Acupuncture therapy for chronic lower back pain: a systematic review

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ABSTRACT

INTRODUCTION Chronic low back pain is a common condition affecting a significant proportion of the population and has large economic implications on the society. Acupuncture has grown in popularity as an alternative therapy for chronic low back pain. Recent National Institute for Health and Clinical Excellence (NICE) guidelines on low back pain offer a course of acupuncture as a baseline treatment option according to patient preference. The aim of this systematic review was to evaluate if this treatment option is justified in view of recent evidence available on the efficacy of acupuncture.

MATERIALS AND METHODS Studies included were identified by a PubMed search for relevant, randomised, controlled trials on the 23 July 2009. A systematic review was performed.

RESULTS Fifteen randomised controlled trials were identified. Of these, four met the eligibility criteria and were critically appraised. These trials suggest acupuncture can be superior to usual care in treating chronic low back pain, especially, when patients have positive expectations about acupuncture.

CONCLUSIONS NICE guidelines of a course of acupuncture, offered according to patient preference as a treatment option for chronic low back pain, are justified.

KEYWORDS

Acupuncture – Chronic lower back pain – Systematic review

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Low back pain is a common condition affecting a significant proportion of the population with an estimated prevalence of 70–85%.¹ In 1998, a survey showed that 40% of adults complained of back pain lasting more than 1 day in the previous 12 months.² In the same survey, it was shown that 5% of back pain sufferers had taken time off during the previous month and 15% of sufferers who were unemployed in the previous month gave back pain as a reason why they were not back in work.² From the above, it becomes apparent that back pain has large economic implications on our society.

Acupuncture has grown in popularity among alternative therapies and it is estimated that 2% of adults in the UK use it each year for a variety of conditions including back pain.³ This increase in popularity is also reflected in the recent National Institute for Health and Clinical Excellence (NICE) guidelines on low back pain published in May 2009.⁴ According to these guidelines, a course of acupuncture of up to 10 sessions over 12 weeks is offered as a treatment option, according to patient preference.

The purpose of this systematic review was to evaluate if

this treatment option is justified in view of the recent evidence available on the efficacy of acupuncture.

Materials and Methods

Studies were identified on 23 July 2009 using the following eligibility criteria. Due to the multifactorial pathophysiology of chronic lower back pain, an attempt was made to reduce the influence of confounders by searching only for randomised controlled trials. Studies from 2005 onwards were included in order to concentrate on recent evidence.

Studies were included when acupuncture treatment was compared to usual care treatment. The exclusion criteria applied were: studies on acute pain, pilot studies, and studies on cost effectiveness.

A PubMed search was performed ('2005/01/01'[Publication Date]: '3000'[Publication Date]) AND ('Acupuncture Therapy'[Mesh] AND 'Low Back Pain'[Mesh]) Limits: Randomised Controlled Trial, English language.

The references cited in articles identified by the above search were reviewed for further eligible studies.

Results

Literature search

The PubMed search yielded 21 studies. Of these, 17 were excluded, leaving four studies that fulfilled the eligibility criteria (Fig. 1). Searching the references of these four citations identified no further studies meeting the inclusion criteria.

Literature review

STUDY 1

Cherkin *et al.*⁵ compared the effectiveness of individualised acupuncture, standardised acupuncture, simulated acupuncture and usual care. They included patients, who were receiving care for back problems in two centres over the previous 5–12 months. To identify these patients, they used electronic records and searched for diagnoses codes consistent with uncomplicated chronic low back pain. Their eligibility criteria were well defined. They recruited the population over 2 years by mailed invitations, letters and advertisements in clinics and newsletters. This was followed

by a telephone assessment to determine final eligibility which required a rating of at least 3 on a 0–10 back pain bothersomeness scale. There were no population size calculations. The participants were randomised in treatment groups using a centrally generated variable-sized block design.

The treatment groups were: individualised acupuncture, standardised acupuncture, simulated acupuncture and usual care group. The treatment was clearly described for each group making the study reproducible. The primary outcome measures were clearly defined. They assessed back-related dysfunction at 8 weeks using the Roland–Morris Disability Questionnaire (RMDQ) and bothersomeness at 8 weeks measured on a scale from 0–10. Secondary outcomes included assessment of back-related dysfunction at 26 weeks and 52 weeks, proportion of participants with decrease of more than 3 points on the RMDQ and 2 points in bothersomeness, self-medication for back pain in the prior week, SF-36, days in bed or sick leave due to back problems during the past month at 52 weeks and any adverse experiences.

The results were presented clearly and were easy to follow. At baseline, the mean score for RMDQ was 10.6 and 5.1 for bothersomeness. Overall, participants were optimistic that acupuncture would help with a mean of 6.7 on a 0–10 scale.

At 8 weeks, all groups showed improved function and decreased symptoms. There was a significant difference between the acupuncture groups and the usual care for both dysfunction and symptom improvement. However, There was no statistical difference between the three acupuncture groups. From weeks 8 to 52, the results for dysfunction improvement were superior in the acupuncture groups, with a statistically significant difference. For bothersomeness, however, the difference among the four groups was smaller and not statistically significant at 52 weeks.

Overall, 60% in the acupuncture groups and 39% in the usual care group had improved at least 3 points on the RMDQ scale at 8 weeks. The difference remained statistically significant at 26 weeks and 52 weeks. For bothersomeness improvement, the results were superior in the acupuncture groups at 8 weeks but not statistically significant at 26 weeks and 52 weeks.

Self-medication for back pain had reduced more for the acupuncture groups compared to the usual care group and remained statistically significant up to 52 weeks.

SF-36 scores were better for the acupuncture groups at 8 weeks but this improvement was not statistically significant at 52 weeks.

More patients cut down on activities or missed work or school for more than 1 day in the usual care group.

With regards to adverse effects, 11 reported short term pain, one reported pain lasting 1 month, one dizziness and one back spasm. All were in the individualised or standardised groups.

The authors concluded that acupuncture-like treatments significantly improved function in patients with chronic low

back pain but the benefits of real acupuncture were no greater than those of sham acupuncture raising questions about acupuncture's mechanism of action. This conclusion is justified according to their results.

STUDY 2

Haake *et al.*,⁶ in a multicentre trial, compared verum acupuncture to sham acupuncture and conventional therapy. The design of the study together with population size calculations were described in a previous pilot study. Their population was recruited by invitation to participate in the study through advertisement in newspapers, radio and television.

Their eligibility criteria were clearly defined. They randomised 1162 patients into three groups using a computer program. The randomisation process was clearly described. The groups were verum acupuncture, sham acupuncture, and conventional therapy. The treatment methodology was clearly described for each group making the study reproducible. The primary outcome measures were treatment response at 6 months with at least 33% improvement on three pain-related items on the Von Kroff pain scale or 12% improvement on the Hanover functional ability questionnaire. Secondary outcomes included response at 6 weeks and 12 weeks after randomisation, SF-12 scores, patient global assessment of therapy effectiveness on a scale of 1 (very good) to 6 (fail), medication use and adverse effects.

The primary outcome could be assessed in 377 patients in verum acupuncture, 376 in sham acupuncture, and 364 in standard treatment of all randomised patients which was an excellent follow-up rate overall. The results were clearly presented in tabulated form. Effectiveness of acupuncture (in either form) was almost twice that of conventional therapy. However, there was no statistically significant difference between the two acupuncture groups. There were 40 serious adverse effects reported all of which were deemed unrelated to the interventions.

The authors concluded that acupuncture constitutes a strong therapy alternative to multimodal conventional therapy but, as in the study by Cherkin *et al.*,⁵ there was no significant difference between the acupuncture groups.

STUDY 3

Thomas *et al.*⁵ conducted a pragmatic trial to determine whether a short course of traditional acupuncture improves longer term outcomes in patients chronic low back pain. They recruited patients with chronic low back pain for 4–52 weeks' duration. Patients were initially assessed by 39 GPs from 16 practices. Potential candidates were then assessed by the study researcher for eligibility. The eligibility criteria were clearly stated. Patients were randomised to either a short course of traditional acupuncture or usual care. The randomisation process was performed using computer-generated, blocked randomisation sequence.

Acupuncture treatment comprised of up to 10 sessions of individualised treatment over a period of 3 months. The treatment was delivered by 1 of 6 experienced acupuncturists who also determined the content and the number of sessions according to each patient's needs.

Patients in the usual care group received treatment according to their GP's assessment of need. The treatment was a mix of interventions including physiotherapy, manipulation, exercises and medication.

The primary outcome measure was the SF-36 body pain measured at 12 months and 24 months, scored on a 0–100 scale. This score represented pain in the past 4 weeks.

Secondary outcomes were the Oswestry disability index, the McGill pain index, the rest of the SF-36 questionnaire, and adverse effects. These were measured at baseline, at 3, 12, and 24 months.

They recruited 241 patients over 18 months. The number of patients was decided on population size calculations based on a pilot study. They aimed to detect a difference in outcome between the groups of 10 points for the SF-36 pain score at 12 months, at 90% power and allowing for a 10–15% drop-out. Patients were randomised into the two groups in a 2:1 ratio, to the acupuncture group, to allow for effects between acupuncturists to be tested.

The primary outcome showed a weak effect of acupuncture treatment at 12 months. However, at 24 months there was a statistically significant difference between the two groups in favour of acupuncture. Secondary outcomes showed that there was a weak difference in favour of the acupuncture group but that was not statistically significant. There were no serious adverse effects reported.

STUDY 4

Brinkhaus *et al.*⁷ conducted a multicentre trial comparing acupuncture with sham acupuncture and with a no acupuncture waiting list control. Patients were recruited through advertisements in the local press. The selection eligibility criteria were clearly stated. Patients were randomised into three groups, using a centralised computer-generated process. In the acupuncture and minimal acupuncture groups, the patients were blinded to treatment.

For the acupuncture group, the treatment was semi-standardised. Each patient received acupuncture at a combination of local and distant points with variable needle sizes. De-qi effect was elicited when possible.

For the minimal acupuncture group, physicians used the same technique but at predefined non-acupuncture points with superficial penetration and without eliciting de-qi.

Patients in the waiting list did not receive acupuncture treatment for 8 weeks after randomisation. After that period, they received 12 sessions of acupuncture in the same way as for the acupuncture group.

The main outcome measure was the change in back pain

intensity from baseline to the end of the 8 weeks. The change was determined using a visual analogue scale (0–100).

A total of 2250 patients were assessed for eligibility over 6 months. Of these, 298 were eligible and randomised into the three groups. The pain intensity decreased from baseline to end of week 8 by a mean of 28.7 mm in the acupuncture group and by a mean of 6.9 mm in the waiting list group. The difference between the two groups was 21.8 mm, which was statistically significant. There was no statistically significant difference between the two acupuncture groups.

Discussion

Cherkin *et al.*⁵ concluded that acupuncture was effective for chronic back pain compared to usual care but they did not identify any statistically significant difference between the acupuncture groups. This was a well-designed study. The main positive points of the study were its reproducibility, its large population, its high power, the high follow-up rates, and its 'blinding' of patients to treatment at the acupuncture groups. The main negative point of this study was the method of population recruitment. Patients were invited to participate in a study comparing different methods of acupuncture, either by mail invitation, or by advertisement in clinics and newsletters. This meant that patients who believed acupuncture can help were more likely to participate. This becomes apparent from the baseline characteristics as, overall, participants were optimistic that acupuncture would help with a mean of 6.7 on a 0–10 scale. This signifies a strong placebo effect for the participants in the acupuncture groups and, possibly, a negative effect on the participants who received usual treatment.

The fact that there was no significant difference between the acupuncture groups may indicate that acupuncture works in an unclear physiological process or that it simply has a strong psychological effect.

Similarly, Haake *et al.*⁶ concluded that low back pain improved after acupuncture and that its effectiveness was almost twice that of conventional therapy. This was a high quality study. Its strong points were the large sizes of the groups, its high power and high follow-up rates. Patients were blinded to the acupuncture treatments and, although the acupuncturists were not blinded, the interviewers that performed the assessment process were. Another strong point is that the patients in the conventional therapy group received a multimodal treatment, consisting of 10 sessions of personal contact with a physician or physiotherapist who administered the therapy, matching in this way, the 10 sessions of acupuncture therapy.

The main criticism, as in the first study, is the method of recruiting the participants. They invited patients to participate in a study comparing two types of acupuncture and conventional therapy via newspapers, radio and television. Therefore, patients with strong positive expectations about acupuncture may have been selected.

Thomas *et al.*⁵ concluded that there was weak evidence of an effect of acupuncture on low back pain at 12 months, but stronger evidence of a small benefit at 24 months. The strong points of this study were that it was pragmatic and that the recruitment of participants was done by GPs. This was the only study that tried to identify an effect at 2 years. However, it was a smaller study, with lower power and higher lost to follow-up rates.

Brinkhaus *et al.*⁷ concluded that acupuncture was more effective in improving pain, than no acupuncture. The main strengths of this study are the central randomisation process, interventions based on expert consensus and the high follow-up rates. The main weaknesses were the smaller size of participants, the relatively lower power, and the difficulty in reproducing the intervention. Also, they recruited their population by advertising in articles and newspapers for a study comparing two types of acupuncture. In this way, patients with strong positive expectations about acupuncture may have been selected, which means that their population may not have been representative of all patients with chronic low back pain.

Conclusions

Acupuncture can be effective in managing patients with low back pain. This is especially true if the patients have positive expectations about acupuncture, suggesting a strong psychological element. Furthermore, the lack of evidence to support traditional acupuncture over sham or simulated acupuncture could mean that the physiology of acupuncture is still unclear or it could further support the argument for a strong psychological effect.

Based on the above, NICE guidelines, offering a course of acupuncture as a treatment option according to patient preference, are justified.

References

1. Anderson GB. Epidemiological features of chronic low-back pain. *Lancet* 1999; **354**: 581–5.
2. Department of Health. *The prevalence of back pain in Great Britain in 1998*. London: Government Statistical Service, 1999.
3. Thomas KJ, MacPherson H, Thorpe L, Brazier J, Fitter M, Campbell MJ *et al.* Randomised controlled trial of a short course of traditional acupuncture compared with usual care for persistent non-specific low back pain. *BMJ* 2006; **333**: 623.
4. National Institute for Health and Clinical Excellence. *Low back pain. Early management of persistent non-specific low back pain*. NICE Clinical Guideline 88. <www.nice.org.uk/CG88/fullguideline>.
5. Cherkin DC, Sherman KJ, Avins AL, Erro JH, Ichikawa L, Barlow WE *et al.* A randomized trial comparing acupuncture, simulated acupuncture, and usual care for chronic low back pain. *Arch Intern Med* 2009; **169**: 858–66.
6. Haake M, Müller HH, Schade-Brittinger C, Basler HD, Schäfer H, Maier C *et al.* German Acupuncture Trials (GERAC) for chronic low back pain: randomized, multicenter, blinded, parallel-group trial with 3 groups. *Arch Intern Med* 2007; **167**: 1892–8.
7. Brinkhaus B, Witt CM, Jena S, Linde K, Streng A, Wagenpfeil S *et al.* Acupuncture in patients with chronic low back pain: a randomized controlled trial. *Arch Intern Med* 2006; **166**: 450–7.