


Inpatients with shoulder osteoarthritis who received integrative Korean medicine treatment

Long-term follow-up of an observation study

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Abstract

This study aimed to investigate the long-term clinical efficacy of and satisfaction with integrative Korean medicine (KM) treatment in patients with shoulder osteoarthritis (SOA). We conducted a prospective observational study of patients with SOA. Patients aged 19 years and older who underwent inpatient treatment for more than 1 week were eligible for enrollment in the study. The primary evaluation index was the numeric rating scale for shoulder pain. Sub-evaluation indices included the Shoulder Pain and Disability Index for shoulder function, EuroQol-5-dimension score for overall quality of life, and Patient Global Impression of Change. Outcome measures were assessed at admission, discharge, and follow-up. For the follow-up questionnaire survey, the following information was collected: current status, surgery after discharge, reasons for finding integrative KM treatment satisfactory/unsatisfactory, and quality of life after discharge. In total, 186 patients were enrolled in the primary analysis, and 103 patients completed the follow-up survey. The mean number of days of follow-up was 1019 ± 439. Compared with the baseline, the mean differences in the numeric rating scale and Shoulder Pain and Disability Index were 3.05 ± 0.34 and 36.06 ± 5.53, respectively. Regarding the Patient Global Impression of Change, 89 out of 103 (86.4%) patients chose “minimally improved” or better. Furthermore, the EuroQol-5-dimension score also increased, showing an improvement of health-related quality of life after treatment. Integrative KM treatment is a potential option for reducing pain severity and improving function and health-related quality of life in patients with SOA. Prospective randomized studies would support this finding for the next step.

Abbreviations: BMI = body mass index; CCI = Charlson Comorbidity Index, CI = confidence interval, EMR = electronic medical record, EQ-5D = EuroQol-5 dimension-5 level questionnaire, HRQOL = health-related quality of life, KM = Korean medicine, LOS = length of stay, MCID = minimal clinically important difference, MRI = magnetic resonance image, NRS = numeric rating scale, PGIC = Patient Global Impression of Change, SOA = shoulder osteoarthritis, SPADI = Shoulder Pain and Disability Index.

Keywords: integrative medicine, questionnaire, shoulder osteoarthritis, survey

1. Introduction

Patients with degenerative diseases need more active management as expected survival increases worldwide.^[1] Particularly, geriatric patients with chronic musculoskeletal pain tend to experience symptoms such as falls, cognitive disorders or dementia, and sleep disturbance more often. These symptoms could directly contribute to a deterioration of quality of life, activities of daily living, and work capacity, thereby inducing high social costs.^[2]

Glenohumeral osteoarthritis, also known as shoulder osteoarthritis (SOA), is a degenerative glenohumeral joint disease.

SOA is characterized by arthralgia, stiffness, loss of joint space accompanied by limited range of motion, bone spur formation, periarticular cysts, and subchondral sclerosis.^[3] It affects approximately 32.8% of adults aged 60 years and older in the United States^[4] and approximately 16.1% to 20.3% of adults aged 65 years and older in East Asia, especially in Japan and the Republic of Korea.^[5,6]

Conservative treatments should be considered before surgical treatment for managing SOA. The conservative treatments for SOA include oral pharmacological treatments, intraarticular injection, and physical therapy. Surgery is considered only for patients who do not respond to conservative treatment or

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The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

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whose pain is severe and intolerable with the conservative management.^[4] Surgical treatment is effective, but 13.4% of postoperative patients undergo reoperation for the following reasons: a fracture near the implanted joint, glenohumeral joint instability, and infection.^[7] Furthermore, geriatric patients are likely to have multiple chronic comorbidities.^[8] When comorbidities are assessed using the Charlson Comorbidity Index (CCI), surgery is not recommended for patients with a high CCI. Patients with a high CCI have higher risks of receiving postoperative blood transfusion and even death.^[9] Another study recommended that conservative treatment should be continued for at least 1 year before the surgical decision.^[10]

Up until now, only a few conservative treatment modalities were known, and more diverse treatment options should be considered. Some pharmacological treatments, such as treatment with non-steroidal anti-inflammatory drugs, were reported to induce adverse reactions, such as kidney injury or digestive ulcers.^[11] Opioid medication can reduce pain but also cause significantly more adverse events than nonopioids.^[12] Integrative Korean medicine (KM) treatment has been found to be safe and effective in some degenerative shoulder joint diseases, such as adhesive capsulitis.^[13,14] One of the integrative KM treatment modalities, acupuncture, was found to be effective for a long-term period in patients with chronic shoulder joint pain.^[15,16] However, no study has reported on the effectiveness of KM treatment in patients with SOA.

Thus, this study aimed to evaluate the clinical outcomes improvement after intensive integrative KM treatment in patients with degenerative SOA.

2. Materials and methods

2.1. Study design

This prospective observational study investigated the effectiveness of integrative KM treatment in patients with degenerative SOA. This study was part of a prospective registry study to investigate the effect of integrated complementary and alternative medicine in hospitalized patients with musculoskeletal disorders (Registration no.: NCT02257723). The protocol was registered prior to the enrollment of patients. The study followed the Strengthening of Reporting of Observational Studies in Epidemiology guidelines. Patients who were hospitalized and received treatment for SOA at 1 of 7 hospitals in the Republic of Korea between January 1, 2015, and July 31, 2020, were eligible for enrollment. However, only those who voluntarily signed the informed consent form were enrolled.

Demographic characteristics and medical records pertaining to disease and treatment were collected from electronic medical records (EMRs). The EMRs were recorded according to the registry protocol. In addition, a follow-up survey was conducted on the same participants from September 2021 to October 2021. Both online, using Google Forms, and telephone surveys were attempted. Participants who did not respond to the phone more than 3 times or those who refused to participate in the follow-up survey over the phone were defined as non-respondents.

2.2. Eligibility

The inclusion criteria were as follows: patients who were diagnosed with SOA; patients who were hospitalized for SOA and received inpatient care for at least 7 days; and adult male or female patients aged 19 years and above.

Patients with the following conditions were ineligible: SOA was not degenerative but caused by other conditions, such as purulent arthritis, rheumatoid arthritis, trauma, or avascular necrosis of the humeral head; coexistence of rotator cuff lesions; superior labrum anterior posterior lesions; bursitis; and pain caused by a biceps lesion.

2.3. Data collection

The data were collected from EMRs and the follow-up survey. The following time points were included: admission, discharge, and follow-up. Data on sociodemographic characteristics and medical history, including preexisting comorbidities (e.g., hypertension, diabetes mellitus, depression, heart diseases, respiratory diseases, and digestive diseases), were collected. The data collected for SOA included the following chief complaints: pain severity; the Shoulder Pain and Disability Index (SPADI) questionnaire for shoulder function; length of stay (LOS); date of onset; trigger events at symptom onset; physical examination results; any objective data, including laboratory and radiological findings, particularly magnetic resonance images (MRIs) of the shoulder; and health-related quality of life (HRQOL).

Prescription records were thoroughly reviewed to assess the contents and frequencies of treatments for shoulder pain during hospital stay. The number of treatment sessions was calculated and the number of packs of prescribed medication was also calculated. Main treatment modalities included acupuncture, electroacupuncture, pharmacopuncture, cupping, herbal medicine, Chuna therapy, and other KM physical therapy.

The follow-up questionnaire contained items about treatment history, surgical events after discharge, satisfaction/dissatisfaction with KM treatment after discharge and the reasons, current status of shoulder joint pain and function impairment, HRQOL scores, and the Patient Global Impression of Change (PGIC) as an index of perceived improvement.

2.4. Intervention

The following interventions were implemented to improve shoulder joint pain and functional recovery.

For acupuncture, sterile stainless steel single-use needles (0.25 × 30 mm; Dongbang Medical, Seongnam, Korea) were used. The acupuncture points were chosen by consensus of expert clinicians. In detail, Ashi points and acupuncture points around the shoulder joint, including LI 15, TE 14, SI 10, SI 9, and LI 16, were generally stimulated. The needles were injected at a depth of 0.5 to 1.0 cm in 15-minute sessions. The treatment was administered twice a day. If needed, needles were additionally stimulated with electric stimulation, StraTek STN-111 (StraTek, Anyang, Korea). For electroacupuncture, 2 acupuncture points (SI 9 and LI 15) were selected, and electric stimulation was applied at these sites at 8 Hz for 15 minutes.

Chuna therapy, a KM manual therapy, was performed for about 10 to 15 minutes depending on the patient's symptoms and progress as diagnosed by a KM doctor. Chuna therapy was administered once a day.

Another integrative KM therapy included herbal steam therapy, pharmacopuncture, cupping therapy, and herbal medicine. External herbal steam therapy used a hot pack containing steamed herbal medicinal products, including *Achyranthes bidentata* Blume, *Saposhnikovia* Radix, and *Angelicae dahuricae* Radix, most of which are known for their anti-inflammatory and analgesic effects. The hot pack was applied on the affected shoulder for 15 to 20 minutes once a day. Shinbaro pharmacopuncture solution (Jaseng Spine and Joint Research Institute, Namyangju, Korea) was administered into the LI 15 and TE 14 points, using a disposable insulin syringe (29 G × 13 mm, 1 mL; Sungshim Medical, Bucheon, Korea). The dose of the solution was 0.5 mL at each point, and the solution was administered at a depth of 1 cm. Dry cupping therapy was performed on 2 points, and the points were selected on the most painful area on the shoulder but leaving acupuncture sites aside. Sterile cups (Dongbang Medical, Seongnam, Korea) were applied with negative pressure for 15 minutes. Herbal medicines were prescribed according to the patient's condition, symptoms, and progress. Herbal medicine was administered during/after mealtime 3 times a day.

When required, conventional manual therapy and physical therapies were administered. The manual and physical therapies were decided after multidisciplinary consultations with the expert physician of the department.

2.5. Outcome measures

2.5.1. Primary outcome. The numeric rating scale (NRS)^[17] score was the primary outcome. The NRS is a subjective pain scale, and patients are asked to indicate their pain by choosing a number on a scale. A score of 0 indicates no pain at all, and 10 indicates the worst imaginable pain. The NRS at admission and discharge were collected from the EMR, and the current NRS was collected during the follow-up questionnaire survey.

2.5.2. Secondary outcomes.

2.5.2.1. Shoulder Pain and Disability Index.^[18] The SPADI was developed to assess shoulder pain and impairment, and it comprises 2 subscales: pain (5 items) and impairment (8 items). A score of 0 indicates the perfect state, and 100 indicates the worst state. The SPADI at admission and discharge were collected from the EMR, and the current SPADI was collected during the follow-up questionnaire survey.

2.5.2.2. EuroQol-5 dimension-5 level questionnaire (EQ-5D) score.^[19] The EQ-5D was developed to assess the current HRQOL, and it comprises 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each item is rated on a 3-level system: no problem (level 1), moderate problem (level 2), and severe problem (level 3). EQ-5D scores at admission and discharge were collected from the EMR, and the current EQ-5D score was collected during the follow-up questionnaire survey.

2.5.2.3. Patient Global Impression of Change.^[20] The PGIC is a system for assessing patients' perceived improvement after treatment. It uses a 7-point Likert scale: very much improved, much improved, minimally improved, no change, minimally worse, much worse, or very much worse. We assessed the degree of improvement in pain and discomfort after discharge, and we operationally defined "improvement" as choosing very much improved, much improved, or minimally improved. "No improvement" was defined as choosing no change, minimally worse, much worse, or very much worse.

2.6. Statement of ethics

This study was reviewed and approved by the institutional review board at our hospital (approval no.: 2021-07-011-003; approval date: August 10, 2021). The study protocol conformed with the ethical guidelines of the Declaration of Helsinki, and the questionnaire was administered in compliance with the good clinical research practice guidelines.

2.7. Statistical analysis

All statistical analyses were performed as 2-tailed tests at a significance level of 0.05. The demographic characteristics (sex, age, and history) were analyzed using descriptive statistics. Unless specified otherwise, continuous variables are presented as mean and standard deviation, and categorical variables (e.g., persistence of symptoms and current treatment) are presented as frequency (%). Missing data were adjusted for via multiple imputation.

Changes in the NRS score (the primary outcome) were treated as a continuous outcome across multiple time points (admission, discharge, and follow-up) and were analyzed using a linear mixed model. A linear mixed model including subject specific random effects was used, and values at each time point were

presented using least square estimates, with the significance level expressed as the 95% confidence interval (CI). The secondary outcomes, namely changes in the SPADI and EQ-5D, were also examined as changes across multiple time points (admission, discharge, and follow-up) and analyzed using a linear mixed model with the 95% CI.

The minimal clinically important difference (MCID) was set to 2, with reference to the range of 1.1 to 2.17 among previous studies that used shoulder joint pain as an outcome measure in patients with degenerative SOA.^[21–24] The MCID was considered to have been achieved when the NRS score decreased by 2 or more, and participants who achieved MCID were analyzed using logistic regression. The results are presented as odds ratios and 95% CIs.

All statistical analyses were performed using the R statistical software package (version 4.1.0; R foundation for statistical computing, Vienna, Austria).

3. Results

3.1. Study flow

A total of 481 patients were diagnosed with degenerative SOA and received inpatient treatment at 1 of the 7 hospitals between January 1, 2015, and July 31, 2020. Of these, 186 participants were included in the main analysis. The most common reason for patient exclusion was failure to meet the inclusion criteria. Of the 186 participants, 83 could not participate in the follow-up survey for various reasons, including being unavailable for the questionnaire survey or declining consent to participate in the follow-up. Thus, 103 participants were included in the analysis of follow-up data. The mean number of days of follow-up was 1019 ± 439 (median: 941). Detailed reasons and proportions are described in Figure 1.

3.2. Baseline characteristics

The mean age was 56.4 ± 11.3 years, and 140 (75.3%) participants were women. The mean LOS was 27.0 ± 18.7 days. The mean body mass index (BMI) was 23.8 ± 3.2, which is within the normal weight (BMI greater than or equal to 18.5–24.9 kg/m²) and overweight (BMI greater than or equal to 25–29.9 kg/m²) ranges according to the BMI classification criteria proposed by the World Health Organization.^[25] More patients had pain in the right shoulder joint (n = 76, 40.9%) than in the left shoulder joint (n = 74, 39.8%). The most common age groups were 50 to 59 years (n = 65, 34.9%) and 60 to 69 years (n = 58, 29.1%). The median time to hospitalization was 69.0 days, and the most common time period from symptom onset to admission date was 31 to 183 days (41 cases, 39.8%). The mean NRS at admission was 6.0 ± 1.4, showing that most patients had moderate chronic pain (Table 1).

There were no statistically significant differences in the baseline characteristics between the respondents and non-respondents, except for the following 2 factors: many of those who did not complete the EQ-5D questionnaire did not answer the question about their occupation and the proportion of right and left lesions differed between those who had radiologically confirmed SOA based on MRI findings and those who did not have remarkable MRI findings (Table S1, Supplemental Digital Content, <http://links.lww.com/MD/H806>).

Eighty-four of the 186 participants (45.1%) had MRI data available along with the expert report by a radiologist. The prevalence of conditions coexisting with SOA was as follows: arthrosis of the acromioclavicular joint, 34.5%; tendinopathy in the rotator cuff, 38.1%; superior labrum from anterior to posterior lesion, 32.1%; and shoulder bursitis or fluid collection, 46.4% (Table S2, Supplemental Digital Content, <http://links.lww.com/MD/H807>).

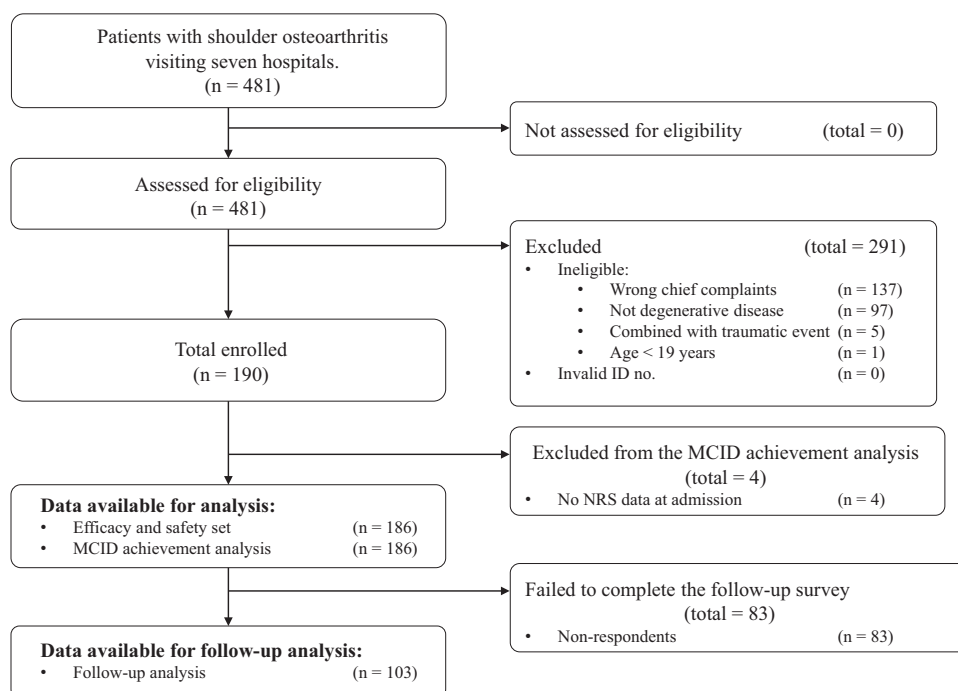


Figure 1. STROBE flowchart of eligible participants for the study. ID no = identification number, MCID = minimal clinically important difference, n = number, NRS = numeric rating scale.

3.3. Treatments

The mean LOS was 27.0 ± 18.7 days. All patients underwent acupuncture, electroacupuncture, and cupping therapy, with a mean number of sessions of 39.1 ± 24.8 , 38.7 ± 24.6 , and 39.0 ± 25.5 , respectively. Chuna therapy was performed on 105 patients (56.5%), with a mean number of 18.2 ± 14.9 sessions. KM physical therapy (herbal steam) was performed on 71 patients (38.2%), with a mean number of 24.8 ± 25.3 sessions. Pharmacopuncture was performed on 174 patients (93.5%), for a mean number of 40.7 ± 30.5 sessions. Herbal medicine was prescribed to 178 patients (95.7%), with an average of 77.9 ± 58.6 packs. Manual therapy (mean, 14.8 ± 12.2 sessions) and extracorporeal shock wave therapy (mean, 10.1 ± 8.1 sessions) were performed on 111 (59.7%) and 67 (36.0%) patients, respectively (Table S3, Supplemental Digital Content, <http://links.lww.com/MD/H808>).

3.4. Post-treatment changes in the evaluation indices

The NRS, SPADI, and EQ-5D scores at admission, discharge, and follow-up were analyzed. All parameters were statistically significantly improved after treatment.

Pain severity was assessed using the NRS. As 36 of 186 participants had bilateral shoulder pain, 222 cases were included in the NRS analysis. The mean NRS dropped by 2.07 at discharge compared with that at admission (from 6.09 [5.90–6.28] at admission to 4.02 [3.76–4.27]; 95% CI: 2.33–1.82] at discharge) and by 3.05 at follow-up (3.04 [2.70–3.38]; $P < .001$) compared with the baseline.

Function impairment was assessed using the SPADI. The SPADI score was analyzed for 81 patients whose baseline SPADI scores were available. The SPADI score decreased by 19.59 at discharge compared with that at admission (from 55.00 [50.89–59.12] to 35.42 [31.34–39.49]; 95% CI: 23.66–15.51) and by 36.06 at follow-up (from 55.00 [50.89–59.12] to 18.95 [13.42–24.47]; $P < .001$) compared with the baseline.

The EQ-5D score was analyzed for 95 patients who had baseline EQ-5D scores available. The EQ-5D score decreased

by 0.13 at discharge compared with that at admission (from 0.61 [0.58–0.65] to 0.74 [0.72–0.77]; 95% CI: 23.66–15.51) and increased by 0.22 at follow-up (from 0.61 [0.58–0.65] to 0.83 [0.80–0.86]; $P < .001$; Table 2, Fig. 2) compared with the baseline.

The results of the Wilcoxon signed-rank test analysis are presented in Table S4, Supplemental Digital Content, <http://links.lww.com/MD/H809>. The Figure S1, Supplemental Digital Content, <http://links.lww.com/MD/H810> displays the notched box and whiskers plot.

3.5. MCID analysis

MCID achievement was additionally analyzed to evaluate whether the change was clinically important and identify the factors contributing to improving the NRS score beyond the MCID. When a reduction in NRS score by 2 or more was defined as MCID achievement, 56.3% of the participants achieved MCID at discharge, while 73.1% achieved MCID at the follow-up. The adjusted NRS at discharge and follow-up was 1.81 (95% CI 1.11–2.94) and 1.99 (95% CI 1.17–3.37), respectively (Table 3).

3.6. Follow-up survey

In the follow-up survey, the number of participants who did not need treatment for shoulder pain in the preceding 3 months ($n = 77$, 74.8%) was higher than the number of participants who received treatment during the same period ($n = 26$, 25.2%). Among the group that received treatment in the 3 months preceding the follow-up, acupuncture was the most common treatment ($n = 16$, 16.7%), followed by physical therapy ($n = 14$, 14.6%) and manual therapy ($n = 13$, 13.5%).

After discharge, the number of participants who were advised not to undergo surgery ($n = 94$, 91.3%) was markedly higher than those for whom surgery was recommended ($n = 9$, 8.7%). In the latter group, 2-thirds of the participants actually underwent surgery ($n = 6$, 66.7%), while a third of the participants

Table 1
Baseline characteristics of patients with shoulder osteoarthritis (n = 186).

| Characteristics | Mean ± SD or median (%) |
|--------------------------------------|-------------------------|
| Age, yr | |
| Mean ± SD | 56.4 ± 11.3 |
| <30 | 5 (2.7) |
| 30–39 | 9 (4.8) |
| 40–49 | 30 (16.1) |
| 50–59 | 65 (34.9) |
| 60–69 | 58 (31.2) |
| ≥70 | 19 (10.2) |
| Sex | |
| Male | 46 (24.7) |
| Female | 140 (75.3) |
| Length of hospital stay, d | |
| Mean ± SD | 27.0 ± 18.7 |
| Median (IQR) | 22.0 (12.5–36.8) |
| Body mass index (kg/m ²) | |
| Mean ± SD | 23.8 ± 3.2 |
| Chief complaints | |
| Right side | 76 (40.9) |
| Left side | 74 (39.8) |
| Both side | 36 (19.4) |
| Period from onset to admission, d | |
| ≤7 | 12 (6.5) |
| 8–14 | 16 (8.6) |
| 15–30 | 21 (11.3) |
| 31–183 | 77 (41.4) |
| ≥184 | 44 (23.7) |
| Unidentified | 16 (8.6) |
| Trigger events at onset | |
| No specific cause | 156 (83.9) |
| Overwork/over exercise | 18 (9.7) |
| Other | 12 (6.5) |
| Comorbidity | |
| Hypertension | 35 (18.8) |
| Diabetes mellitus | 22 (11.8) |
| Depression disorder | 1 (0.5) |
| Cardiovascular disease | 21 (11.3) |
| Respiratory disease | 5 (2.7) |
| Gastrointestinal disease | 14 (7.5) |
| Drinking | 24 (12.9) |
| Smoking | 16 (8.6) |
| Occupation | |
| Unemployed | 110 (59.1) |
| Office worker | 31 (16.7) |
| Service industry worker | 14 (7.5) |
| Manual labor | 9 (4.8) |
| Unknown | 22 (11.8) |

IQR = interquartile range, SD = standard deviation.

did not undergo surgery (n = 3, 33.3%). Of the 6 participants who underwent surgery, 4 did not know the exact type of surgery that they underwent (66.7%), while 2 underwent total shoulder arthroplasty (33.3%).

The most common reasons for satisfaction with inpatient KM treatments were “significant pain reduction” (n = 75, 23.4%) and “skilled medical staff” (n = 43, 13.4%). The most common reasons for dissatisfaction with inpatient KM treatment were “no pain reduction” (n = 18, 40.9%) and “painful treatment” (n = 8, 18.2%).

Regarding the PGIC, 89 participants (86.4%) chose any degree of improvement: “minimally improved,” “much improved,” or “very much improved.” Twelve participants reported “no change” or being “minimally worse.” Since only degenerative SOA was included, the PGIC data for geriatric patients were also analyzed. For 23 participants aged 65 years or older, 2 reports were excluded because the participants selected

both “improved” and “worsened,” and 78.3% stated that their symptoms had improved (Table 4).

3.7. Safety

Any kinds of adverse events were reviewed based on the medical records, and no treatment-related adverse events were reported.

4. Discussion

The study results showed that integrative KM treatment can reduce pain severity and improve function and health-related quality of life in patients with SOA. This prospective observational study was designed to assess the efficacy of and satisfaction with integrative KM treatment in patients with degenerative SOA.

Life expectancy is continuously increasing and particularly the 65-and-over population has become larger with the accelerating population aging. As a result, degenerative diseases have become more important.^[26] In the past century, the incidence and mortality rates of chronic diseases have been substantially higher than those of acute diseases, including in the United States (US). Moreover, individuals with chronic conditions are reported to be more vulnerable to infectious and communicable diseases.^[27] Thus, the management of chronic diseases has become a more important issue than before.^[28] Although chronic musculoskeletal disorders are not internal medical diseases, they significantly deteriorate activities of daily living and induce poor outcomes in geriatric patients. SOA is the most common joint disorder worldwide, affecting approximately 28% of the global geriatric population.^[29] The younger population is experiencing degenerative SOA more frequently than before.^[30] The prevalence of adulthood SOA ranges from 10.5% to 13.4% among the US and British populations. The prevalence is continuously on the rise, doubling between 1999 and 2014 in the US and increasing 1.3-fold between 1998 and 2017 in the UK.^[29,31] Owing to the consequent pain in the upper extremities and functional impairment, mental and physical health is impaired in patients with SOA. This affects the patients’ overall lives, including daily life, work, and hobbies, as well as undermines physical independence in older adults.^[3] The study population for this study included all adult age groups. This allowed the study to explore effective treatment modalities for degenerative SOA in a broader patient population compared with the populations of previous studies.^[10]

Moreover, conservative treatments need more diverse options. Existing studies on degenerative SOA have mostly focused on surgical approaches and have not yet focused on non-surgical treatment modalities much.^[32–37] Recently, there were some issues to consider regarding opioid use, 1 of the most effective non-surgical options for chronic musculoskeletal pain.^[12] The overall improvement rate was 70.5% for SOA using conservative treatment.^[10]

Additional management can help increase the improvement rate. Integrative KM treatment could be applicable because the Republic of Korea features a dual healthcare system, and there are more diverse options already possible. The options were preferred by the patients in the Republic of Korea, since the treatment options were already approved, less invasive or not invasive, and patient-centered.^[38] Considering that the vast majority of KM users have musculoskeletal disorders and that KM healthcare utilization was highest for osteoarthritis,^[39] KM integrative treatment for osteoarthritis is worth studying.

Our results supported previous results, where female sex, overweight or obesity, and older age, specifically age greater than 50 years, were the key risk factors for degenerative SOA.^[40] Pain severity and shoulder function were significantly improved at the follow-up, achieving MCID. Moreover, HRQOL was

Table 2
Post-treatment changes in the evaluation indices.

| Outcome | Outcome | Case (N) | Value | Difference | P value |
|----------|-----------|------------------------|---------------------|------------------------|---------|
| NRS | Admission | 222 [†] (186) | 6.09 (5.90–6.28) | – | – |
| | Discharge | 222 (186) | 4.02 (3.76–4.27) | 2.07 (1.82–2.33) | <.001* |
| | Follow-up | 124 (103) | 3.04 (2.70–3.38) | 3.05 (2.71–3.39) | <.001* |
| SPADI | Admission | 81 (81) | 55.00 (50.89–59.12) | – | – |
| | Discharge | 81 (81) | 35.42 (31.34–39.49) | 19.59 (15.51–23.66) | <.001* |
| | Follow-up | 45 (45) | 18.95 (13.42–24.47) | 36.06 (30.53–41.58) | <.001* |
| EQ-5D-5L | Admission | 95 (95) | 0.61 (0.58–0.65) | – | – |
| | Discharge | 95 (95) | 0.74 (0.72–0.77) | –0.13 (–0.15 to –0.11) | <.001* |
| | Follow-up | 56 (56) | 0.83 (0.80–0.86) | –0.22 (–0.25 to –0.18) | <.001* |

A linear mixed model including subject-specific random effects was used. Values at each time point are presented as least square estimates and change from the admission baseline value was analyzed. Estimates are presented with 95% confidence intervals.

EQ-5D-5L = EuroQol 5-dimension 5-levels, N = number, NRS = numeric rating scale, SPADI = Shoulder Pain and Disability Index.

*P values indicating statistical significance.

[†]A total of 36 patients had bilateral lesions on both shoulders and pain severity was evaluated at each site.

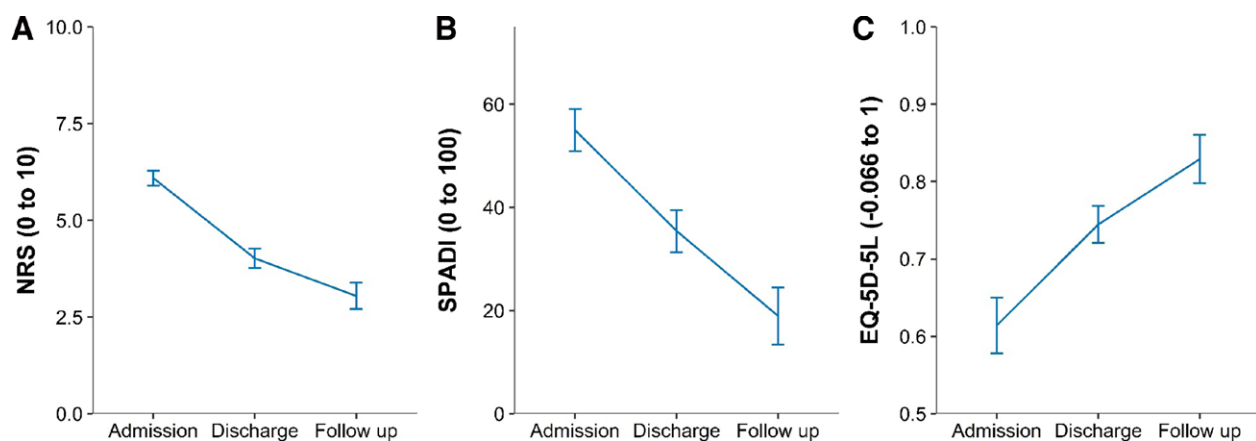


Figure 2. Changes in pain severity, function, and quality of life in patients with shoulder osteoarthritis. (A) NRS. (B) SPADI. (C) EQ-5D-5L. Values are presented as least square estimates with 95% confidence intervals. EQ-5D-5L = EuroQol 5-dimension 5-level, NRS = numeric rating scale, SPADI = Shoulder Pain and Disability Index.

Table 3
Analysis on factors affecting MCID achievement.

| | | Discharge | | Follow-up | |
|--------------------|-------------------|------------------|------------------|------------------|------------------|
| | | Unadjusted | Adjusted | Unadjusted | Adjusted |
| Sex | Female | 0.96 (0.52–1.77) | 1.43 (0.63–3.29) | 0.66 (0.30–1.45) | 1.07 (0.34–3.41) |
| Age, yr | ≥65 | 0.69 (0.36–1.31) | 0.57 (0.26–1.24) | 1.02 (0.47–2.25) | 0.97 (0.34–2.78) |
| Body type | Obese | 0.91 (0.51–1.62) | 0.72 (0.33–1.57) | 1.06 (0.54–2.07) | 0.66 (0.24–1.80) |
| Social history | Drinking | 0.40 (0.18–0.88) | 1.08 (0.37–3.15) | 0.55 (0.20–1.46) | 2.11 (0.54–8.18) |
| | Smoking | 0.59 (0.22–1.58) | 1.23 (0.31–4.86) | 0.48 (0.13–1.70) | 0.87 (0.14–5.47) |
| | Occupation | 1.38 (0.77–2.48) | 0.93 (0.47–1.85) | 1.51 (0.77–2.97) | 0.85 (0.36–2.01) |
| Duration | Chronic | 0.60 (0.34–1.07) | 0.96 (0.44–2.10) | 0.55 (0.30–1.03) | 0.87 (0.35–2.14) |
| Chief complaints | Both side | 0.53 (0.30–0.94) | 0.74 (0.36–1.54) | 0.50 (0.27–0.93) | 0.64 (0.27–1.51) |
| Comorbidity | Hypertension | 0.77 (0.40–1.51) | 0.49 (0.22–1.13) | 0.62 (0.27–1.41) | 0.33 (0.10–1.04) |
| | Diabetes mellitus | 1.23 (0.55–2.78) | 0.77 (0.31–1.93) | 1.38 (0.55–3.47) | 0.93 (0.31–2.79) |
| Baseline NRS score | | 1.37 (1.12–1.68) | 1.81 (1.11–2.94) | 1.44 (1.14–1.80) | 1.99 (1.17–3.37) |
| AUC | | – | 0.69 (0.62–0.76) | – | 0.75 (0.64–0.87) |

For 222 cases, a reduction in the NRS score by 2 or more was deemed MCID, and the number and percentage of cases that achieved MCID are presented. Logistic regression was performed, and odds ratios and 95% confidence intervals are presented. Missing data in the follow-up survey were addressed via multiple imputation.

AUC = area under the curve, MCID = minimal clinically important difference, NRS = numeric rating scale.

also significantly increased after integrative and intensive KM treatments.

For the interventions in this study, the patients received mostly standardized KM treatment. During hospital stay, every participant received acupuncture, electroacupuncture, and cupping

therapies. Herbal medicine and herbal steam therapy, the next most frequently performed treatments, also accounted for over 95% of treatments: herbal medicine in 97.1% and herbal steam therapy in 95.1%. Acupuncture has been documented to relieve pain by lowering the levels of inflammation-triggering

Table 4
Follow-up survey of Korean medicine treatment (n = 103).

| | Mean ± SD or median (%) |
|--|-------------------------|
| Present treatment within 3 mo | |
| Yes | 26 (25.2) |
| No | 77 (74.8) |
| Type of present treatment* | |
| Acupuncture | 16 (16.7) |
| Physical therapy (ESWT, TENS, ICT) | 14 (14.6) |
| Manual therapy | 13 (13.5) |
| Pharmacopuncture | 11 (11.5) |
| Cupping | 11 (11.5) |
| Chuna manual therapy | 9 (9.4) |
| Intraarticular injection | 7 (7.3) |
| Moxibustion | 6 (6.3) |
| Herbal medicine | 5 (5.2) |
| Medication | 4 (4.2) |
| Surgery | 0 (0) |
| Other | 0 (0) |
| Recommendation for surgery after discharge | |
| Yes | 9 (8.7) |
| No | 94 (91.3) |
| Surgery | |
| Yes | 6 (6.7) |
| No | 3 (3.3) |
| Type of surgery | |
| Unknown | 4 (66.7) |
| Total shoulder arthroplasty | 2 (33.3) |
| Arthroscopic debridement | 0 (0) |
| Arthroscopic shoulder decompression | 0 (0) |
| Reason for finding treatment ⁽¹⁾ satisfactory | |
| Significant pain reduction | 75 (23.4) |
| Skilled medical staff | 43 (13.4) |
| Favoring provided treatment | 41 (12.8) |
| Multiple options of treatment | 39 (12.2) |
| Satisfied with the multidisciplinary approach | 38 (11.9) |
| Low side effects | 38 (11.9) |
| Feeling the pain was fundamentally treated | 30 (9.4) |
| Mannered medical staff | 9 (2.8) |
| Received intensive care during the hospitalization period | 3 (0.9) |
| Providing psychological comfort | 2 (0.6) |
| Systemic treatment program | 1 (0.3) |
| Easy communication with the medical staff | 1 (0.3) |
| Reason for finding the treatment ⁽¹⁾ unsatisfactory | |
| No pain reduction | 18 (40.9) |
| Painful treatment | 8 (18.2) |
| Dissatisfied with the diagnostic assessment | 6 (13.6) |
| Cost burden | 4 (9.0) |
| Limitation of treatment options | 3 (6.8) |
| Dissatisfied with the multidisciplinary approach | 2 (4.5) |
| Pain recurrence | 1 (2.3) |
| Dissatisfaction with meals | 1 (2.3) |
| Insufficient information regarding the home workout plan | 1 (2.3) |
| PGIC for treatment | |
| Very much improved | 35 (34.0) |
| Much improved | 38 (36.9) |
| Minimally improved | 16 (15.5) |
| No change | 11 (10.7) |
| Minimally worse | 1 (1.0) |
| Much worse | 2 (1.9) |
| Very much worse | 0 (0) |

ESWT = extracorporeal shockwave therapy, ICT = interferential current therapy, PGIC = Patient Global Impression for Change, SD = standard deviation, TENS = transcutaneous electrical nerve stimulation.

*Multiple answers were allowed.

substances in the body,^[41] and its effect on musculoskeletal pain was demonstrated in mechanism studies and systematic reviews.^[42] Electroacupuncture is a treatment that combines electrical stimulation with acupuncture. It stimulates the acupoints and facilitates blood and synovial fluid circulation around the joints and relieves pain by activating the endogenous opioid system.^[43] Pharmacopuncture is a type of acupuncture combined with herbal medicine. With this treatment, herbal extracts are directly injected into acupoints, which generates clinical efficacy by both mechanical and chemical stimulation. One benefit of pharmacopuncture is that it is a potential alternative to oral intake of herbal medicines for patients who have difficulty taking herbal medicines orally.^[44] Pharmacopuncture is considered to be effective and safe in various types of studies, including systematic reviews.^[44-46] Cupping therapy, along with acupuncture, is widely used for chronic musculoskeletal disorders. A randomized clinical trial also proved the effectiveness of cupping therapy in pain relief.^[47] The negative pressure on skin surface dilated subcutaneous capillaries facilitates blood circulation to provide a local recovery effect and pain relief. Herbal medicine is a pharmacological approach that has been reported to alleviate clinical symptoms and lower the surgery rate for SOA. This effect can be approximate based on the anti-inflammatory or anti-oxidative effects of a natural extract or compound.^[48-50] For pain relief, herbal medicines were reported to have lower rates of adverse reactions, especially kidney damage and digestive ulcer, including gastrointestinal bleeding risks, than non-steroidal anti-inflammatory drugs.^[51]

Participants also regarded their global impression as improved in 86.4% of the cases, answering “minimally improved,” “much improved,” or “very much improved.” Regarding the existing literature on the conservative treatment approaches for degenerative SOA, 1 study conducted a long-term follow-up of 129 geriatric patients who had been diagnosed with degenerative SOA and received standard conservative treatment.^[10] In the study, the conservative treatments included oral pharmacological treatment, intraarticular injection, and physical therapy. In aspects of perceived improvement by patients, the improvement rate was higher when the integrative KM treatment was added to the conservative treatments (86.4% vs 70.5%). The improvement was still higher when we additionally analyzed the improvement rate in a subgroup of patients aged 65 years and older, after considering the population difference (78.3% vs 70.5%). This discrepancy may be attributable to the characteristics of the interventions. The patients received integrative KM treatment in addition to the conservative treatment or as an alternative to the conservative treatment; therefore, they could have a more diverse option. Furthermore, the patients received intensive KM treatment since they were hospitalized, and the treatments were provided during hospital stay.

One key strength of this study is that we directly reviewed inpatients who received multilateral integrative KM treatments to investigate the effectiveness of these treatments using various parameters and confirmed that the treatments produce clinically significant effects. Further, the treatments were provided as an intensive inpatient care regimen using other additional treatment modalities. The results of this study indicate that patients who received integrative treatment combining conservative treatment and KM treatments perceived greater improvement than those who received conservative treatment alone.

This study has some limitations. Although we strived to eliminate researcher bias, the study design has its fundamental limitation in comparison with the rigorous design of a randomized clinical trial. We documented long-term follow-up survey data, but only 55.4% of the patients completed the follow-up owing to various clinical situations and practical limitations. Participants were not adequately encouraged during participation in this prospective observational study; thus, the long-term follow-up surveillance data were not fully complete. In addition,

the results were confirmed based solely on subjective patient-reported outcomes, and there is a limitation in that neither range of motion nor physical examination by a physician nor radiological comparisons were performed.

Notwithstanding these limitations, 1 major strength of this study is that a large-scale survey involving 7 hospitals in various regions of Korea was conducted, thereby eliminating locality in the study findings. Further, this study provides data on intensive and integrative treatment for patients with degenerative SOA for maintaining a painless life with normal shoulder function for a long-term period.

5. Conclusions

This study prospectively evaluated the effectiveness and long-term effects of KM integrative treatment of degenerative SOA for a long-term period. The results of this study suggested that integrative KM treatment significantly improves both shoulder pain and function in patients with degenerative SOA. This study could contribute to the development of prospective randomized clinical trials and formulation of guidelines for integrative treatment to be added to the conservative treatments in future studies.

Author contributions

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