

Review

Randomized Clinical Trials on Acupuncture in Korean Literature: A Systematic Review

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The aim of this systematic review was to summarize randomized clinical trials (RCTs) assessing the effectiveness of acupuncture as published in Korean literature. Systematic searches were conducted on eight Korean medical databases. Manual searches were also conducted through eight major Korean medical journals. The methodological quality was assessed using a Jadad score. Studies evaluating needle acupuncture or auricular acupuncture (AA) with or without electrical stimulation were considered if they were sham or placebo-controlled or controlled against a comparative intervention. We also excluded acupuncture as an adjuvant to other treatments and other forms of acupuncture were excluded. Seven hundred and nine possibly relevant studies were identified and 10 RCTs were included. The methodological quality of the trials was generally poor. Manual acupuncture was compared to placebo acupuncture in four studies of patients with chronic low back pain, shoulder pain, premenstrual syndrome and allergic rhinitis. Three studies tested AA (two trials) and electroacupuncture (one trial) against no treatment, while three trials compared acupuncture with other active therapeutic controls. The methodological limitations of the included trials make their contribution to the current clinical evidence of acupuncture somewhat limited. The trial for premenstrual syndrome, shoulder pain and chronic low back pain added a limited contribution among those included RCTs. However, well-designed RCTs of acupuncture with a rigorous methodology are in progress or have been completed in Korea and will contribute to establish or contribute to the current progress of research in this field.

Keywords: acupuncture – clinical trial – Korean medicine – systematic review

Introduction

Acupuncture can be defined as the insertion of needles into the skin and underlying tissues at particular sites, known as points, for therapeutic or preventive purposes (1). The points can also be stimulated with electricity, lasers, pressure, heat or ultrasound waves (1).

Acupuncture is now a widely accepted intervention for the treatment of a variety of conditions, many of which are associated with pain (2).

Classical acupuncture, which originated in China, is used for treating various conditions in Korea (3). While maintaining a close relationship with China, however, Korea has continued to develop a unique medicine of its own over time and established different types of acupuncture methods from those used in traditional Chinese medicine (3, 4). Numerous clinical studies using acupuncture have been performed to demonstrate its efficacy in many types of disease, including pain conditions, stroke and facial palsy (3).

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A recently published Korean review summarized the clinical effectiveness of acupuncture (3). However, they did not include references to other recent studies or a systematic assessment. Moreover, many Korean studies have not included western databases, even though many Korean clinical trials on acupuncture have been reported in western journals. Therefore, as systematic reviews should include all relevant trials, regardless of their language, it is necessary to summarize randomized clinical trials (RCTs) in Korean literature for future systematic approaches on the effectiveness of acupuncture. The aim of this systematic review was to summarize RCTs assessing the effectiveness of acupuncture as published in Korean literature.

Methods

Data Sources

The computerized Korean databases listed in Table 1 were searched from their respective inceptions up to May 2007. The search terms used were ‘acu’, ‘acupuncture’ and random or Korean language terms related to acupuncture and clinical trials. Several specialized journals were also manually searched for relevant articles (Table 1).

Study Selection

Studies testing with needle acupuncture with or without electrical stimulation were included. We also include any form of auricular acupuncture (AA). Trials testing other forms of acupuncture, such as laser acupuncture or acupuncture using moxibustion or Transcutaneous Electrical Nerve Stimulator (TENS) were excluded. Studies comparing two different forms of acupuncture and those in which no data were reported were also excluded. We also excluded acupuncture as an adjuvant to other treatments, bee-venom therapy and herbal acupuncture, in which potentially pharmacologically active substances are injected at the acupuncture points. The control interventions were other active intervention without acupuncture or placebo acupuncture or no intervention.

The main outcome measures considered were the efficacy of acupuncture for treating the relevant condition. Trials were excluded if the outcomes related only to immunological or biological parameters, and if the subjects are healthy participants. Hardcopies of all articles were obtained and read in full.

Data Extraction and Quality Assessment

All articles were read by two independent reviewers (JCK, MSL), and data from the articles were validated

Table 1. The list of databases and journals (hand searched) searched in the course of this review

Title	Publisher	URL
Database		
National Assembly Library	National Assembly Library of the Republic of Korea	www.nanet.go.kr
Research Information Service System	Korea Education & Research Information Service	www.riss4u.net
Oriental Medicine Information System	Daegu Haany University (Korea)	omis.dhu.ac.kr
Korean Medical Database	Medical Research Information Center (Korea)	kmbase.medric.or.kr
DBPIA	Kyobo Book Center & Nurimedia (Korea)	www.dbpia.co.kr
Korean Studies Information Service System	Korean Studies Information Co.	kiss.kstudy.com
Database of RICH	Research Information Center for Health	www.richis.org
Several Libraries of Oriental Medical School		
Journal		
Journal of Korean Oriental Medicine	Korean Oriental Medical Society	koms.or.kr
The Journal of Korean Acupuncture & Moxibustion Society	Korean Acupuncture & Moxibustion Society	www.acumoxa.or.kr
The Korean Journal of Meridian & Acupoint	The Korean Society of Meridian & Acupoint	www.acupoint.org
Journal of Oriental Rehabilitation Medicine	The Korean Academy of Oriental Rehabilitation Medicine	www.ormkorea.org
Journal of Korean Institute of Herbal Acupuncture	Korean Institute of Herbal Acupuncture	www.kiha.co.kr
The Journal of Korea CHUNA Manual Medicine	Korean Society of Chuna Manual Medicine for Spine & Nerves	www.chuna.or.kr
Korean Journal of Oriental Physiology & Pathology	The Korean Association of Oriental Medical Physiology and The Korean Society of Oriental Medical Pathology	Not available
The Journal of Korean Oriental Internal Medicine	The Korean Society for Oriental Internal Medicine	www.oim.or.kr

and extracted according to predefined criteria. Since it is virtually impossible for an acupuncturist to be blinded to the treatment, we employed a modified version of the Jadad score (5, 6). Points were awarded as follows: study described as randomized, 1 point; appropriate randomization method, 1 point; inappropriate randomization method, 1 point deducted; patient blinded to intervention, 1 point; evaluator blinded to intervention, 1 point and description of withdrawals and dropouts, 1 point. The highest possible score was 5 points. Patient blinding was assumed where the control intervention was indistinguishable from acupuncture, even if the word 'blinding' did not occur in the report. The point for evaluator blinding was only given if specified in the text. Trials with 4 or 5 points were considered to be of high quality. Allocation concealment was assessed using the Cochrane classification (7). Discrepancies were resolved by discussion between the two reviewers (JCK, MSL) via E-mail and telephone, and if needed, by seeking the opinion of the third reviewer (BCS).

The quality of acupuncture was assessed by two reviewers (JCK, BCS), who are certified Korean oriental medical doctors, according to previous study (8). Discrepancies were resolved by discussion. They answered for the question, 'how would you treat the patients included in the study?', on five categories including 'exactly or almost exactly the same way', 'similarly', 'differently', 'completely differently', or 'could not assess' due to insufficient information (on acupuncture or on the patient). The degree of confidence that acupuncture was applied in an appropriate manner was assessed on the 100 mm visual analog scale (with 0% = complete absence of evidence that the acupuncture was appropriate, and 100% = total certainty that the acupuncture was appropriate).

Results

Study Description

The searches identified 709 potentially relevant studies, of which 10 met our inclusion criteria (Fig. 1). The key data are summarized in Table 2. Excluded non-randomized controlled clinical trials (CCTs) and their reasons for exclusion are summarized in Supplement 1, while the details of excluded RCTs were summarized in Supplement 2. The treated conditions were insomnia (one trial), post-operative nausea and vomiting (one trial), temporomandibular disorder (TMD) (one trial), allergic rhinitis (one trial), premenstrual syndrome (one trial), frozen shoulder (one trial), chronic low back pain (one trial), chronic headache (one trial), post-thoracotomy pain (one trial) and dysmenorrhea (one trial). The acupuncture techniques used were AA (two trials), electroacupuncture (EA) (one trial) and classic acupuncture (seven trials). Regarding types of

control, a placebo procedure was employed in four trials (9–12), other therapeutic methods in three trials (13–15) and no treatment in three other trials (16–18).

Study Quality and Acupuncture Validity

The methodological quality of the trials was poor. Only three (9, 10, 12) of the 10 RCTs exhibited a Jadad score above three, one trial (10) described the methods of randomization, none described allocation concealment. Only two of the included RCTs described subject and evaluator blinding (10, 12), while one other described subject and acupuncturist blinding (9). One trial reported subject blinding (11). Sufficient details on dropouts and withdrawals were described in four trials (9, 10, 14, 15). Adverse events and ethical approval procedures were mentioned in only two (10, 12) and four trials (9–12), respectively.

Regarding the quality of acupuncture, the authors would have treated the patients completely differently (15, 18) in two trials, similarly in three trials (9, 10, 13) and exactly (11, 16, 17) or almost exactly the same way (12, 14) in four

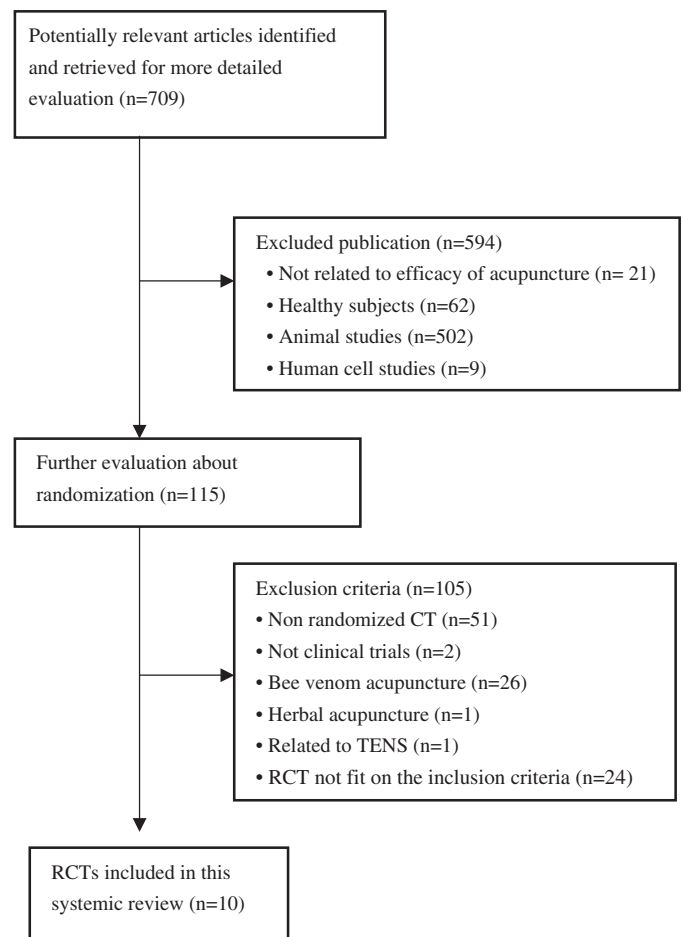


Figure 1. Flowchart of trial selection process.

Table 2. Key data of RCTs of acupuncture in Korean literatures

First author (Year) (Ref)	Conditions Sample size (randomized/analysed)	Study design Quality score, ^a Acupuncture validity score [quality of acupuncture ^b , degree of confidence ^c], allocation concealment ^d	Experimental treatment (Regimen)	Control treatment (Regimen)	Concomitant treatment	Main outcomes	Intergroup difference	Authors conclusion
Sok (2000) (18)	Insomnia 74/74	2 parallel arms 1, [1, 15%], unclear	AA (1 time, retain for 4 days, thumbtack-type needle), plus press(1~2 min, 3 times daily for 4 days, $n=37$)	No treatment ($n=37$)	n.r.	(1) Sleep quality (2) Self-satisfaction (Sleep)	(1) $P < 0.001$ (2) $P < 0.001$	'Auricular acupuncture can reduce the frequent insomnia of the elderly and increase the satisfaction they find in sleep.'
Kim (1996) (16)	Post-operative nausea and vomiting 100/100	2 parallel arms 1, [4, 95%], unclear	AA (thumbtack-type needle, $n=50$)	No treatment ($n=50$)	n.r.	(1) Incidence of vomiting/retching, or nausea	(1) $P < 0.01$	'Auricular acupuncture is effective in reducing nausea and vomiting after trans-abdominal hysterectomy in female patients.'
Park (1999) (17)	Temporomandibular disorder 38/38	2 parallel arms 1, [4, 90%], unclear	EA (3-15Hz, 20 min, 3 times weekly for 2 weeks, $n=28$)	No-treatment ($n=10$)	None	(1) Pain (Numeric analog scale) (2) Maximal mouth opening	(1) $P < 0.05$ (2) NS	'The clinical indexes of the treated patient group are more significantly changed than those of the non-treated patient group.'
Park (2005) (12)	Allergic rhinitis 101/101	2 parallel arms (subject and evaluator blinding) 3, [4, 85%], unclear	AT (15 min, one time, $n=50$)	Placebo AT on non acupuncture point, (15 min, one time, $n=51$)	None	(1) Total nasal volume (2) Total nasal minimum cross-sectional area	(1) NS at immediate after, after 7.5 min and 15 min ^e (2) $P < 0.05$ after 15 min ^e	'Acupuncture reduces nasal obstruction due to persistent allergic rhinitis'
Kim (2005) (9)	Premenstrual syndrome 20/13	2 parallel arms (subject and acupuncturist blinding) 4, [3, 75%], unclear	AT (n.r., 2 times weekly for 8weeks, $n=n.r.$)	Placebo AT on acupuncture point (n.r., 2 times weekly for 8weeks, $n=n.r.$)	None	(1) Menstrual symptom severity	(1) $P < 0.05$	'Acupuncture results in significant improvement in physical and psychological symptoms compared to placebo treatment.'
Lee (2006) (11)	Frozen shoulder 86/85	3 parallel arms (subject blinding) 2, [4, 90%], unclear	(A) AT (nearby acupuncture point, 30 min, 3 times weekly for 4 weeks, $n=28$) (B) AT [(A) + remote acupuncture point, 30 min, 3 times weekly for 4 weeks, $n=28$]	Placebo AT on non acupuncture point, (30 min, 3 times weekly for 4 weeks, $n=29$)	n.r.	(1) Pain (VAS) (2) Shoulder Pain and Disability Index (3) Patient's Global Assessment (4) ROM	(1)-(3) NS (4) NS, (A) vs. control $P < 0.05$, external rotation of upper arm: (B) vs. control	'Acupuncture at both remote and nearby acupoints may be effective in improving external rotation of frozen shoulder.'

Kwon (2007) (10)	Chronic low back pain 50/50	2 parallel arms (subject and evaluator blinding) 5, [3, 75%], unclear	AT (20 min, 3 times weekly for 4 weeks, $n=25$)	Placebo AT on non acupuncture point, (20 min, 3 times weekly for 4 weeks, $n=25$)	n.r.	(1) Pain (VAS) (2) Ronald disability index	(1) NS (2) NS	'The manual acupuncture is effective for chronic low back pain, compared with the sham acupuncture.'
Choi (2005) (14)	Chronic headache 86/51	2 parallel arms 2, [4, 90%], unclear	AT (20 min, 2 times weekly for 4 weeks, $n=43$)	Stellate ganglion block therapy (2 times weekly for 4 weeks, $n=43$)	None	(1) Pain (VAS) (2) Pain (Brief Pain Inventory)	(1) NS (2) NS	'The four-week acupuncture and stellate ganglion block therapy in chronic headache patients is effective for reducing headache.'
Cho (1997) (13)	Post-thoracotomy pain 20/20	2 parallel arms 1, [3, 85%], unclear	AT (20-30min one time and retain it for 2 day, $n=10$)	Analgesic treatment group ($n=10$)	NSAID	(1) Pain (Lickert scales) (2) Limitation of motion (3) Analgesics requirement	(1), (2) NS (3) $P < 0.05$	'Acupuncture is an effective method by which to control post-thoracotomy pain and it is safer than analgesics.'
Yuk (2005) (15)	Primary dysmenorrhea 22/17	Cross-over 2, [1, 40%], unclear	AT (20 min, total 2 or 3 times, $n=17$)	Herbal medicine (3 times daily for 5 days, $n=17$)	n.r.	(1) Pain (VAS)	(1) NS	'The acupuncture or herbal medicine during the 5 or 7 days before menstruation will be efficacious against primary dysmenorrheal'

AA: auricular acupuncture; AT: classic acupuncture; EA: electroacupuncture; n.r.: not reported; NS: not significant; ROM: range of motion; VAS: visual analogue scale.

^aQuality score: Jadad score.

^bQuality of acupuncture: 0, could not assess; 1, completely differently; 2, differently; 3, similarly; 4, exactly or almost exactly the same way.

^cDegree of confidence: degree of confidence that acupuncture was applied appropriate manner 100mm visual scale (with 0% = complete absence of evidence that the acupuncture was appropriate, and 100% = total certainty that the acupuncture was appropriate) please see supplement 3 for details.

^dClassified by Cochrane criteria: adequate, unclear, inadequate, or not used.

^eAuthors did not report the intergroup difference. We have calculated the intergroup difference with their reported values.

trials. The degree of confidence that acupuncture was applied appropriately ranged from 15 to 95%.

Outcomes

Acupuncture methods versus placebo acupuncture

Four studies compared the effects of classic acupuncture with placebo acupuncture on allergic rhinitis (12), premenstrual syndrome (9) shoulder pain (11) and chronic low back pain (10). Acupuncture reduced the pain associated with premenstrual syndrome, but failed to do so in frozen shoulder pain and chronic low back pain compared to that of the placebo controls. One time treatment improved total nasal minimum cross-sectional area after 15 min compared to placebo, while no intergroup differences were observed for total nasal volume.

Comparison with no treatment

Three trials tested AA (16, 18) and EA (17) versus no treatment. One study in this category showed better effectiveness of AA on the sleep quality of insomnia sufferers compared to no treatment (18). The other trial found that AA was superior to no treatment in terms of the incidence of vomiting, retching, or nausea (16). Further RCTs found favorable effects of EA on pain and limitation of motion in TMD patients compared to no treatment (17).

Testing against other therapeutic methods

Three RCTs compared acupuncture with stellate-ganglion-block (SGB) therapy (14), analgesic treatment (13) and herbal medicine (15) in treating several pain conditions including chronic headache, post-thoracotomy pain and dysmenorrhea, respectively. None of them found a significant difference in pain between two treatments. Only one trial found acupuncture to reduce the analgesics requirement compared to analgesic treatment (13).

Discussion

This review involved a systematic assessment of RCTs related to the effectiveness of acupuncture by evaluating articles published in Korean literature. The trials assessed the efficacy of several types of acupuncture on various medical conditions. However, each trial involved only a small sample and short intervention time, while the methodological quality of the trials was low.

Of the 10 RCTs, only four trials were both patient and assessor blinded (10, 12) or both patient and acupuncturist blinded (9) or subject blinded (11), whereas six studies did not make any attempt at either subject or assessor blinding. Trials with inadequate levels of

blinding are likely to show exaggerated treatment effects, thus limiting the reliability of the study results. The concealment of treatment allocation was not reported in all 10 trials. Also, the intervention period was short [once in each of four trials (12, 13, 16, 18) and twice in one trial (14)]. A matter of concern is the reporting of details of ethical approval and adverse events. Four trials reported the ethical approval (9–12), while two reported adverse events (10, 12).

It is meaningful to compare which discrepancies or agreements are shown for each condition in the included studies with the conclusions of previous systematic reviews. The evidence is scarce that AA and EA are more effective than no treatment for treating insomnia (18), post-operative nausea or vomiting (16) and TMD (17). We cannot completely elucidate placebo effects of acupuncture. Thus, they cannot influence the current level of evidence for these conditions. The four trials tested the effects of acupuncture on allergic rhinitis (12), premenstrual syndrome (9), shoulder pain (11) and chronic low back pain (10) as compared to placebo acupuncture. The RCT-tested effects of acupuncture on allergic rhinitis showed it to be beneficial for the reduction of nasal obstructions (12). Even though this showed significant difference at 15 min after acupuncture, uncertainty of effectiveness remains by one-time treatment and short-time follow-up measurements. Hence, it cannot contribute to current evidence. The other RCT, which assessed the effects of acupuncture on premenstrual syndrome, reported positive results on the reduction of menstrual symptom severity (9). This can add positive effects to the current evidence (2, 19). However, the included sample size was too small and the contribution limited. The other RCT, which tested effects of acupuncture on chronic low back pain (10), failed to show positive results. This was contradicting to current positive evidence (2, 19) and made it to a more negative direction. Further RCT, which assessed effects of acupuncture on shoulder pain (11), failed to show positive results. This can add more evidence to current evidence of this condition, which reported no effectiveness of acupuncture (2). One trial tested the effects of acupuncture on post-thoracotomy pain compared to analgesic treatment (13). The results showed the favorable effect of acupuncture on the analgesics requirement, but with no significant difference on pain. There was no systematic review on post-operative pain control with acupuncture. One review suggested that acupuncture may be effective for post-operative analgesic consumption (20). This trial may contribute more evidence in the future systematic reviews, but the small sample size provides a limited contribution. Furthermore, the RCT assessed the effects of acupuncture on primary dysmenorrhea compared to herbal medicine (15). This trial comparing the effects with any of the two cannot be informative.

Most of the excluded RCTs tested the effectiveness of particular acupuncture methods or compared certain treatments adjunct with acupuncture against acupuncture techniques. Furthermore, more than two therapies were simultaneously applied in the majority of the excluded trials, and thus evaluating the clinical effectiveness was either impossible or uninformative. Another concern about the excluded RCTs (73% of Korean RCTs on acupuncture) was that various types of control groups were used, such as classical acupuncture, other therapies and no treatment at all. Since the overall clinical efficacy of acupuncture on many conditions remains controversial, this may not be a satisfactory approach for assessing the efficacy of specific acupuncture methods.

As noted earlier, the studies of acupuncture in Korea, reviewed here, have several methodological limitations. We highlight some of the difficulties inherent in research on acupuncture and offer some suggestions for future research. First, appropriate randomization was described in only four trials (about 12%, one trial was included in this review and three were in excluded trials because of not fitting to inclusion criteria) and allocation concealment in only one of the RCT trials on acupuncture published in Korean literature. These are likely to show exaggerated treatment effects. Furthermore, most of the trials have neither adequate sample sizes nor sufficient statistical powers, often resulting in negative findings (Type II errors). Hence, a more rigorous methodology should be applied to future studies. Second, in an effort to explain non-specific effects, various sham acupuncture methods have been used. The success of blinding was checked in only one study. To reliably account for the placebo effect, it is crucial that the sham procedure be indistinguishable from the real treatment. Therefore, the success of the blinding procedures should be assessed. Third, as noted, comparing one type of acupuncture to another without ensuring appropriate controls can lead us nowhere. Carrying out studies with comparable controls would be one way to establish or contribute to the current evidence of acupuncture.

This systematic review has several limitations. Although we attempted to retrieve all relevant RCTs, we cannot be certain that our searches were all inclusive. In fact, Korean databases may have incorrectly reported results and several early papers missing from the search. Moreover, some acupuncture trials may have been published in journals not listed in any electronic database. The distorting effects arising from publication bias and location bias are well documented (21–24). Further problems include the paucity and often sub-optimal quality of the primary data.

In conclusion, because more than two therapies were simultaneously assessed in the majority of the allegeable trials, evaluated RCTs represented only a small portion of RCTs that have been published in Korean literature. The contributions to the current evidence are limited in

cases of on premenstrual syndrome, shoulder pain and low back pain. However, well-designed RCTs of acupuncture with rigorous methodology are in progress or have been completed at several institutions through funding from the Korean government. Thus, acupuncture research from Korea will contribute to establish or contribute to progress in the field.

Supplementary Data

Supplementary data are available at eCAM Online.

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