

## Testing the claims of traditionally based acupuncture

S. Birch

APT Foundation/Yale University School of Medicine, New Haven, CT, USA

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**SUMMARY.** The author discusses the historical nature of acupuncture, examining issues that emerge in the investigation of traditionally based systems of practice. He proposes a three-step process for investigating such systems. The first step involves defining traditionally based systems and determining what constitutes sufficient evidence to satisfy such a definition. The second step identifies claims made by traditionally based systems that are characteristic of specific systems or all such systems. The third step explores implications for clinical trial and basic science investigations of acupuncture with examples of theoretical and methodological issues for both clinical trial and basic science studies. Many investigating acupuncture's clinical efficacy propound the use of research methods and models that, while useful to test some aspects of acupuncture, are often incapable of examining the very issues they set out to test. Few of the basic science investigations of acupuncture have focused on testing the nature of traditionally based systems of practice. Those that have focused on these systems usually lack the logical bridge between the research techniques they use and the models they test, without which it is difficult to clearly link the results of their studies to the theories or mechanisms that they sought to explore. Suggestions are offered of how to address these issues.

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### OVERVIEW

Acupuncture has been practised for over 2000 years in China and probably in Vietnam, over 1450 years in Japan and Korea, arriving in Europe around 300 years ago and North America over 150 years ago,<sup>1,2</sup> recently spreading to most countries around the world.<sup>3,4</sup> The earliest texts on acupuncture, the *Huang Di Nei Jing* (circa 200 BC)<sup>5,6</sup> and the *Nan Jing* (circa 100 AD),<sup>7</sup> are revered as primary sources, with numerous commentaries, and are still studied by many acupuncturists. Frequently the authenticity of a treatment approach is claimed by citing appropriate passages from these and later texts.<sup>8-13</sup>

However, differences within<sup>14</sup> and between<sup>15</sup> these texts, and the sociopolitical and cultural variations in countries where acupuncture has been practised, have fostered a wide variety of conceptual models and methods of practice.<sup>1,2</sup> The term 'acupuncture' can be misleading, as it is understood by many to imply a coherent and uniform model of practice. Not only is there historical and modern evidence of a wide range of treatment techniques<sup>16</sup> and diagnostic assessment methods,<sup>1,15-16</sup> but the conceptual frameworks underpinning acupuncture practice also show considerable

variety, in both traditionally based and modern frameworks. There were many historical systems of acupuncture,<sup>1,2,5,7,11,17</sup> and today there are many traditionally based systems, such as traditional Chinese medical (TCM) acupuncture,<sup>3,9,10</sup> traditional or five-element acupuncture,<sup>8</sup> pre-TCM acupuncture,<sup>13,18</sup> meridian therapy,<sup>12</sup> or yin-yang channel balancing therapy.<sup>19</sup> If traditionally based systems of acupuncture (TBSAs) are to be appropriately investigated, this diversity needs further exploration so that the terrain can be carefully mapped, and appropriate questions asked and investigated. The author proposes a three-step process for investigating the claims of TBSAs.

The first step involves defining what constitutes a genuine TBSA, so that specific systems can be examined to see if they are indeed TBSAs, or what might be further required to validate them as TBSAs. The second step involves examining claims made by TBSAs, both those specific to a particular TBSA, and those common to TBSAs in general. The third step involves exploring research designs in relation to testing TBSA-related claims. For example, what study designs are needed to be able to test efficacy-related TBSA claims in clinical trials of acupuncture? What study designs may be needed to test mechanism (explanatory model)-related TBSA claims? What intermediate steps may be necessary to be able to conduct such studies and relate results back to those claims?

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Stephen Birch, APT Foundation/Yale University School of Medicine, CRU, 914 1/2 Howard Avenue, New Haven, CT 06519, USA.

## PROPOSALS

### Step one: what constitutes a genuine TBSA?

What are the defining characteristics of a TBSA? The first and most obvious characteristic is that each system utilizes the language and concepts derived from the historical texts of acupuncture. Terms and concepts such as 'yin-yang', 'jing-luo', 'zang-fu', and 'qi' are used by each system, but in different patterns, to describe both normal and abnormal physiology, treatment principles and targets.<sup>1,3,8-13,17-19</sup> The following two examples briefly illustrate that diversity. The system of 'zhong yi', Chinese medicine, that includes TCM acupuncture<sup>1,5,20</sup> primarily focuses on the zang-fu (organ) functions utilizing yin-yang theory to structure an analysis of patients.<sup>1,21</sup> On the other hand, the system of 'keiraku chiryo', Japanese meridian therapy, focuses instead on the jing-luo (meridians/channels), utilizing five-phase and yin-yang theories to structure an analysis of patients.<sup>1,12</sup>

However, there are some systems of acupuncture that use these traditional terms and concepts within systems of practice that are recently developed and have no historical precedents, such as the Korean hand acupuncture system developed by Tae Woo Yoo.<sup>22</sup> We would not classify such a system as 'traditionally based', as it has no historical precedent. Therefore, a second defining characteristic must be that there be documentable historical precedents for each TBSA. This in turn leads to the requirement that a TBSA have adequate citation of its historical precedents as justification for its claim to be a TBSA. It is beyond the scope of this paper to discuss what would be necessary to substantiate such requirements; suffice to say that utilization of appropriate translation methods (discussed by Wiseman<sup>23</sup>), and/or translated sources, with adequate source referencing would be prerequisite.<sup>24</sup> Given the diversity of techniques that can be found in modern versions of TBSAs,<sup>16</sup> it does not seem appropriate to limit the techniques employed within a TBSA to those only based on historical descriptions, as this would eliminate many TBSAs that have incorporated modern techniques such as electrical stimulation.<sup>3,18,19</sup> Rather, it seems to this author that the principal emphases in a TBSA are the employment of documented historically based explanatory models.

### Step two: defining specific and general TBSA-related claims

After establishing what would qualify as a TBSA, the next step explores specific TBSA-related claims, both those tied to a particular TBSA and those common across TBSAs. For example, the zhong yi system claims that obtaining 'de qi' (specific sensations such as soreness, numbness, heaviness, distension,<sup>3</sup> felt at or radiating out from the site of needle insertion) is

required when needling if the treatment is to be effective.<sup>3</sup> However, the same patient evaluated by a 'keiraku chiryo' practitioner would be needled with shallower techniques, explicitly with no sensations, especially the so-called de qi-type sensations.<sup>1,12</sup> While many researching acupuncture believe that the de qi sensations must be obtained if the treatment is to be effective, this claim is specific to a particular TBSA and not common across all TBSAs.

Practitioners also claim that if their TBSA is followed, better clinical results would be found than if it were not followed.<sup>8,10,25-28</sup> Specifically, utilization of the theories and diagnostic assessments of the TBSA to individualize treatment is seen as the key to the greater success of that system,<sup>25-28</sup> especially as compared with standardized (formulary) treatments,<sup>25-27</sup> and compared with other TBSAs.<sup>28</sup> It is important to note that since too few controlled studies have been conducted that utilized TBSA-related methods of individualizing treatment, there is insufficient evidence to support the claim that acupuncture applied in an individualized manner according to a TBSA approach performs better than when not individualized. Such a claim begs the question. Rather, this appears to be a fundamental claim common to TBSAs regardless of the details of each approach: variation in the selection of points (location of stimulation) and treatment techniques maximizes treatment efficacy. Requirements for testing this fundamental TBSA-related claim are discussed below.

There are also many conceptually based claims about TBSAs. For example, a basic claim common to most TBSA approaches is that there is a system of channels (jing-luo) on which the primary acupuncture points are located, and which serves the function of nurturing and regulating the body through its role in distributing qi.<sup>1,3,8,13,17,19,21</sup> While there are multiple interpretations of how to use this system of channels,<sup>1,12,19,21</sup> a basic claim is that they do exist. This is therefore an important claim that needs to be tested. As an example of issues in the basic science investigations of acupuncture, conceptual and methodological problems important in testing this TBSA-related claim are discussed below.

### Step three: implications in clinical trial and basic science investigations of TBSAs

#### *Clinical trial implications*

Since a claim common to TBSAs is that individualized variation of treatments is essential to a more successful outcome, clinical trials of TBSAs will need to incorporate design features that allow this basic TBSA claim to be tested.

The majority of controlled clinical trials of acupuncture have used what is often termed 'formulary' acupuncture treatments, meaning that the same treatments were administered to all patients based on

their symptoms, rather than varied treatments based on a TBSA approach. To date, only a few controlled studies have utilized a TBSA treatment approach,<sup>30,31</sup> such as the back and neck pain studies of Coan et al.<sup>25,32</sup> and the asthma study by Jobst et al.<sup>33</sup> Of the few studies that utilized a TBSA treatment, only one, as far as can be determined, described what treatments were administered.<sup>34</sup> Other studies neither described what treatments were administered, nor referenced sufficient sources to determine what treatments were given.<sup>25,32,33</sup> The paucity of such studies and the frequent lack of clear description of what was done, makes it difficult, if not impossible, to draw conclusions about the efficacy of individualized TBSA treatments.<sup>35</sup>

An additional issue that compounds this problem is that the individualization of treatments in these studies had no demonstrated reliability, as no inter-rater reliability data were offered, and virtually none exist.<sup>30,31</sup> It is not only important that we have clear documented descriptions about what treatments were administered, but, since the treatments are tailored according to individual characteristics to match TBSA-related diagnoses (for example 'kidney yin vacuity'<sup>21</sup> or 'liver vacuity',<sup>12</sup> we also need to establish that this process of individualizing treatments broadly matches the system it claims to follow. Establishing that there is general agreement in patient assessments and the individualization of treatments through demonstration of the inter-rater reliability of those decision-making processes is an important step for these TBSA-related clinical trials. Future trials of TBSA treatments will need to more explicitly describe the diagnostic and treatment methods used,<sup>35</sup> and demonstrate the inter-rater reliability of the decision-making processes,<sup>31</sup> otherwise it is not possible to determine if a TBSA treatment is being tested.

Besides these issues, the role of point location and selection also needs to be addressed. A number of researchers writing about study design for TBSA approaches promote research models that are incapable of testing the role of point location and selection. Coan et al.<sup>25</sup> argue for the use of a model comparing acupuncture to a waiting list control (delayed acupuncture treatment) group. Another proposed model is to compare the TBSA treatment to standard treatment such as medication, physical therapy, TENS, etc.<sup>26,36,37</sup> The first model tests whether acupuncture is better than no treatment at all; the second tests how well acupuncture performs relative to standard treatments, but neither model can test the role of point location, thereby not testing the basic claim of TBSA approaches. As Ter Riet and colleagues put it,<sup>38</sup> if the specificity of acupuncture points cannot be demonstrated by controlling for the relevant non-specific effects, TBSA-related practices could become largely irrelevant. To be able to demonstrate the specificity of needling certain points (set or varied), it will be necessary to control for a range of non-specific treatment effects including psychological

and mechanical stimulation effects.<sup>39</sup> This could take the form of comparing systems of acupuncture with each other, a model used in almost no studies to date. It could also take the form of control needling such as so-called 'sham', 'minimal' or 'shallow needling', each of which could be an active treatment.<sup>29</sup> The design model chosen will need to address various non-specific treatment effects if it is to be truly capable of testing the role of point location in treatment. The author has explored issues in the design of such studies elsewhere.<sup>29,35,39</sup>

#### *Basic science implications*

While a number of different avenues of research have been pursued that have explored TBSA-related concepts,<sup>40</sup> the underlying conceptual issues can be exposed by focusing on the commonly encountered use of electrodermal measurement methods.

Many authors understand the 'circulation of qi' model of acupuncture to imply the circulation of some kind of energy.<sup>13</sup> In recent decades, this has led researchers to use electrodermal measurement technologies to attempt measurement of correlates of the model<sup>41</sup> or to attempt direct measurement of the circulation.<sup>42</sup> The correlation of the concept 'qi' with 'energy' (e.g. electrical energy), may not be unreasonable as it seems to provide a useful conceptual bridge,<sup>1</sup> nevertheless, it is based on a common but faulty translation of the term 'qi' as 'energy'.<sup>1,20,23</sup> This commonly encountered association-translation of 'qi' as energy naturally predisposes many researchers to attempt measurement with, for example, electrodermal technologies, without discussion of whether or not it is appropriate if qi is (electrical) energy, the pathways through which this energy flows (the channels) and the sites at which it is accessed (acupoints) may show electrical characteristics such as lower skin resistance. The finding of lower skin resistance in the proximity of channels and acupoints is thus taken as scientific proof of the existence of the channels and acupoints. Variations in electrical measurements at acupoints are further associated with problems (pathology) of the channels and are thus thought to constitute a diagnosis.<sup>41,43</sup> Treatment that corrects the variations in electrodermal measurements is also taken as indicating that the channel problems have been corrected. However, this logic is circular, ultimately deriving from the 'qi = energy' association-translation.<sup>1</sup> There is no way of knowing if the application of this measurement technology has actually measured TBSA concepts such as the channels, their points and the circulation of qi. Conceptually there are two basic problems that need to be addressed.

First, without a clearly developed model of the TBSA concepts and a translation of them into a framework from which testable hypotheses can be derived, it is logically very difficult, if not impossible, to relate measurements made with electrodermal

technologies back to those TBSA concepts.<sup>44</sup> Second, the appropriateness and the relevance of the measurement technologies need to be validated. In this case, there have been considerable problems with the appropriateness of the electrodermal measurement techniques used, making interpretation of results unclear, if not impossible.<sup>44-46</sup>

After carefully developing a supportable model of the TBSA and its concepts, the first problem requires the 'translation' of that model and its components into a format from which testable hypotheses can be derived. For example, how can we test the hypothesis that there is a 'vacuity of qi' in a particular channel with electrical measurements when we have no way of relating this 'qi' and 'qi vacuity' to electrical concepts? Electrodermal measurement techniques can test hypotheses stated in electrical terms, so when testing TBSA concepts or models, these concepts or models need first to be translated into electrical terms.<sup>47</sup> One approach that the author has worked on involves the development of mathematical translations of TBSA concepts and models as a bridge between the concepts and measurement technologies.<sup>44,47-49</sup> Modifying electrical circuit models of electrodermal measurements by incorporating the mathematical reformulations of TBSA concepts and models can potentially allow testing of specific TBSA-related hypotheses.<sup>44,47</sup>

The second problem, that of using validated measurement techniques, has two areas of major focus. First, it is essential that electrodermal measurement techniques be developed that avoid introducing measurement artifacts which can render the measurements uninterpretable. While such technologies have been developed, they are rarely used in such research.<sup>44-46</sup> Second, once such techniques have been developed, they will need to be validated by demonstrating that they can be used to measure potential electrodermal changes associated with TBSAs, i.e. that they are sensitive to the questions at hand; this is a non-trivial problem requiring significant research efforts.<sup>44</sup>

With the development of more precise testable hypotheses from TBSA models and the development of technologies that make cleaner measurements, it may be possible to start testing some of the conceptual and physical components important in TBSA claims, such as channel pathways, acupoint locations and more complex concepts such as qi vacuity or qi repletion. While much research has been done in the area of electrodermal measurements and acupuncture, it has not followed the above logical process. However, it has generated a lot of important data<sup>41-43</sup> that indicate useful directions for future research.

## CONCLUSION

While significant progress has been made in the general study of acupuncture, little headway has been made yet in the study of traditionally based systems

of acupuncture, both in clinical trial research and basic science research. This paper has identified some key problems that will need to be addressed and outlined several strategies for investigating them.

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