

# Large clinical acupuncture trials in the news

Mark Bovey, April 2004

The clinical trial reports described below were presented at the 10th Annual Symposium on Complementary Health Care in London in November 2003 (and the abstracts published in Focus on Alternative and Complementary Therapies, Dec 2003;8(4)). We chose to summarise these because of their large scale, and the potential significance of their results. In addition they received coverage in the UK press, both favourable ('Acupuncture passes NHS costs test for headache treatment') and unfavourable ('the beginning of the end of this therapy').

## **A. Acupuncture for migraine and chronic tension headache in primary care: a large, pragmatic, randomised trial. (Vickers et al)**

401 patients with chronic headache, predominantly migraine, were recruited from general practices in England and Wales. They were randomised either to receive acupuncture (up to 12 treatments over 3 months) or just their usual care (but not acupuncture). Patients in the acupuncture group were free to use their GP's treatment in addition if they wanted to. The practitioners were all physiotherapists, higher level trained AACP members. Treatment was entirely at the discretion of the practitioner. Hence this was a pragmatic randomised controlled trial (RCT): no placebo, no blinding, but routine practice.

The primary assessment was on headache severity at 12 months (i.e. 9 months after the treatment course finished).

- The acupuncture group showed a 34% reduction from baseline v. only 16% for the control, a highly significant advantage for the former.

In addition it was superior in:

- number of headache days per year (23.4 fewer)
- quality of life measures
- medication use (14% greater reduction)
- visits to GPs (30% fewer)
- days off work (25% fewer).
- cost-effectiveness (although acupuncture was more expensive the greater benefits made it highly cost effective).

The authors recommended consideration of expanding NHS acupuncture services for chronic headache.

## **B. German patient care evaluation programme for chronic pain**

This is a massive programme with collaboration between medical acupuncturists, insurance companies and several universities. The aim was to provide the evidence to help decide whether or not acupuncture treatment should be paid for by the state/insurance companies. It involved several different types of study: a) cohorts (uncontrolled) – for safety data primarily; b) 'pragmatic' RCTs (routine practice acupuncture v. no acupuncture) – for effectiveness and costs of the service; c) 'explanatory' RCTs (real v. sham acupuncture) – for efficacy (i.e. how much of the response is due to the specific action of the chosen points and needling method?) The conditions studied were largely headache, low back pain and osteoarthritis of the knee. The doctor acupuncturists (most of whom had had some degree of TCM training, and used TCM in practice) selected for these trials were among the better trained ones.

### **a) Cohort study (Weidenhammer et al)**

Out of about a half million patients and almost 10,000 medical acupuncturists covered by the insurance company schemes from all over Germany during 2001-3, a sample of 6140 cases (with complete data) from 2793 practitioners, were chosen. The presenting conditions were mostly headache and low back pain. Up to 15 treatments were given (average 8.6), the nature of which was entirely at the discretion of the acupuncturist. Various questionnaires were used, before and after treatment, to measure well-being, depressive mood, pain and functional impairment

Responses for most measures were substantial (0.4-0.8 standardised units) and stayed at a similar level for the six months after the end of the treatment. The greatest effect was seen in headache patients.

#### **b) Pragmatic RCT: low back pain (Becker-Witt et al)**

This was another study in routine acupuncture care, but this time compared to a control group. Again it was a very large study, by far the largest acupuncture RCT recorded in the West. 2807 patients with chronic low back pain were randomised either to have acupuncture or no acupuncture (patients in the control group were offered treatment at the end of the trial). Again, up to 15 treatments could be given. Both groups were free to use additional conventional treatments (and most did). Thus the design was very similar to the UK migraine study described earlier.

After three months of treatment there were statistically and clinically significant differences in back function (FFbHR scores: acupuncture group 74.0, control 65.4) and quality of life (SF36). Furthermore, when control group members received acupuncture after three months they then responded similarly, and after 6 months were approaching the level of the original acupuncture group.

#### **c) Explanatory RCTs**

In these, the treatment provided is no longer routine best practice, but a much more regulated semi-standardised approach. A consensus process was used to determine a formula for each condition, with a mix of local and distal points. Some additional points could be used ad lib, depending on circumstances (hence semi-standardised). Deqi was required. 12 sessions were given over 2 months. There were two control groups. One received 'minimal' acupuncture (shallow insertion, no deqi, at nearby non-points); the other control group had no intervention. The results of three such trials were presented – for back pain, knee pain and migraine.

##### (i) Low back pain (Brinkhaus et al)

- Number of patients: 298
- Main outcome measures: pain intensity (visual analogue scale); back function (FFbHR)
- Results at two months:
  - pain intensity: AC –28.7, MINAC –23.6, NOAC –6.9
  - back function: AC 66.8, MINAC 62.0, NOAC 57.7

In both cases acupuncture (AC) was very significantly better than no acupuncture (NOAC), but statistically no different from minimal acupuncture (MINAC), even though it was ahead.

##### (ii) Osteoarthritic knee pain (Becker-Witt et al)

- Number of patients: 299
- Main outcome measure: specialised arthritis pain score (WOMAC)
- Results at two months: acupuncture significantly better than MINAC as well as NOAC. The superiority was greater still in quality of life but less for functional assessment.
- Results at six months: AC still superior to MINAC, but no longer statistically significant.

##### (iii) Migraine (+/- aura) (Linde et al)

- Number of patients: 302

- Main outcome measure: number of days with at least a moderate headache – comparison of pre- and post-treatment.
- Results at three months: AC significantly better than NOAC, but only slightly ahead of MINAC – i.e. very similar to the back pain results. The size of the response in both acupuncture groups (cf. no acupuncture) was impressive – more than 50% improvement in the number of people with at least a 50% reduction in migraine frequency – larger than that seen with many conventional treatments (drugs, physiotherapy etc).

## Implications

This is the picture. The vast majority of chronic pain patients get noticeable benefits from a course of acupuncture. When compared against those not offered the treatment there are highly significant advantages for acupuncture (in measures such as pain intensity, headache frequency, general well-being and days off work). But when compared to sham acupuncture these differences are greatly reduced, usually to statistical insignificance. For some, this implied that acupuncture was no better than placebo. However, the researchers who presented these results acknowledged that minimal acupuncture is not the same thing as placebo, hence it is not possible to separate the placebo effects from those caused by various other non-specific causes (for example, pricking the skin anywhere evokes various physiological reactions in the body). Thus comparisons with sham acupuncture tend to underestimate the specific benefits of the therapy.

The other major consideration is the nature of the ‘real’ acupuncture given. Does a standardised, or even semi-standardised, formula undervalue acupuncture? Were the amount and frequency of treatment appropriate? Were the practitioners well enough trained? We don’t yet have enough information to answer these questions.

It is notoriously difficult to demonstrate acupuncture as superior to sham, in fact the evidence is only wholly convincing in respect of P6 for nausea. There are many possible reasons for this and until the German work is completed and published it is dangerous to speculate. In the meantime we should make the most of the positive UK migraine study.