

Clinical Trials on Acupuncture in Japan

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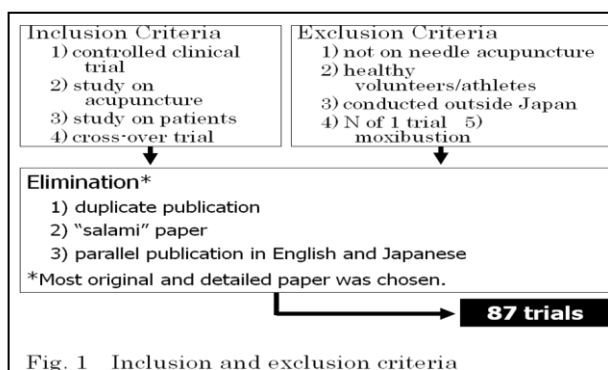
1. Introduction

The concept of evidence-based medicine (EBM) has permeated Japanese clinical research on acupuncture and moxibustion, and the number of randomized controlled trials (RCT) is also increasing in Japan. For RCTs conducted in Japan, some reviews were published¹⁻³⁾. However, data has not been updated for several years. Therefore, we reviewed and evaluated the relevant papers in order to identify the current status of clinical trials on acupuncture conducted in Japan and to assess the quality of them.

2. Methods

We performed a literature search by using “Ichushi (Japana Centra Revuo Medicina) Web”, PubMed, reviewing papers already published^{2,3)}, and our own files. In using Ichushi Web and PubMed, we used the keywords “acupuncture” and limited to RCT or quasi-RCT.

We included only controlled clinical trials (CCTs) or RCTs which were conducted in Japan, published before 2008, focusing on the effect of acupuncture for patients. Cross-over RCTs were included. We excluded experimental studies which stressed or loaded healthy subjects/athletes, N of 1 trials, trials on moxibustion. After eliminating duplications, we extracted data from the located papers, and assessed sample size, randomization, blinding, language, type of control group, modified Jadad score, and so on. (Fig. 1)



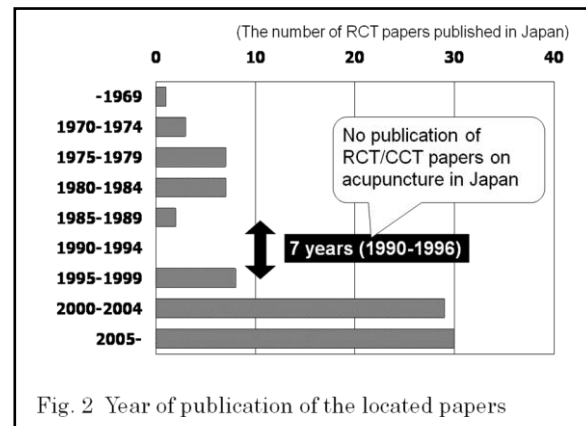
3. Results

We located 87 RCTs/CCTs on acupuncture conducted in Japan. In fact, some clinical trials were reported in the 1960’s, most of which papers, however, were unavailable. Consequently, whether these papers are of independent trial or duplicates was not clear. Therefore, trials after CCT by Kinoshita published in 1969 will be analyzed in this paper.

The 87 trails were RCTs or CCTs conducted during 1969 through 2007 and their abstracts have been published in journals as full paper or abstract. These trials do not contain experimental RCTs which stressed or loaded healthy volunteers or athletes. If we included trials using healthy subjects or athletes, the number of trials would have been more than 150.

Of the 87 trials, 76 were reported in Japanese, and 11 were reported in English. Eighty-one trials were parallel-armed, and 6 were cross-over trials. There were 5 multi-center RCTs. Sample size ranged between 4 and 170.

RCT on acupuncture was conducted at a relatively early stage. This may be because of the influence of Dr. Kosei Takahashi and Oubu-Kai. However, there was no publication of clinical trial on acupuncture between 1990 and 1996, after which the number of clinical trials increased again, especially after 2000. (Fig. 2)



Most of the trials were published in acupuncture journals. While some trials used more than 100 subjects, the sample size has not been increasing even after 2000. Most of the trials used patients with musculoskeletal problems such as low back pain or neck and shoulder pain. (Fig. 3, Table 1)

At the early stage, until the 1980s, clinical trials were mainly conducted and published by practicing

acupuncturists, but after the 1990s, the authors are mainly acupuncturists who work for a university or school. (Fig. 4)

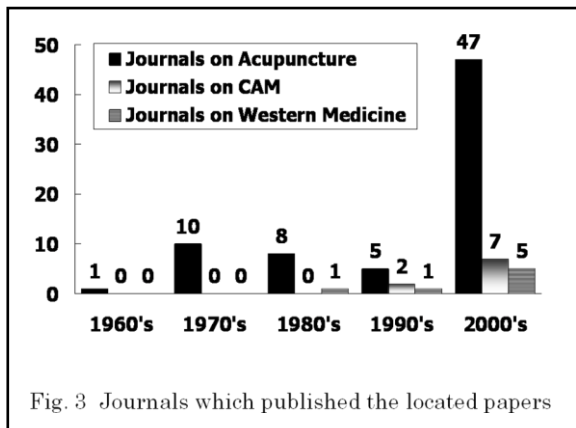


Fig. 3 Journals which published the located papers

Musculoskeletal (62 trials)
Circulatory (4)
Neurological (3)
Urological (2)
Respiratory (1)
Digestive (1)
Others (14)

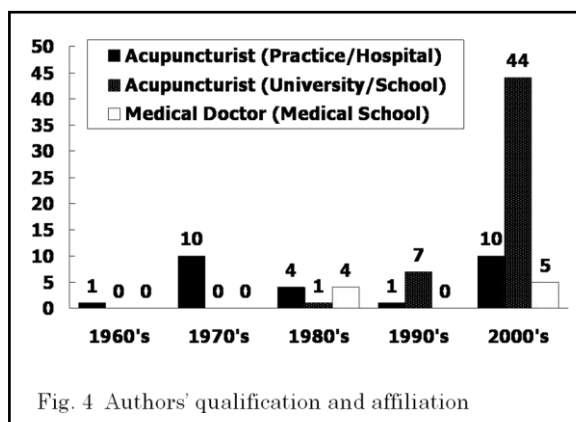


Fig. 4 Authors' qualification and affiliation

At an early stage, trials focused on comparison of different styles of acupuncture, and then shifted to comparison of acupuncture with sham needling after 2000. This may be related to the author's acupuncture affiliation because it is difficult to set the no treatment or sham needling group for practicing acupuncturists. (Fig. 5)

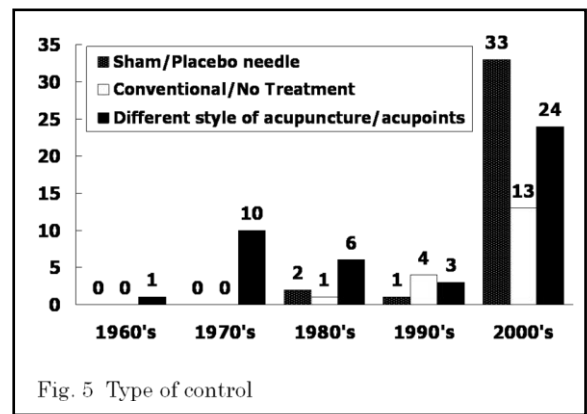


Fig. 5 Type of control

If we look at the average Jadad score (Table 2) in each decade, the quality of the trials improved gradually. However, even after 2000, the Jadad score is 0 in some trials. Sample size decreased after the 1980s. The reason for low quality has two aspects: one is that the trial itself is poor, and the other is that reporting methods are poor, but actually both may be poor in the trials of zero score. (Fig. 6,7)

Described as "randomized"	Give 1 point
Appropriate method (table of random numbers, computer generated, etc.)	Give 1 point
Inappropriate method (allocating alternately, hospital number, etc.)	Deduct 1 point
Subject blinded	Give 1 point
Evaluator blinded	Give 1 point
Dropouts/withdrawals described	Give 1 point
Worst score = 0 Best score = 5	

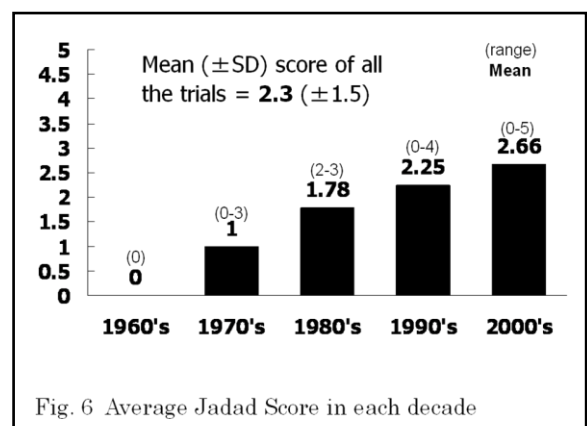


Fig. 6 Average Jadad Score in each decade

There were 5 multi-center RCTs. However, the sample size is not very large, and average Jadad score is 2.2. This means that the quality of multi-center

RCTs on acupuncture in Japan is not necessarily high. (Table 3)

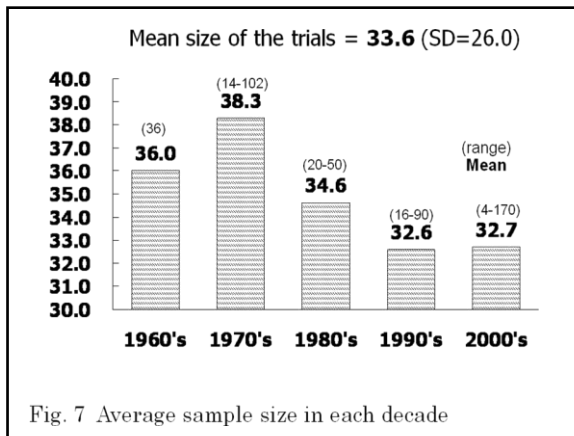


Fig. 7 Average sample size in each decade

Table 3 Five multi-center RCTs

1999	Dysuria	n= 90	Jadad=1	Practitioner group
2000	Hypertension	n= 24	Jadad=2	Practitioner group
2001	Low back pain	n= 68	Jadad=4	University group
2005	Rheumatoid Arthritis	n=170	Jadad=1	University group
2006	Low back pain	n= 64	Jadad=3	Practitioner group
Mean: 2.2		(Jadad score: 0 (worst) – 5 (best))		

4. Discussion

We summarize the points as follows: RCTs or CCTs on acupuncture in Japan suddenly increased after 2000. They once were conducted mainly by practicing acupuncturists, and then mainly by school acupuncturists after 1990s.

Initially, they focused mainly on comparison of different styles of acupuncture, then shifted to comparison of acupuncture with sham needling after 2000. Most trials assessed the effect of acupuncture for musculoskeletal conditions. The quality of the trials is improving slightly, but generally not very high.

The result of PubMed search (Keyword: acupuncture, Limits: randomized controlled trial) as of December 31, 2007 showed that the earliest

literature was written by Strom in 1974⁴⁾. In contrast, it deserves special mention that RCT literature was published in the 1960s in Japan. Although far more RCT literature on acupuncture has been published in European countries and the U.S. than in Japan, there were some practitioners in acupuncture and moxibustion who had interest in RCT from earlier times and implemented it in Japan. Then-RCTs were performed by private-practice acupuncturists and moxibustionists under the guidance of scholars of universities. In the latter half of 1990s and onward, most of the RCTs have begun to be conducted by acupuncturists and moxibustionists working in universities. This may have caused a rise after 2000 in the number of RCTs comparing acupuncture with sham needling.

Through the evaluation of the trials we found some problems with controlled clinical trials in Japan. The trials on acupuncture in Japan are not easy accessible from overseas, because most of the reports are written in Japanese and published in domestic acupuncture journals. There were some inappropriate papers, such as duplicate publications or so-called “salami” papers to increase the number of literature entries by fragmentation of data. Data fragmentation, which may be seen in other countries, is a major impediment for literature reviews to get muddled and also an objectionable act as a researcher. Overall, we have an impression that acupuncture RCTs in Japan tends to be conducted too easily without careful consideration. We propose that acupuncture schools/societies in Japan strengthen the functions of their Institutional Review Board for better quality of clinical trials on acupuncture in Japan.

In conclusion, the number of RCTs on acupuncture and moxibustion is growing, whereas the quality is not necessarily high. Thus we consider it necessary to cope with the tasks ahead; quality improvement, adequate control group setting, and English publications accessible from abroad.

References

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