



Evidence of the AKA-Hakata Method

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9.1 Randomized-Controlled Trial and EBM

The randomized-controlled trial (RCT) is used to determine whether one treatment method is better than another. The RCT is indispensable to “evidence-based medicine” (EBM), and serves as a basis for the approval of numerous therapies implemented in modern medicine. The RCT was first reported in 1948 in a study on the use of streptomycin for pulmonary tuberculosis [1].

The concept of EBM was introduced by Guyatt in Canada in 1991 [2]. He described that diagnostic methods based on scientific evidence are the future of medical care, using methods in the diagnosis of anemia as an example. The contents of the paper were not new, and followed the methods of clinical epidemiology, which has played a key role in medical examination, treatment, and research since the 1970s. Clinical epidemiology unravels causal relationships quantitatively and examines the effectiveness and efficiency of examination and treatment methods for disease by taking advantage of a variety of epidemiological techniques that are used in other fields such as statistics and social psychology. Clinical epidemiology is considered by some to be identical to EBM. While clinical epidemiology is considered to have a stronger research implication, EBM collects answers and information concerning problems and questions related to patients and diseases, considers whether the information helps patients based on clinical epidemiological methods, and applies the information to the treatment of the patient.

In other words, EBM can be considered a medical procedure that indicates the best medical treatment for individual patients. Furthermore, the RCT, which is an essential

research method for EBM, is considered an effective method to demonstrate objectively that a certain treatment is effective. Thus, the RCT can provide powerful evidence to determine the efficacy of the AKA-Hakata method.

9.2 A Randomized-Controlled Trial of the AKA-Hakata Method for the Treatment of Chronic Low Back Pain

There are various methods to evaluate pain [3]. Of the methods, the visual analogue scale (VAS) is the most simplest and widely used [4, 5]. Of two RCT manuscripts examining the AKA-Hakata method published in international journals as of February 2016 [6, 7], one of them is concerned with chronic low back pain. In that report, the effects of VAS on chronic low back pain were reported, as outlined below.

Approximately 60–85% of people have been reported to suffer from low back pain at least once during their lifetime [8]. Many of these individuals have multiple relapses [9], and 75% have low back pain that persists for more than a year after onset [10]. In Japan, in “Health situation in household members: Subjective symptoms” (Fig. 9.1) of the *Outline of the Comprehensive Survey of Living Conditions 2010* by the Ministry of Health, Labour and Welfare, low back pain showed the highest symptom prevalence in males, with a rate of 89.1 per 1000 persons [11]. The symptom with the highest prevalence in females was shoulder stiffness, followed by low back pain at 117.6 per 1000 persons.

There are a variety of conservative treatments for chronic low back pain; however, each, including medication therapy, exercise therapy, massage, cognitive behavioral therapy, and manual treatment, has advantages and disadvantages. In addition, different countries and areas have published guidelines for the treatment of low back pain. In Japan, the *Clinical Practice Guidelines for Low Back Pain 2012* from the Japanese Orthopaedic Association and the Japanese Society

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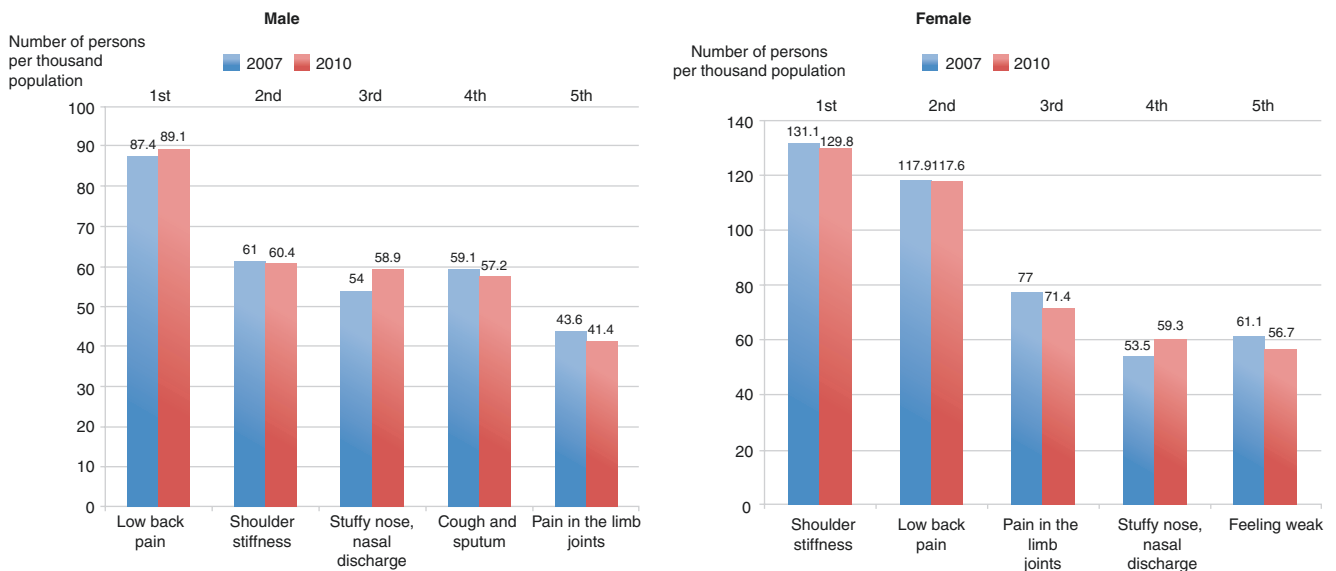


Fig. 9.1 Top five symptoms by gender (multiple answers) in Japan. Source: *The outline of the Comprehensive Survey of Living Conditions 2010*. Website of the Ministry of Health, Labour and Welfare

for the Study of Low Back Pain provides detailed evidence ranging from the definition of low back pain to its epidemiology, diagnosis, and treatment [12]. Furthermore, the *Clinical Practice Handbook for Chronic Pain in the Locomotor System* (Japanese Orthopaedic Association) was published in November 2013 [13]. However, none of the treatments described in these handbooks are absolutely effective for chronic low back pain, which frustrates orthopedists and primary care physicians in clinical practice.

Recently, an outline of the RCT for chronic low back pain conducted by the authors has been described. The subjects were patients with low back pain lasting more than 6 months, with chronic low back pain being defined as lasting 12 weeks or more. However, this study aimed to show the effects on symptoms lasting for a prolonged period. Thus, patients with low back pain lasting more than 6 months and those having a previous history of treatment for the low back pain were included. Patients who received lumbar surgery in the past 6 months were excluded.

Included patients were divided randomly into 2 groups of equal patient number. One group was treated by the AKA-Hakata method alone, and the other group was treated by a sham procedure. The effects were compared over time. Patients received sufficient explanation that they may receive the sham procedure at a 50% chance, and written consent for the study was obtained from all patients. VAS was used as the index for effect. For the evaluation, patients recorded VAS values everyday themselves from a month before the start of treatment to the completion of the study (6 months after the start of the treatment). The recording sheets were collected once a month during an outpatient visit.

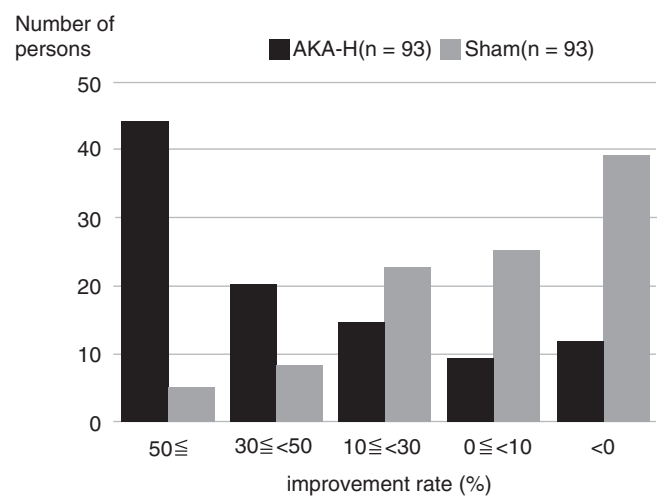


Fig. 9.2 Comparison at the VAS improvement rate before and at 6 months after treatment

The results of the comparison of the VAS improvement rate between groups are shown in Fig. 9.2. The rate of the subjects with much improvement was high in the AKA-Hakata group compared to the sham group. Furthermore, when changes in VAS was compared continuously between these 2 groups for 6 months, statistically significant differences were observed at 3 months and later after the start of treatment (Fig. 9.3). These results suggest that the therapeutic effect of the AKA-Hakata method on chronic low back pain is not a placebo effect and that this method can be an effective treatment for chronic low back pain.

Future studies plan that the supervisory physicians specified by the Japan Medical Society of Arthrokinematic

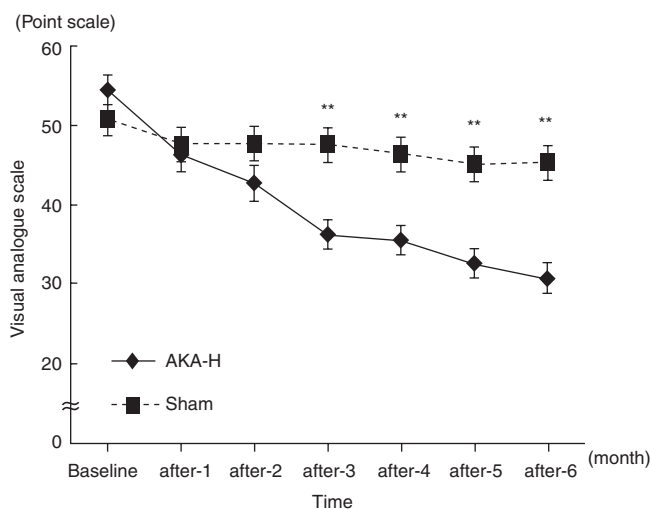


Fig. 9.3 Temporal changes in the average VAS values in patients treated using the AKA-Hakata method and in patients treated with the sham technique. **Statistical significance ($P < 0.01$: Two-way [group and month] ANOVA). From Kogure A et al. Plos One 2015

Approach (AKA) will perform a large-scale, multicenter research study to accumulate further data concerning the AKA-Hakata method.

9.3 RCT of AKA-Hakata Method for Acute Low Back Pain

The first paper concerning acute low back pain and the AKA-Hakata method was published in *Manuelle Medizin* (Springer; in German), which specializes in manual treatment [6]. Hakata et al. examined the efficacy of the AKA-Hakata method in the treatment of acute low back pain. The study included patients with low back pain at less than 1 month after onset in accordance with the definition of acute low back pain by the Japanese Orthopaedic Association. For the RCT method, 118 patients who visited clinics were assigned randomly into the AKA group, in which patients receive treatment by AKA-Hakata method, and the traditional group, in which patients receive traditional conservative treatment such as epidural anesthesia injection, oral medicines including NSAIDs, thermotherapy, and corset fixation. Effect was judged in accordance with the score rating system for low back pain established by the Japanese Orthopaedic Association [14].

Results showed that the rate of patients whose low back pain completely disappeared was 76.4% in the AKA group and was 33.3% in the traditional group. On the other hand, low back pain was persistent in 18.2% of patients in the AKA group and 60.3% of patients in the traditional group at 1 month or later (Fig. 9.4). These results are consistent with the long-term prognosis of low back pain published

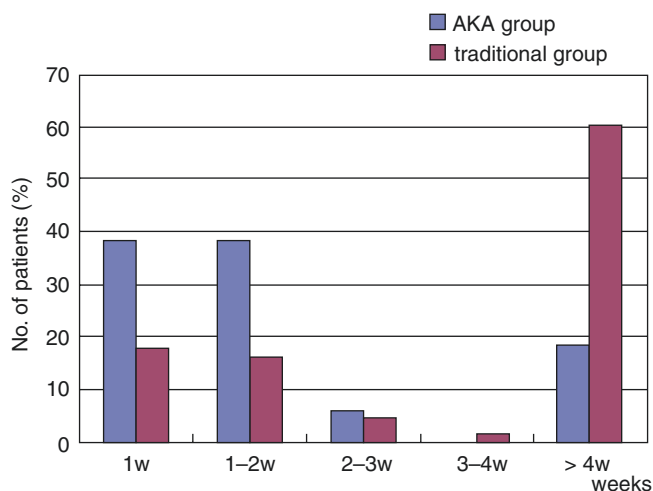


Fig. 9.4 Comparison of AKA group and traditional group in the periods to procedure complete relief of pain. (Cited from *Manuelle Medicine*)

previously [10], which described that an average of 62% of patients report persistent low back pain at 12 months after onset, and a recurrence rate of 60%.

Even if limited to acute low back pain alone, the results showed that the AKA-Hakata method, which can treat the cause of the symptoms, exerted superior therapeutic effects.

9.4 Effects of the AKA-Hakata Method on Health-Related Quality of Life (QOL)

The 36-Item Short Form Health Survey (SF-36) [15, 16] is a QOL questionnaire used to measure health-related function with subscales. Currently, the SF-36 is translated to over 130 languages and is used widely internationally. The website of iHope International [17], an authorized NPO, defines the SF-36 as “not structured based on the contents limited to a certain disease, but a concept about health common to all people, and can measure QOL in patients with various diseases and healthy persons without disease. It is also possible to compare among patients with different diseases or compare health conditions of patients with people in general.”

Our study mentioned above used the SF-36 in addition to the VAS as a major indicator of effects. We asked patients to fill out the questionnaire at every monthly office visit. Answers were processed statistically by a standardized scoring algorithm. The statistical processing was designed so that scores are automatically calculated by entering the results of the answers in to an Excel sheet. Norm-based scoring (NBS) was employed, such that the standard value of the entire Japanese population became 50 ± 10 points (mean \pm standard deviation).

In our study, the AKA-Hakata method showed a significant improvement in all subscales at 6 months after the start of treatment as compared with a sham group, indicating that AKA provided improvement of pain and physical functions. Even social function and mental health may also be improved. In other words, the AKA-Hakata method shows great promise in terms of improvement of QOL.

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