GERAC Trials Review

January 2008
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GERAC Results Summary:
GERAC trials\(^1\) showed superiority of sham and non-sham acupuncture over conventional treatment. Trials showed sham and non-sham treatments to be similar in effect.

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<tr>
<th>Conventional Treatment</th>
<th>Sham Acupuncture</th>
<th>Non-sham Acupuncture</th>
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<tr>
<td>27.4%</td>
<td>44.2%</td>
<td>47.6%</td>
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Response Rate

GERAC Conclusions:
Low back pain improved for at least six months after acupuncture treatment.
Effectiveness of acupuncture, sham or non-sham, was almost twice that of conventional therapy.
Acupuncture, regardless of technique, was significantly more effective than conventional therapy at all follow-up points.

Definitions:
All interventions comprised a course of treatment of ten 30-minute sessions, generally 2 sessions per week, with claimed adherence to principles of TCM in the non-sham acupuncture group.
Sham acupuncture patients received the same course of treatment, but with needles inserted superficially (remaining within the dermis), at least 5 cm away from acupuncture points or channels, and with no stimulation.
Conventional therapy consisted of a combination of drugs, physical therapy and exercise.
Primary outcome was response after 6 months and defined as a 33% improvement or better on pain-related items on the Von Korff Chronic Pain Scale questionnaire, or a 12% improvement or better on the back-specific Hanover Functional Ability questionnaire.

A pivotal yet underemphasized fact:
Physicians of various specialisations administered the acupuncture. They had “at least” 140 hours of acupuncture training: 55% had undergone “basic” training (mean, 213 hours) and 45% had “advanced” training (mean, 376 hours). The study physicians had practiced acupuncture for anywhere between 2 to 36 years (median, 8 years).

Some beneficial outcomes of GERAC for the acupuncture profession:
In terms of standard scientific research, the use of acupuncture for the treatment of back pain is considered controversial. A recent Cochrane review could only conclude that acupuncture may be useful as an adjunt to other therapies. The GERAC authors state that, to their knowledge, acupuncture has never been directly compared to guideline-based conventional therapy. This is the first time in the
western world that the superiority of acupuncture has been unequivocally demonstrated for the primary and secondary outcomes, including medication reduction, in contrast to studies with a usual care group.
Problematic aspects of the GERAC study, and Discussion:

1. Number of Needles, Selection of Points, and Pattern Differentiation

“The physician using more than 8 needles is detestable”
- Chinese Medical saying expressing the principle that a skilled physician uses few needles (1 to 3), and that the unskilled or fraudulent need to resort to a shotgun approach.

The non-sham acupuncture group used points claimed to be derived from a TCM assessment. **Fourteen to twenty needles** were used per treatment, inserted to a depth of 5 to 40 mm depending on location. Stimulation elicited De Qi.

Sham acupuncture also used fourteen to twenty needles at non-acupoint sites with a depth of only 1 to 3 mm. No additional stimulation was used beyond the insertion of the needle.

a. Assertion: There is no point specificity
It is already established, not only in the canons of acupuncture but also in modern research, that acupuncture, applied in any fashion, causes a homeostatic (more properly a homeodynamic) response in the body. It is also established that there are point-specific effects over and above the homeostatic response, although contemporary research is incomplete in this area (it has not yet been shown that all points have specific effects). The selection, in the sham acupuncture arm, of points in the area of complaint but at least 5 cm away from mapped acupuncture points **violates the sham protocol by introducing a frequently used and important classical acupuncture protocol**: the treatment of “ashi” points (clinically remarkable points located off the main meridian pathways).

b. Assertion: Superficial insertion is equal to “sham”
A part of Chinese medical differentiation serves to determine the depth of a puncture site. Standard puncture depths range from superficial (1 mm) to deep (several centimetres). All styles of acupuncture use minimal depth at some point in treatment.

c. Assertion: Only a limited patient differentiation is necessary
To postulate both that every case of back pain will require fourteen to twenty needles and that this follows TCM guidelines is patently untrue and violates a basic tenet of all schools of Chinese Medicine: differentiate patients / no two cases are the same. In this author’s personal practice, successful treatment of back pain has occurred with one needle and one treatment many times. This same patient might have had their condition aggravated or prolonged with the application of fourteen needles.

In Chinese Medicine, there are many potential presentations of back pain which are not to be treated by acupuncture. There are many types that, because of their nature, cannot be treated by acupuncture alone, and there are many types that, again, because of their nature, will need protracted treatment. To lump all these types together contravenes basic CM differentiation (less so for TCM). We cannot say that a trial of this kind is testing either CM or acupuncture. Can we imagine a trial that tested antibiotics against a patient population randomly affected by either bacterial or viral infections? This type of thinking is nonsensical.

d. Assertion: TCM is, or represents, Chinese Medicine
Science is inextricably bound up with politics, culture and business. So it is with every human activity. TCM as a system was a political creation of 1950s PRC, and, as such, reflects that China's attempts to modernise, industrialise and scientificalise all aspects of itself.

“In recent years, the unique characteristics of Chinese medicine, its advantages over Western medicine, and its standards of academic excellence, have not been developed according to the wishes of the people, but have rather been tossed into a state of severe crisis and chaotic actions. Underneath the bright and cheap glitter at the surface, the essence and the characteristics of Chinese medicine are being metamorphosed and annihilated at a most perturbing rate. The primary expression of this crisis is the Westernisation of all guiding principles and methodologies of Chinese medicine.”

Lü Bingkui, former director of the PRC’s Ministry of TCM Administration, July 1991

For the above reasons, it is possible and likely that, in this study, sham and verum acupuncture were improperly codified and contrasted, leading to confusion in the interpretation of results, resulting in a) political and non-scientific suggestions that Chinese Medical theory may be a complete fabrication and b) unnecessary speculation upon a so-called “super-placebo” effect.

2. Blinding of Skilled Procedures is Not Possible
Many commentators have noted that the so-called gold-standard in research is only applicable in limited situations. Full blinding cannot be achieved for both ethical and practical reasons in many areas – examples are heart surgery, medical education, psychotherapy, and mortality studies on parachute use. The forced application of RCT standards to acupuncture cannot be supported by current understanding of an RCT’s scope of use:

“The randomised controlled trial (RCT) is the principal method for evaluating the effectiveness of health care interventions. Although the best method we have at present, the RCT is nevertheless problematic. The approach is based upon experimental methods developed for use in laboratories with inanimate objects, rather than for research on human beings in the dynamic setting of a health service.”


† The PRC China is representative of the generally short-lived Chinas of the past that have engaged in book burning and so on. The China of today is experiencing the reactionary reassertion of the “old” values which have kept China vital for so many thousands of years.
It is important and interesting to note that our “best” tools, if inapplicable, are clearly not the best: A nuclear weapon destroys a building “best”, but demolition has certain needs that preclude the use of our “best” tool.

“The two approaches to [RCT] trial design [, explanatory and pragmatic,] will sometimes arrive at different conclusions about the benefit of a treatment, either because a treatment which works in an ideal setting does not work in real life or because improvement in a biomedical endpoint does not produce the expected health gain—for example, sodium fluoride increases non-vertebral bone density in osteoporosis but increases fracture rates.”

Conclusions and Discussions:

This is one of at least two high-quality studies that show agreement over the non-superiority of non-sham over sham acupuncture.

The authors indulged an idea which is, at best, premature: “[T]he unexpected finding of similar effectiveness of sham and verum acupuncture forces us to question the underlying action mechanism of acupuncture and to ask whether the emphasis placed on learning the traditional Chinese acupuncture points may be superfluous.”

A strange explanation eliminating a trained operator from the picture emerges later:

“Several other hypothesis must be considered instead (to explain the similar results of non-sham and sham acupuncture): 1. There are no specific acupuncture effects at all; 2. the specific acupuncture effect is very small and is overlaid by non-specific effects; and 3. there exist specific acupuncture effects, the nature of which is still unknown, that lead to symptom improvement independent of point selection and depth of needling.” In a clearly thought-out paper, a fourth and fifth option would be present: “for an unidentified reason, acupuncture's posited specific effects could not be triggered reliably” and “operator skill is likely to have a major effect on outcomes”.

Further, a “superplacebo” effect is postulated by the authors to account for the above-placebo effect of acupuncture, sham or not. This intellectual cop-out clearly underlines the authors' inability to tie together the phenomena detailed by their investigation. “Placebo” can't be the answer for everything, can it? Can the “super-duper-placebo” be next? These types of conclusions are suspect in the face of the wealth of evidence for the ability of acupuncture to create dramatic changes in human physiology.

The authors also point out that “the effectiveness of sham acupuncture and the principle of nihil nocere suggest that a discussion is called for about the necessary depth of insertion of acupuncture needles.”

The intellectual fatigue that leads to so many recommendations based on such a small dataset and so much ground obviously left to cover makes one wonder whether we are exploring new frontiers, or marking out turf. Even Felix Mann, turncoat par excellence, clearly states in his newest publication that even he does not understand how acupuncture works, physiologically speaking.

The potential limitations of the study were listed as; 1. restricting acupuncture to needling only; 2. restricting the number of sessions to 10 or 15; 3. inability to blind acupuncturists as to form of acupuncture. It is interesting to note that, in the application of a technology where operator skill is a main determinant of effectiveness, the so-called “physician acupuncturists” not once called into question their own potential limitations as therapists, despite their overall poor education as well as highly disparate experience/years of practice.

What is the justification for assuming that acupuncture is operator independent, when it is well known that reading radiographs, performing surgery, driving a motor vehicle, or arriving at a diagnosis all have successful outcomes dependent largely upon operator skill?

Is there any evidence that justifies the lack of control for operator skill in acupuncture research?

It is possible that operator skill is ignored in all papers that this author is aware of for neo-colonialist...
reasons – in other words, only a western educated person is likely to understand the complexities of the world. In short, it is a thinly veiled type of racism and elitism\textsuperscript{3-4}. In fact, this opinion has a stronghold in the western humanities, and it must be said that not all the modern sciences buy into this type of prejudice. As Wolpe explains:

“The most commonly used surrogate theories are the “placebo” or “psychosomatic” explanations of phenomena, and the related categories of “hypnosis” and “suggestability”. Any nonconventional treatment that is shown to be effective – and for which biomedicine has no existing categorisation or relevant theory – is almost always initially credited to one of these categories.”


Please note the name of the journal.

In fact, this entire situation reminds the author of the recent opinion of geneticists that there were large chunks of the human genome that were “junk code”. To know so little about a topic, and then to label the parts that are not understood as “junk”, “useless”, or as “errors” is the height of hubris. Of course, at this point it is recognised that there are sophisticated layerings, recursions and further complexities in how the code is read such that the junk no longer appears so, and now appears, rightly, as an immensely complex and intelligent rendering of instructions.

It is this author’s opinion that acupuncture research will be led astray until operator skill\textsuperscript{†} is controlled for or the issue is dealt with. In an operator dependent technology and therapy, not controlling for operator skill will lead to nonsensical, confounding and conflicting results, and will be littered with artifacts of incompetence.

References


\textsuperscript{†} “Operator skill” is a far-reaching term that encompasses everything that makes a therapist good at what they do and adaptable to every situation. “Operator skill” is the single reason (because the therapy is only in small part placebo) that acupuncture and similar technologies are non-reducible, or become damaged and inaccessible when attempts are made to reduce them.