-Human-14-001), Semyung University Korean Medicine Hospital (2015-01-02), Kyung Hee University Oriental Medical Center (KOMCIRB-150102-HR-001-05), Wooseok University Oriental Medical Center (WSOHIRB-1604-01), Dunsan Korean Medicine Hospital of Daejeon University (DJDSKH-15-1-2) and Pusan National University Korean Medicine Hospital (2015001). Study findings will be disseminated via peer-reviewed publications and conference presentations.

## 4. Discussion

LBP is the leading cause of non-fatal disease burden that currently lists as the most frequent clinic visit in Korean medical institutions. This study explores the patient general characteristics and treatment patterns of LBP patient in traditional Korean medicine hospitals. To our best knowledge, this is the first pilot

prospective, multicenter, Korean medical institution patient based registry of newly diagnosed LBP patients in the university affiliated Korean medicine hospitals.

There are several limitations in this study. First, due to the limited funding resources, there were restrictions on the selection of study sites and sample size. Second, due to the potential of the study methodology, the confounding biases will be existed and study results cannot be provide empirical evidence than well designed experimental studies. However, various attempts will be made to control or reduce any potential biases that may affect the trial results.

Therefore, this study will provide supportive information regarding current patient characteristics and treatment patterns for development of future systematic and comprehensive large-scale Korean medicine patient registry. Also, it will provide evidences for empirical decision-making on healthcare policy of Korean medicine in the future.

### Data availability

Conceptualization: YK, BHJ and YKS. Methodology: BHJ. Formal Analysis: BHJ and YK. Investigation: BHJ and YK. Data Curation: BHJ and YK. Writing - Original Draft: YK, BHJ and YKS. Writing - Review & Editing: MSO, BCS, YYC, SJK, YSK, JYJ, EJL, EHH and JBj. Supervision: YKS and SGK. Funding Acquisition: YKS and SGK.

The authors declare no conflict of interest.

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The data will be made available upon request.

### References

1. Lee YH, Yoon SJ, Kim A, Seo H, Ko S. Health performance and challenges in Korea: a review of the global burden of disease study 2013. *J Korean Med Sci* 2016;31(Suppl 2):S114–20.
2. Lee SY, Cho NH, Jung YO, Seo YI, Kim HA. Prevalence and risk factors for lumbar spondylosis and its association with low back pain among rural Korean residents. *J Korean Neurosurg Soc* 2017;60:67–74.
3. Yoon JH, Seom HY, Oh IH, Yoon SJ. The non-communicable disease burden in Korea: findings from the 2012 Korean burden of disease study. *J Korean Med Sci* 2016;31(Suppl 2):S158–67.
4. Wang BR, Choi IY, Kim KJ, Kwon YD. Use of traditional Korean medicine by patients with musculoskeletal disorders. *PLoS One* 2013;8:e63209.
5. Choi JH, Kang S, You CH, Kwon YD. The determinants of choosing traditional Korean medicine or conventional medicine: findings from the Korea health panel. *Evid Based Complement Alternat Med* 2015;2015:9, <http://dx.doi.org/10.1155/2015/147408>. Article ID 147408.
6. Cho JG, Kim NS, Do SR. 2011 National Survey on the use of Korean Medicine and Korean Herbal Medicine. Sejong: Korea Ministry of Health and Welfare, Korea Institute for Health and Social Affairs; 2012:1–554, 11-1352000-000547-12.
7. Choi BH, Son CH, Lim BM. The Relationship between the use of Korean and western medicine in treating musculoskeletal disease. *J Korean Med* 2014;35:22–31.
8. Cho KS, unpublished doctoral dissertation (*The*) differences in behaviors of utilization on western and oriental medical care in Korea. Seoul, Korea: Yonsei University; 2001.
9. Gliklich RE, Dreyer NA, Leavy MB. *Registries for evaluating patient outcomes: a user's guide [Internet]*. 3rd ed. Rockville (MD): Agency for Healthcare Research and Quality (US); 2014 April. Report No.: 13(14)-EHC111.
10. Han KS, Ha IH, Lee JW. Application of health care big data and necessity of traditional Korean medicine data registry. *J Korean Med Obes Res* 2017;17:46–53.
11. Hu J (Writer). *The Research Center of DongEui (Translator)*. Humanist: DongEui-Bogam NaKyung; 2002.
12. Ahn MY, Song YK, Ko SG, et al. Development of questionnaire for pattern identification of chronic low back pain by Delphi method. *J Korean Med Rehabil* 2013;23:143–58.
13. Ko HY, Ko YS, Lee JH, Chung WS, Shin BC, Cha YY, et al. Cross-sectional study of therapy type and pattern identification in lumbago patients. *J Korean Med Rehabil* 2013;23:177–84.
14. Monticone M, Baiardi P, Vanti C, Ferrari S, Pillastrini P, Mugnai R, Foti C. Responsiveness of the Oswestry disability index and the Roland Morris disability questionnaire in Italian subjects with sub-acute and chronic low back pain. *Eur Spine J* 2012;21:122–9.
15. Dansie EJ, Turk DC. Assessment of patients with chronic pain. *Br J Anaesth* 2013;111:19–25.
16. Herdman M, Gudex C, Lloyd A, Hanssen MF, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–36.
17. Korea Ministry of Food Drug Safety. Guidelines for Low back pain clinical trial of Korean herbal drugs. *Seoul* 2010;5:21–5.
18. Kim DM, Kim HK, Cho SY, Kim YS, Naml SS. Retrospective observation of liver function parameters for 101 patients using herbal drugs for one month. *J Korean Orient Med* 2010;31:149–57.
19. Maeng TH, Kim JY, Yi WS, Chung WS, Ko YS, Lee JH, et al. A descriptive statistical analysis of the hospitalized patients with low back pain in departments of Korean rehabilitation medicine of Korean medicine hospitals. *J Korean Med Rehabil* 2013;23:213–23.
20. Jeon H. "KoNLP: Korean NLP Package." The Comprehensive R Archive Network. CRAN, 15.12.2016. Available from: <https://cran.r-project.org/web/packages/KoNLP/index.html>.
21. Aizawa A. An information-theoretic perspective of tf-idf measures. *Inform Process Manag* 2003;39:45–65.