

A Critical Evaluation of Acupuncture Research Physiologization of Chinese Medicine in Germany

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Abstract As Chinese medicine is going global, it is simultaneously adapting swiftly to local patterns of perception and interpretation, thereby being shaped into hitherto unknown forms. The globalization of Chinese medicine produces multiple localized visions of a healing system whose trademark is an “innate heterodoxy”. Barnes described the “psychologizing” of Chinese medicine in the USA (Barnes *Cult Med Psychiatry* 22(4):413–443, 1998). In Germany, however, biomedical instead of “holistic” patterns of perception and interpretation and a tendency to “physiologize” prevail among patients and Chinese Medical therapists. Here the recent German Acupuncture trials, and Acupuncture Randomized Trials (ART) and Cochrane data base metaanalysis (Linde et al., 2009a) shall serve as a prominent example of how German research centers around physiological phenomena and how these studies have triggered an international debate concerning the point-specific nature of acupuncture interventions. In order to evaluate the specific effect of acupuncture in randomized controlled trials, verum acupuncture, defined as acupuncture at “classical” acupuncture points, and sham acupuncture, defined as acupuncture at “non-acupuncture points”, are frequently compared. The anatomically exact location and specificity of acupuncture points are basic assumptions underlying this concept. But how clearly divisible are verum and sham acupuncture points if acupuncture physiology itself is a historical construct? To more adequately evaluate acupuncture’s effectiveness future clinical studies will have to tailor their methodology to the reality of the acupuncture encounter.

Keywords Acupuncture research · ART · GERAC

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1 Introduction

1.1 Dissimilarities in Reception and Development of Chinese Medicine in the USA and Germany

In 1976, California became the first Western government agency ever to give licensure to “acupuncturists” and thereby recognize Chinese medicine as an independent profession. This legitimized Chinese medicine’s existence unconstrained by biomedical directives and allowed it to develop within a unique American conceptual framework.

“Reacting to what is perceived as biomedicine’s focus on the physiological, those who describe themselves as favoring a holistic orientation often use the language of “energy blockage” to explain illness, whether thought of as “physical”, “emotional,” or “spiritual.” Acupuncture in particular has been appropriated as one modality with which to “unblock” such conditions, leading to its being used by some practitioners in conjunction with more psychotherapeutic approaches.” (Barnes 1998: 413)

In this American appropriation of Chinese medical practices, psychological and spiritual elements once inherent to Chinese medicine in terms of religious categories are reemerging.¹ Such developments have not taken place in Germany, where the acupuncturist as an independent profession does not exist and acupuncture is dominated by the biomedical establishment. More than 40,000 medical doctors practice acupuncture and more than 40 acupuncture societies offer certified teaching programs that cater mostly to physicians and, to a smaller extent, to “Heilpraktiker” (naturopaths). While the majority of these societies are dominated by doctors trained in biomedicine, the great number of practicing acupuncturists (both doctors and naturopaths) reflects the high demand for this therapy.

A 2003 poll of the German Allensbach Institute showed that 83% of the Germans are in favor of naturopathy. In this same poll, a striking 64% provided positive associations with the keyword “Acupuncture”, which is the most prominent of all Chinese medical practices in Germany, almost becoming synonymous with Chinese medicine (Dobos 2007: 63–64). Another more recent Allensbach survey (August 2005) showed that 31% of the German population have experience with treatment methods of Chinese medicine (26% with acupuncture plus 5% with other methods). When asked to choose between biomedicine, Chinese medicine, or a synthesis of both, 61% opted for the synthesis. Among those who had experience with Chinese medicine, 89% favored an integration of Chinese and biomedicine (Dobos 2007: 63).

These results seem to show that the great majority of patients that have been treated with methods of Chinese medicine in Germany are satisfied. Further, this indicates that Chinese healing practices must somehow be effective, or be perceived

¹ Since the mid-1950s, we can observe a process of standardization of Chinese medicine in the People’s Republic of China that is still ongoing. It is politically, socially, and economically motivated and among other aspects systematically discards psychological and religious elements of Chinese medicine in favor of biomedical interpretations. See Taylor (2005).

as being effective by patients and Chinese medical practitioners.² What then are the factors involved in shaping our perception of effectiveness?

1.2 Factors that Shape Our Perception of Effectiveness

The complex process by which patients' and practitioners' perception of Chinese medicine is shaped cannot be understood independent of sociological, medical, and historical factors. On sociological grounds, the strong support for acupuncture and other natural healing practices in Germany may be interpreted as a reflection of postmodern values: An ever-changing and increasingly technologized biomedicine has alienated patients (Bakx 1991: 13, 20–37). Here, Chinese medicine offers a conceptual approach for complex bodily processes that seems to appeal to many people. In addition, biomedical orthodoxy is increasingly challenged by medical diversity. In clinical reality, biomedical and complementary and alternative therapies are intermingling in complex often conflicting ways. Cant and Sharma (1996) have presented a thought-provoking account of what this clinical reality looks like and how knowledge is generated within complementary and alternative therapies.

On medical grounds, it is commonly perceived that the great progress made in biomedicine only applies to certain fields: The number of deaths resulting from common infectious diseases such as malaria, tuberculosis, HIV, diarrheal diseases, pneumonia, etc. has steadily decreased in wealthy as well as some poorer nations.³ Chronic illnesses, however, are developing into a new scourge worldwide, considered by the World Health Organisation to be a "global epidemic".⁴ Although new techniques in surgery and research into new drugs are often promising, in effect, little has been done to prevent and treat chronic diseases. The majority of people above the age of 65 are suffering from some sort of chronic disease. A small percentage of these patients benefit from biomedical therapies, but only to a certain degree and only in wealthy countries.

Long-term medication is usually required to control or suppress the symptoms of chronic illnesses from which side effects can be very severe and may even cause death. Official figures reveal that in the USA, more than 100,000 patients die annually because of the side effects of their medication (Lazarou et al. 1998: 1200–1205; US population in 1998—270,000,000). Relative to Germany's population (82,500,000 in 2004) that figure is even higher. A 2003 study of the Institute of Clinical Pharmacology at the University of Hannover estimates that each year, 58,000 patients die because of

² Ironically, while Chinese medicine is steadily gaining popularity in Germany, a very recent 2006 online survey by China Youth Daily and Tencent.com revealed opposite tendencies in China itself where TCM is losing out to western medicine in the popularity stakes: "Only 28 percent of the 14,677 respondents surveyed said they would turn to TCM first even though 87 percent said they still had faith in the centuries-old practice. Half of the respondents who voiced their support for TCM believe it is an effective cure for many diseases but 27 percent only trust it because it is "the quintessence of China". As for the future of TCM, more than 60 percent said they were not optimistic" (China Youth Daily 2006).

³ "Although we are the first generation ever to have the means of protecting itself from the most deadly and common infectious diseases... underuse and misuse of recent health breakthroughs has been catastrophic for people living and working in developing countries. Two out of every three deaths among young people in the poorest countries of Africa and Asia continue to result from just a handful of illnesses..." (WHO 2000).

⁴ See, for instance: http://www.who.int/chp/media/Video_gallery/en/index.html.

medication errors and side effects (Frölich 2003: 15). Thus, biomedicine's highly efficacious modes of treatment come at a high price. This has led to disappointment and even fear among patients, who then turn to natural remedies that are thought to be safer while still delivering acceptable results. Natural remedies are used to both complement and replace conventional treatment.

On a historical level, the growing popularity of naturopathy in Germany may also be perceived as the rediscovery of time-honored traditions. Some of today's most popular naturopathic methods are of German origin and they were well established in clinics throughout the country prior to the arrival of biomedicine and the widespread use of modern pharmaceuticals. Kneipp's hydrotherapy (the systematic application of water as a natural cure) or Hahnemann's homeopathy are prominent examples. Kneipp's idea of "Ordnungstherapie", which aims at activating the self-regulating properties of the human system through a balanced and natural lifestyle, has to a large degree influenced modern concepts of naturopathy. The modern version of *Ordnungstherapie* is a transtheoretical approach that combines naturopathic definitions of *Ordnungstherapie* with concepts of mind-body medicine, a system developed at the Mind/Body Medical Institute of Harvard University (Dobos et al. 2006: 334). While hydrotherapy, *Ordnungstherapie*, or homeopathy are generally viewed as mere treatment methods, Chinese medicine is widely perceived (and promoted) as a complete and coherent medical system with a written tradition that dates back more than two millennia. Like the German traditions, it has survived the arrival of biomedicine and must therefore be effective.

The German embrace of irregular, non-orthodox, alternative, complementary, or integrative healing (the names have changed notably over the past two decades) is thus not new. This, by the way, also applies to US history. Long before David Eisenberg's famous 1993 study revealed to an astonished medical establishment that one in three Americans had used at least one form of unconventional therapy (Eisenberg et al. 1993: 246–252), a 1924 survey of Philadelphia households had found exactly the same: 34% of the patients surveyed reported that they had tried alternative or unconventional methods in the previous year (Whorton 2002).

We may conclude that sociological, cultural, historical, and medical factors all play a part in the German representation of Chinese medicine. This paper will focus on the latter one, namely on how medical perceptions, reduced to physiological and mathematical visions, shape and influence the representation of this ancient healing art. The discussion of Chinese medicine's effectiveness in Germany centers around physiological phenomena and methods of evidenced-based medicine like randomized controlled trials (RCTs) that have proven to be an invaluable tool for testing the efficacy of new drugs. But because of the great number of possible sources of bias and the questionability of their underlying assumptions, current RCT designs are not suitable to evaluate complex non-pharmaceutical medical procedures like acupuncture.

2 Physiologizing Chinese Healing Practices in Germany

Biomedical doctors have, with some variation in theoretical background and application, appropriated certain aspects of Chinese medicine into their daily practice. Although there are individuals who pursue high standards in terms of

practicing the “real” traditional Chinese medicine (TCM)⁵, the great majority feels comfortable with reductionist versions of mere needling techniques that they believe can do completely without a complex Chinese theoretical framework. A 2004 study by Frank and Stollberg supports this view:

“Half of the medical acupuncturists isolate acupuncture from the context of Chinese medical theory. (...) scientific explanations of acupuncture (e.g. efficacy via endorphins) are used for teaching and for increasing societal acceptance of Asian medicine...” (Frank and Stollberg 2004: 367–368)

This focus on physiological aspects and the great popularity of acupuncture described above has, among other factors, even led to the establishment of a university chair of naturopathy within the medical faculty of a German university.⁶ Its aim is:

“to provide a scientific assessment of the heterogenous techniques used in complementary and Chinese Medicine, to build a bridge between biomedicine and evidence-based complementary medicine and to support long-term systematic research”.⁷

This department rests on three pillars: teaching, research, and clinical practice. Significantly, Chinese medicine penetrates into all three areas. Emphasis is put on research into and the integration of Chinese medicine with biomedicine. Studies that have been or currently are being conducted at this department range from basic science and research into Chinese diagnostic methods to the establishment of quality control criteria of so called “TCM-centers”.⁸

The establishment of this department serves as an example of contemporary tendencies and reflects the German *Zeitgeist* insofar as it focuses on the “scientific” and physiological aspects of Chinese medicine. It is a very significant development, because hitherto, a clear division existed between naturopathy and biomedicine on the university level.⁹ Naturopathy and acupuncture have long been looked down upon as folk medicine without scientific backing. Having entered academia, they are now being forced to play according to the same rules and standards that apply to

⁵ For a detailed discussion of the term “TCM” and the transmission of standardized medical knowledge in China see Hsu (1999: 128–224). The Chinese medical community has, according to Taylor, “contributed to the Western illusion of a static, unchanging medical system, by repeated advertising of the long and rich history of their medicine, and by the use of the translation “Traditional Chinese Medicine (TCM)”” (Taylor 2004: 93). In China, Chinese medicine is simply termed *zhongyi* and never referred to as *chuantong zhongguo yixue* which would be the correct translation of TCM.

⁶ Lehrstuhl für Naturheilkunde der Alfried Krupp von Bohlen und Halbach-Stiftung an der Universität Duisburg-Essen.

⁷ <http://www.uni-essen.de/naturheilkunde/en/index.php>.

⁸ Such centers have opened all over the country and offer treatment in Chinese healing methods at quite varying degrees of quality. Because of growing quality concerns, the German government funded this particular study to ensure the quality of services in Chinese medicine.

⁹ While it is true that a number of universities in the USA (Harvard, Stanford, University of California, Los Angeles, University of California, San Francisco, etc.) have also established centers of Integrative Medicine, the German department is the only one that enjoys equal status with other medical departments. While lectures on naturopathy and/or integrative medicine are elective courses at these US universities, they are required courses for medical students at the University of Duisburg-Essen.

evaluate biomedicine in order to legitimate their very existence, namely to provide evidence for their effectiveness by means of randomized controlled trials. But how did these methods become the gold standard for the evaluation of effectiveness in the first place?

2.1 Evidence-Based Medicine and Randomized Controlled Trials

Let us look at the environment from which the terms “evidence based” and “randomized controlled trials” first arose.¹⁰ Until about the mid-1960s, medical decisions were not subject to questioning or analysis. The fundamental assumption that lay behind this complacency was that the difficulties of earning a medical degree and the high standards of continuing education in the medical field provided a framework rigorous enough to assure physicians somehow always knew what they were doing in a clinical encounter. The complex process of how a medical decision came about was not yet subject to analysis or study but was rather regarded as part of the art of the medical profession.

“Analytical methods and mathematical models were limited to research projects. Guidelines were merely a way for experts to pass occasional pieces of advice to nonexperts. Coverage and medical necessity were defined tautologically; if the majority of physicians were doing it, it was medically necessary and should be covered. Diseases did not require any management beyond what physicians were already providing, and performance was taken for granted. Beginning in the early 1970s, however, two major flaws began to appear in this fundamental assumption. One was a growing body of research showing that key aspects of the assumption were simply wrong” (Eddy 2005: 11).

A study by Wennberg and Gittelsohn (1973) revealed wide variations in patterns of practice and raised the question: If two physicians recommend different therapies for the same patient and perform different treatment methods, how can both claim to do be doing what is right and necessary? A decade later, further studies measured how appropriately physicians performed coronary angiography in a randomly selected community-based sample of cases. Using ratings of appropriateness derived from an expert physician panel, these studies showed that 17% of the procedures were considered inappropriate (Chassin et al. 1987). Analyzing these observations, the physician and mathematician D. M. Eddy termed the differences in practice “alarming” and concluded that medical decisions were far too complex to be solely based on subjective reasoning and experience. He argued that some form of institutionalized procedure had to be found that would enable the physician to adequately select from the array of available options those considered most appropriate and useful (Eddy 1982, 1983, 1984).

¹⁰ “The idea of randomization as a method of control was introduced by the English statistician and geneticist Ronald Aylmer Fisher (1890–1962) in an article in the *Journal of the Ministry of Agriculture* in 1926, and the first randomized controlled trial was designed by the English medical statistician Sir Austin Bradford Hill (1897–1991) and carried out in 1948 by the Medical Research Council of the UK to study the therapeutic efficacy of the antibiotic drug streptomycin” (Oxford Dictionary of Psychology 2003: 614).

On the other hand, the famous estimate that only 15% of medical practices were based on solid clinical trials, urgently called for a bridging of the gap between scientific research and clinical practice.¹¹ If, in reverse, 85% of the medical decision making were not based on good evidence, how could physicians claim effectiveness for their various methods?

Into this environment, the idea of randomized controlled trials was born. In his seminal article, Archie Cochrane (1972) argued that much of the evidence underpinning medical practices was flawed. He demanded a shift away from opinion-based medicine to a new paradigm that recognized the importance of the quality of evidence that informs clinical decision making, advocating randomized (controlled) trials. This research practice is defined as:

“a form of clinical trial, or scientific procedure used in testing the efficacy of medicines or medical procedures...” and “widely considered the most reliable form of scientific evidence because it is the best known design for eliminating the variety of biases that regularly compromise the validity of medical research.”¹²

2.2 Are RCTs an Appropriate Method for Acupuncture Research?

We shall now analyze whether the randomized controlled trial is an adequate study design to evaluate complex non-pharmaceutical medical procedures such as acupuncture. A great number of possible sources of bias have been identified in controlled trials (Kramer and Shapiro 1984). Confounding results may be due to vague enrollment criteria, inappropriate statistical procedures, wrong choice of endpoints, high dropout rates, inadequate follow-ups, etc. These factors are handicaps that all controlled trials share, but there are also some sources of bias peculiar to acupuncture (Ernst and White 1997). No matter how good the overall design, an acupuncture study can never be double blind: The acupuncturist will always know whether he is applying real or sham acupuncture. Because it can never be ruled out that he will somehow communicate this, single-blinding remains a serious methodological problem (Reilly and Findley 1989).

Other difficulties arise from the Chinese medical theory which differs greatly from the biomedical conceptual models that are usually applied in acupuncture studies. For example, how can a Western diagnosis be translated into a Chinese one that is based on pulse and tongue diagnosis to describe abnormal functions of vital forces in the body? If, on the other hand, the theoretical framework of Chinese medicine is ignored, what implications does that have for clinical parameters like formulating a treatment principle, point selection, and so on? Furthermore, there are many different types of acupuncture performed throughout the world. Many studies do not specify what kind of acupuncture they refer to or what kind of background the acupuncturists involved come from. Last but not least, great variations in training and inadequate qualification of acupuncturists involved in the studies are common shortcomings that have always plagued acupuncture trials (Hammerschlag 1998).

¹¹ See Committee for Evaluating Medical Technologies in Clinical Use (1985: 5).

¹² See http://en.wikipedia.org/wiki/Randomized_controlled_trial.

While each of these factors could be extensively commented on, I will focus on the concept of sham acupuncture which I consider the single most important source of bias in acupuncture research.

The two central postulates of an RCT are randomization and control. This means patients are randomly assigned to a treatment (*verum*) or control group (*sham/placebo*) group. The intervention is thus thought to be divided into characteristic (specific) and incidental (*placebo, non-specific*) effects. But does it make sense to split complex interventions such as acupuncture into characteristic and incidental effects? Recent research has shown that elements categorized as “incidental” in drug trials are integral to an acupuncture intervention (Paterson and Dieppe 2005). Paterson and Dieppe argued that fundamental assumptions underlying the design of RCTs do not apply to an acupuncture intervention concluding:

“Treatment factors that are characteristic of acupuncture include, in addition to the needling, the diagnostic process and aspects of talking and listening. Within the treatment sessions these characteristic factors are distinct but not divisible from incidental elements, such as empathy and focused attention. These findings have important consequences for the design of trials. A sham controlled acupuncture trial, the classic design for efficacy or explanatory trials, is based on the supposition that the needling alone is the characteristic treatment element. Therefore participants in the control group receive everything except the needling. If, however, other aspects of treatment are characteristic, the sham acupuncture design is inappropriate because it delivers these other characteristic elements to both groups. Consequently, the difference between the groups may greatly underestimate the total treatment effect of the intervention” (Paterson and Dieppe 2005: 1204).

Although this study may help to focus on the whole characteristic effect more precisely and thus prevent false negative results, its concept of sham acupuncture remains elusive. If the control group receives “everything except the needling”, what exactly is meant by that? In the present context, we have to assume that Paterson and Dieppe propose no treatment as sham control. This would closely resemble a waiting list and by definition is not a sham design. So what are procedures commonly used as sham controls in acupuncture studies and what are the possible biases resulting from them?

Besides early procedures of rubbing the needle against the skin (Borglum-Jensen et al. 1979) or gluing it to it (Gallachi 1981), more recent inventions such as the Streitberger needle (a device that retracts into the handle when pressed onto the skin like a theatrical dagger) are currently being used as sham controls in acupuncture research. But many critics argue that even patients with no experience of acupuncture treatment are likely to know that needle insertion is involved in “real” acupuncture and how it should feel when a needle penetrates the skin.

This may explain why the majority of studies use another form of sham control, namely, needling at “non-acupuncture” points.¹³ There are two basic assumptions behind this method: First, there are “classical” acupuncture points and there are “non-

¹³ Starting with early acupuncture studies such as Gaw et al. (1975) and Godfrey and Morgan (1978), to the very recent German GERAC and ART studies that will be discussed in detail below.

acupuncture” points and second, insertion of needles at “non-acupuncture” points has no significant physiological effects. Both assumptions need to be investigated.

The second assumption has been questioned since the early 1980s. Lewith and Machin found that needling at “non-acupuncture” points had an analgesic effect in 40–50% of patients, compared to 60% at “classic” acupuncture points (Leewith and Machin 1983). A possible explanation for this phenomenon was given by le Bars, who suggested that a mechanism called “diffuse noxious inhibitory control” produces this analgesic effect, which can be evoked even if very shallow needling without stimulation is applied at “non-acupuncture” points (Le Bars et al. 1991). Other controlled trials since the late 1970s have also shown significant therapeutic effects for both “verum” and “sham” acupuncture.¹⁴

I have challenged the first assumption that there are “classical” acupuncture points and “non-acupuncture” points, by tracing the concept of the “meridian” and its course and the acupuncture point and its localization and specificity through the history of Chinese medicine from the earliest primary sources to modern textbooks. My doctoral thesis presents the development of the acupuncture system with a focus on the concept of the acupuncture point. From the vague descriptions of the pathways of the “vessels” and “acupuncture loci” in the early sources of Chinese medicine, how did we arrive at the exact anatomical depictions of the “meridians” and “acupuncture points” in modern textbooks?¹⁵ The results of my research suggest that classical acupuncture points do not exist in the sense of exactly defined spots, but rather as vaguely defined areas. For the research domain, this implies that the concept of sham acupuncture points needs to be abandoned, because if the “classic” or real acupuncture point cannot be exactly defined and thus accurately located, the sham point cannot either (Tao 2007).

The notion that needling anywhere in the body may produce physiological effects is not new. But never in the history of acupuncture research has so much data supported a “non-specific” effect of acupuncture than the recent Acupuncture Randomized Trials (ART) and the German Acupuncture Trials (GERAC), which shall now be discussed in more detail.

2.3 The ART and GERAC Trials

With their very large sample sizes, the ART and GERAC trials provide a new dimension in acupuncture research.¹⁶ Since small sample sizes have always been a major source of bias in acupuncture research, the most obvious advantage of large studies like these is that they eliminate beta-type errors that are created by a too small sample.¹⁷ These studies were initiated by the German public health insurance

¹⁴ See the study cited in Tao (2007)—Gaw AC et al.—and Melzack (1977), or Richardson and Vincent (1986).

¹⁵ The literal translation of *mai* is vessel and that of *shuxue* transport *loci*. In the modern reception, *mai* has become meridian and *shuxue* acupuncture point.

¹⁶ See Melchart et al. (2003), Melchart et al. (2005), Linde et al. (2005), and Witt et al. (2005).

¹⁷ Beta-type errors occur if the sample size does not produce sufficient statistical power to suggest a difference between verum and sham.

companies in order to decide whether acupuncture should be included in their catalog of reimbursable treatment methods, with the aim to investigate the evidence base for acupuncture in pain treatment.

The results of the ART and GERAC studies and their implications for the field will now be discussed. I have chosen to extensively comment on these studies because the debate over the outcome of these trials has exclusively centered around physiological effects and therefore supports the hypothesis of a physiologizing tendency of Chinese medicine in Germany. What would rather be needed is a unified approach that includes physiological, psychological, and social categories that describe more precisely how acupuncture effects may be mediated. Understanding these categories seems crucial for the interpretation of the results of acupuncture studies.

ART and GERAC each consisted of four randomized trials for the indications of migraine, tension headache, osteoarthritis of the knee, and chronic lower back pain. In the ART studies, 300 patients were included in each indication while the GERAC studies each had around 1,000 patients per indication. This is the largest number of patients in randomized controlled trials of acupuncture recorded to date. A semistandardized acupuncture therapy with freely selectable points combined with compulsory points was used. In order to examine the clinical effectiveness, acupuncture in the GERAC studies was compared with a guideline-oriented conventional standard therapy and in the ART studies with a group of wait-listed patients. In order to investigate the effect mechanism, in particular, the relevance of “point-specific effects” both sets of studies included a third group where “minimal acupuncture”, defined as superficial needling at “non-acupuncture points” without stimulation, was applied.

The essential results of ART and GERAC can be summarized as follows:¹⁸ (1) Acupuncture clearly showed a better therapeutic effect compared with the conventional standard therapy for osteoarthritis of the knee and chronic lower back pain (GERAC), as well as a clearly better results than “no treatment” (waiting list) with osteoarthritis of the knee, chronic lower back pain, migraine, and tension headache (ART). (2) In comparison to the standard pharmacological treatment for the prevention of migraine headaches, acupuncture was more effective. (3) Acupuncture showed a significantly better effect in the treatment of osteoarthritis of the knee in the ART study when compared with minimal (sham) acupuncture. In all other studies, however, no statistically significant difference could be detected between verum and sham acupuncture.

2.4 Interpretation of the Study Results of ART and GERAC

In the framework of ART and GERAC, minimal acupuncture was applied as a sham acupuncture design to test the relevance of “point-specific” effects. Both classical as well as minimal acupuncture showed a therapeutic effectiveness in the GERAC study, which was clearly superior to the conventional guideline-oriented standard biomedical therapy in the treatment of migraine headaches, tension headaches, osteoarthritis, and chronic lower back pain. These results are supported by previous

¹⁸ See studies listed in footnote 19 as well as <http://www.gerac.de/deu/pdf/5ErgebnisseinZahlen.pdf>.

clinical studies¹⁹ and the most recent systematic reviews on the examined indications (Linde et al. 2009b).

But these results also clearly indicate that the significance of the specific physiological needle effects for migraine, tension type headache, and chronic lower back pain have been overestimated. Only one study (ART-gonarthrosis) showed a significant difference between sham and verum acupuncture (Witt et al. 2005).

The fact that in three out of four examined indications, sham acupuncture was only slightly less effective than verum acupuncture at the points specified in Chinese medical theory has led to heated debates among scientists and practitioners. Detractors of Chinese medicine have already used the findings of the GERAC and ART studies to proclaim that acupuncture theory is dead and that it makes no difference where to insert the needle (Ernst 2004; Henderson 2005). The media in Germany quickly seized the subject creating the term “no-matter-where-acupuncture” which led to doubts and uncertainty among the public and patients.²⁰ Obviously, on the basis of the current data, these are untenable conclusions. As Ots has pointed out, to state that it does not matter where to insert the needle would require that repeated studies for the same indication with needling at different areas (in different neural segments), using identical needle techniques, arrive at the same result (Ots 2004), and even then, the statement would be limited to the examined indication.

Still, a strong non-specific effect of acupuncture demands further explanation. Apart from neurophysiological findings, such as the above-described mechanism termed “diffuse noxious inhibitory control”, history here may deliver some answers.

3 Acupuncture Physiology: A Historical Construct

An explanation for the above-described phenomenon can be found if we trace the origins of acupuncture physiology to the earliest descriptions of meridians and acupuncture points and compare them to modern textbooks that serve as guidelines for present day acupuncture research. In the context of this paper, two examples shall serve as evidence for my thesis. Let us look at the development of the pathway of the “urinary bladder meridian” and at the evolution of the location of the prominent “acupuncture point” *san yin jiao*.

The earliest mention of the vessel that is today termed “urinary bladder meridian” is in two texts that are known as the *Zu Bi Shiyi Mai Jiu Jing* “Cauterization canon of the eleven vessels of the foot and forearm” and the *Yin Yang Shiyi Mai Jiu Jing Jia Ben* “Cauterization canon of the eleven Yin and Yang vessels, Ed. A” which were unearthed as part of a large cache of manuscripts from the Mawangdui tomb No. 3 in 1973 near the city of Changsha, Hunan, People’s Republic of China. The tomb was closed in 168 B.C. These manuscripts have been translated and analyzed by Donald Harper (Harper 1998: 192–212). In the first text, we read:

“Foot. Foot Great Yang vessel. It emerges in the hollow by the outer malleolus.

¹⁹ See Vas et al. (2004), Vickers et al. (2004), and Furlan et al. (2005).

²⁰ See <http://www.akupunktur-aktuell.de/2005/beitrag/01-20-1.htm>.

Ascending, it penetrates the calf and emerges at the poples. A branch goes to the lower xun. The direct path penetrates the (1) and presses laterally on the spine. It (2) and ascends to the head. A branch at the lower part of the center of the forehead goes to the ear. The direct path penetrates the inner canthus of the eye goes to the nose.

In the second text, we find some similarities but also dissimilarities concerning the pathway of the Great Yang vessel.

“Great Yang vessel. It is attached to the heel, in the outer malleolus. It emerges in the poples. Ascending, it bores the buttock, emerges in the hip joint, and presses laterally on the spine. It emerges at the nape, ascends the corner of the head, descends the center of the forehead, presses laterally on the bridge of the nose, and is attached to the inner edge of the eye.²¹

Let us now compare these rough sketches of the Great Yang Vessel to the finished drawings of the bladder “meridian” in the first edition of an acupuncture text book specifically compiled for a Western reception (Beijing College of Traditional Chinese Medicine et al. 1980).²²

The Urinary Bladder Channel of Foot Taiyang starts from the inner canthus (Jingming, U.B.1) (1). Ascending to the forehead (2) it joins the Du Channel at the vertex (Baihui, Du 20) (3), where a branch arises running to the temple (4). The straight portion of the channel enters and communicates with the brain from the vertex (5). It then emerges and bifurcates into two lines, descending along the posterior aspect of the neck (6). Running downward alongside the medial aspect of the scapula and parallel to the vertebral column (7), it reaches the lumbar region (8), where it enters the body cavity via the paravertebral muscle (9) to connect with the kidney (10) and join its pertaining organ, the urinary bladder (11). The branch of the lumbar region descends through the gluteal region (12) and ends in the popliteal fossa (13). The branch from the posterior aspect of the neck runs straight downward along the medial border of the scapula (14). Passing through the gluteal region (Huantiao, G.B. 30) (15) downward along the posterior aspect of the thigh on the lateral side (16), it meets the preceding branch descending from the lumbar region in the popliteal fossa (17). From there it descends to the leg (18) and further to the posterior aspect of the external malleolus (19). Then, running along the tuberosity of the 5th metatarsal bone (20), it reaches the lateral side of

²¹ I have left out the extensive comments on the translation by Harper. The numbers in the first citation stand for lacunae in the original manuscript. There is controversy about the question which of these two texts represents the oldest attested stage of vessel theory and whether between them a developmental progression has taken place. See Harper (1998: 89–90).

²² This textbook had an enormous influence on the Western reception of acupuncture in the era after the process of systematization and standardization that started in the 1950s. It served as reference work for teaching and translation into many other languages. The German standard textbook on acupuncture *Quintessenz der Chinesischen Akupunktur und Moxibustion. Lehrbuch der chinesischen Hochschulen für Traditionelle Chinesische Medizin* is a literal translation of this work. See Wühr (1988).

the tip of the little toe (Zhiyin U.B. 67), where it links with the kidney channel of Foot-Shaoyin (21).²³

Modern textbooks of acupuncture constantly refer to the “classics” of Chinese medicine such as the “Inner Canon of the Yellow Thearch” (*Huangdi Neijing* 200–100 B.C.), the “Canon of Acupuncture and Moxibustion” (*Zhenjiu Jiayi Jing* 300 A. D.), or the “Great Compendium of Acupuncture” (*Zhenjiu Dacheng* 1601), etc. emphasizing that the descriptions of the exact pathways of the “meridians” and the acupuncture points located on them have remained unchanged over more than two millennia. Works that predate the *Huangdi Neijing* such as the above Mawangdui manuscripts are not referred to possibly because they do not contribute to the picture of an unchanging coherent medical system. But as we can see, the course and directionality of the vessels in their infancy differ greatly from modern “meridians”. Interconnection between vessels to build a circuit or their linking to organs is also absent in early vessel theory and only established since the *Huangdi Neijing*.

Through history, the location of acupuncture points has always been described on a topographical basis with reference to salient body parts (bones, skin folds, etc.). Once located, these points serve as reference points for the location of others and so on. It is self-evident that there is ample room for interpretation in such a system.

Li Jianmin compares 12 acupuncture loci in works like the *Maijing* (compiled in the Western Jin dynasty (265–316) with later texts and concludes that the vague descriptions in early texts stand in stark contrast to the exact depictions of later works that use *cun* and *fen* measurements (Li 1999: 60). The acupuncture loci that is known as *sanyinjiao* (or: SP 6) for example was first located at eight cun above the internal maleolus. For reasons unknown, its location changed to its present locus at three cun above the internal maleolus only in writings after the six dynasties that is after 589 A.D. (ibid: 56).

The extent to which the effect of an acupuncture point can be considered specific thus depends on the definition of the size of that “point” (point, area, segment, dermatome, myotome, etc.). The above examples leave us with the picture of a reactive area rather than that of a point (Bäcker et al. 2007).

The great increase in numbers of acupuncture loci through time and the fairly recent discoveries of the so-called micropoint systems such as the French ear acupuncture, Chinese sculp acupuncture, Yamamoto New Scalp Acupuncture, etc. seem to replace the classical concept of an acupuncture point by a concept of a dynamic reactive area that changes individually and under given conditions (Tao 2007).

Assessing efficacy anthropologically and medically will always remain a very complex issue, and although other authors have commented on the topic of diversity and complexity within acupuncture and I agree that the implementation of pragmatic trials would be a step forward (MacPherson 2005), it seems important to more clearly define effect categories of acupuncture therapy in order to elucidate why and how it works. Although physiological and psychological effects intermingle in a clinical acupuncture encounter, for the purpose of clarity, I will define and discuss each category separately.

²³ The numbers in the text refer to a chart that illustrates the described pathway. The pinyin names followed by U.B.xx are the Chinese and international names of acupuncture points.

4 Defining Effect Categories of Acupuncture Therapy

We may differentiate between specific and non-specific effects. Physiological needle effects are effects that derive primarily from the response of the organism to the somatosensory (mostly nociceptive) needle stimulus on the level of tissue and organ systems (nervous system, immune system, cardiovascular system).

Specific physiological needle effects can only be evoked by the needling of a clearly defined area of the body in a specific manner—that is, by stimulating local points, in localized painful conditions or specific points remote to the affected region. At present, “point-specific” effects have only been confirmed for a very limited number of points, such as PC 6 (*nei guan*), which has a proven antiemetic effect (Lee and Done 2004) and has been successfully used for the treatment of epicondylitis humeroradialis (Trinh et al. 2004).

Non-specific physiological needle effects are defined as effects that can be triggered by the stimulation of different areas of the body producing the same or comparable reactions. Acupuncture patients frequently report to be very relaxed following acupuncture. A “post-stimulative” decrease of sympathetic nerve activity might be an explanation for this (Andersson and Lundeberg 1995).²⁴ Other studies show that repeated stimulation leads to a change in the reaction of the organism, which may be due to an adaptation to the stimulus (Bäcker et al. 2004). The intensity of stimulation that is strength of needle manipulation, number and thickness of the needles, frequency, and duration of the treatments used is substantial for adaptive processes (Schandry 1998: 60–70). The stimulation intensity may also play a role in acupuncture-induced, non-specific, physiological effects. Related psychophysiological studies in this area are required.

Psychological effects are defined as the effects that arise from the interaction between physician and patient and the psychological processing of the therapy situation by the patient. Specific effects in this category are effects that result from the specific nature of the acupuncture treatment. Hsu in an article that highlights the therapeutic effectiveness of the perception of *de qi*²⁵ during the clinical encounter argues, for example, that acute pain infliction is central to the therapeutic process in acupuncture and suggests that “an acute pain event can cause a bodily felt, immediate social connectedness between patient and healer, which might be therapeutic” (Hsu 2005: 78). Hsu speaks to a social anthropological audience when arguing that acute pain infliction makes real the feeling of social cohesion. In the medical context, *de qi* and effects like the physician-to-patient interaction would be defined as non-specific or placebo effects in pharmacological trials. But in the context of an acupuncture treatment, they become specific. The significance of the interaction between physician and patient in an acupuncture encounter is already emphasized in the earliest classic of Chinese medicine, the *Huangdi Neijing*:

²⁴ From a psychophysiological point of view, the needle stimulus is a stressor for the patient, owing to its usually painful character. This evokes a distinct increase of sympathetic nerve activity during needling and a sympathetic withdrawal after the needling as has been shown by Ernst and Lee (1986) and Bäcker et al. (2002).

²⁵ *De qi* literally translated means receiving *qi*. It is a distending sensation or a sensation of numbness or flow of “energy” that is felt by the patient upon insertion and manipulation of the needle.

Huangdi said: “I should like to know the Tao of acupuncture.” Qibo replied: “The most important thing is that you must concentrate your mind (shen). Only if you are clear about the state of (the patients) five viscera (wu zang) and the nine pulse observations (jiu hou) (at the three regions), can you start to think how to perform acupuncture.(...) When performing acupuncture the movement of the hand must be concentrated and harmonious, manipulating the needle in an even way, quietly and attentively observing the changes (in the patient) when the qi arrives after the insertion of the needle. One can not see the qi arriving. It is smooth like the chirp of a bird and fast as birds flying by- only too easily can one miss the fleeting moment. When applying needles and the qi hasn’t arrived, hold the needle and wait like the crossbowman for the right moment to pull his trigger. When the qi arrives don’t hesitate a second.(...) Performing acupuncture is like treading the edge of a precipice; your hands should be firm and strong—as if grasping a tiger—and the mind oblivious to all other things.”²⁶

This excerpt also illustrates the ritualistic character of acupuncture. Among many other factors, suggestive elements may play a role in this context. It may be that *de qi* under certain circumstances resembles a certain form of hypnotic induction predisposing patients to be more suggestible during the interaction with the therapist. Further studies will have to clarify this hypothesis.

Non-specific psychological effects are defined as effects that occur in all clinical encounters in a similar way. Here, general factors such as care and empathy on the part of the therapist as well as the expectation of the patient play a role. In two independently conducted trials evaluating acupuncture as an adjunctive therapy for dental surgery, the analgesic effect of acupuncture following surgery was compared with the analgesic effects based on the expectation of benefit. Participants in both experiments who believed they received real acupuncture reported significantly less pain than patients who believed that they received a placebo, although no statistically significant analgesic effect was observed between the acupuncture and placebo groups. The authors concluded that patients’ beliefs regarding the receipt of acupuncture bore a stronger relationship to pain than any specific action possessed by acupuncture (Bausell et al. 2005). Non-specific therapy effects also occur without intervention. The spontaneous healing process of an illness or, in studies, the statistical regression to the mean are considered natural effects that fall into this category.

5 Conclusion

The classical design of the sham controlled acupuncture trial needs to be revised, firstly, because the two main assumptions at the basis of the sham acupuncture concept are flawed: “non-acupuncture” points cannot be clearly defined and insertion of needles at “non-acupuncture” points does produce significant effects. Secondly, the supposition that the insertion of the needle alone is the only

²⁶ Translated from *Huangdi Neijing Suwen jiaoyi* (1982: 352–355).

characteristic treatment element in acupuncture cannot be held true. Apart from the diagnostic process and the ritualistic character of an acupuncture session, this complex intervention involves many non-divisible incidental elements that produce specific and non-specific effects. Ignoring these elements will greatly underestimate the total treatment effect.

If the therapeutic effect of acupuncture concerning certain indications cannot be explained by “point-specific” effects, this does not render acupuncture theory useless. Nor does it justify the conclusion that it does not matter where to insert the needle. Although the significance of point-exact needling of acupuncture points is only secured for a very limited number of indications, future studies will have to show in which indications the locus of needling is more important than the mode of needling.

Acupuncture has a very high experiential validity. Like in any other complex intervention that involves human interaction, many factors mediate its therapeutic effect. Cultural and social as well as physiological and psychological factors all play an important role and need further investigation. In order to adequately evaluate acupuncture’s effectiveness, future clinical studies will have to tailor their methodology to the reality of the acupuncture encounter.

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