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## RESEARCH PERSPECTIVES

# Issues in Acupuncture Research: The Failure of Quantitative Methodologies and the Possibilities for Viable, Alternative Solutions

*Alex Moroz*

Howard A. Rusk Institute of Rehabilitation Medicine  
New York University Medical Center, New York, NY 10016 U.S.A

**Abstract:** Thirty years of active acupuncture research have failed to unequivocally demonstrate its clinical efficacy. Certain characteristics of acupuncture are difficult to fit into an experimental study. Many researchers mention selection of appropriate controls, single- or double-blind research design, and application of relevant outcome measures as areas causing most difficulties. Also cited are the variability of acupuncture techniques, difficulty of standardizing acupuncture treatments, inadequate population size, significant variability of response to treatments, the use of a distinctive terminology, and importance of practitioner's experience. Acupuncture and Chinese traditional medicine are based on a unique philosophical model, and the instruments of biomedical research may be inadequate and inappropriate. In contrast to the quantitative experimental method, introspective self-observation and qualitative observation are offered as a means of studying the effectiveness of acupuncture.

*The investigator should have a robust faith—and yet not believe.*

—Tristan Bernard<sup>1</sup>

*The physician should be ever ready to make use of a valuable discovery, but never to further fraud.*

—Oliver T. Osborne<sup>2</sup>

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Please address all correspondence and reprint requests to the author at: 50 Brighton First Rd, #12C, Brooklyn, NY 11235 U.S.A.

*There are two objectionable types of believers: those who believe the incredible and those who believe that "belief" must be discarded and replaced by "the scientific method."*

—Max Born<sup>3</sup>

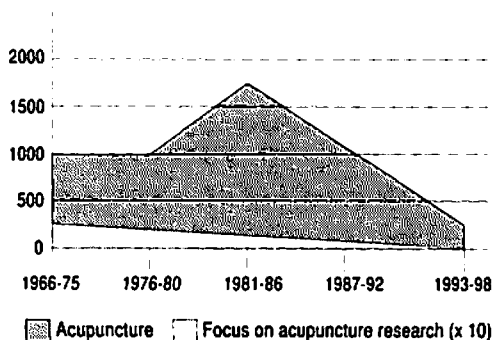
## Acupuncture in America: A Brief History

**A**CUPUNCTURE is getting old. With a history of several thousand years it has been old as a healing art for quite some time. As such, it successfully crossed geographical, cultural, and economical boundaries, and is accepted and used worldwide.

Now it is also getting old as a subject of scientific research. It has been proposed that acupuncture could have been brought to the U.S. in colonial days by whaling captains and China traders together with silk, porcelain and other things Chinese. However, the first known medical writing in the U.S. on "acupuncturation" (as it was then known) appeared in 1825 when Franklin Bache, physician and grandson of Benjamin Frank-

lin, published a translation of case reports by French physician M. Morand<sup>4(p29)</sup> (not to be confused with Soulié de Morant). In 1892, the use of acupuncture in treatment of lumbago and sciatica was described in the first edition of William Osler's *The Principles and Practice of Medicine*. That description continued to appear in Osler's text through the final (14th) edition.<sup>4(p31)</sup> However, perhaps due to an innate discrepancy in philosophical foundations of the Eastern and Western medical models<sup>5</sup> acupuncture was practically forgotten in the United States by the end of the last century. It was also suggested that frequent infections caused by lack of aseptic techniques had contributed to the declining use of acupuncture.<sup>6(p238)</sup>

The frequently cited experience of James Reston, a reporter with *The New York Times*, revived popular interest in the subject when his post-appendectomy pain was relieved with acupuncture in 1971. His wife wrote "whatever the scientific basis for the treatment, the result was relief."<sup>6(p238)</sup> Late President Richard Nixon's visit to China in 1972 brought further publicity to acupuncture. It was generously covered by the media and enthusiastically embraced by the public.



**Figure 1.**  
Number of Medline citations 1966-1998  
(adapted from Shepard<sup>21</sup>)

## Acupuncture and the Scientific Community

The scientific community responded with a number of publications investigating and discussing acupuncture; these increased steadily, peaking in the early 1980s (see Figure 1).

Conflicting results and a lack of explanations followed. Attempts at histologically defining acupuncture points and explaining the variability of its effects have not been successful. Even the clinical efficacy of acupuncture therapy has not been definitively proven after more than thirty years of intensive research. Since the utility and value of acupuncture has been experimentally neither proven nor disproven, the views of investigators still form a colorful spectrum. Some are cautious:

"The Chinese theory of acupuncture analgesia, which involves energy passing along meridians of the body (as yet undemonstrated) does not meet Occam's criteria.<sup>7</sup> On the basis of our knowledge about anatomy, this theory is unnecessarily speculative and must be treated with respected skepticism."<sup>8(p355)</sup>

Some investigators are very positive in evaluating the efficacy of acupuncture: "It is effective in as many as 85% of the patients who failed to respond to conventional medical or surgical management."<sup>4(p387)</sup> Others are less enthusiastic about traditional theories: Ulett states, "...some MDs and DOs... were comfortable in ignoring the advances of modern medical science and regressing to an acceptance of metaphysical theories of disease dating from pre-scientific times."<sup>9(p13)</sup>

## Practical Difficulties in Acupuncture Research

The lack of success in attempts to apply time-tested conventional experimental methods

to an "unknown" therapy has exposed certain problems intrinsic to acupuncture research to date. Such difficulties arise during the "...application of [the] scientific method to the assessment of treatment methods which derive from a system of medicine that is unfamiliar and not in itself scientifically based."<sup>10(p1)</sup>

When referring to areas of difficulty, most researchers include the selection of appropriate controls, an appropriate design for a single- or double-blind study, and the application of relevant outcome measures.

In 1993, the newly created Office of Alternative Medicine (OAM) within the National Institutes of Health (NIH) announced its intent to fund investigations in alternative therapies. Fifty-five out of 460 proposals submitted focused on acupuncture. Among the control methods suggested were needling at true but inappropriate acupoints, needling at inactive locations (determined by conductivity measures), shallow needling, non-invasive pressure with a guide-tube, mock TENS (disconnected unit with blinking lights), and treatment with appropriate Western medications.<sup>11</sup> Vincent and Richardson<sup>10</sup> reviewed the major choices of controls in the acupuncture literature in terms of no treatment, alternative treatment, and placebo. The placebos were described as non-acupuncture (TENS, etc.), or acupuncture placebo, which could involve no needle insertion, or needling of therapeutically inert points. Since even the least alternatively-oriented patients realize that acupuncture involves needles, it is unlikely that anything other than a needle insertion may serve as a placebo control for an acupuncture treatment. It was even thought that acupuncture was a form of hypnosis and a needle was considered to be "...a part of the ritual of cure."<sup>4(p88)</sup>

Needling at inert or "sham" points as a valid placebo control has also been questioned. Liao, et al note that since "...there are about 1600 Extra-Jing (Extra-Meridian) Odd Acupoints and New Acupoints scattered all over the body, such a 'sham' acupoint might well be one of these therapeutically effective Odd Acupoints."<sup>4(p126)</sup> Supposedly inert points may also localize to one of the Luo Mai (channels connecting the main meridians) and lose their "innocence" that way. To complicate matters further, traditional theory holds that meridians are functionally interrelated, or paired, so that choosing an acupoint away from a meridian used in treatment does not guarantee a therapeutically neutral location.

It was also pointed out that physiological effects of individual needle insertions may extend beyond an intended location as evidenced by expanding local erythema at the insertion site, commonly seen in the clinic. Therefore, local effects of needling at an inert site may involve an active point nearby. In addition, the "deqi" sensation, which in the Chinese school is a necessary verification of the correct needle placement, may allow patients to discover the difference between the experimental and control treatments.

Along with randomization and stratification, single- and double-blind experimental design is a major strategy for avoiding bias. However frustrating, the problem of blind design as applied to acupuncture is rather straightforward. "Acupuncture by its very nature cannot be subject to double-blind studies."<sup>12(p405)</sup> Whereas a trained practitioner knows the difference between true and "sham" (bearing in mind the above discussion) points and therefore cannot be "blind," an operator inexperienced in acupuncture may fail to produce the same nee-

ding experience and/or desired results.<sup>10</sup> Single-blind design is also problematic in that subjective sensation of authentic acupuncture is unique and patients may readily discover the difference between that and "the other treatment." On a less serious note, several authors have commented on the negative impact of the "waiting room comparisons" on the blinded experimental design.<sup>4,12</sup>

Outcome measures have also been considered to be inadequate in many of the acupuncture studies to date. Although subjective instruments such as the Visual Analog Scale (VAS) or McGill Pain Questionnaire may be useful in evaluating the immediate results, they may not be sensitive enough for long-term study of pain and disability. "Acupuncturists have always recognized that many patients count their treatment as successful if they feel better, sleep well and lose depression."<sup>12(p405)</sup> A related problem is a significant temporal variability in response to acupuncture treatment.<sup>10</sup> Multidimensional assessment with long-term follow-up including evaluation of patients' quality of life changes would be a more appropriate, but time-consuming and expensive, alternative. An additional advantage of using several assessment variables is that one measure may offer a degree of concurrent validation for another.<sup>10</sup>

Also problematic in the context of research design is the variability in acupuncture technique, the difficulty in standardizing acupuncture treatments, variability in the training and experience of the acupuncturist, inadequate population size, and the use of a distinctive terminology.

In acupuncture research, investigators must contend with decisions regarding the various styles used for point selection. In traditional styles, acupoints are chosen strictly according to theory and diagnosis,

and are less commonly employed in research designs than the "formula" approach which prescribes a set combination of points for a given condition. Proponents of the traditional approach employ a variety of specific needle insertion and manipulation techniques that are said to affect the efficacy of therapy. Use of electrical stimulation further diversifies treatments. Hybrid techniques, such as Electroacupuncture According to Voll and Ryodoraku, incorporate electrically measured diagnosis and treatment. In research, point locations that are not classical, such as trigger points, are also sometimes used. Finally, there are the infrequently discussed needles of various lengths, diameters, and materials (stainless steel, silver, gold).

Investigators that decide against early dismissal of traditional acupuncture theories and then proceed to design their research accordingly, soon realize that "...each treatment is individual and cannot be standardized."<sup>12(p405)</sup> It is well known to proponents of acupuncture, that two patients with the same Western diagnosis may receive different traditional diagnoses and treatment plans.<sup>13</sup> Therefore, standardization of many of the above variables, such as point selection, needle insertion techniques and the number of treatment sessions, is not appropriate from that perspective. Western-oriented reviewers agree that "...the process of evaluation may be made a great deal simpler by standardized practice, but this may constrain the clinician in such a way that the maximal benefits are not obtained for each individual patient."<sup>10(p7)</sup>

Some authors feel that most studies to date have been based on small population samples.<sup>6</sup> It has been calculated that a sample must contain at least 122 subjects to demonstrate a statistically significant difference.<sup>4</sup>

Another difficulty closely related to the outcome measures is a sizable variation in response to acupuncture. As noted by Liao, et al, "...the response to acupuncture can vary greatly from individual to individual, from none, to the immediate, to the delayed. The duration of relief also varies tremendously. It may last for minutes, hours, days, months, or years."<sup>4(p129)</sup> These two characteristics complicate the planning of outcome measures and the duration of the follow-up period.

The distinctive language of Chinese traditional medicine is sometimes singled out as the "...first tripwire for the researcher in acupuncture..."<sup>14(p357)</sup> Although it can be viewed as part of a broader gap between medical models, on a practical level, terms such as "Qi" and "channels" require some understanding of traditional theory. This is also the case, for example, in understanding the difference between the Western notion of heart as an organ and the Eastern concept of "Heart" as an energy system.

As for the experience of the person inserting the needles, the duration of training for acupuncturists is highly varied (from 300 hours required from New York doctors to 5 or 6 years of study by traditional physicians in China and masters-level U.S. students). Traditionally-minded practitioners are rarely involved in research, whereas people involved in research are often not adequately trained in acupuncture, which some feel may undermine its efficacy.<sup>6,12</sup>

#### **The Differences in Philosophy**

Thus, the unique differences intrinsic to acupuncture research are great in number and difficult to avoid. If these are gently pushed aside, however, a more fundamental problem becomes evident. The practice of acupuncture and Chinese traditional medicine is based on a philosophical model very

different from that of contemporary Western medicine. Assumptions concerning the nature of disease entities, canons of possible explanations, and the modes of proper treatment are merely extensions of the paradigm that dominates a particular medical system. The characteristics of a given system of medicine can ultimately be traced to the notions held by the then current society as a whole.

Numerous attempts have been made to compare and contrast the two medical models. The characteristics of relational, subjective, functional, and intuitive Eastern medicine have been compared to the tendency of Western medicine to be absolute, objective, structural, and logical.<sup>14-16</sup> The latter has also been described as a "reductive isolation" model that "...emphasizes quantification and measurement and aims to peer beneath variability, subjectivity, and the infinite variety of patients' experiences to something universally definable, measurable, and objective."<sup>17(p676)</sup>

According to Shepard, the dominant paradigm of researchers today is a positivistic perspective where observable phenomena are determined objectively, that is, separately and distinctly from the internal reality of the researcher.<sup>21(p89)</sup> As a "holistic" approach, Eastern medicine would then fit the "ascendant interrelation" framework that "...takes as its starting point a special and prototypical property of the living organism—metabolism—in which the organism has an identity that transcends the material of which it is made, and in which such characteristics as form, wholeness, self-generation, and integration dominate."<sup>17(p676)</sup> It has also been noted that the Yin-Yang dichotomy integrates the above mentioned qualities; those describing Eastern medicine being relatively more Yin, and those de-

scribing Western medicine relatively more Yang.<sup>5</sup>

Biophysicist Milburn feels that as an extension of the contemporary scientific paradigm, "...biomedical research on the phenomenon of acupuncture has not been particularly fruitful and has only served to demonstrate the wide philosophical gaps between the two approaches."<sup>15(p145)</sup>

Australian acupuncturist Bensoussan remarks that as opposed to the Western scientific model in which there is often a single objective observation from which a diagnostic conclusion can be made, the Oriental model appears to be more dependent upon the integration of a wide range of data, with every contributing factor being viewed in relation to the others. No single piece of data is absolute and therefore it may be assigned different meanings depending upon associated information. He concludes that "...the very nature of traditional Chinese medical theory and practice (to integrate variables) may be in direct conflict with the nature and method of current scientific research techniques (to control or eliminate variables)."<sup>14(p359)</sup>

Gillet states that "...anybody from orthodox medicine who presumes to engage in heresy is asking to have their intellectual credentials closely examined."<sup>18(p1125)</sup> I will ignore that for a moment and agree that a paucity of definitive results after 30 years of acupuncture research may indeed reflect an inappropriate choice of research instruments, rather than the unworthiness of acupuncture as a successful therapeutic modality.

**Possible Alternatives:  
Introspective Self-Observation and  
Qualitative Research**

What then is an investigator to do if the armamentarium of the experimental method

has been taken away? Two alternative approaches for the of study Eastern medicine can be offered. Both provide a wealth of information; however, they ask the researcher to work on the fringes of the biomedical paradigm.

1. Introspective self-observation<sup>15(p153)</sup> is just that—noting one's own physical and mental phenomena. René Descartes (1596-1650AD), the founder of modern scientific philosophy and responsible for the experimental method, uncovered the "foundations of the marvelous science" in a flash of intuition following a period of intense concentration.<sup>15(p153)</sup> In 1869, Mendeleev "saw" the draft of the periodic table of elements while asleep after weeks of rigorous thinking.

Introspective self-observation is also an important part of many Eastern religious and philosophical systems that encompass a "...variety of methods for directly accessing physical and mental phenomena and guiding these processes for specific ends (meditation, Qi Gong, etc.)."<sup>16(p153)</sup> It has even been hypothesized that these practices have led to the discovery and elaboration of the meridian theory with the description of the complex system of energetic pathways resulting from the practitioners' subjective experiences.<sup>15</sup> In fact, it is not uncommon for people engaged in meditation today to feel "propagated sensations along channels"<sup>15</sup> that correspond to the map of acupuncture meridians. A highly subjective way of examining the phenomenon of acupuncture, which is itself based on a subjective, relational and intuitive model, seems appropriate, albeit unorthodox.

2. Qualitative observation refers to "...taking note of features of an organism that cannot be precisely and quantitatively described."<sup>15(p152)</sup> Lee and Yang argue that since the definition of science does not sug-

**Table 1.**  
Alternative approaches to research: Positivism and phenomenology†

<b>Dimension</b>	<b>Positivism</b>	<b>Phenomenology</b>
Philosophical Perspective	Single, objective reality	Multiple realities
Research Purpose	Test, verify, describe (discrete variables)	Explain, interpret, describe (phenomenon)
Research Design	Experimental Quasi-experimental Descriptive	Qualitative case study Ethnography Grounded theory
Research Methods	Controlled intervention Sequential clinical trials Survey	Observation Interview Review of artifacts
Research Data	Quantitative Statistical analysis	Qualitative Constant comparative

† Adapted from Shepard<sup>20</sup>

gest that "...experiment is the hallmark of scientific activity or that it is intrinsically superior to other means of observing...."<sup>16(p1209)</sup> non-experimental observational studies are being unjustly avoided. "Today, the dominant investigative lineage of virtually every research-oriented medical institution runs from the Cartesian duality through reductionist methodologies to quantitative studies."<sup>19(p31)</sup>

An alternative system of beliefs developed in the 19th century supports qualitative inquiry. The school of phenomenology maintains that phenomena cannot be separated from the experience of them, and thus, there is no objective, absolute reality. Phenomenology is the "...study of the live world, the world as one experiences it, rather than as one conceptualizes, categorizes, or theorizes about it."<sup>20(p311)</sup> Appropriately, qualitative inquiry is concerned with the beliefs, perceptions, motivations and actions of people involved with the phenomena under study.

Another important characteristic of qualitative observation is its major emphasis on viewing phenomena in context. The notion that an accurate understanding of an event is frequently idiosyncratic and time-bound<sup>19</sup> is very similar to the concept of "relative meaning" of diagnostic information in Chinese traditional medicine and acupuncture. Table 1 compares the alternative philosophical approaches to research.<sup>21</sup>

While rarely used by biomedical researchers, qualitative methods are commonly used in anthropology, psychology, and certain schools of sociology.<sup>19</sup> There seems to be a growing interest in qualitative research in the allied health fields. Shepard argues that research instruments appropriate to the study of social phenomena are applicable to the investigation of human health, which is itself a socially constructed concept that involves human perception, interpretation, and individual meaning.<sup>21</sup> The end result of qualitative inquiry as an instrument of phenomenological research is to describe

and interpret a phenomenon from the point of view of the person experiencing that phenomenon. Researchers in nursing have endorsed phenomenology as an approach which "...enables the needs of the client to be identified and to be of foremost importance in the provision and justification of high-quality nursing care."<sup>22(p313)</sup>

A study by Beck<sup>23</sup> illustrates the potential utility of qualitative research. Seven women with postpartum depression were interviewed about their subjective experiences. Forty-five significant statements that emerged from the data were combined into 11 themes that described the lived experience of women with postpartum depression. In comparing these themes with those generated by quantitative survey instruments, such as the Edinburgh Postnatal Depression Scale (EPDS), it was found that EPDS did not address all the themes revealed by Beck's phenomenologic study. Thus, the application of qualitative research methods substantially enhanced the dimensions of the findings.

It is likely that research in acupuncture, as an extension of an integrative, context-dependent model, would benefit from the application of a qualitative methodology.

Research is a way of furthering one's knowledge. In medicine, that also translates into expanding one's ability to heal. When the ends offer gains that are so remarkable, the means should not assume restrictive self-importance.

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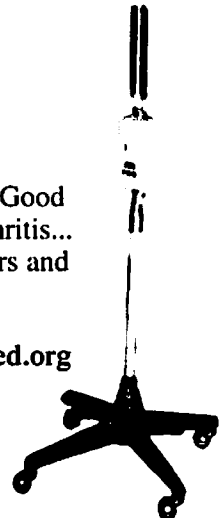
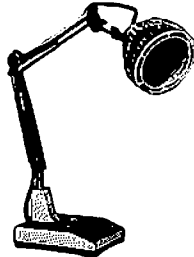
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#### About the Author

Alex Moroz was born and raised in the Soviet Union where he received his early education. Arriving in the U.S. in 1989, he received a BA from Brooklyn College of the City University of New York. He maintained an active interest in Eastern arts while at New York University School of Medicine where he received his medical degree in 1996. He is now a resident at the Rusk Institute of Rehabilitation Medicine, New York University Medical Center. He adds that he "enjoys teaching and research, and hopes to find a way to integrate Eastern and Western medicine for the benefit of his patients." □

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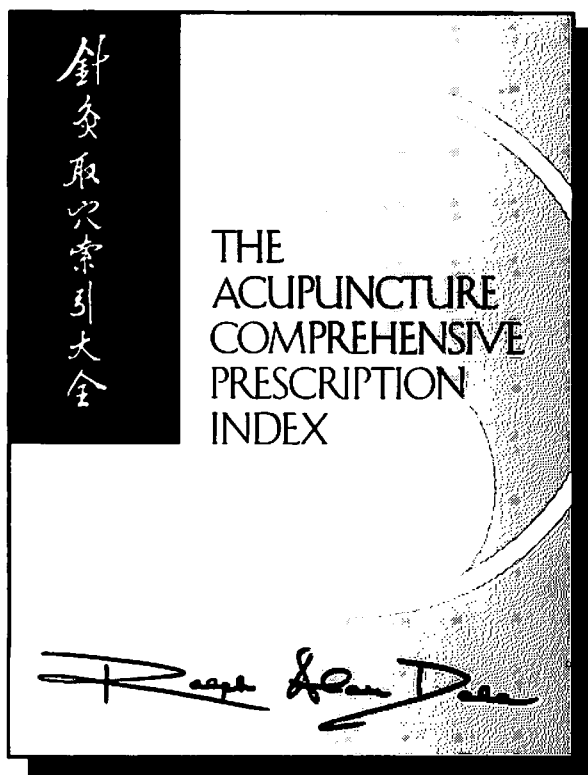
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