

Original Article

Acupuncture for Chronic Pain in Japan: A Review

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Many Japanese reports of acupuncture and moxibustion for chronic pain are not listed in medical databases such as Medline. Therefore, they are not easily accessible to researchers outside of Japan. To complement existing reviews of acupuncture and moxibustion for chronic pain and to provide more detailed discussion and analysis, we did a literature search using 'Igakyo Chuo Zasshi Wed' (Japania Centra Revuo Medicina) and 'Citation Information by National Institute of Information' covering the period 1978–2006. Original articles and case reports of acupuncture and moxibustion treatment of chronic pain were included. Animal studies, surveys, and news articles were excluded. Two independent reviewers extracted data from located articles in a pre-defined structured way, and assessed the likelihood of causality in each case. We located 57 papers written in Japanese (20 full papers, 37 case reports). Conditions examined were headache (12 trials), chronic low back pain (9 trials), rheumatoid arthritis (8 trials), temporomandibular dysfunction (8 trials), katakori (8 trials) and others (12 trials). While 23 were described as clinical control trials (CCTs), 11 employed a quasi-random method. Applying the 5-point Jadad quality assessment scoring system, the mean score was 1.5 ± 1.3 (SD). Eleven (52%) of the CCTs were conducted to determine a more effective procedure for acupuncture; these compared a certain type of acupuncture with another type of acupuncture or specific additional points. In particular, the trigger point acupuncture was widely used to treat chronic low back pain in Japan. Many reports of chronic pain treatment by acupuncture and moxibustion are listed in Japanese databases. From the data, we conclude that there is limited evidence that acupuncture is more effective than no treatment, and inconclusive evidence that trigger point acupuncture is more effective than placebo, sham acupuncture or standard care.

Keywords: chronic pain – acupuncture – Japanese literature – clinical trials – trigger point

Introduction

Every year many people use acupuncture, primarily seeking relief of pain (1). Acupuncture is now available as a treatment option in most chronic pain clinics (2). There is much scientific evidence regarding the effects of acupuncture and moxibustion (3). In spite of laboratory evidence documenting a biological basis for acupuncture analgesia, the increasing use of acupuncture by people in pain, and the widespread availability of acupuncture at chronic pain clinics, the effectiveness of acupuncture for chronic pain relief remains in question. A few systematic reviews (4–7) have been published examining the efficacy of acupuncture for the relief of chronic

pain. These systematic reviews conclude that acupuncture is more effective than no treatment for chronic pain.

Acupuncture has been used for many centuries and scientific evaluation of acupuncture began relatively early in Japan. However, most of the publications regarding acupuncture published in Japan are written in Japanese, and cannot be retrieved using Western databases.

The purpose of this work is to evaluate and establish the current status of clinical trials of acupuncture for chronic pain conducted in Japan.

Methods

Database Search

Computerized literature searches were performed for case reports and controlled trials (CCTs) of acupuncture therapies

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for chronic pain, using the following databases: Igaku Chuo Zasshi (Japan Centra Revuo Medicina) (from 1983) and Citation Information by National Institute of Information (from 1978), all to May 2006. Search terms used were 'acupuncture' or 'moxibustion' and 'chronic pain', 'chronic low back pain', 'chronic neck pain', 'chronic shoulder pain', 'rheumatoid arthritis (RA)', 'headache', 'fibromyalgia', 'temporomandibular dysfunction (TMD)', or 'chronic neck and shoulder pain and stiffness (Japanese: katakori)'. The search was also limited to 'original paper' and 'case report'.

We also had papers that we had already obtained in an independent search (8). These papers have been included in our previous review of clinical trials of acupuncture treatment for chronic pain.

Study Selection Criteria

Clinical trials (case reports, parallel or crossover designed trials, and controlled clinical trials) that assessed the efficacy of needle acupuncture were included. Experimental studies, animal studies, and duplication of published papers were excluded.

Data Extraction

For each study trial design, randomization, blinding, handling of dropouts, publication year, health condition examined, treatment and control procedures, number of participants, main result, number of treatments, type of control used, main outcome measure, descriptions of informed consent, affiliations of author, and publication type were recorded.

For the CCTs, from the description of the articles, the type of control was classified into six categories as follows: sham, no treatment, other therapeutic method, adjunctive acupuncture, routine acupuncture treatment plus additional acupoints or another type of acupuncture. The two authors independently assessed the quality of trials using principles of the Jadad score (9). The 5-point Jadad quality assessment score is suited to assess internal validity of a trial and this simple method has already been validated. Points were awarded as follows: study described as randomized, 1 point; additional point for appropriate method, 1 point; inappropriate randomization method, reduce 1 point; subject blinded to intervention, 1 point; evaluator blinded to intervention, 1 point; description of withdrawals or dropouts, 1 point.

Additional Information

Control groups were classified into one of five categories as follows: (i) waiting lists; (ii) physiologically inert controls, e.g. sham transcutaneous electrical nerve stimulation (TENS), sugar pills, placebo acupuncture; (iii) sham acupuncture; (iv) standard medical care, e.g. drug therapy or physiotherapy; (v) other acupuncture method.

Placebo acupuncture was defined as a mock acupuncture procedure in which needles were not actually inserted. On the other hand, sham acupuncture was defined as a mock

acupuncture procedure in which needles were inserted in the skin. Therefore, placebo acupuncture was considered a physiologically inert control whereas sham acupuncture was considered as a separate control group, because the growing body of evidence indicates that sham acupuncture may actually produce some analgesic effects that are not specific to the points used (NIH, 1998). When the proportions responding were cited in the article, this information was also extracted, in order to compare proportions responding to physiologically inert controls to those responding to sham acupuncture. The country of the study was also recorded due to recent research indicating that certain countries may be associated with positive outcomes (Vickers *et al.*, 1998).

Results

We located 57 papers written in Japanese (20 full papers, 37 case reports). Twenty (35.1%) of the 57 Japanese trials were published before 2000. The remaining trials were published after 2001 (Fig. 1). They included 34 case reports regarding acupuncture treatment. A summary of these case reports are shown in Table 1. Conditions examined were chronic pain (2 trials) (10,11), chronic low back pain (2 trials) (12,13), chronic neck pain (4 trials) (14–17), chronic shoulder pain (1 trial) (18), rheumatoid arthritis (3 trials) (19–21) and headache (9 trials) (22–30), temporomandibular dysfunction (9 trials) (31–39), katakori (4 trials) (40–43) (Fig. 2). All results (34 trials) were positive. Unusual techniques and concepts of acupuncture were included in these case reports. For example, moxibustion in a box (Japanese: hako-kyu) and intradermal needle (Japanese: hinai-sin) were very unusual techniques. Ryodoraku and muscle meridians are traditional Japanese concepts. However, they are not very well known worldwide.

The reports included 23 CCTs of acupuncture for chronic pain. The first CCT trial was published in 1976. A summary of these CCTs is shown in Table 2. Conditions examined included chronic low back pain (7 trials) (44–50), rheumatoid arthritis (5 trials) (51–55), katakori (4 trials) (56–59), headache

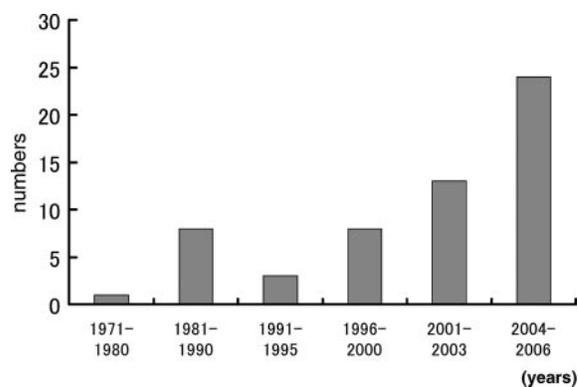


Figure 1. Published articles by years regarding acupuncture treatment of chronic pain in the Japanese literature.

Table 1. Summary of case reports on acupuncture and moxibustion in the Japanese literature

S. no.	Authors	Years	Diagnosis	n	Intervention (methods)	No. of treatment	Outcome measures	Result	Reference nos
1	Ishizaki and Yano	2005	Chronic pain (polymyalgia rheumatic)	1	Acupuncture point (EA)	6	FS, PPT	+	(10)
2	Kitade <i>et al.</i>	1998	Chronic pain	2	Ryodoraku	10–30	Progress	+	(11)
3	Kawachi and Kamei	2006	Chronic low back pain	1	TCM (moxibustion in box)	48	VAS	+	(12)
4	Itoh <i>et al.</i>	2003	Chronic low back pain	1	Trigger point acupuncture	6	VAS, PDAS, JOA	+	(13)
5	Matsumoto	2004	Chronic neck pain	1	TCM (intradermal needle)	4	Progress	+	(14)
6	Shinohara <i>et al.</i>	2004	Chronic neck pain	1	Muscle meridians (intradermal needle)	4	VAS	+	(15)
7	Seki <i>et al.</i>	2004	Chronic neck pain	1	Muscle meridians (intradermal needle)	1	Progress	+	(16)
8	Okumura	2004	Chronic neck pain	1	TCM	1	Progress	+	(17)
9	Terasawa <i>et al.</i>	2005	Chronic shoulder pain	1	Muscle meridians (intradermal needle)	2	Pain scale, ROM	+	(18)
10	Yazu	2004	RA	2	TCM	1 year		+	(19)
11	Hosoe	2004	RA	1	TCM	13	Progress	+	(20)
12	Omata	2002	RA	49	TCM	1–203 (29.7±40.3)	Progress	+	(21)
13	Yukimachi <i>et al.</i>	2002	Chronic headache	3	Acupuncture point (EA)		Progress	+	(22)
14	Suzuki	2002	Chronic headache	3	Acupuncture point (retaining needle)		Progress	+	(23)
15	Yoshizaki	2002	Chronic headache	1	Acupuncture point (retaining needle)	4	TCM	+	(24)
16	Wang	2000	Chronic headache	1	TCM	17	VAS	+	(25)
17	Kinoshita <i>et al.</i>	1987	Chronic headache	1	Acupuncture point (retaining needle)	49	Progress	+	(26)
18	Yamaguchi	1987	Chronic headache	22	Acupuncture point (retaining needle)		Category	+	(27)
19	Kinoshita	1986	Chronic headache	1	Acupuncture point (retaining needle)	11	Progress	+	(28)
20	Manabe <i>et al.</i>	1999	Chronic headache	1	Acupuncture point (moxa needle)	24	Category	+	(29)
21	Manabe <i>et al.</i>	1999	Chronic headache	1	Acupuncture point (retaining needle)	24	Category	+	(30)
22	Imai <i>et al.</i>	2006	TMJ	1	Acupuncture point (retaining needle)	6	VAS, mouth opening	+	(31)
23	Mizumuma <i>et al.</i>	2004	TMJ	1	Muscle meridians (intradermal needle)	1	Progress	+	(32)
24	Imai <i>et al.</i>	2003	TMJ	1	Acupuncture point (retaining needle)	6	VAS, Helkimo	+	(33)
25	Ozaki <i>et al.</i>	2003	TMJ	1	Acupuncture point (retaining needle)	68	Mouth opening	+	(34)
26	Ajisaka	2003	TMJ	26	Acupuncture point (retaining needle)		Category	+	(35)
27	Ozaki <i>et al.</i>	2000	TMJ	1	Acupuncture point (retaining needle)	30	Mouth opening	+	(36)
28	Ozaki <i>et al.</i>	1995	TMJ	3	Acupuncture point (retaining needle)	19	Mouth opening	+	(37)
29	Kono	1990	TMJ	1	Acupuncture point (retaining needle)	19	Progress	+	(38)
30	Tanabe <i>et al.</i>	1986	TMJ	12	Acupuncture point (EA)		Category	+	(39)
31	Kurobe	1999	Katakori	1	Meridian treatment	3	Progress	+	(40)
32	Hori <i>et al.</i>	1997	Katakori	2	Muscle	5–8	Progress	+	(41)
33	Mori	1986	Katakori	1	Tender point	45	Progress	+	(42)
34	Hoshino and Kinoshita	2004	Katakori	1	TCM	63	Progress	+	(43)

EA, electroacupuncture; TCM, traditional Chinese medicine; VAS, visual analog scale; FS, face scale; PPT, pressure pain thresholds; PDAS, pain disability assessment scale; JOA, Japanese Orthopaedic Association Score; ROM, range of motion. Acupuncture point, there is no description on concept of treatment; +, positive.

(3 trials) (60–62) and fibromyalgia (3 trials) (Fig. 3). Four trials used a sham procedure for the control group. The main outcome measures were response on a visual analog scale (VAS) (17 trials) and a quality of life (QOL) score, such as pain disability assessment scale (PDAS) and Roland–Morris Disability Questionnaire (RDQ) (7 trials). The methods of

acupuncture were trigger point (8 trials), electrical acupuncture (3 trials), traditional Chinese medicine (1 trials) and intradermal needle (1 trial). Regarding types of control, sham or placebo procedure was employed in 4 trials, other therapeutic methods in 7 trials, other types of acupuncture methods in 11 trials, no treatment in 2 trials and minimum

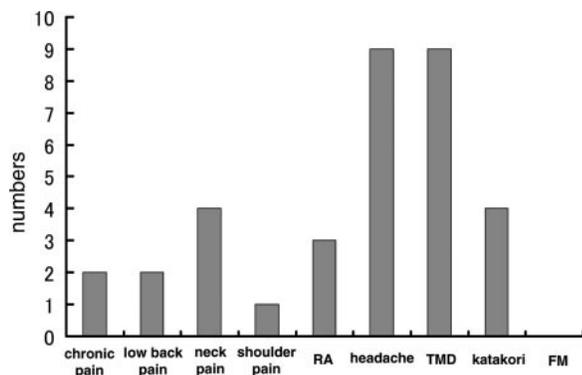


Figure 2. The number of case reports regarding acupuncture treatment of chronic pain in the Japanese literature.

acupuncture in one trial (Fig. 4). Mean Jadad score was 1.5 ± 1.3 in trials described as randomized (Fig. 5), although six trials employed quasirandom methods such as using odd–even numbers or drawing lots. Therefore, four trials were regarded as genuine randomized controlled trials (RCTs). Subjects were blinded in seven trials, evaluators were blinded in six trials, and one trial did not mention blinding. Dropouts or withdrawal from the study was described in five trials.

Results were positive in 21 trials and inconclusive in 2 trials. Eleven trials (52%) were conducted to determine more effective procedures for acupuncture. These data indicated that there is limited evidence that acupuncture is more effective than no treatment, and inconclusive evidence that trigger point acupuncture is more effective than placebo, sham acupuncture, or standard care. These trials also compared a certain type of acupuncture with another type of acupuncture or additional points. For example, trigger point acupuncture is more effective in the treatment of chronic low back pain and katakori than other acupuncture methods in Japan. Therefore, trigger point acupuncture may be more effective for chronic pain than other acupuncture methods.

Discussion

We examined the methodological quality, acupuncture treatment characteristics and pain outcomes of 23 Japanese CCTs of acupuncture for the treatment of chronic pain. Seventeen of the trials received a low-quality score (0–2). The proportion of high-quality studies in this review differs from the findings of a previous systematic review (6,7) that concluded ‘no studies of high quality seem to exist’. Our findings are similar to those of ter Reit *et al.*, Ezzo *et al.* and Tsukayama *et al.* in that we have found an important association between study quality and study outcome (6,7,67). Low-quality scores were significantly associated with positive findings. Barring the presence of an unknown confounder, we interpret these findings to mean that weaker study designs may bias study results and overestimate positive effects of the treatment. This is consistent with the finding of other investigators (68,69).

An additional methodological issue arises in the real versus sham acupuncture studies. This study design had the largest proportion of high-quality studies. Although sham has frequently been called a placebo, the proportion improving in the sham group was significantly higher than that in the inert placebos. This may be due to chance, an unknown confounder, a powerful placebo effect or that these are indirect comparisons across studies performed in different settings and populations by different examiners. Yet another possibility, and one expressed at the NIH Consensus Development Conference, is that sham acupuncture is not a physiologically inert placebo. This body of evidence is based on at least four observations as follows: (i) animal studies of needling non-acupuncture points suggest analgesic responses (70); (ii) some sham acupuncture techniques used in traditional Chinese acupuncture trials such as superficial needling or non-puncture needling, may inadvertently replicate true forms of Japanese acupuncture (71); (iii) when superficial (sham) needling has been compared to sham TENS in the sham randomized study population, results significantly favored superficial needling (72); (iv) many of the pathways by which acupuncture can reduce pain are engaged by needle puncture, but are not point specific.

If true sham acupuncture produces non-specific needling analgesic effects then it has important implications for both clinical trial managers and systematic reviewers. Clinical trial managers using sham acupuncture are challenged to find ways to minimize non-specific effects in a trial and need to estimate sample sizes that anticipate a high proportion improving in the sham group. Future systematic reviews on acupuncture for painful conditions should be cautious not to combine sham acupuncture with placebo controls and not assume that sham acupuncture only controls for placebo effects. We should in future plan Japanese CCTs of high quality, such as sham-controlled, double-blinded RCT trials.

Tsukayama *et al.* found at first that CCTs of acupuncture began in Japan as early as in the West (67). However, as the authors mentioned in the literature, many of the earlier reports focused on an appropriate choice of acupuncture techniques. This is in contrast with Western CCTs, which focus mainly on the specific effects of acupuncture, perhaps because the social position of acupuncture differs between Japan and Western countries. Acupuncture has already been accepted in Japanese society, whereas generally it has not in the Western world. For Japanese acupuncturists, there has been no option of using treatment methods other than acupuncture. Japanese acupuncturists may have therefore been more interested in what type of acupuncture technique to use (67). Therefore, the Japanese acupuncturists have various methods (techniques and concepts of acupuncture and moxibustion). For example, the methods of moxa needling (Japanese: kyu-to-shin) and intradermal needle (Japanese: hinai-sin) are very unusual and unique techniques. Moxa needling is a method of burning a ball of moxa in the handle of needle after inserting it. Moxa needling is used for its warming and tonifying effect on acupuncture points. Moxa needling has the combined effect of acupuncture and that of indirect moxibustion. The heat of the burning moxa is

Table 2. Summary of controlled clinical trials on acupuncture and moxibustion in the Japanese literature

S. no.	Author	years	Diagnosis	Design	n	Intervention (methods)	Control	No. of treatment	Outcome measures	Result	Jadad score	Reference nos
1	Ito <i>et al.</i>	2003	Chronic low back pain	Crossover	3	A: trigger point	B: v (acupuncture point)	6	VAS, PDAS	A>B	1	(44)
2	Hirota <i>et al.</i>	2006	Chronic low back pain	Parallel	9	A: trigger point	B: v (tender point)	5	VAS, RDQ	A>B	3	(45)
3	Itoh and Katsumi	2005	Chronic low back pain	RCT	44	A: trigger point	B: v (acupuncture point), C: ii (placebo)	3	VAS, RDQ	A>B>C	4	(46)
4	Itoh <i>et al.</i>	2005	Chronic low back pain	Crossover	8	A: trigger point	B: v (acupuncture point)	6	VAS, JOA	A>B	1	(47)
5	Katsumi <i>et al.</i>	2004	Chronic low back pain	RCT, crossover	9	A: trigger point	B: ii (placebo)	6	VAS, RDQ	A>B	4	(48)
6	Itoh	2004	Chronic low back pain	RCT	18	A: trigger point	B: v (acupuncture point)	6	VAS, RDQ	A>B	2	(49)
7	Itoh <i>et al.</i>	2004	Chronic low back pain	Crossover	4	A: acupuncture point (EA)	B: v (retaining needle)	10	VAS, PDAS	A>B	1	(50)
8	Yamamoto <i>et al.</i>	2003	RA	Parallel	170	A: drug + acupuncture point	B: iv (drug)	1 year	AIMS-2, ACR	A>B	0	(51)
9	Kitsukawa	2002	RA	Parallel	49	A: drug + acupuncture point (moxibustion)	B: iv (drug)	6	VAS, mHAQ	A>B	1	(52)
11	Kasuya	2002	RA	Parallel	20	A: drug + acupuncture point	B: iv (drug)	1 year	VAS, AIMS-2, ACR	A>B	0	(53)
12	Kasuya and Etoh	2004	RA	Parallel	178	A: drug + acupuncture point	B: iv (drug)	1 year	VAS, AIMS-2, ACR	A>B	1	(54)
13	Kasuya <i>et al.</i>	2004	RA	Parallel	170	A: drug + acupuncture point	B: iv (drug)	1 year	VAS, AIMS-2, ACR	A>B	1	(55)
14	Furuya <i>et al.</i>	2002	Katakori	RCT	53	A: tender point (intradermal needle)	B: ii (placebo)	1	VAS	A>B	4	(56)
15	Nabeta <i>et al.</i>	1997	Katakori	Parallel	32	A: acupuncture point	B: iii (sham)	3	VAS	A>B	3	(57)
16	Kitade <i>et al.</i>	1995	Katakori	Parallel	59	A: acupuncture point	B: iv (nerve block)	3 month	Category	A>B	0	(58)
17	Itoh <i>et al.</i>	2006	Katakori	Parallel	30	A: trigger point	B: v (acupuncture point), C: ii (placebo)	4	VAS	A>B=C	3	(59)
18	Yamaguchi	1987	Chronic headache	Parallel	10	A: acupuncture point	B: i (volunteers)	10	Pulse waves	A>B	1	(60)
19	Yamaguchi	1987	Chronic headache	Parallel	16	A: acupuncture point	B: i (volunteers)	10	EMG	A>B	1	(61)
20	Mustura	1976	Chronic headache	Parallel	12	A: honchiho	B: v (honchiho + hyouchiho)	7	Category	A=B	0	(62)
21	Kitade and Hyodo	1994	Chronic pain	Parallel	1247	A: acupuncture point	B: iv (nerve block), C: iv (acupuncture and block)		Category	A<B<C	0	(63)
22	Itoh <i>et al.</i>	2003	Fibromyalgia	Crossover	1	A: acupuncture point (EA)	B: v (TCM)	14	VAS, PPT	A>B	1	(64)
23	Itoh <i>et al.</i>	2004	Fibromyalgia	Crossover	4	A: acupuncture point (EA)	B: v (TCM)	11	VAS, PDAS	A>B	1	(65)
24	Itoh	2005	Fibromyalgia	Crossover	1	A: TMC	B: v (tender point)	5	VAS, PPT	A>B	1	(66)

RCT, randomized controlled trials; EA, electroacupuncture; TCM, traditional Chinese medicine; VAS, visual analog scale; PDAS, pain disability assessment scale; RDQ, Roland-Morris disability questionnaire; AIMS-2, Arthritis Impact Measurement Scales Version 2; ACR, American College of Rheumatology core set variables; mHAQ, modified Health Assessment Questionnaire; PPT, pressure pain thresholds (i) waiting lists; (ii) physiologically inert controls, e.g. sham TENS, sugar pills, placebo acupuncture; (iii) sham acupuncture; (iv) standard medical care, e.g. drug therapy or physiotherapy; (v) other acupuncture method. Hyouchiho refers to local or symptomatic treatment and honchiho to causal or essential treatment. Acupuncture point, there is no description on concept of treatment.

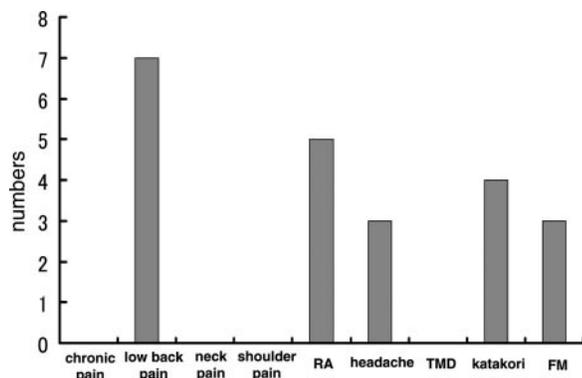


Figure 3. The number of controlled trials regarding acupuncture treatment of chronic pain in the Japanese literature.

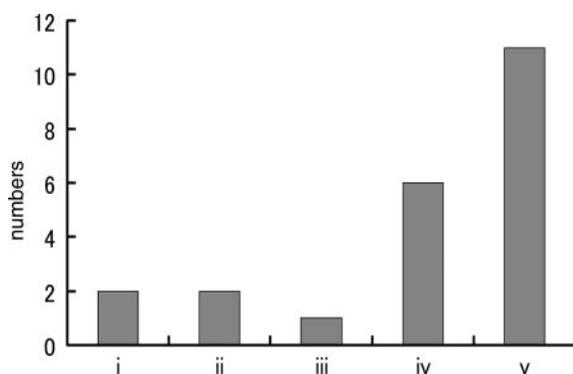


Figure 4. The number of control groups for acupuncture treatment of chronic pain in the Japanese literature control groups were classified into one of five categories as follows: (i) waiting lists; (ii) physiologically inert controls, e.g. sham TENS, sugar pills, placebo acupuncture; (iii) sham acupuncture; (iv) standard medical care, e.g. drug therapy or physiotherapy and (v) other acupuncture method.

conducted through the needle and is also radiated to the surrounding skin surface (73). Also, the use of minuscule intradermal needles is very widespread among Japanese acupuncturists, and a large number of intradermal needles are used. The simplest ones to use are the ring-type intradermal needles, which are shaped like tiny tacks. Otherwise, many varieties of pin-type intradermal needles are commonly used. The inserted portion of the ring-shaped intradermal needles extends 2–5 mm vertically down into the skin. The pin-type intradermal needles are inserted horizontally so that they remain within the epidermis. Intradermal needles are usually imbedded for a minimum of 2 days for the prolonged effect of the minute stimulation of retained intradermal needles (73).

Ryodoraku and muscle meridians are traditional Japanese concepts (74). In China, essential treatment is approached through consideration of diagnoses determined according to traditional logic. This includes diagnosis based on concepts of the eight guiding factors, diagnosis of the pathogenesis of bowel and visceral diseases, and diagnosis based on the meridian system and muscle meridian system. In Japan, essential treatment is supported by such systems as meridian therapy, a traditional approach to acupuncture that places

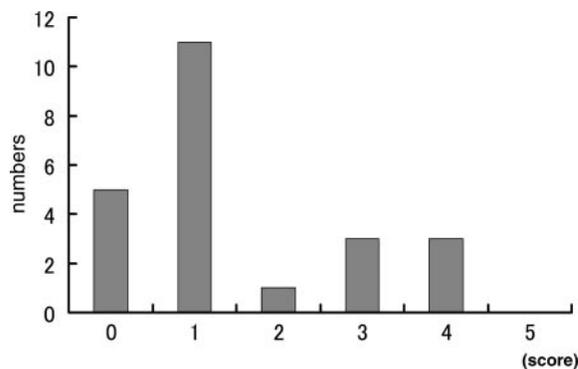


Figure 5. The distributions of Jadad score for studies of acupuncture treatment for chronic pain in the Japanese literature. The 5-point Jadad quality assessment score is suited to assess internal validity of a trial and this simple method has already been validated. 0 is low quality, 5 is high quality. Mean Jadad score for studies of acupuncture treatment for chronic pain reported in the Japanese literature was 1.5 ± 1.3 .

emphasis on the meridians; taikyoku therapy, which advocates a holistic approach to acupuncture and moxibustion treatment; and ryodoraku therapy, a modern form of acupuncture that includes electrical stimulation of acupoints. These methods are thought to be very effective and are popular in Japan (74). However, they are not very well known outside Japan because there are few case reports in English. Intradermal needles are especially a very popular and safe technique. This method was considered more effective than sham needle in CCTs (56). Therefore, we conclude that intradermal needles are a very safe and useful method (74).

Recently, several high quality systematic reviews and meta-analyses have been published for treatment of low back pain and headache (75–77). In most systematic reviews of treatment of low back pain, the stimulation sites were traditional acupuncture points (75,76). However, the data reported in Japanese literature suggest that the response to trigger points may be greater than the response to treating traditional acupoints. These results suggest that the site of stimulation is important, and that the acupuncture stimulation of myofascial trigger points might be most effective for chronic low back pain. On the other hand, in most systematic reviews of headache treatment, the treatment was for migraine (77). However, acupuncture has mainly been used for the treatment of tension-type headache in Japan. Though the reason is unclear, the treatment of tension-headache by acupuncture is more effective than the treatment of migraine in Japan.

Tsukayama *et al.* said that most of the Japanese reports regarding acupuncture cannot be retrieved using Western databases, although the number of Japanese RCTs on acupuncture is increasing and their quality is improving (67). In order to complete systematic reviews on acupuncture, they encourage the publication of relevant results of RCTs in English and to register RCTs in English databases. English reviews of non-English papers on RCTs and collaboration between workers in different countries would promote more thorough scientific evaluation of acupuncture (67).

In conclusion, it is important to point out that there is bias to publish only studies that show positive effects. Thus, the published literature may be heavily biased towards effective studies. Moreover, the main conclusion is that the overall quality of the studies is low. Therefore, it is very problematic to draw definitive conclusions from this review. On the other hand, it is important to point out that there was bias in the collection of the literature. The methodology of this review was such that only Japanese literature was collected. It is necessary to emphasize that the English literature included in this study was published in Japan. Thus, it is necessary to add findings reported in the English language literature to ensure an accurate grasp of the Japanese literature.

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