Do single subject research designs hold any promise for acupuncture?

Adrian White

There is little doubt that some forms of acupuncture treatment are effective, at least for some patients. But we know little about the best treatment to offer, and who is likely to respond best. This information would be really useful both in guiding practitioners in their everyday decisions about which treatments to offer which patients, and in guiding the design of randomised controlled trials (RCTs) so they have the best chance of finding any real effects that exist. But how can we get this information?

One method of rigorous research, increasingly used in behavioural and rehabilitation medicine, is the single subject research designs (SSRD). Enblom and colleagues used a modified form of this design in the linked paper, so it is opportune to consider whether this holds any promise for acupuncture.

The essence of SSRD is to make careful, repeated assessments of a single patient over time in a planned way while you introduce treatment. This is the basic AB design (A, baseline; B, treatment). Each patient acts as his or her own control. Though similar to a case report, an SSRD has to be distinguished because it is prospective; it emphasises thorough documentation; measurements are repeated, including during the baseline period; and the treatment is controlled and carefully recorded. In some ways, an SSRD is just one step up from careful, organised clinical practice.

The SSRD can be used in a similar way for many patients, (though, formally, they have to be regarded as individuals, not a group). The results are best shown as a line chart (figure 1) and analysed simply by inspection.

But SSRDs are rather despised in the research world. The AB design is essentially anecdotal and sits low on the hierarchy of evidence of effectiveness: any improvement may be due to ‘non-specific effects’—which, incidentally, could be exactly what modifies the response to acupuncture. Also, the results of SSRDs are not generalisable in the same way as results of an RCT: an RCT might conclude that there is a mean 56% reduction in pain, so a service should be provided (though this information is little help in deciding whether to use acupuncture for the next patient or not).

The great strengths of SSRDs are that they require few resources; they make the most of clinical experience and observation in real clinical practice; and they maximise the information available from a minimum number of patients. They do not require patients or treatments that are exactly similar, in fact they exploit the differences which might lead to different outcomes. They do, however, need care and attention in setting up if they are to be worthwhile.

Variations on the SSRD idea should be mentioned for the sake of completeness—in particular, those that introduce an element of randomisation can greatly increase a study’s validity.

The first variation is the well-known ABABA design (also called ‘withdrawal’, n-of-1, or n=1). However, it only applies when the condition responds to treatment but recurs immediately on stopping, which is rarely the case with acupuncture.

The second is the ‘multiple baseline’ design used for conditions with spontaneous improvement, common in rehabilitation—for example, in patients attending with acute neck pain. Patients are randomised to different duration of baseline before starting acupuncture, so that the effect of acupuncture can be distinguished from the natural history of the condition.

The third variation compares two different forms of treatment, for example, using different frequency of stimulation, or treatment and placebo, (ABACA, or ABC as repeat of A is not strictly necessary) given in random order and with a suitable washout period. This may be appropriate when a condition requires continued treatment for a long period of time.

The main SSRD method that can be applied to acupuncture is the basic AB design. So what could be achieved with it? On a small scale, it offers the

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Figure 1 Conjectural line chart of symptom scores of four responders and two non-responders.
Commentary

opportunity for qualitative studies on the process of acupuncture that might throw light on the reasons for the particular response. On a larger scale, it offers the chance for collaboration between practitioners, in an organised way, to accumulate information on the response of patients with one or two specified conditions, generating hypotheses about who responds and to which treatments.5

The acupuncture community has the massive untapped resource of skilled, experienced and observant professionals who have repeated contact with thousands of patients. Collaborative SSRDs could provide the opportunity for individual practitioners to contribute (at last) to the great research endeavour of acupuncture. Members of a professional organisation could unite to deal efficiently with formalities such as writing protocols and obtaining ethics approval. Repeated, large studies using SSRD on a few conditions in different centres over a prolonged period of time for specific, defined purposes could be a profitable way to explore questions such as identifying responders and optimising treatments.

RCTs make the greatest waves and will remain the ‘ocean liners’ of the evidence base, but they simply cannot even set sail properly without the help of the small but powerful tugboats, tenders and pilots to set them off in the right direction. RCTs have taken research a long way away from everyday practice: SSRDs could offer the chance to bring research back to the bedside.

Competing interests None.
Provenance and peer review Not commissioned; not externally peer reviewed.
Accepted 16 March 2011

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*Acupunct Med* published online April 6, 2011

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