

## Japanese Acupuncture - Current Research

*Japanese Traditional Medicine Text (15) – Neurology A*  
Ikuro Wakayama

### General Neurology

#### 1. Acupuncture Indications in Neurological Disorders

The World Health Organization (WHO) presented a list of 43 disorders treatable by acupuncture in 1979. The list was amended to 49 disorders in 1996. Current research on these disorders will be presented here. Each neurological disorder category contained various symptoms and diseases, such as headache, migraine, tension-type headache, sciatic neuralgia, post-herpetic neuralgia, and hemiplegia. However, rigorous clinical trials have not been conducted to prove the effectiveness of acupuncture for these conditions. The 1979 list of conditions was clearly not based on clinical evidence. Therefore, reflection on the 1996 draft led to the conclusion that future amendments of acupuncture indications should be adapted based on rigorous clinical evidence<sup>1)</sup>. Work began in 1996, and was eventually published by the WHO in 2002 as "Acupuncture: Review and analysis of reports on controlled clinical trials"<sup>2)</sup>. As the title of this book indicates, clinical acupuncture research designed as randomized controlled trials (RCT) and controlled clinical trials (CCT) has demonstrated that 28 conditions have been shown to be effectively treatable with acupuncture. An additional 63 conditions may be effectively treatable but further evidence is required, 9 conditions warrant clinical trials as the current Western treatment has proven difficult, and 7 conditions seem promising but still require an appropriate method of evaluating current clinical results. Even though clinical trials are the basis for this book, it should be noted that a majority of the research presented is still of low quality. Since 1996, when these results were first collared, neurological disorders confirmed to be effectively treatable by acupuncture included facial pain, headaches, sciatica, and stroke.

On the other hand, in 1997, the National Institutes of Health (NIH) issued a Consensus Statement that the effectiveness of acupuncture was

based on scientific evidence, and it included the relief of nausea and vomiting caused by surgery and/or chemotherapy, hyperemesis gravidarum, and toothache following surgery. Also cited were conditions related to pain, drug addiction, stroke, headache, menstrual pain, tennis elbow, fibromyalgia, low back pain, carpal tunnel syndrome, and asthma; of these, only headache and stroke are neurological disorders. Concerning the 2002 statement by the NIH, there have been recent publications on the Internet indicating that the statement may no longer be valid<sup>3)</sup>.

Although most of the fundamental results were based on poorly designed clinical research, the WHO and NIH, internationally recognized agencies, announced which conditions can be treated by acupuncture. However, very few neurological disorders were mentioned. This has been the situation regarding acupuncture therapy for neurological disorders until just recently. Concerning the future of moxibustion therapy, high-quality, integrated clinical trials are eagerly awaited, with it only occasionally being reported in clinical trials at the present time. For this reason, the current volume focuses on acupuncture therapy.

#### 2. Review of Acupuncture for Neurological Disorders as Presented in the Cochrane Collaboration

The Cochrane Collaboration was founded in 1993, and it assists people involved in health care by referring them to online information. It currently consists of over 4,000 Cochrane reviews, helping patients obtain accurate information so that they can make informed health decisions. Cochrane reviews are based on systematic reviews of primary research in human health care. Reviews are posted on some neurological disorders, such as stroke, Bell's palsy, dysphagia due to stroke, epilepsy, prevention of migraine, restless legs syndrome, stroke rehabilitation, tension-type headache, and vascular dementia<sup>4)</sup>.

Reviews of the results for the neurological disorders are displayed in Table 11. They have yet to draw conclusions or post prospects for the future

because most current reviews are based mostly on low-quality clinical trials. However, reviewers suggested that, for the prevention of migraine and tension-type headache, acupuncture treatment is effective<sup>5, 6</sup>. In addition, for these 2 notable diseases, by adding a new clinical trial in the 2008 Edition, for which evidence was insufficient in 2001, reviews of the effectiveness were verified. That is to say, the quality of clinical trials for the conditions listed in Table 11, as well as other diseases, or diseases not listed here, will confirm the effectiveness of acupuncture for neurological disorders once large-scale, high-quality clinical research can be conducted. Additionally, there are some neurological disorders for which trials have not yet been conducted but protocols for them have been established. They are Guillain-Barre syndrome, multiple sclerosis, Parkinson's disease, post-herpetic neuralgia, and diabetic neuropathy.

Regarding whether or not acupuncture is effective for specific neurological disorders, there are currently few studies and little evidence besides migraine and tension-type headaches. However, this article refers to the Cochrane reviews as a potential source of evidence for the validation of acupuncture's effectiveness for neurological disorders: (1) migraine, (2) tension-type headaches, (3) epilepsy for functional disorders; (4) Parkinson's disease, (5) stroke, and (6) multiple sclerosis for central nervous system disorders; and (7) diabetic neuropathy, (8) Bell's palsy, (9) Guillain-Barre syndrome, and (10) post-herpetic neuralgia for peripheral nerve disorders. Here, we introduce international and domestic research results on acupuncture treatment for these 10 conditions.

**Table 11. Neurological disorders for which the effectiveness of acupuncture has been assessed by the Cochrane Review**

Disorders	Year	No. of trials	No. of patients	Evidence
Acute stroke	2004	14	1,208	No evidence*
Bell's palsy	2010	6	537	Inconclusive**
Dysphagia due to acute stroke	2008	1	66	Inconclusive**
Epilepsy	2008	11	914	No evidence*
Prevention of migraine	2008	22	4,419	Similar or superior to drug treatment
Restless legs syndrome	2008	2	170	Inconclusive**
Stroke rehabilitation	2006	5	368	Inconclusive**
Tension-type headache	2008	11	2,317	Reduced frequency of headaches
Vascular dementia	2007	0	0	No data***

\*: No evidence suggesting the effectiveness of acupuncture treatment. Further, larger scale research would be desirable.

\*\* : The quality and the scale of trials were inadequate. The effectiveness of acupuncture cannot be determined.

\*\*\*: No randomized controlled trials available.

### 3. International Research on Acupuncture Treatment for Neurological Disorders

Most of the international clinical research on the above-mentioned neurological disorders, including stroke, migraine, and tension-type headache, involve relatively *common* diseases. Regarding stroke, the effect of acupuncture for stroke rehabilitation in the Cochrane review was inconclusive as shown in Table 11, but later, a systematic review (SR) indicating acupuncture as effective treatment was reported (Table 12)<sup>7, 8)</sup>. In addition, an SR has been reported on the effectiveness of moxibustion for stroke rehabilitation (Table 13)<sup>9)</sup>. Thus, it cannot be stated that there is sufficient SR-based evidence for either acupuncture or moxibustion; however, it could be confirmed if more RCT are conducted and integrated as SR in the near future.

Concerning other disorders, for example Parkinson's disease, there are 2 SR, and only one or at most 2 RCT available. Both of these Parkinson's disease SR were presented in 2008. However, the first SR reported on the significant effectiveness of acupuncture treatment. The second SR included an RCT on scalp acupuncture within the effectiveness of acupuncture therapy, and a meta-analysis provided further evidence of its efficacy, although the overall effectiveness of acupuncture treatment for Parkinson's disease was not conclusive (Table 14)<sup>10, 11)</sup>. Thus, at present, convincing evidence for the effectiveness of acupuncture treatment on neurological disorders is definitely lacking, but, recently, there has been a gradual increase in reliable evidence.

**Table 12. Systematic reviews of acupuncture combined with rehabilitation in patients with stroke**

	No. of databases searched	Year of searches	Inclusion criteria	No. of RCTs	Evidence
Kong JC (2010)	25	~Sep. 2009	Sham controlled RCT	10	No evidence*
Wu P (2010)	9	~Sep. 2009	RCT	9	Likely effective**

**Table 13. Systematic reviews of moxibustion combined with rehabilitation in patients with stroke**

	No. of databases searched	Year of searches	Year of searches	No. of RCTs	Evidence
Lee MS (2010)	14	~Nov. 2009	RCT	9	Effective with some limitations**

\*: No evidence suggesting the effectiveness of acupuncture treatment. Further, larger scale research would be desirable.

\*\* : Acupuncture treatment appears effective; however, large-scale, high-quality research is still desirable.

**Table 14. Systematic review of acupuncture for Parkinson's disease**

	No. of databases searched	Year of searches	Inclusion criteria	No. of RCTs	Evidence
Lam YC (2008)	13	~ July 2007	Sham or waiting list controlled RCT	10	Appears to be effective*
Lee MS (2008)	17	~ Sep. 2007	RCT	11	Inconclusive**

\*: Acupuncture treatment appears effective; however, large-scale, high-quality research is still desirable.

\*\* : The quality and scale of trials were inadequate. The effectiveness of acupuncture cannot be determined.

This concludes our overview of the results of the Cochrane review with references to SR and RCT in foreign countries. Gradually, evidence for the effectiveness of acupuncture in some neurological diseases such as migraine and tension-type headache has been increasing. In addition, as I indicated in Parkinson's disease and stroke, the quality of trials improved, the scale of the trials increased, and the SRs integrated those trials, and so the effectiveness of acupuncture will be more strongly supported.

#### 4. Domestic Research on Acupuncture Treatment for Neurological disorders

##### a. Clinical Trials

Of the 10 conditions listed above, unfortunately, no RCT have been from Japan. Among comparative studies using multiple subjects, one report involved 38 patients suffering from diabetic neuropathy treated with acupuncture<sup>12)</sup>, and another study treated 113 patients with peripheral facial paralysis (Bell's palsy or Hunt syndrome)<sup>13)</sup>. Three comparative studies reported on the clinical effects of acupuncture and moxibustion treatment for stroke patients combined with rehabilitation<sup>14-16)</sup>. Also, there was a report on the n-of-1 trial method for Parkinson's disease<sup>17)</sup>. Comparative research in Japan has not been conducted for other neurological disorders. Therefore, as discussed above, there are

very few comparative studies investigating acupuncture intervention for neurological disorders conducted in Japan.

##### b. Case Series

There are case series studies demonstrating the effect of acupuncture treatment for tension-type headache (86 patients)<sup>18)</sup> and refractory cases of Bell's palsy/Hunt syndrome (29 patients)<sup>19)</sup>. Results from these studies showed almost or complete clinical improvement at rates of 19.7 and 17.2%, respectively, indicating the reliable effects of acupuncture treatment for these conditions. Also, successful acupuncture treatment for 48 subjects with cervical dystonia<sup>20)</sup> was reported. High-quality, comparative clinical trials in the future are desirable.

##### c. Case Reports

As for case reports, especially treatment results of acupuncture interventions, it has generally been the case that reports of these results focus primarily on atypical treatment courses or unexpected favorable results. Case reports suggesting special mechanisms of action of acupuncture that were not previously reported are also important. Unfortunately, those kinds of case reports are very rare among Japanese clinical reports; instead, most reports merely mention that acupuncture could be used to successfully treat the presenting symptoms.

Acupuncture case reports within the field of neurological disorders in Japan usually focus on the

10 disorders addressed above. However, recently, acupuncture treatments are being increasingly reported for specific central nervous system neurological disorders, such as Parkinson's disease and cervical dystonia in which muscle tone increases pathologically.

#### **d. Acupuncture Treatment for Neurological Disorders in Japan**

Regarding acupuncture treatment methods in Japan for functional headache, including both tension-type headache and migraines, the treatment generally centers on acupoints and tender points of the neck and shoulders<sup>18)</sup>. For Parkinson's disease, acupuncture points were selected based on visceral pattern identification, and the acupuncture session will also include points for local tenderness and induration<sup>21)</sup>. For diabetic neuropathy, the needle retention method or electro-acupuncture generally utilizes distal extremity acupoints<sup>12, 22)</sup>. Treatment for facial paralysis usually includes the 6 acupoints on yang channels of the face combined with peripheral acupoints of the upper extremities<sup>13, 19)</sup>.

### **5. Future Perspective**

With the current development of medicine, we are seeing the era of a team approach in health care. Acupuncture was introduced from China in the 6<sup>th</sup> Century, and later developed as Japanese acupuncture during the Edo era; however, medical teams integrating acupuncture and other forms of medicine have not yet been realized. The medical system in Japan has only recently started to emphasize the importance of a team approach.

The development of clinical research without the consolidation of the team approach is impossible. That is to say, for conducting good clinical research, research team composed of more than several kinds of professionals, such as supervisor, physicians, clinical epidemiologists, statisticians, and others, are necessary, and good study designs are also needed. This type of research system was developed in Western countries, but has not yet been fully developed in Japan. Why have clinical trials of

acupuncture not been well-developed in East Asian countries such as China, Korea, and Japan where acupuncture originated? It is because the team approach as seen in Western countries has not been practiced. Large-scale trials of acupuncture conducted in the West have been, as mentioned above, extremely precise, co-authored, and carried out by multi-talented teams of professionals from different fields. In addition, there is the possibility that because acupuncture and moxibustion developed gradually since ancient times in Japan, there was never any doubt about their clinical validity or effectiveness, so clinical trials did not develop. However, as a more significant factor, acupuncture was not considered appropriate in a hospital setting where large-scale trials conducted by qualified research teams took place, so acupuncture and acupuncturists were largely left unexplored and under-utilized.

Most clinical trials of acupuncture involving Japanese interventions include just low number and small-scale clinical trials on low back pain<sup>23)</sup>. Considering international clinical trials for low back pain, relatively reliable evidence for the effectiveness of acupuncture is readily available. However, establishing evidence may not be desirable even for low back pain if the current research system in Japan does not change, being much less desirable for neurological disorders.

As mentioned above, high-quality, large-scale clinical trials are thought to be necessary to verify the clinical effect of acupuncture in Japan. However, we cannot have high hopes for the relevancy of acupuncture research in Western hospitals until an established system of team research develops, and acupuncture is used as a matter of course within that system.

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