The evidence on acupuncture for knee osteoarthritis – editorial summary on the implications for health policy

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This paper was not presented at the Kyoto Conference, but arose out of discussions between the authors and presenters before, during and after the symposium

Abstract

Decisions on whether a health service should provide a particular treatment are based on the evidence on three questions: 1) whether the treatment can work, ie it is biologically active; 2) whether the treatment is safe and effective in daily practice; and 3) whether it is economically worthwhile. Evidence presented at the Kyoto conference shows that acupuncture for osteoarthritis of the knee has a biological effect, has a large clinical effect in practice, has negligible risk, and has a cost effectiveness which is well within the usual acceptable limit. On the present evidence, acupuncture is likely to offer an alternative to treatment with non-steroidal anti-inflammatory drugs (NSAIDs).

Keywords

Acupuncture, knee osteoarthritis, effectiveness, safety, cost effectiveness, public health service, non-steroidal anti-inflammatory agents (NSAIDs).

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Introduction

A policy decision on whether a health service should provide a particular treatment is generally based, in theory at least, on the evidence on three questions: 1) whether the treatment *can work*, ie does it have a biological effect, preferably with a known mechanism; 2) whether the treatment is *safe* and *effective* in daily practice; and 3) whether it is *economically worthwhile*. In practice, politics and cultural considerations may override scientific evidence,[1] and clinical decisions on the management of individual patients are made on the basis of many factors, which are often not explicit.[2] The principles of evidence based medicine apply equally to acupuncture as to conventional treatments, but cultural bias may mean that evidence is interpreted according to whether its mechanism is seen as acceptable according to the current world view.

The conference proceedings reported in this Supplement provide a considerable body of evidence addressing these questions for the topic of acupuncture for osteoarthritis (OA) of the knee. This article summarises that evidence and comments on its interpretation. In particular, one of the most relevant questions for any health service seems to be whether acupuncture can fill the therapeutic gap left by the rejection of non-steroidal anti-inflammatory drugs (NSAIDs) which are becoming increasingly discredited because of their side effects including gastric bleeding and cardiovascular disease.[3-5]

Acupuncture has a biological effect for knee OA

A large programme of research projects sponsored by the German health insurance organisations has provided a valuable collection of evidence on a range of questions about acupuncture.[6;7] One of these projects was a sham-controlled study of acupuncture for OA knee by Witt, Linde and colleagues, which showed that acupuncture was significantly better than sham, both for pain and disability.[8] Two other recent high quality studies, by research teams led by Berman,[9] in the US, and Vas,[10] in Spain, strongly

support this conclusion, and are reported in these proceedings.[11;12]

All the trials of acupuncture for OA knee have now been systematically reviewed, and a meta-analysis provides robust evidence that acupuncture is significantly superior to placebo (sham acupuncture) for pain and disability of OA knee.[13] A possible limitation is that the expectation of acupuncture in patients enrolled on these studies was likely to have been enhanced, since their current treatments were presumably unsatisfactory. There now seems little doubt that acupuncture does have a biological effect on the symptoms of OA knee. The evidence here that acupuncture is significantly superior to placebo is entirely consistent with systematic reviews of acupuncture in postoperative nausea,[14;15] chemotherapy vomiting[15] and back pain.[16]

At first sight, a trial by Scharf and colleagues[17] (one of the German trials on OA knee) appears to contradict this conclusion: it was reported as negative for the main outcome measure, the responder rate according to a 36% improvement in the WOMAC scale at 6 months. However, this headline summary is an oversimplification of the overall findings, and misrepresents them: the results showed trends in favour of acupuncture compared with sham for nearly all WOMAC subscales and for patients' global assessment at both three and six months. The confidence intervals of the mean scores for pain and function are in close agreement with those of other studies (shown in Figures 1 and 2 in the systematic review[18]). A likely explanation for the fact that Scharf's study did not show a large effect of acupuncture compared with sham is that patients were given exercises simultaneously, and exercises probably act, to some extent, on the muscles with a similar mechanism to acupuncture.[19] (So this study design is rather like testing for the effectiveness of antibiotic A when all patients are already receiving antibiotic B.)

Mechanism of acupuncture

From a scientific viewpoint, acupuncture is a form of stimulation of the central nervous system through sensory nerves, including the polymodal receptors.[20] Its effects can largely be explained using current concepts of physiology and pathology, such as the release of biologically active neuropeptides locally in the tissues around the needle,[21;22] neuronal depression in the dorsal horn of the spinal cord,[23] activation of the endogenous descending inhibitory pain control pathways,[24] and other central nervous system changes involving the limbic system.[25-27] There is also good evidence that the effects of acupuncture are sustained, and increase during a course of treatment.[28]

Until the scientific explanation of acupuncture is complete, it is understandable that some acupuncturists continue to practise using the traditional concepts.

Acupuncture's effectiveness in practice

It is one thing to show that a treatment has a biological effect, and quite another to show that the effect is useful for patients. There is now no question about this, in the case of OA knee: acupuncture invariably shows large benefits for patient groups, both in terms of pain and function, when compared either with usual treatment including NSAIDs,[7;12] or with standardised care with both NSAIDs and exercises.[17] The overall effect size of acupuncture treatment for OA knee, shown in the meta-analysis,[18] is in the region of 0.8 – which is considered 'large' by the usual standards.[29] Figure 1 shows that this is considerably larger than the effect of exercise compared with various controls[30] or NSAIDs compared with placebo.[31]

Acupuncture has a large overall effect on knee pain, even though it is only slightly superior to sham acupuncture. This is because sham acupuncture itself has a beneficial effect which has been demonstrated consistently in these trials in knee pain, and in many other conditions including for example headaches and migraine,[32;33] neck pain,[34] and back pain.[35]

The whole process of acupuncture treatment includes much more than choosing the correct points and stimulating the needles (which is the so-called *specific* effect). The factors that contribute to the overall effect are still relatively unexplored but are likely to include psychological factors such as the therapeutic relationship, the meaning of a diagnosis and the expectations of treatment,[36] and physical factors such as the effect of touch on the limbic system[37;38] and activation of the reward system.[39] These effects have known mechanisms and patients can benefit from them, so it seems pointless to dismiss them as 'non-specific' or 'placebo' effects.

The question arises whether the effect of acupuncture seen in practice is likely to be as large as that seen in the highly controlled conditions of an

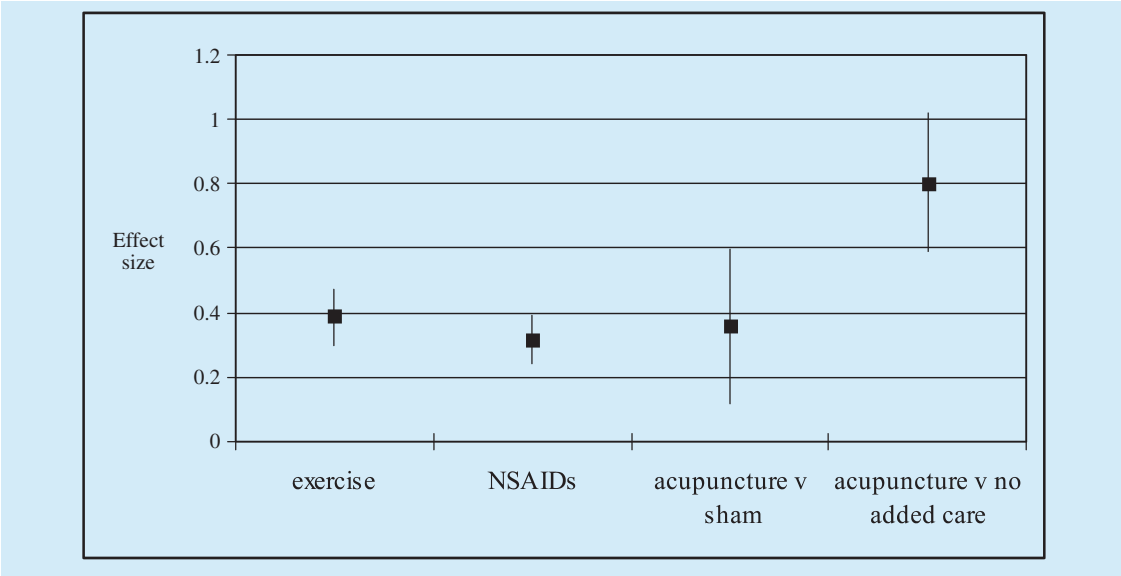

Figure 1 Effect sizes and confidence intervals of various treatments for pain of OA knee are shown, derived from systematic reviews of RCTs (reference in the text).

RCT. Fortunately, the answer is provided by one of the German trials, where patients could opt for treatment outside the study if they wished.[40] The benefit of acupuncture inside the study was the same as that outside it.

Evidence from three of the trials shows that the effect of acupuncture seems to be prolonged well beyond the end of the treatment period (See Figure 2).

Finally, in practice, patients may be using other treatments. The systematic review showed that acupuncture can be used as an adjunct in patients who are taking NSAIDs or other analgesics. However, one trial found that the impact of acupuncture was not so large if it is given at the same time as physiotherapy exercises.[17]

Acupuncture's safety in practice

Several prospective surveys in the UK and other countries have repeatedly confirmed that the rate of adverse events with acupuncture is negligible.[41] The

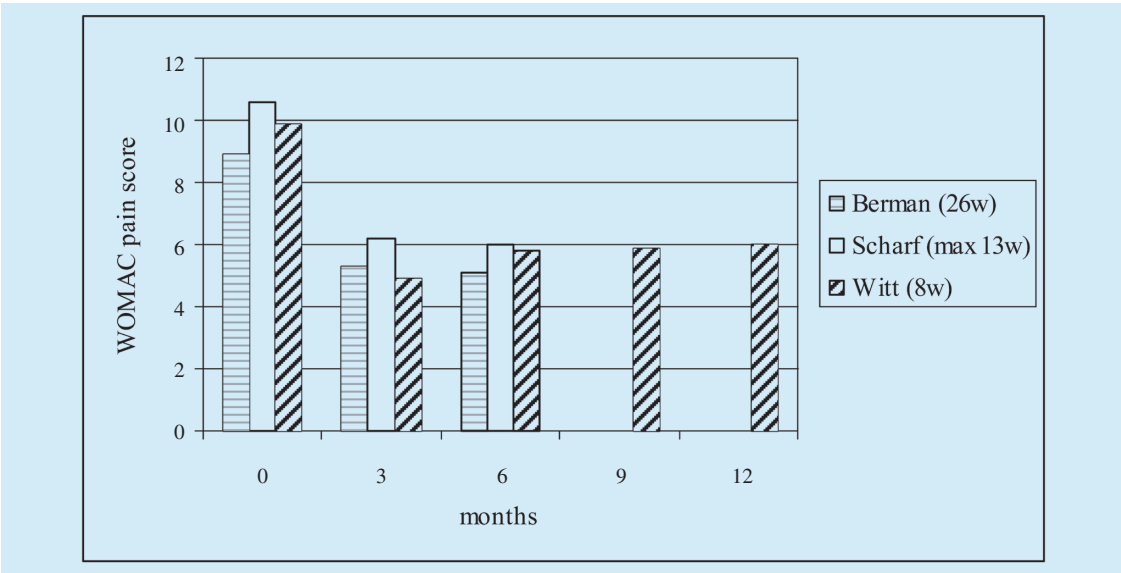

Figure 2 Mean WOMAC pain scores for acupuncture groups in RCTs that had at least 6 months follow up (treatment period in brackets; w = weeks).

knee joint is not close to vulnerable organs, and acupuncture for knee OA seems inherently safe. This is confirmed by Yamashita who found fewer adverse events in the acupuncture group than the controls.[42] Acupuncture can indeed be accurately described as a very safe intervention in the hands of competent practitioners.

Cost effectiveness of acupuncture

One study provides data on the cost effectiveness of acupuncture for OA knee: in Germany, Witt found that the incremental cost effectiveness ratio was €17 845 (£12 000) per QALY (Quality Adjusted Life Years) gained over 3 months, compared with usual care.[43] This figure is of the same order as the costs per QALY in studies of acupuncture for chronic headache[44] and back pain,[45] and is well within the range of acceptability for the UK's National Institute for Health and Clinical Excellence (NICE).[46] The main cost of acupuncture is the practitioner's fee, since needles are inexpensive. In the UK studies, the cost of acupuncture was in the range of £132-144 for a course of six treatments;[44;45] the figure for the German study was similar (Witt C, personal communication). In some circumstances it may be possible to reduce treatment costs without diminishing the effect, for example by treating several patients simultaneously. The cost effectiveness of a treatment also increases significantly when the effects last more than one year, as suggested by the evidence on knee pain.

Comparison with other treatments

An economic analysis of various treatments for OA was performed by an Australian group using trial data converted to utility data. The cost effectiveness of NSAIDs (including selective and non-selective cyclo-oxygenase inhibitors) was estimated in 2004 to be between A$15 000 (ca £5900 at 2004 rates) and infinity per QALY: effectively, they concluded that the benefits of NSAIDs were likely to be cancelled out by the costs of treating the side effects such as gastrointestinal haemorrhage.[47] The same group estimated that the cost effectiveness of out-patient based intensive exercise and strength training is between A$3000 (ca £1170) and A$15 000 (ca £5900) per QALY.

Because of its expense, acupuncture is not likely to be offered instead of cheaper effective treatments such as exercise, weight loss if necessary, and paracetamol, but it certainly seems to offer a suitable substitute for NSAIDs.

Current provision of acupuncture in health care

In the UK, acupuncture is already available to many patients in the health service; about a third of primary care practices offer it either on site or by referral,[48] and acupuncture is available in 84% of chronic pain clinics.[49]

The large series of trials in Germany were conducted to provide information for the Federal Committee of Physicians and Health Insurers to decide whether acupuncture should be provided within the health service or not. In April 2006, the Committee concluded that acupuncture should be provided as a routine option for treatment of OA knee, as well as for chronic low back pain.[6]

The Swedish Council on Technology Assessment in Health Care (SBU), an independent governmental agency that reviews the evidence to identify interventions that offer the greatest benefits for patients while utilising resources in the most efficient way, recently concluded that there is evidence for the usefulness of acupuncture as treatment for different chronic pain states.[50] Acupuncture has been funded by the Swedish health service since 1985.

In Australia, over 90% of GPs consider that acupuncture treatment should be paid for by Medicare,[51] and the Australian Medical Association has issued a formal position statement that acupuncture is 'part of the repertoire of patient care'.[52]

Conclusion

In conclusion, there is sufficient evidence for acupuncture to be considered as an option for treatment of chronic knee pain that has not responded to first line interventions. On present evidence, acupuncture is likely to provide a replacement for NSAIDs, being at least equally effective, probably more cost effective, and much safer.

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