

Acupuncture Research (1996-2003) for Physicians

By Brian Benjamin Carter

In 1997, experts from various fields including MD's, PhD's, and acupuncturists reviewed the evidence and made what was called the **National Institutes of Health Consensus Statement on Acupuncture**

"There is clear evidence that needle acupuncture is efficacious for adult postoperative and chemotherapy nausea and vomiting and probably for the nausea of pregnancy. Much of the research is on various pain problems. There is evidence of efficacy for postoperative dental pain. There are reasonable studies (although sometimes only single studies) showing relief of pain with acupuncture on diverse pain conditions such as menstrual cramps, tennis elbow, and fibromyalgia. This suggests that acupuncture may have a more general effect on pain. However, there are also studies that do not find efficacy for acupuncture in pain."

Please note that RCT's are about 50 years old, while Chinese Medicine is 4500 years old, and there has only been adequate funding sources for alternative medicine research in the last 4 or 5 years.

Acupuncture RCT's

All of the following are placebo-controlled RCT's with at least 33 subjects in each group.

1. **Acute Cerebral Infarction (Pei, 2001):** "Early acupuncture treatment for acute stroke patients may improve motor functions, and consequently the activities of daily living." 86 patients.
2. **Acute Spinal Cord Injury (Wong, 2003):** "The use of concomitant auricular and electrical acupuncture therapies, when implemented early in acute spinal cord injury, can contribute to significant neurologic and functional recoveries." 100 subjects.
3. **Alcoholism (Bullock, 2002):** "49% of subjects reported acupuncture reduced their desire for alcohol... (although) acupuncture was not found to make a significant contribution over and above that achieved by conventional treatment alone in reduction of alcohol use." 503 subjects.
4. **Breech birth (Cardini, 1998):** "Cardini and Weixin found that moxibustion (stimulation of an acupuncture point by heat generated from burning a specific herb) is helpful for correction of breech presentation in late pregnancy. 260 subjects.
5. **Cocaine Dependence (Avants, 2000):** "Findings from the current study suggest that acupuncture shows promise for the treatment of cocaine dependence. Further investigation of this treatment modality appears to be warranted." 82 subjects.
6. **Dysmenorrhea, Primary (Pouresmail, 2002):** "the therapeutic efficacies of acupuncture and Ibuprofen were similar with no significant difference, and were significantly better than the

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placebo. Thus acupressure, with no complications, is recommended as an alternative and also a better choice in the decrease of the severity of PD.” 216 subjects.

7. **Labor pain (Skilnand E, 2002 & Ramnero, 2002):** “The results indicate that acupuncture reduces the experience of pain in labor. A secondary outcome of acupuncture was a shorter delivery time, which mainly, if not exclusively, can be explained by the reduced need for epidural analgesia.” 210 subjects.
8. **Migraine without Aura (Allais, 2002):** “Acupuncture proved to be adequate for migraine prophylaxis. Relative to flunarizine, acupuncture treatment exhibited greater effectiveness in the first months of therapy and superior tolerability.” Comparison without placebo groups. 160 subjects.
9. **Nausea and Vomiting after Abdominal Hysterectomy (Kim, 2002):** 1 group each for 2 points, and one placebo group. “Capsicum plaster at either the Korean hand acupuncture point K-D2 or the Pericardium 6 acupoint reduces postoperative nausea and vomiting in patients undergoing abdominal hysterectomy.” 160 subjects.
10. **Nausea and Vomiting; Comparing and Combining Acupressure and Zofran (White, 2002):** “The ReliefBand compared favorably to ondansetron (4 mg intravenously) when used for prophylaxis against postoperative nausea and vomiting. Furthermore, the acustimulation device enhanced the antiemetic efficacy of ondansetron after plastic surgery.” 120 subjects.
11. **Nausea and Vomiting in Children (Wang SM, 2002):** “In children, P6 acupoint injections are as effective as droperidol in controlling early postoperative nausea and vomiting.” 4 groups of 43-50 children.
12. **Smoking Cessation (Bier, 2002):** Quasi-factorial design, sham-controlled. “Acupuncture and education, alone and in combination, significantly reduce smoking; however, combined they show a significantly greater effect, as seen in subjects with a greater pack-year history.” 141 subjects.

Results have been mixed or unfavorable for:

1. (Acupuncture only) Smoking cessation, Alcoholism, or Cocaine Addiction.
Acupuncture has been helpful when combined with standard treatments.
2. Low back pain (Henderson, 2002)
3. RA – However, the acupuncture protocol used is highly questionable (David, 1999)

Acupuncture RCT's currently underway (as of 1/27/03):

1. The Acupressure (Acupuncture Without Needles) Study
2. Acupuncture and Hypertension
3. Acupuncture and Moxa: A RCT for Chronic Diarrhea in HIV Patients
4. Acupuncture in Cardiovascular Disease
5. Acupuncture in Fibromyalgia
6. Acupuncture in the Treatment of Depression
7. Acupuncture Safety/Efficacy in Knee Osteoarthritis
8. Acupuncture to Reduce Symptoms of Advanced Colorectal Cancer
9. Complementary Medicine Approaches to TMD Pain Management

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10. Cost-Effectiveness of and Long-term Outcomes Following Acupuncture Treatment for Osteoarthritis of the Knee
11. Efficacy of Acupuncture in the Treatment of Fibromyalgia
12. Endometriosis: Traditional Medicine vs. Hormone Therapy
13. Prospective Studies of the Use of Self Hypnosis, Acupuncture, and Osteopathic Manipulation on Muscle Tension in Children with Spastic Cerebral Palsy
14. A Randomized Study of Electroacupuncture Treatment for Delayed Chemotherapy-Induced Nausea and Vomiting in Patients with Pediatric Sarcomas
15. Sham Device, Pill Placebo, or Treatment for Arm Pain
16. Use of Acupuncture for Dental Pain: Testing a Model
17. Usual Care vs. Choice of Alternative Rx: Low Back Pain

Acupuncture Research Issues

The placebo-controlled RCT paradigm is hard to adapt to acupuncture. Despite what less informed medical acupuncturists think, there is no such thing as a "sham" acupuncture point. There are hundreds of (Philippe Sionneau says at least 800) extra points located off the regular 14 meridians. Traditionally, any pressure on the skin can be therapy... non-puncture therapies on acupuncture points include cupping, plum-blossom, and acupressure. Japanese acupuncture often uses needling that doesn't completely penetrate the dermal layer, and may not be retained after the initial puncture. Just because the stimulus is subtle does not mean it has no effect. That, in itself, needs to be studied.

Acupuncture Safety

"One of the advantages of acupuncture is that the incidence of adverse effects is substantially lower than that of many drugs or other accepted medical procedures used for the same conditions. As an example, musculoskeletal conditions, such as fibromyalgia, myofascial pain, and tennis elbow, or epicondylitis, are conditions for which acupuncture may be beneficial.

"These painful conditions are often treated with, among other things, anti-inflammatory medications (aspirin, ibuprofen, etc.) or with steroid injections. Both medical interventions have a potential for deleterious side effects but are still widely used and are considered acceptable treatments. The evidence supporting these therapies is no better than that for acupuncture.

"In addition, ample clinical experience, supported by some research data, suggests that acupuncture may be a reasonable option for a number of clinical conditions. Examples are postoperative pain and myofascial and low back pain. Examples of disorders for which the research evidence is less convincing but for which there are some positive clinical trials include addiction, stroke rehabilitation, carpal tunnel syndrome, osteoarthritis, and headache. Acupuncture treatment for many conditions such as asthma or addiction should be part of a comprehensive management program." - National Institutes of Health Consensus Statement on Acupuncture, 1997

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1. **Safety of Acupuncture in terms of Insurance Malpractice Claims (JAMA 1998):** "In an analysis of data from malpractice insurers from 1990 through 1996, Studdert and colleagues found that claims against chiropractors, massage therapists, and acupuncturists generally occurred less frequently and usually involved less severe injury than claims against medical doctors." - Phil B. Fontanarosa, MD; George D. Lundberg, MD
2. **Frequency and Types of Adverse Events in 55,291 Acupuncture Treatments (Rosted, 1996 & Yamashita, 1998):** 64 minor adverse events. 99.8% of these acupuncture treatments were performed without even *minor* adverse events; "During these 5 years, a total of 76 acupuncturists (13 preceptors and 63 interns) participated in the study, and the total number of acupuncture treatments was 55291... The most frequent adverse event was failure to remove needles after treatment; no sequelae occurred after removal of the needles. The second most common adverse event was dizziness, discomfort, or perspiration probably due to transient hypotension associated with the acupuncture treatment."

The most serious adverse events during acupuncture are pneumothorax and septicemia. "Instruction is given by both lectures and practical training and includes information about anatomically risky depth of insertion and use of aseptic procedure for puncturing... Most important, no serious events such as pneumothorax, spinal lesion, or infection were reported... We may, therefore, reasonably conclude that serious adverse events in acupuncture treatment are uncommon in the practice of adequately trained acupuncturists."

3. **Acupuncture Safety (White, 2001 & MacPherson, 2001):** 2 September 2001 Studies of safety of acupuncture in the British Medical Journal; Details of 43 minor adverse events associated with 34,407 acupuncture treatments; 91 minor events in 31,822 acupuncture treatments; if combined with the other study above = total of 121,520 treatments with 198 minor adverse events (0.16% incidence), and no pneumothoraxes (in the conclusion they are considered to be "extremely rare").
4. **Pregnancy and Acupuncture (Smith, 2002):** In treatment for nausea and vomiting, "our findings suggest that no serious adverse effects arise from acupuncture administered in early pregnancy." 593 subjects.

Biomedical Mechanisms of Acupuncture

(NIH, 1997): "Many studies in animals and humans have demonstrated that acupuncture can cause multiple biological responses. These responses can occur locally, i.e., at or close to the site of application, or at a distance, mediated mainly by sensory neurons to many structures within the central nervous system. This can lead to activation of pathways affecting various physiological systems in the brain as well as in the periphery. A focus of attention has been the role of endogenous opioids in acupuncture analgesia. Considerable evidence supports the claim that opioid peptides are released during acupuncture and that the analgesic effects of acupuncture are at least partially explained by their actions. That opioid

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antagonists such as naloxone reverse the analgesic effects of acupuncture further strengthens this hypothesis. Stimulation by acupuncture may also

1. "activate the hypothalamus and the pituitary gland, resulting in a broad spectrum of systemic effects.
2. "Alteration in the secretion of neurotransmitters and neurohormones and changes in the regulation of blood flow, both centrally and peripherally, have been documented.
3. "There is also evidence of alterations in immune functions produced by acupuncture. Which of these and other physiological changes mediate clinical effects is at present unclear.

"Findings from basic research have begun to elucidate the mechanisms of action of acupuncture, including the release of opioids and other peptides in the central nervous system and the periphery and changes in neuroendocrine function. Although much needs to be accomplished, the emergence of plausible mechanisms for the therapeutic effects of acupuncture is encouraging."

One of the studies cited by the NIH was conducted by Abass Alavi, M.D., chief of nuclear medicine at the University of Pennsylvania Medical Center, who showed that acupuncture affects the flow of blood in the brain. He used SPECT (single photon emission computed tomography) to view the brains of four people with pain and five pain-free people who served as the control group. Dr. Alavi found that after acupuncture needles were inserted, all of the patients had increased blood flow to the thalamus, the area of the brain that relays pain and other sensory messages. Because the brains of the pain-free group showed the same reactions as those with pain, the changes in blood flow couldn't be attributed to placebo.

1. **PET-Scans of the brain during acupuncture (Dold, 1998):** University of California Irvine professor and physicist Zang-Hee Cho, a member of the highly respected National Academy of Science, the inventor of an early version of the Positron Emission Tomograph, or PET scan, and a pioneer of the MRI scanner, both of which have revolutionized our ability to see into the body and brain, found that stimulation of the vision-related acupoint showed the same reaction in the brain as stimulation of the eye. As the acupuncture signal passes to the brain via nerves, it possibly stimulates the hypothalamus, the "executive center" of the brain, responsible for the production and release of hundreds of neurochemicals, Cho said.
2. **Acupuncture: pain management coupled to immune stimulation (Gollub, 1999):** "The phenomenon of acupuncture is both complex and dynamic. Recent information demonstrates that acupuncture may exert its actions on pain and immune processes. The coupling of these two systems occurs via common signaling molecules, i.e., opioid peptides. In this regard, we surmise that
 - i. opioid activation leads to the processing of opioid peptides from their precursor, proenkephalin, and
 - ii. the simultaneous release of antibacterial peptides contained within the precursor as well. Thus,
 - iii. central nervous system pain circuits may be coupled to immune enhancement.
 - iv. Furthermore, acupuncture needle manipulation elicited signal increases bilaterally in the region of the primary and secondary somatosensory cortices in human brain as determined by magnetic resonance imaging.

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- v. The maps reveal marked signal decreases bilaterally in multiple limbic and deep gray structures including the nucleus accumbens, amygdala, hypothalamus, hippocampus, and ventral tegmental area.
 - vi. Taken together, we surmise a major central nervous system pathway as well as local pain and immune modulation during acupuncture."
3. **(Fu, 2000):** "In recent years, more and more laboratory proof has accumulated that acupuncture can
 - i. change the **charge and potential of neurons**,
 - ii. the **concentrations of K(+), Na(+), Ca(++)** and
 - iii. the **content of neuro-transmitters** such as aspartate, and taurine and
 - iv. the **quantities of neuro-peptides** such as beta-endorphin and leu-enkephalin.
 - v. All these phenomena are directly related to nerve cells."
 4. **Immune System effects of Acupuncture (Joos, 2002):** "The following changes were found in the TCM group: within the lymphocyte subpopulations the CD3+ cells (p = 0.005) and CD4+ cells (p = 0.014) increased significantly. There were also significant changes in cytokine concentrations: interleukin (IL)-6 (p = 0.026) and IL-10 (p = 0.001) decreased whereas IL-8 (p = 0.050) rose significantly. Additionally, the in vitro lymphocyte proliferation rate increased significantly (p = 0.035) while the number of eosinophils decreased from 4.4% to 3.3% after acupuncture (p > 0.05). The control group, however, showed no significant changes apart from an increase in the CD4+ cells (p = 0.012)."
 5. **Difference between Manual and Electro Acupuncture (Kong, 2002):** "Results showed that electroacupuncture mainly produced fMRI signal increases in precentral gyrus, postcentral gyrus/inferior parietal lobule, and putamen/insula; in contrast, manual needle manipulation produced prominent decreases of fMRI signals in posterior cingulate, superior temporal gyrus, putamen/insula. These results indicate that different brain networks are involved during manual and electroacupuncture stimulation. It suggests that different brain mechanisms may be recruited during manual and electroacupuncture."
 6. **Use of Auricular Acupuncture with Anesthesia (Taguchi, 2002):** "Acupuncture thus reduced anaesthetic requirement by 8.5 (7)%."
 7. **In Parkinson's Disease (Wang L., 2002):** "Under the auditory evoked brain stem potential (ABP) examination, the latent period of V wave and the intermittent periods of III-V peak and I-V peak were significantly shortened in Parkinson's disease patients of the treatment group (N = 29) after acupuncture treatment. The difference of cumulative scores in Webster's scale was also decreased in correlation analysis."

Acupuncture and Placebo

Only 1/3 of people respond to placebo treatment, but "Both animal and human laboratory and clinical experience suggest that the majority (more than half) of subjects respond to acupuncture, with a minority not responding" (NIH, 1997).

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Explain how the placebo effect is working in a dog or cat who is healed by acupuncture. We can't tell them what to expect, etc. There is an RCT that shows significant success with hind-limb paralysis in dogs (Jan S, 2000).

The existence of Qi, Yin and Yang?

Skeptical views of OM and acupuncture often focus on whether or not yin and yang and qi actually exist. Let's end that debate right here - the truth is: they do not. That is not central to Chinese medicine. Those concepts are parts of theories (a la scientific method) that attempt to explain why acupuncture and chinese herbal medicine work, and how they can work better. It is clear that the system is not complete or perfect, or else it would always work. Like many things in this world, it is a work in progress. Theories can be discarded for new ones. **The entire system of chinese medical theory may one day be discarded for an integrated biomedical understanding of its mechanisms.**

The reason for all the confusion? It is possible that the heterogenous, multi-traditional, overlapping, organic, complex nature of chinese medical theory, which leads to disagreements between and different representations from CM practitioners, confuses both the public and other medical practitioners.

Some scholars of oriental medicine now believe that the translation of 'qi' as 'energy' (which came from Morant in the 1930's) is inaccurate. It is also translated as 'breaths,' or 'vital air.' It must be remembered that this all comes from the chinese language which is composed of characters that are basically simplified drawings of real objects- so the character for 'qi' is the steam coming off a pot of rice. How we interpret that, whether it is properly interpreted or not, is still up for grabs.

We do know from MRI studies that the nervous system is activated by acupuncture- but in biomedical terms, qi could be related to so many things (oxygen, carbohydrates, proteins, synaptic transmission). Oriental medicine, like the Chinese language itself, is largely metaphorical. It is to some degree mechanical, but nowhere near as much as biomedicine is, and how could it be, without microscopes, autopsies, MRI's, and lab tests? None of those tests were available for thousands of years of CM.

More than One Kind of Qi

As stated above, understanding qi is a matter of interpretation of the Chinese characters. This is a metaphorical language; please re-read that section above. As far as whether qi pervades everything, I do not believe that is an accurate representation of chinese medical theory. Qi can mean many different things in different contexts; air, gas, vapor, flatus, smell, environmental influences, character, breath, circumstance, activity, defense, containment, strength, transformation, disease; but I believe the idea that qi pervades everything is actually a non-traditional new-age idea grafted onto chinese medicine. [There are actually quite specific ways in which qi enters the body or is formed (through food or air intake), and how it moves to defend the body from attack (the wei qi or immune system)]. This is the kind of thing that disturbs me. No matter what additional research should be done in regard to acupuncture, and what questions can be raised, it's clear that it has many good effects and insights, and not only should we not allow the new-agers to claim it as their own, but also we should keep it pure, we should be clear about what really is oriental medicine and what isn't.

As far as qi goes, in CM metaphorical terms, yes, if qi does not flow, there is stagnation, and that often causes symptoms like pain, intestinal gas, anger, etc. There can also be qi deficiency, which manifests as fatigue, loose

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stool, low appetite, etc. There is also the belief in two universal energies, yin and yang, which must be balanced. If anything is blocking the chi or unbalancing the yin and yang, then illness results. The chi is believed to flow through invisible channels in the body called meridians.

Invisible channels/meridians

Again, I must emphasize the metaphorical nature of chinese medical theory. And refer to the work of Dr. Zang-he Cho (Dold, 1998), which proves via SPECT, a credible, objective biomedical visual imaging technique that acupuncture points can stimulate aspects of the CNS without direct neural connection- this implies that the nervous system is more complex than we know and that acupuncture works via some computer-like code interpreted by the brain. It would mean that the map of the body described by CM's system of meridians probably is accurate in terms of the correspondences it suggests- that, e.g., the points on the foot from the discover article are on a meridian connected with the eye, telling us that although there may be no neural connection between the foot and the eye, there is a relationship that the CNS can understand and act upon.

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