’Nothing Better’ For Chronic Knee Pain Than (Electro-) Acupuncture

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BACKGROUND OF THE CLINICAL PROBLEM. Patients with OA knee pain are suffering the commonest cause of pain and disability in older people. More than half have inadequate pain relief.2 They face a choice between ineffective paracetamol, non-steroidal drugs that can harm the heart, (kidneys) and gastrointestinal tract, gels that scarcely work, physiotherapy, opioids that cause dependency and lose effectiveness, arthroscopic washouts that do nothing or surgery.3 They deserve a fuller, more considered answer to their question: “Is it worth trying acupuncture?”

2. **NIFTY DESIGN OF TRIAL.** The neat part of the Zelen design that Hinman et al used was that the control group, who were not given acupuncture, were not even aware that their pain scores were used in a trial of acupuncture so disappointment could not influence their scores, as was claimed for other studies. This ’no acupuncture’ group was compared with acupuncture (manual) and with sham laser (and with real laser, which is not considered here, to keep things simple).

3. **WHERE THE ANALYSIS BEGINS TO STUMBLE.** The problems started with the trialists’ choice of the threshold minimum clinically important difference (MCID) to estimate sample size. They chose a value based on one chosen by six self-styled ’expert’ physicians,4 namely a 35% fall in baseline pain score (1.8/sample mean baseline 5.1). This is equivalent to an effect size (ES) of 0.6, calculated using their assumed baseline SD of 30 (the actual SD was 21, giving a higher threshold ES of 0.86). A different figure for MCID was generated by 192 patients with OA, who registered improvement scores as well as changes in pain.5 This showed a more modest MCID, equivalent to an ES of 0.39 (shown in figure 1). The National Institute for Health and Care Excellence (NICE) did not regard any value for MCID as valid6 and chose a generic value of 0.5 (see figure 1). Hinman et al chose a high threshold and also failed to discuss the effect that alternative threshold MCID values would have on the interpretation of their findings. We also note that the MCID for any treatment should be chosen to take account of acceptability, safety and cost-effectiveness,7 which would argue for a lower threshold for acupuncture for knee pain.

4. **THE OLD “BETA ERROR” BUGABOO: SHORT ON STATISTICAL POWER.** Hinman et al applied this ’clinically important’ difference to a ’clinically irrelevant’ comparison--acupuncture versus sham laser. Sham laser is not an available therapy. The only reason for comparing acupuncture with sham would be to estimate the effects of the needles themselves, but this is already well known from the Cochrane review8 and an individual patient data meta-analysis (figure 1).9 It is known that the effect of needles alone is small, and so is unlikely to be identifiable

reliably with sample sizes of less than about 800.10 The sample size in the study by Hinman et al (n=70) clearly appears to be inadequate for the question, according to the existing evidence, and not best use of resources. The resulting ES of acupuncture against sham that was actually found by Hinman is similar to that shown by the best evidence8 (see figure 1), although the wide CI means the data can only be of any importance when they are included in a meta-analysis in the future.

5. **WHO DECIDES WHAT TREATMENT EFFECT IS MEANINGFUL?** Hinman et al found that, after 12â€…weeks, knee pain was significantly reduced by acupuncture compared with no acupuncture control, with an ES of 0.6 (data from their table 2; see figure 1). The difference did not quite meet the MCID they had postulated--although the estimated ES is the same size as the MCID--but it more than meets the MCID chosen by patients themselves (ES 0.39) and that selected by NICE (ES 0.5). In interpreting this result, the secondary outcomes should also have been brought into thoughtful consideration: there were significant differences in favour of acupuncture for six out of eight secondary outcomes (see eTable 5 in their paper) and the response rate, which is the most patient-orientated measure of success,7 was 76% in the acupuncture group compared with 32% in the no acupuncture control group.

6. **TO MAKE MATTERS WORSE, THE AUSTRALIANS STUDIED THE LEAST EFFECTIVE ACUPUNCTURE TECHNIQUE.** Hinman et al did not apply optimal acupuncture. Use of electroacupuncture has been shown superior to manual stimulation for knee pain in 2010.8

A couple of weeks ago, I also came across a study of “needle-less” acupuncture, also for chronic knee pain of the OA variety. Basically it involved warming the knee with these stick on cones of burning mugwort--sort of like (very carefully) burning incense around your knee cap. That too showed clinical effectiveness, although now I am prompted to dig up the original study and see if we can fit that “effect size” into our acupuncture, warm baths, exercise line-up above. Stay tuned.
