British Acupuncture Council

EVALUATING ACUPUNCTURE. WHAT WORKS FOR THE PATIENT?

1 INTRODUCTION

There have been hundreds of acupuncture RCTs in the last 20 years,[1] across the whole efficacy-effectiveness spectrum.

In Western countries the pressure through funders and ethics committees has been for explanatory trials, even though, as with physical or psychological therapies, placebo controls are problematic. Arguments over interpretation of acupuncture RCT results have stimulated serious scientific contributions[2,3,4,5,6] but there is a robust evidence base for chronic pain[7] and a rapidly advancing one in many other areas.

2 WHAT IS ACUPUNCTURE?

Acupuncture is a complex intervention.

We struggle to define the active ingredients and their interrelationships[8]. Numerous wide-ranging physiological effects have been demonstrated in the experimental literature[9]. Isolating components and treating them as the sole active agent is misconceived and may lead to biased effect estimates.

Consensus methods have been used to identify components seen as specific to acupuncture, i.e. 'theoretically derived, unique to a specific treatment and believed to be causally related to outcome'[10]. MacPherson and Schroer[11] derived a list of 16, from making a traditional acupuncture diagnosis to selecting points and inserting needles; from discussing the patient's condition, diagnosis and treatment to giving them lifestyle support. These components are implemented in ways specific to acupuncture theory and to the individual acupuncture diagnosis.

We know little about their relative importance but can expect them to be synergistic and interdependent, not easily addressed by linear methods[12].

3 WHAT IS SHAM ACUPUNCTURE? WHAT QUESTIONS CAN IT ANSWER?

- Sham acupuncture comes in various guises: needle and non-needle (e.g. deactivated TENS), penetrating or not, superficial or deep insertion, true or false points on the body.
- It answers questions such as: is point X better than point Y? Is deep insertion better than shallow, or no insertion? These questions are useful for acupuncturists and researchers but not for patients and service providers.
- It cannot tell you how effective acupuncture is, only how effective one component is. It works for efficacy but not effectiveness trials.
- Worse still, acupuncture shams are physiologically active, thus biasing estimates of specific and non-specific effects[6,13].
- Comparisons of two active treatments, one a milder version (sham acupuncture) of the other, can be conceptualised as dosing trials, or comparisons of different styles. Note that superficial, even non-insertional, needling is normal practice for some acupuncturists[6].

4 EFFECT SIZE AND CLINICAL SIGNIFICANCE

The best estimates come from an individual patient data meta-analysis for chronic pain:[7]

Acupuncture vs sham

0.15-0.23 SD

Acup vs no acup/std care

0.42-0.57 SD

We believe that clinical significance should be based on overall benefit, not derived from sham comparisons. As well as the technical shortcomings already discussed, the latter has limited relevance to real-world decision making for patients, clinicians, funders or policy makers.

5 CASE STUDY: OSTEOARTHRITIS

A handful of network meta-analyses mention acupuncture – to favourable effect.[14]

For OA knee pain 114 trials provided data on 22 physical treatments. Acupuncture was statistically better than exercise and clinically better than most other guideline endorsed treatments. Even sham acupuncture ranked above most other interventions.

The recent NICE guideline update[15] told a different story. Sham comparison effect sizes were used for acupuncture, which inevitably fell short of the 0.5 SD target for clinical significance. Most other interventions managed to avoid this hurdle and were endorsed. Paradoxically, acupuncture was found to be cost-effective.

6 RESEARCH FOR THE REAL WORLD: RESEARCH FOR PATIENTS

In 2015 we look beyond the deadlocked sham/placebo debate to a new era in EBM, to:

- mosaics rather than hierarchies of evidence
- 'real' EBM, with individual patient care at its heart[16]
- P4 medicine – predictive, preventive, personalised, participatory[17]
- more research questions set by patients and clinicians, shifting the emphasis from drugs and surgery to a wider range of healthcare options[18]
- methods that can produce generalisable data, able to guide clinical care. Comparative effectiveness research (CER) explicitly aims to inform real-world healthcare decisions[19,20]
- more use of patient-centred outcomes[21]
- complex systems science for characterising and evaluating complex interventions[12]
- 'omics techniques for identifying diagnostic subgroups and improving outcomes; in future, facilitating preventive healthcare[17].

Acupuncture fits well for all of these aims:

- it operates with personalised diagnosis and treatment
- it addresses root problems as well as symptoms and hence can work preventively
- it has a fundamental patient participatory element
- CER thinking is already well established for acupuncture, though comparisons with other interventions are scarce outside of China. An effectiveness guidance document for future acupuncture CER has been developed[19]
- its systems-based concepts align well with 'omics; there are already extensive programmes in East Asia and the EC. Studies in several diseases have shown biological mechanisms to be correlated with Chinese medicine diagnostic patterns[17].

7 CONCLUSIONS

After more than 20 years of EBM patients and clinicians still have insufficient information to guide many of their healthcare decisions, for acupuncture as much as conventional medicine.

This is unlikely to change soon. We believe that complex systems approaches are needed to better characterise an intervention such as acupuncture and to determine how best to use it in relation to other available interventions. In the meantime, pragmatic trials can provide the gold standard evidence.

FURTHER INFORMATION

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