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REVIEW

Clinical acupuncture research in the West

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Abstract **In recent years, acupuncture has rapidly become part of mainstream medicine in the West, where new developments in acupuncture clinical research show extensive progress in evaluating the efficacy and safety of the modality in many categories of disease, especially in pain conditions. Although challenges and difficulties remain, the acupuncture research community has matured and its past experience may lead to even better methods and more innovative research.**

Keywords acupuncture; clinical research; research methodology; the West

Development of acupuncture in the West

Acupuncture in the United States can be traced back to 1826, when Dr. Franklin Bache published the first clinical study of the modality, a report of his observations on acupuncture for lumbago (low back pain) [1]. Acupuncture was not widely accepted until after President Nixon visited China in 1972, but since then, its practice, usage, and research have developed rapidly [2]. In 1974, the US Food and Drug Administration labeled the acupuncture needle as an investigational device; 22 years later, in 1996, they reclassified it as a medical device [3]. According to a recent National Institutes of Health (NIH) survey, there were 79.2 visits to acupuncturists per 1000 in 2007, a significant increase from the 27.2 cited for 1997 [4]. In 2002, approximately two million US adults used acupuncture [5]. By 2007, the number had expanded to three million, a 50% increase in five years [6].

Rapid development has also occurred in other Western countries such as the UK and Germany, as reflected by the large amount of recent acupuncture research conducted in these countries. A recent review shows that SCI-Expanded indexed 6004 publications on acupuncture, including 3975 research articles, between 1991 and 2009, the USA being the top producing country, the UK third, and Germany fifth. The second and fourth are China and Korea, respectively. These data suggest that along with the increasing use, the demand for scientific research on the modality has dramatically increased in the West. Research articles on acupuncture averaged 85 a year between 1973 and 1997, increased by 40% in 1998, and continued to grow rapidly throughout the last decade [7].

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Clinical acupuncture research in evidence-based medicine

Most remarkable during the last two decades is the use of evidence-based medicine to evaluate the efficacy and safety of, and evidence for, acupuncture. Published randomized controlled clinical trials (RCTs) started to emerge in 1992. From 12 in 2000, they increased 9-fold to more than 100 in 2009, making acupuncture a mainstream SCI category [7]. Systematic analytical reviews have also flourished.

In 1997, the NIH held a consensus conference based on reviews and expert presentations of studies published between 1970 and 1997, which laid the foundation for rigorous research in acupuncture over the next decade [2,8]. Finding clear evidence that acupuncture is efficacious for adult postoperative and chemotherapy nausea and vomiting and postoperative dental pain, and may be useful in such conditions as menstrual cramps, tennis elbow, and fibromyalgia, the panel proposed that more rigorously designed research was warranted due to the poor quality of many of the previous trials [2]. This conference spurred the development of high-quality acupuncture RCTs, especially on pain.

Large RCTs and systematic reviews on acupuncture for pain

Examples of large, well-designed clinical acupuncture trials on pain include two American studies on knee osteoarthritis. A 2004 RCT conducted by Berman *et al*. found acupuncture to be statistically effective compared to sham and education-only controls. Acupuncture produced greater improvement in Western Ontario and McMaster Universities' Osteoarthritis Index (WOMAC) function, pain, and patient global assessment compared to sham, and at 26 weeks, the improvement was statistically significant in all three categories. That RCT, with its large randomized sample, good control, and intensive acupuncture regimen, provided credible evidence for acupuncture as an adjunctive therapy for knee osteoarthritis [9]. In a 2008 RCT, Jubb *et al*. compared manual and electroacupuncture to non-penetrating sham; acupuncture produced significant improvement in pain ($P < 0.001$) while sham did not ($P = 0.12$). The researchers concluded that acupuncture provides symptomatic improvement in knee osteoarthritis and is significantly superior to non-penetrating sham [10].

In an American RCT of 638 adults with chronic back mechanical low pain, Cherkin *et al*. compared 10 individualized, standardized, and simulated acupuncture treatments to usual care. One week after conclusion, symptom and function scores for acupuncture and simulated acupuncture had improved compared to usual care ($P < 0.001$). Moreover, the outcomes were still more likely to show significant improvement in function ($P = 0.02$) although not in symptoms ($P > 0.05$) one year later. There were no significant differences between real acupuncture and sham control [11]. A German multicenter, blinded, parallel-group RCT on chronic lower back pain that compared acupuncture, needle-insertion sham acupuncture, and conventional therapy, followed patient outcomes for six months after treatment and showed similar results in which both acupuncture and sham acupuncture were better than conventional therapy. Again, there were no differences between acupuncture and sham control [12]. In contrast, in a 2010 German RCT on chronic shoulder pain in 424 outpatients, acupuncture performed significantly better than either needle-insertion sham or conventional treatment controls ($P < 0.01$) and produced greater improvement in shoulder mobility immediately after treatment and after three months [13].

Systematic reviews also show positive results or positive trends for acupuncture in various kinds of pain [14–19]. In a recent Cochrane review of 22 trials totaling 4419 participants on acupuncture for headache, Linde *et al*. found 6, including 2 large trials with 401 and 1715 patients respectively, comparing acupuncture to no treatment and to routine care. Three to four months after treatment, acupuncture subjects had higher response rates and fewer headaches [19]. In another systematic review, Trinh *et al*. found strong evidence suggesting that acupuncture is effective for the short-term relief of lateral epicondyle pain [17].

Large RCTs and systematic reviews of acupuncture for non-pain disorders

Acupuncture may also alleviate non-pain disorders such as insomnia, depression, nausea, and vomiting. In 2010, an RCT with 150 women on acupuncture for depression during pregnancy compared acupuncture specifically for depression to acupuncture and massage controls. Those who received specific acupuncture experienced a greater rate of decrease in symptom severity ($P < 0.05$) and had significantly greater response rate (63.0%; $P < 0.05$) compared to the controls [20].

Strong evidence for acupuncture in nausea and vomiting comes from five high-quality systematic reviews [21–25], all of which show positive results or positive trends. In 2009, Le *et al*. included 40 trials for a total of 4858 participants. Compared to sham, P6 acupoint stimulation significantly reduced nausea (RR 0.71, 95% CI 0.61 to 0.83), vomiting (RR 0.70, 95% CI 0.59 to 0.83), and the need for rescue antiemetics (RR 0.69, 95% CI 0.57 to 0.83) [21].

A 2009 systematic review of 46 RCTs involving 3811 patients found acupuncture beneficial compared to sham and to no treatment based on the total scores of the Pittsburgh Sleep Quality Index. Acupuncture was superior to medication in number of patients with a total sleep duration increase of > 3 h ($P < 0.0001$). Acupuncture plus medication showed better effects than did medication alone ($P < 0.0001$), and acupuncture plus herbs was significantly better than herbs alone ($P = 0.01$). There were no serious adverse effects related to acupuncture treatment in these trials [26].

Modern technology and acupuncture studies on human subjects

Another trend in acupuncture clinical research is the use of modern technology to explore acupuncture's mechanisms of action. Although animal research clearly supports a role for antinociceptive limbic, hypothalamic, and brainstem networks in acupuncture analgesia [27], it is difficult to extrapolate the results of these studies to human tissue and the human brain. Advances in mapping acupuncture-associated changes in brain function with functional neuroimaging, positron emission tomography, electroencephalography, functional magnetic resonance imaging (fMRI), and magnetoencephalography provide means to monitor neurophysiological brain effects [28]. For example, Asghar *et al*. recently investigated the effects of *deqi* and acute pain needling sensations on brain fMRI blood oxygen level-dependent signals to show that *deqi* causes significant deactivations, while acute pain produces a mixture of

activations and deactivations [29]. Biomechanical studies are also useful. Langevin *et al*. measured pullout force in humans with and without needle penetration of muscle and found that connective tissue winding is the mechanism responsible for the increase in pullout force induced by needle rotation. Winding may allow needle movements to deliver a mechanical signal into the tissue and may be the key to acupuncture's therapeutic mechanism [30].

Challenges of acupuncture research

Despite the many high-quality acupuncture RCTs, there are challenges especially in setting up adequate controls, assuring acupuncturists' skills, and selecting acupoints [31]. Unlike drug studies, in which quality control of the intervention, the drug, is insured by the manufacturer, quality control in acupuncture depends on the skill and experience of the acupuncturist. Practitioner ability presents a challenge, since acupuncture has no standard implementation. Point selection, needle depth, and stimulation method may all influence treatment outcome. Ability may profoundly determine therapeutic outcome, as may the degree of trust, patient expectation, compatibility of the practitioner and patient's backgrounds and belief systems, and a myriad of factors that together define the therapeutic milieu [2]. Point selection is an important challenge because, in theory, acupuncture effects differ when needles are inserted into different acupoints and non-acupoints, a theory supported by some of the clinical trials that use insertion sham as control [13,32–38]. However, the control may be the most critical factor which strongly influences research results.

Three controls are commonly used in acupuncture clinical trials: wait-list, non-insertion sham, and needle-insertion sham. Wait-list control was most frequently used in earlier RCTs. In a literature search on RCTs published in 2006–2007 [12,38–52], most outcomes were positive (Table 1). Needless to say, blinding is impossible with this type of control.

More recent trials often report non-insertion sham, also known as "placebo control," with a device that looks and feels like a real acupuncture needle but has a blunt tip that retracts into a hollow shaft handle and touches the skin without penetration [53]. As shown in Table 2, clinical trials employ this type of control with mixed results, probably because the control triggers minimal physiologic response, but positive studies outweigh the negative [8].

Needle-insertion sham control, needle penetration at a non-point or "wrong" point [2], is also common, but this sham is poorly defined, as there is disagreement on needle placement. According to acupuncture theory, acupoints are located on meridians ("Jin") that possess multiple branches ("Luo") [7]. Unless the sham point can be clearly located, this control is unlikely to be useful. However, identifying any part of the body surface not influenced by "Jin" and "Luo" is difficult. And while numerous ancient sources describe useful points and treatment techniques, there is no documentation on ineffective "sham" points or treatment. Designers of a large Germany RCT on knee osteoarthritis found that, compared to physiotherapy and as-needed anti-inflammatory drugs, both acupuncture and sham improved WOMAC scores at 26 weeks with no statistically significant difference [46]. This result caused a controversy as to whether the acupuncture effect was mere placebo. Indeed, it is difficult to explain why even sham acupuncture shows positive outcomes in RCTs and sometimes leads to greater improvement than physiotherapy or drugs [16].

Table 1 RCTs using "Wait-List" control for pain conditions (2006–2007)

Disorder	Author	Conclusion
Low back pain [39]	Brinkhaus *et al.* (2006)	Positive
Experimental pain [40]	Barlas *et al*. (2006)	Positive
Migraine [41]	Diener *et al*. (2006)	**Negative**
Migraine [42]	Linde *et al*. (2006)	Positive
Perioperative pain [43]	Sator-Katzenschlager *et al*. (2006)	Positive
Chronic neck pain [44]	Witt *et al*. (2006)	Positive
Chronic low back pain [45]	Witt *et al*. (2006)	Positive
Knee osteoarthritis [46]	Scharf *et al*. (2006)	Positive
Uncomplicated neck pain [47]	Vas *et al*. (2006)	Positive
Persistent non-specific low back pain [48]	Thomas *et al*. (2006)	Positive
Osteoarthritis of the knee or hip [49]	Witt *et al*. (2006)	Positive
Pain after third molar tooth extraction [50]	Michalek-Sauberer *et al*. (2007)	**Negative**
Severe knee osteoarthritis [51]	Williamson *et al*. (2007)	Positive
Osteoarthritis of the knee [52]	Foster *et al*. (2007)	**Negative**
Migraine [38]	Facco *et al*. (2007)	Positive
Low back pain [12]	Haake *et al*. (2007)	Positive

Based on our own early reports [54] comparing different acupuncture controls for RCTs [12,38–52,55–64] on pain, more invasive controls clearly tend to yield more "negative" studies, as wait-list controls produce more positive outcomes (Tables 1, 2, and 3). This result suggests that needle insertion sham may induce a non-specific effect greater than that of placebo, particularly in pain conditions, in which endorphin release may play a major therapeutic role. Skin penetration may not be inert; it may excite a physiologic response, diffuse noxious inhibitory control [65]. As the NIH Consensus Development Conference Statement notes, sham acupuncture seems to have effects intermediate between those of placebo and "real" acupuncture, and sometimes even effects similar to those of acupuncture. Because any needle insertion may elicit a biologic response, there is substantial controversy over the use of sham control, especially in pain studies [2].

Since many factors may profoundly determine therapeutic outcome, the so-called negative outcomes produced in some RCTs may be false negatives due to non-specific responses. More careful design and more innovative approaches should be considered in order to minimize such non-specific confounders.

Recommendations for future research

Considering the challenges, the SAR Board of Directors, in a collaboratively written White Paper, identifies gaps in our knowledge that underlie problems and paradoxes in acupuncture research. The Board proposes the following strategies to resolve these issues through translational research: (1) "top down" multi-component "whole-system" interventions and (2) "bottom up" mechanistic studies that focus on how individual treatment components interact and translate into physiologic outcomes. Such a combined approach, incorporating considerations of efficacy, effectiveness, and qualitative measures, can strengthen the evidence base for complex interventions such as acupuncture [66].

Conclusions

In recent years, the acupuncture research community has become more mature and has incorporated many previous lessons learned. In surveying the current literature, we found that more RCTs with positive outcomes have been published during the last three years. Even more RCTs using needle insertion sham control for pain conditions showed positive outcomes, as summarized in Table 4 [13,32–38,67–71], which shows positive outcomes for 8 of the 13 RCTs compared to only 2 out of the 8 from 2006 to 2007 shown in Table 3.

Acupuncture is rapidly becoming part of mainstream medicine in the West. Patient visits to acupuncture clinics have dramatically increased. The quality of clinical research has significantly improved, and a growing body of evidence shows the efficacy and effectiveness of acupuncture. Despite remaining challenges, the field of acupuncture research is now more mature than ever.

Table 2 RCTs using "Non-Insertion Sham Acupuncture" control for pain conditions (2006–2007)

Disorder	Author	Conclusion
Myofascial pain [55]	Shen *et al.* (2007)	Positive
Toothache [50]	Michalek-Sauberer *et al.* (2007)	**Negative**
Temporomandibular joint pain [56]	Smith *et al.* (2007)	Positive
Chronic neck pain [57]	Itoh *et al.* (2007)	Positive
Postthoracotomy pain [58]	Wong *et al.* (2006)	Positive
Chronic low back pain [59]	Itoh *et al.* (2006)	Positive
Low back pain [60]	Inoue *et al.* (2006)	Positive

Table 3 RCTs using "Needling Insertion Sham Acupuncture" control for pain conditions (2006–2007)

Disorder	Author	Conclusion
Migraine prophylaxis [61]	Alecrim-Andrade *et al.* (2006)	**Negative**
Chronic shoulder pain [62]	Dyson-Hudson *et al.* (2007)	Positive trend
Knee osteoarthritis [46]	Scharf *et al.* (2006)	**Negative**
Knee pain [63]	Tsang *et al.* (2007)	**Negative**
Hip arthroplasty pain [64]	Usichenko *et al.* (2006)	Positive
Chronic low back pain [39]	Brinkhaus *et al.* (2006)	**Negative**
Migraine [41]	Diener *et al.* (2006)	**Negative**
Low back pain [12]	Haake *et al.* (2007)	**Negative**

Table 4 RCTs using "Insertion Sham Acupuncture" control for pain conditions (2008–2010)

Disorder	Author	Conclusion
Knee osteoarthritis pain [32]	Huang *et al*. (2010)	Positive
Chronic shoulder pain [13]	Molsberger *et al*. (2010)	Positive
Chronic neck pain [67]	Sahin *et al*. (2010)	**Negative**
Osteoarthritis of the knee [68]	Suarez-Almazor *et al*. (2010)	**Negative**
Aromatase inhibitor-associated joint symptoms (joint pain and stiffness) [33]	Crew *et al*. (2010)	Positive
Opioid detoxification and pain [34]	Meade *et al*. (2009)	Positive
Low back and posterior pelvic pain in pregnant women [35]	Wang *et al*. (2009)	Positive
Delayed-onset muscle soreness [36]	Hübscher M *et al*. (2009)	Positive
Migraine pain [69]	Bäcker *et al*. (2008)	**Negative**
Migraine pain [37]	Alecrim-Andrade *et al*. (2008)	Positive
Chronic pain [70]	Zheng *et al*. (2008)	**Negative**
Rheumatoid arthritis [71]	Zanette *et al*. (2008)	**Negative**
Migraine pain [38]	Facco *et al*. (2008)	Positive

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