

Why recommend acupuncture for low back pain but not for osteoarthritis? A commentary on recent NICE guidelines

Mike Cummings

I attended a dinner in November 2005 with Sir Michael Rawlins (chairman of the National Institute for Health and Clinical Excellence (NICE)) organised by the King's Fund to explore some of the issues around the assessment of complementary interventions in the NHS. It was a valuable opportunity to gain an insight into policy making processes and principles, and I specifically remember Sir Michael's mantra: "Does it work? Is it safe? How much does it cost?" I realised that "Does it work?" referred to specific efficacy confirmed in systematic review of randomised controlled trials (RCTs), rather than pragmatic data on effectiveness in clinical practice. He indicated that there was a growing quantity of suitable evidence (systematic reviews) in the complementary medicine field, and when referring specifically to acupuncture I'm sure he said "We will probably buy acupuncture for back pain, but definitely not for migraine". At this point I spluttered on my glass of water, and was subsequently invited to comment. I briefly described the issues surrounding sham acupuncture,¹ "missing the point"² and the extraordinary effectiveness of these procedures in the prophylaxis of migraine.³ Sir Michael's response was simply to comment: "That is your (*viz* the acupuncture profession's) problem!"

Around the same time I had a detailed discussion of the research issues of acupuncture for headaches with one of the leading academics in field of migraine. He took a similar approach to the chairman of NICE, in that he would not consider the data on effectiveness or cost effectiveness until the question over specific efficacy ("Does it work?") was answered satisfactorily.

These interactions with leading academics who had (and still have) direct involvement in determining health policy through development of guidelines were frustrating at the time, but they focussed my thinking on the nature and priorities of evidence required to influence national policy. It was clear that the first thing to address was the question of specific efficacy through systematic review and meta-analysis of sham controlled trials of acupuncture, despite the problems in developing a truly inactive sham for acupuncture.

As a result of the early presentation of data from the Acupuncture Randomised Trials (ART—part of the *Modellvorhaben Akupunktur*)⁴ it seemed likely that the pooled data of acupuncture over sham in osteoarthritis of the knee (OA knee) was the most likely to become positive, since the ART study on OA knee was the only one of the four ART studies that showed a significant benefit of true (manual) over sham (minimal off-point) acupuncture (see fig 1). Adrian White agreed to lead the review of acupuncture for chronic knee pain.⁵ The group took advantage of the need to revise the submission to include newly published data from the largest RCT of acupuncture in OA knee.⁶ This was one the German Acupuncture (GERAC) trials, also part of the *Modellvorhaben Akupunktur*.⁴ This study found there was no significant difference between true (manual) and (minimal off-point) sham acupuncture, but a small trend in favour of true acupuncture. Adrian updated the meta-analysis and specifically noted that despite the latter trial being very large, and not showing a statistically significant difference between groups, it actually increased the strength of the positive conclusion in favour of acupuncture compared with sham.

At this stage I was feeling relatively confident that acupuncture might be incorporated into routine NHS practice as one possible intervention in treatment of chronic low back pain and chronic OA knee, since the systematic reviews in these areas demonstrated efficacy, and in April 2006 the German health authorities decided that acupuncture would be included into routine reimbursement by social health insurance funds for both these conditions.⁴ My confidence led to the initiation of a project to set up a high volume acupuncture clinic for treatment of chronic knee pain using electroacupuncture (EA) at the Royal London Homœopathic Hospital. The project was run by Saul Berkovitz, and the initial audit of the clinic was published in this journal in March 2008 issue.⁷ It is somewhat ironic that the NICE guideline on osteoarthritis issued in February 2008 included the recommendation⁸:

R15 Electro-acupuncture should not be used to treat people with osteoarthritis.*

* There is not enough consistent evidence of clinical or cost-effectiveness to allow a firm recommendation on the use of acupuncture for the treatment of osteoarthritis.

It seems clear from reading the full guideline and appendices that the negative recommendation for EA was based purely on health economic modelling from a secondary outcome (WOMAC) in a single RCT (n = 193). It is of passing interest but no consequence to note that the primary outcome of the same RCT demonstrated EA to be superior to diclofenac in treatment of pain related to OA knee. Non-steroidal anti-inflammatory drugs were recommended as adjuncts to core therapy in the guideline. Detailed discussions for and against the health economic modelling against placebo can be found in the debate article in the June 2009 issue of this journal.^{9 10}

In May 2009, a NICE guideline on low back pain was issued.¹¹ It included the following under key priorities for implementation:

Information, education and patient preferences

- ▶ Provide people with advice and information to promote self-management of their low back pain.
- ▶ Offer one of the following treatment options, taking into account patient preference: an exercise programme, a course of manual therapy or a course of acupuncture. Consider offering another of these options if the chosen treatment does not result in satisfactory improvement.

Invasive procedures

- ▶ Consider offering a course of acupuncture needling comprising up to a maximum of 10 sessions over a period of up to 12 weeks.
- ▶ Do not offer injections of therapeutic substances into the back for non-specific low back pain.

So we have a similar evidence base for each condition but directly opposing recommendations. We have systematic reviews in both chronic low back pain and OA knee that demonstrate specific efficacy of acupuncture over sham.^{5 12} Safety data from large prospective surveys consistently demonstrate that acupuncture performed by trained healthcare professionals is associated with minimal or negligible risk of serious adverse events (such as pneumothorax). Very large pragmatic studies (Acupuncture in Routine Care (ARC) studies),⁴ performed as part of

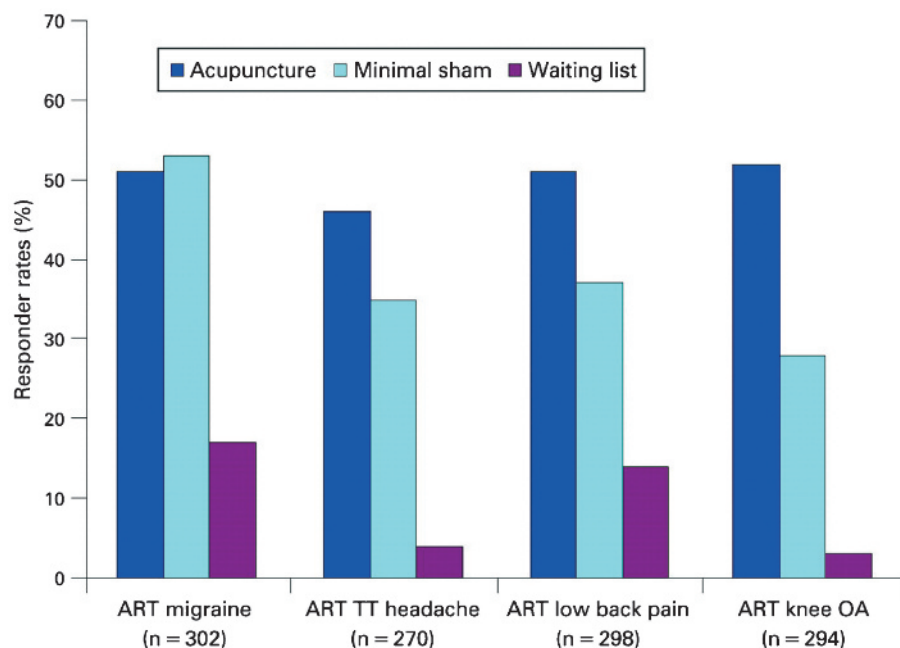


Figure 1 Responder rates in the Acupuncture Randomised Trials (ART) after eight weeks from baseline (9–12 weeks in ART migraine and tension-type (TT) headache); responder rates were defined (post hoc) as a 50% or greater reduction in the primary outcome measure. Acupuncture and minimal acupuncture were significantly superior to waiting list in all trials. Acupuncture was superior to minimal acupuncture only in ART knee osteoarthritis (OA). Reproduced from fig 1 of Cummings M. *Acupunct Med* 2009;27:26–30.

the *Modellvorhaben Akupunktur*, show that acupuncture is effective in practice for a range of chronic conditions, and it seems likely to have acceptable cost utility (at least at a rate of €35 per session) (see fig 2).

The reason that we have a difference in the recommendations is that the German health economic assessments were not considered acceptable to NICE—they took a societal perspective (ie, included costs related to return to work) rather than direct costs alone, and they were not based

in the NHS. One small pragmatic trial of acupuncture for chronic back pain in the UK included a health economic evaluation that demonstrated a favourable incremental cost effectiveness ratio, that is a cost per additional quality adjusted life year within the NICE threshold.¹³ This, in addition to the safety and efficacy data, resulted in the positive recommendation for acupuncture in the low back pain guideline. There is no equivalent study for osteoarthritis based in the UK, so the guideline team decided to

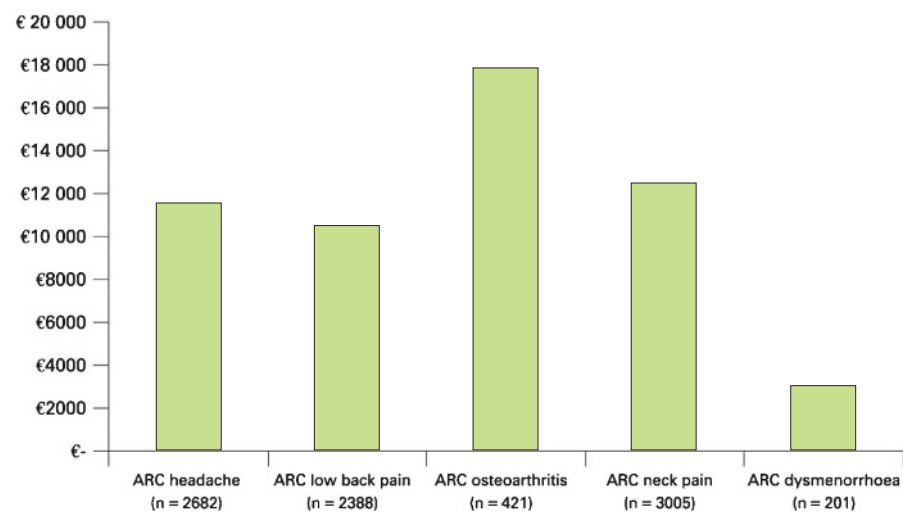


Figure 2 This figure illustrates the cost utility of acupuncture in various conditions, expressed as a cost per quality-adjusted life-year gained at three months from baseline, compared with usual care alone. The data are derived from within the Acupuncture in Routine Care (ARC) trials, and represent societal costs. Reproduced from fig 4 of Cummings M. *Acupunct Med* 2009;27:26–30.

perform health economic modelling on data from the larger sham controlled trials. The results suggested that the estimate for the cost of electroacupuncture within the NHS was clearly above the threshold (cost per quality adjusted life year gained between £20 000 and £30 000) and those for acupuncture spanned a large range both well below and well above the threshold. Thus the Guideline Development Group for osteoarthritis gave a negative recommendation regarding the use of EA and made no recommendation regarding acupuncture.

There are all manner of limitations to health economic modelling on data derived from explanatory trials. So it seems that the best way forward is to avoid having to perform such modelling at all. We need instead to carry out some pragmatic research in the UK to directly measure the costs and benefits of acupuncture and electroacupuncture aimed at treatment of pain and improvement of function in patients with osteoarthritis.

Mike Cummings

Correspondence to: Dr Mike Cummings, Medical Director, BMAS; BMASLondon@aol.com

Competing interests: None.

Provenance and peer review: Not commissioned; not externally peer reviewed.

Acupunct Med 2009;27:128–129.
doi:10.1136/aim.2009.001214

REFERENCES

- White AR, Filshie J, Cummings TM. Clinical trials of acupuncture: consensus recommendations for optimal treatment, sham controls and blinding. *Complement Ther Med* 2001;9:237–45.
- Cummings M. Commentary: Controls for acupuncture—can we finally see the light? *BMJ* 2001;322:1578.
- Linde K, Streng A, Jurgens S, et al. Acupuncture for patients with migraine: a randomized controlled trial. *JAMA* 2005;293:2118–25.
- Cummings M. Modellvorhaben Akupunktur—a summary of the ART, ARC and GERAC trials. *Acupunct Med* 2009;27:26–30.
- White A, Foster NE, Cummings M, et al. Acupuncture treatment for chronic knee pain: a systematic review. *Rheumatology (Oxford)* 2007;46:384–90.
- Scharf HP, Mansmann U, Streitberger K, et al. Acupuncture and knee osteoarthritis: a three-armed randomized trial. *Ann Intern Med* 2006;145:12–20.
- Berkovitz S, Cummings M, Perrin C, et al. High volume acupuncture clinic (HVAC) for chronic knee pain—audit of a possible model for delivery of acupuncture in the National Health Service. *Acupunct Med* 2008;26:46–50.
- NICE guideline on osteoarthritis: the care and management of osteoarthritis in adults. <http://guidance.nice.org.uk/CG59> (accessed 10 Jul 2009).
- Latimer N. NICE guideline on osteoarthritis: is it fair to acupuncture? Yes. *Acupunct Med* 2009;27:72–5.
- White A. NICE guideline on osteoarthritis: is it fair to acupuncture? No. *Acupunct Med* 2009;27:70–2.
- NICE guideline on low back pain: early management of persistent non-specific low back pain. <http://guidance.nice.org.uk/CG88> (accessed 10 Jul 2009).
- Furlan AD, van Tulder MW, Cherkin DC, et al. Acupuncture and dry-needling for low back pain. *Cochrane Database Syst Rev* 2005;(1):CD001351.
- Ratcliffe J, Thomas KJ, MacPherson H, et al. A randomised controlled trial of acupuncture care for persistent low back pain: cost effectiveness analysis. *BMJ* 2006;333:626.