An evidence-based approach to acupuncture

Edzard Ernst

Summary
Evidence-based medicine relies mainly on the findings from clinical trials, and to minimise selection bias such trials should ideally be randomised. As the results of clinical studies are rarely identical, the fairest judgement on the effectiveness of a therapeutic intervention is generated through systematic review of clinical trials. Systematic reviews have to demonstrate that all the available evidence that fulfils appropriate criteria has been considered. Once systematic reviews have established the current evidence on a given subject, this knowledge needs to be implemented in clinical practice.

In a nutshell, these are the principles of evidence-based medicine (EBM) (1). For evaluating treatment modalities, EBM does not rely on criteria such as plausibility of mechanisms of action nor is it dominated by the opinions or experiences of experts in a given field of therapeutics. EBM relies mainly on the results of rigorous clinical investigation and analysis. This is perhaps best illustrated through the hierarchy of evidence which can be viewed as the backbone of EBM (Figure 1).

Applying the rules of evidence-based medicine to acupuncture proves it to be effective for some conditions and ineffective for others, while its effects on many medical problems remain inconclusive: this indicates areas that require further research. Evidence based medicine should not be regarded as a threat to acupuncture, but as a challenge and an opportunity Importantly, this approach is strongly in the interests of patients.

Key words
Acupuncture, Clinical trials, Cochrane collaboration, Evidence based medicine, Systematic reviews.

Introduction
Acupuncture has stood the test of time and therefore does not require testing through scientific methods. This belief is as widespread as it is wrong. Today it is generally considered essential that all therapeutic interventions are tested rigorously to determine their efficacy, regardless of whether they are mainstream or alternative, modern or traditional. In the course of this exercise, many insufficiently tested mainstream treatments are now being evaluated. Only if a positive conclusion is reached, should a given mainstream therapy continue to be a part of routine healthcare. Those treatments which are as yet outside routine care, such as acupuncture, also require proper evaluation. Only if this process comes to a positive conclusion, can acupuncture be seriously considered for integration into routine care.

Evidence based medicine
In a nutshell, these are the principles of evidence-based medicine (EBM) (1). For evaluating treatment modalities, EBM does not rely on criteria such as plausibility of mechanisms of action nor is it dominated by the opinions or experiences of experts in a given field of therapeutics. EBM relies mainly on the results of rigorous clinical investigation and analysis. This is perhaps best illustrated through the hierarchy of evidence which can be viewed as the backbone of EBM (Figure 1).

Figure 1. The hierarchy of evidence.

According to this hierarchy, the base of all clinical knowledge and research is represented by clinical observations (case studies, observational data, etc.). It is important to note that experience and traditions are therefore not devalued by EBM. On the contrary, they are the basis for everything that follows: they lead to the formulation of a hypothesis (e.g. acupuncture is effective in the treatment of pain). However, observations of this nature are never sufficient to test, prove or disprove a hypothesis. The history of medicine abounds with examples where, on the basis of uncontrolled data, a treatment was deemed efficacious only to be found later to be of no specific value at all. For testing hypotheses we need controlled experiments, preferably randomised
clinical trials. Only with controlled trials can we hope to determine whether an observed outcome was actually due to the specific effects of our intervention rather than, for instance, spontaneous recovery (that is, the natural history of the disease) or non-specific (placebo) effects. And only with randomised trials can we be reasonably sure of comparing groups of patients that are in all respects comparable; one might account for all known prognostic factors through stratification (a technique which separates a sample into subsamples according to specified criteria), but only through randomisation can we hope to distribute all variables, even those which are unknown at present, evenly between the experimental and control groups.

Thus the randomised trial is the best available method to assess the efficacy of therapeutic interventions. This is true for conventional therapies as much as it is true for acupuncture (2). It does not, however, mean that the randomised trial is without flaws and problems: it does indeed have many pitfalls, but at present there is no better method for exclusion of bias in efficacy studies.

Even if the methodology of a randomised trial were flawless, we would be ill advised to rely on a single study; it is always necessary to insist on independent validation to be sure, More often than not, the repetition of a study will yield a slightly different result. This can be for a variety of reasons, for instance: slightly different types of patient or medical problem, or a slight variation in the treatment (e.g. a different form of acupuncture). Eventually we might end up with several randomised trials, some of them showing that a treatment is effective and others that it is ineffective. In such a situation it is all too human to select the evidence which fits one’s own belief. A proponent of acupuncture, for instance, could publish a review which focuses on the positive evidence. Likewise, an opponent could write a paper entirely based on the negative evidence. On the surface, both reviews would seem to be evidence-based, yet, neither is providing the full story. It seems obvious that it is in the interest of future patients to determine the whole truth.

Systematic reviews
This simple (and necessarily somewhat simplistic) example makes it clear that only systematic reviews can hope to create a fair picture. Such reviews have demonstrably to include the totality of evidence on a given subject, while fitting certain predefined inclusion and exclusion criteria. In this way, systematic reviews minimise selection bias and random error. To put it in the simplest terms, systematic reviews aim to analyse all available data on a given subject objectively and transparently so that two independent groups of authors would arrive at the same reproducible conclusions. The Cochrane Collaboration is an international organisation dedicated to producing and updating the clinical evidence in all fields of medicine. A Cochrane Field devoted to complementary medicine has been established recently (3).

Again few people would say that the methodology of systematic reviews is a flawless approach in determining the truth. In fact it has numerous problems and has been rightly criticised by several authors (4). Most experts nevertheless agree that it is the best available method of producing fair judgements about the efficacy of therapies. It is important to note that “truth” in medicine is never absolute and usually changes over time. Thus systematic reviews require updating as new evidence emerges, a task to which the Cochrane Collaboration is fully committed.

A sizeable number of systematic reviews of acupuncture have been published (Table 1). According to this evidence, there are now four well documented indications for acupuncture, two where acupuncture seems to be no more effective than control interventions, and a relatively large list of indications where randomised trials are available, but the systematic review of their data is inconclusive. The reasons for being inconclusive vary. In the case of stroke, for instance, most studies are positive yet the average methodological quality of these trials is so poor that no firm conclusions are permissible (5). In the case of osteoarthritis, on the other hand, some rigorous trials imply efficacy of acupuncture while other, equally rigorous studies, suggest the opposite. Again, no firm conclusion is possible (6).

Table 1

<table>
<thead>
<tr>
<th>Conclusively positive</th>
<th>Inconclusive</th>
<th>Conclusively negative</th>
</tr>
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<tbody>
<tr>
<td>Dental pain</td>
<td>Addictions</td>
<td>Smoking cessation</td>
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<tr>
<td>Low back pain</td>
<td>Asthma</td>
<td>Weight loss</td>
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<td>Migraine</td>
<td>Experimental pain</td>
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<td>Nausea and vomiting</td>
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<td>Tinnitus</td>
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For an overview of the evidence with full references see (10)
Implementation of evidence

One important part of EBM is the implementation of evidence from sound systematic reviews into routine care. This is a complex task because decisions must rely also on factors like cost, safety and relative efficacy. The costs of acupuncture are dominated by the expense of therapists' time. At present no reliable cost comparisons with other treatment options exist (7). Regarding the safety issue, a recent systematic review (8) concluded that acupuncture is not risk-free, but that serious complications are probably true rarities. The question of relative efficacy (that is, efficacy in relation to other treatment options) is complex. One systematic review has recently demonstrated an embarrassing lack of randomised clinical trials addressing the issue (9). Following these lines of thought, it would seem that potentially fruitful topics for further study are the cost-effectiveness and comparative effectiveness, particularly of the four indications which are backed up by positive systematic reviews (Table 1). These are not subjects of merely academic interest: they are relevant for our everyday practice, and their study is clearly in the interest of the patient.

Conclusion

The methods of EBM can and should be applied to acupuncture. If this is done properly, areas will be identified for which the evidence is compelling and where (applying the logic and standards of EBM) acupuncture should be considered for integration into routine healthcare. We will also identify areas where more and better studies are needed to determine the (comparative) efficacy and cost of acupuncture. EBM is no threat to acupuncture, on the contrary, it provides opportunity and challenge. Most importantly, perhaps, evidence based medicine serves the interests of patients.

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