

Summaries of recent papers

CLINICAL TRIALS OF EFFECTIVENESS

Radiation-induced xerostomia

► Simcock R, Fallowfield L, Monson K, *et al.* ARIX: a randomised trial of acupuncture v oral care sessions in patients with chronic xerostomia following treatment of head and neck cancer. *Ann Oncol* Published Online First: 25 October 2012. doi: 10.1093/annonc/mds515

Randomised crossover trial (n=145) comparing acupuncture to oral care education.

Methods

Patients treated for head and neck cancer have a high incidence of developing a dry mouth (xerostomia) following radiation treatment. In this study, such patients who were free of recurrence after 18 months were recruited from seven UK oncology centres. They were randomised to receive eight weekly 20-min sessions of acupuncture or two sessions of oral care education, and were then crossed over after 4 weeks to receive the other treatment. Acupuncture treatment consisted of manual needling of three ear points: Salivary Gland 2, Modified Point Zero, *Shenmen* and LI2; and the addition of LI20 at the suggestion of British Medical Acupuncture Society (BMAS) members. Needles were inserted and manipulated manually at 10 min to increase the chances of achieving *de qi*. Patients in the oral care group received two standardised educational sessions lasting 1 h, given 4 weeks apart.

Subjective assessments were carried out using the European Organisation of Cancer Quality of Life Questionnaire and the Head and Neck subscale. Objective assessment of stimulated and unstimulated saliva production was carried out using Schirmer strips placed in the floor of the mouth for 2 min.

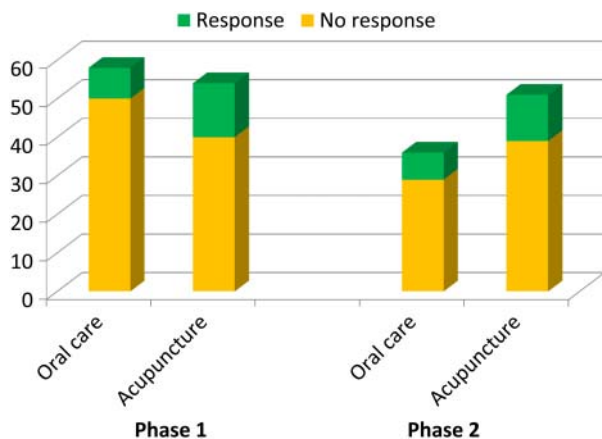


Figure 1 'Severe' dry mouth after treatment. Based on *Ann Oncol* Published Online First: 25 October 2012. doi: 10.1093/annonc/mds515

Results

Improvements in five out of six symptoms of xerostomia were noted after acupuncture; see figure 1 for dry mouth. The OR of improved dry mouth 9 weeks after acupuncture was 2 ($p=0.031$). No significant differences were found in stimulated or unstimulated saliva production over time or by intervention.

Comments

This is the largest reported randomised trial of acupuncture for the alleviation of radiation-induced xerostomia in patients treated for head and neck cancer, and was rigorously performed. In the absence of other useful treatments, the authors suggest that acupuncture may be a beneficial treatment.

Cancer-related fatigue: randomised controlled trial

► Molassiotis A, Bardy J, Finnegan-John J, *et al.* Acupuncture for cancer-related fatigue in patients with breast cancer: a pragmatic randomized controlled trial. *J Clin Oncol* Published Online First: 29 October 2012. doi: 10.1200/JCO.2012.41.6222

A pragmatic multicentre randomised controlled trial (RCT) (n=302) comparing acupuncture to enhanced standard care.

Methods

Patients with breast cancer who had completed chemotherapy were screened for fatigue using a 10-point scale to identify those with significant fatigue (score 5 or more). Sensible inclusion and exclusion criteria were applied. The patients were randomly allocated to enhanced usual care or acupuncture in a ratio of 3 : 1, to allow further studies to be performed at the end of this reported trial. Patients were given six sessions of 20 min duration over 6 weeks, at the following points: ST36, SP6 and LI4, either unilaterally or bilaterally. There was some scope for variation if one of these points could not be needled for clinical reasons (for example, lymphoedema). The needles were inserted perpendicularly to a depth of 0.5–1 inches. No further stimulation of the needles occurred. Regular audit took place to ensure the techniques were standardised across practitioners. Patients were followed-up for 18 weeks.

The primary outcome measurement was a difference in Multidimensional Fatigue Inventory score at 6 weeks.

Results

Data were completed for 246 of the 302 patients. The difference between the two groups general fatigue score was -3.11 (95% CI -3.97 to -2.25 ; $p<0.001$), showing the acupuncture treatment arm to be highly significantly superior. The acupuncture intervention also improved all other aspects of the Multidimensional

Fatigue Inventory, with statistical significance. The acupuncture effect was reduced to -2.49 (95% CI, -3.29 to -1.69 ; $p < 0.001$) when missing data were included assuming no improvement at 6 weeks, though this was still highly significant.

An analysis was performed to establish if patient expectations, ongoing maintenance treatment or the centre where the treatment was performed had an impact, and no significant effect on outcome was found.

Comments

There has been some debate about the fact that baseline fatigue scores were not reported except as categories, so the effect size cannot be calculated (nor a figure generated).

This RCT showed acupuncture to be an effective intervention for cancer-related fatigue, with statistically significant improvements in all primary and secondary outcomes measured, and therefore acupuncture should perhaps be considered as a treatment option for symptomatic relief.

Chronic low back pain

► Cho YJ, Song YK, Cha YY, *et al.* Acupuncture for chronic low back pain: a multicenter, randomized, patient-assessor blind, sham-controlled clinical trial. *Spine (Phila Pa 1976)* Published Online First 20 Sept 2012. PMID: 23026870

A randomised trial (n=130) comparing acupuncture to non-penetrating sham.

Methods

Patients aged 18–65 years with chronic low back pain (LBP) were randomised to receive twice weekly acupuncture for 6 weeks or treatment with a non-penetrating sham device, at one of three centres. Treatment was carried out by experienced medical acupuncture practitioners who had undergone training in the study protocol and use of the sham device to maintain blinding of the participants. All patients were also given a manual of good posture and exercises for LBP. They were advised to complete at least 80% of the 12 possible treatments.

Participants in the real acupuncture group received individualised acupuncture treatments with manual stimulation to induce *de qi*. Needles were left in place for 15–20 min. Sham acupuncture using semi-blunt, non-penetrating needles (Acuprime, Exeter, UK) was carried out on eight predefined non-acupuncture points located over the lower back.

In order to assess the impact of LBP on the patient's life, the primary outcome measure was a visual analogue scale (VAS) of the bothersomeness of LBP. This was measured at weeks 0, 6, 8, 12 and 24 with the primary endpoint being at week 8 (2 weeks following the end of treatment). Secondary outcomes included VAS for pain, the Oswestry Disability Index for pain-related dysfunction, the Short-Form 36 (SF-36)

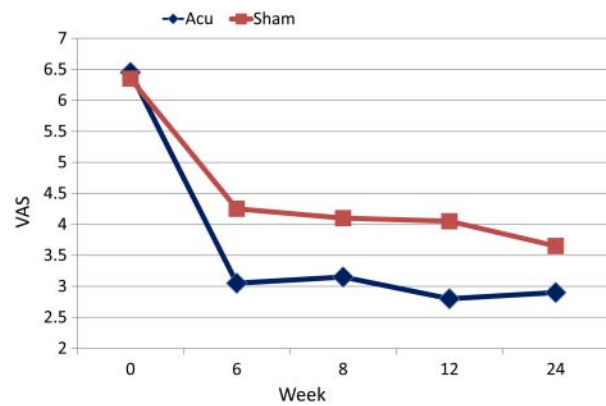


Figure 2 Bothersomeness of low back pain (LBP). Based on *Spine (Phila Pa 1976)* Published Online First 20 Sept 2012. PMID: 23026870

questionnaire for quality of life and the Beck Depression Inventory.

Results

The mean reduction in VAS for bothersomeness, shown in figure 2, was significantly ($p < 0.05$) greater for real acupuncture (3.36) compared to sham (2.27). All secondary outcomes were also better in the real acupuncture group but only significant on the VAS for bothersomeness and pain intensity at the primary endpoint and all follow-up points ($p < 0.05$).

Comments

This study has a number of methodological strengths including the training of experienced practitioners in the use of the sham device, the use of individualised points as would be used in practice and the achievement of *de qi* to give a higher probability of clinical response. In addition, no differences were found between groups with respect to expectation of benefit or credibility of the sham device.

Irritable bowel syndrome (one study, two papers)

► MacPherson H, Tilbrook H, Bland MJ, *et al.* Acupuncture for irritable bowel syndrome: primary care based pragmatic randomised trial. *BMC Gastroenterol* 2012;12:150.

► Stamuli E, Bloor K, MacPherson H, *et al.* Cost-effectiveness of acupuncture for irritable bowel syndrome: findings from an economic evaluation conducted alongside a pragmatic randomised trial in primary care. *BMC Gastroenterol* 2012;12:149.

A randomised pragmatic trial (n=233) of traditional acupuncture plus usual care versus usual care alone for irritable bowel syndrome (IBS), with economic evaluation.

Methods

Patients were randomised to either usual care alone (n=117) or acupuncture plus usual care (n=116). The usual care was at the discretion of the patient's general practitioner (GP). Acupuncture was given using a traditional Chinese medicine (TCM) approach

for 10 sessions over 12 weeks, with lifestyle advice. The primary outcome measure was a reduction in the IBS Symptom Severity Score (IBS SSS) at 3 months; further evaluations were undertaken at 6, 9 and 12 months. A reduction of 50 points (on a scale from 0–500) was considered a successful response. For the economic evaluation, the EQ-5D instrument was used (a quality-of-life questionnaire, not symptom specific). There was no control or sham procedure applied in the usual care group.

Results

Patients in both groups experienced improvement at 3, 6 and 9 months, but no longer at 12 months. Comparison between the groups showed a significant improvement favouring added acupuncture at 3 months (-27.43 ; CI -48.66 to -6.21 ; $p=0.012$), see figure 3. The difference was also significant at 6 and 9 months, but not at 12 months. Successful treatment was achieved in 57 patients (49%) in the acupuncture group and 36 patients (31%) in the usual care alone group, resulting in a number needed to treat of 6 patients. The authors concluded that addition of acupuncture to usual care results in significant benefits for patients.

Patients receiving acupuncture had more GP and outpatient appointments than those receiving usual care alone, but fewer emergency admissions. Addition of acupuncture resulted in higher costs per patient (£940 for acupuncture, £574 for usual care alone). The EQ-5D score improved significantly from baseline at 3 months, but no longer at 6, 9 and 12 months. The costs per quality-adjusted life year (QALY) gained was estimated at over £60 000. The estimate was lower in patients with severe symptoms (IBS SSS >300), but the small numbers in that subgroup made the analysis uncertain. The authors concluded that given a willingness to pay £30 000 per QALY gained, addition for acupuncture was not an appropriate use of NHS resources; for patients with

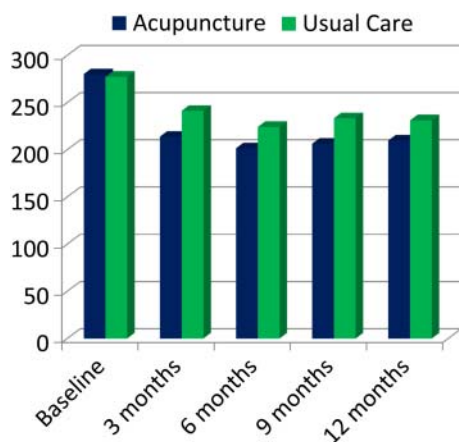


Figure 3 Irritable bowel syndrome symptom severity scores. Based on *BMC Gastroenterol* 2012;12:150.

severe symptoms, the likelihood for acupuncture being cost effective was estimated at 60%.

Comments

This trial was the first large trial in a primary care setting; however, due to a number of dropouts, there were fewer in the economic analysis than the power calculation considered necessary. The trial also suffers from a lack of a sham control procedure. Admittedly, there are a number of controversies about the control procedure in acupuncture research, but it would have been possible to add one even if that would have increased the cost of the trial. Not blinding patients to their treatment allocation introduces bias here. The accompanying economic analysis also shows that the treatment is expensive. As someone grudgingly involved in commissioning, the reviewer can sympathise with a financial director objecting to spending £339 per patient, with little to show for it.

Quality of life in patients with multiple sclerosis

► Quispe-Cabanillas JG, Damanesco A, Glehn F, *et al.* Impact of electroacupuncture of quality of life for patients with relapsing-remitting multiple sclerosis under treatment with immunomodulators: a randomized study. *BMC Complement Altern Med* 2012;12:209.

Patient and evaluator-blinded randomised trial of electroacupuncture (EA) to improve quality of life in patients with multiple sclerosis (MS) ($n=31$).

Methods

Patients with relapsing-remitting MS treated with immunomodulators were randomised to receive treatment with either (1) EA to ST36, SP6, LI4, LI11, all bilaterally, (KWD 808 stimulator, 4 Hz, 0.5 ms pulse width) and EX-HN3 (manual acupuncture only); or (2) sham EA, with needles inserted superficially <0.2 cm depth 1 cm away from the points, with sham electrical stimulation. Treatments were given weekly for 30 min per session, over 6 months. Assessments were performed prior to treatment period and at 3 and 6 months by Expanded Disability Status Scale (EDSS; assessment by neurologist), Functional Assessment of Multiple Sclerosis (FAMS) questionnaire (self-reported) for quality of life and 10-point VAS (self-reported) for pain.

Results

All measurements were similar in both groups prior to treatment. EDSS at 6 months showed less deterioration in patients receiving EA than in the sham group (although the difference was only just about significant). Quality of life measured by FAMS, shown in figure 4, was significantly better in the EA group at 3 ($p=0.0026$) and 6 months ($p<0.0001$). Pain improved in both groups at 3 months, but significant pain improvement was seen only in the EA group at 6 months. The authors conclude that EA improves quality of life significantly in these patients.

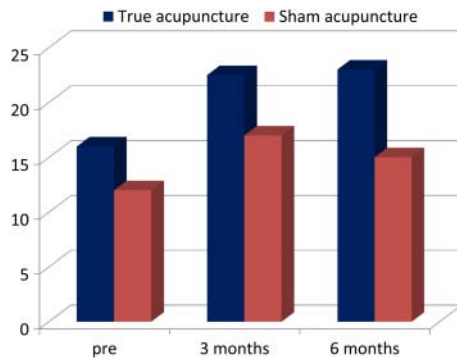


Figure 4 Functional assessment of multiple sclerosis score. Based on *BMC Complement Altern Med* 2012;12:209.

Comments

The treatment was well described and should be easy to apply to readers' patients. The paper does not give a power calculation, nor does it show the figures for the outcome measures. It also does not define primary and secondary outcomes. The study also excluded patients on ground of residence; probably dictated by practicality, but it opens the trial to bias. All this makes it very difficult to judge just how well this treatment works. Despite those problems, the treatment may be worth a try for individual patients, if the time can be justified.

Myofascial pain syndrome

► Tekin L, Arkasu S, Durmuş O, *et al.* The effect of dry needling in the treatment of myofascial pain syndrome: a randomized double-blinded placebo-controlled trial. *Clin Rheumatol* Published Online First: 9 Nov 2012. doi: 10.1007/s10067-012-2112-3

Randomised trial (n=46) of myofascial trigger point dry needling versus non-penetrating sham acupuncture.

Methods

Patients with myofascial pain syndrome were randomised to receive either dry needling of trigger points (n=23) or a non-penetrating sham procedure (n=23), six treatments spread over 4 weeks. Patients and assessing clinicians were masked as to treatment allocation. Outcomes were measured as pain relief by 10 cm VAS and as improvement in quality of life by Short Form 36 questionnaire (SF-36).

Results

One patient dropped out of the treatment group and six patients dropped out of the sham group. As shown in figure 5, in the sham group VAS scored improved from 6.4 ± 1.6 before treatment to 5.4 ± 1.6 after the first treatment to 5.3 ± 1.8 after the sixth session; in the treatment group, there was also improvement from VAS 6.6 ± 1.3 before treatment to 4.0 ± 1.6 after the first treatment to 2.2 ± 1.0 after the sixth treatment. The scores were significantly more improved in the dry needling group after the first ($p=0.034$) and

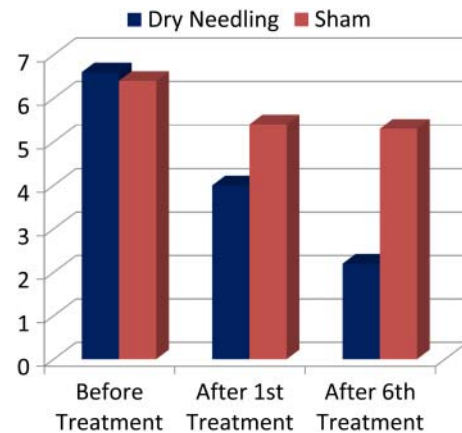


Figure 5 Myofascial pain visual analogue scale. Based on *Clin Rheumatol* Published Online First: 9 Nov 2012. doi: 10.1007/s10067-012-2112-3

the sixth treatment ($p<0.001$). SF-36 scores improved significantly in all subgroups after dry needling, but not after sham. Patients receiving dry needling also used significantly less paracetamol for pain relief.

Comments

This was a small study, but it had enough participants according to the power calculation. The authors concluded that dry needling was shown to be effective, although they conceded that four similar studies did not show this superiority of needling over sham. They felt that this was an effect of therapist variability and that having just one therapist delivering treatment in this study overcame this problem. However, the authors perhaps should have aimed for a larger trial instead.

Whiplash

► Tobbackx Y, Meeus M, Wauters L, *et al.* Does acupuncture activate endogenous analgesia in chronic whiplash-associated disorders? A randomized crossover trial. *Eur J Pain* 2012;17:279–8.

A randomised crossover pilot trial (n=39) comparing one session of acupuncture with relaxation treatment.

Methods

A total of 39 patients with chronic whiplash-associated disorder (WAD) were randomised to receive either 1 session of acupuncture treatment or a session of relaxation treatment first. The groups were then crossed over after 1 week to receive the other treatment so that the acupuncture group received a session of relaxation treatment and vice versa.

Manual acupuncture was performed by an experienced practitioner at unilateral or bilateral acupuncture points locally (neck) and distally (back, arms and legs) as well as ear points. The treatment was tailored to each individual by needling additional acupuncture points based on traditional Chinese medicine tongue and pulse diagnosis. A sensation of *de qi* was sometimes achieved on insertion of the needles but no

purposeful stimulation was attempted to achieve *de qi*. A minimum of six needles were used for each patient for a period of 20 min. The relaxation group listened to a recorded CD containing relaxation music and guided imagery for the same length of time as the acupuncture treatment and in the presence of the same therapist.

The primary outcome measure was a four-phase procedure that consisted of measuring the pressure pain sensitivities over the muscle bellies of the left upper trapezius and left calf using an algometer, and assessing pain induced by inflating an occlusion cuff around the right arm. Secondary outcome measures of self-rated pain and disability included the Neck Disability Index and the Whiplash Associated Disorders Symptom List questionnaires. All measurements and questionnaires were implemented before and after each treatment.

Results

One session of acupuncture resulted in acute improvements in pressure pain sensitivity in the neck and calf of patients with chronic WAD, as shown in figure 6.

Comments

This study was not designed to assess the mechanism of action of acupuncture, but rather its efficacy as an intervention that would require expanding to a course of treatment. It showed a generalised effect of acupuncture on reducing pain that was not restricted to the site of needling, which suggests an effect on reducing central sensitisation of pain. This hints at one of the potential mechanisms of action of acupuncture and at the lack of point specificity for at least some of its effects.

Traditional Chinese medicine (TCM) diagnosis as prognosis

► Liu YQ, Ma LX, Xing JM, *et al.* Does Traditional Chinese Medicine pattern affect acupoint specific effect? Analysis of data from a multicenter, randomized, controlled trial for primary dysmenorrhoea. *J Altern Complement Med* 2013;19:43–9.

This paper is a further analysis of a trial of TCM acupuncture.

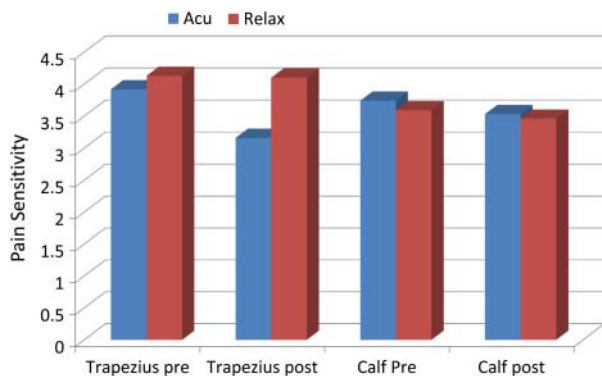


Figure 6 Pressure pain sensitivity. Based on *Eur J Pain* 2012;17:279–8.

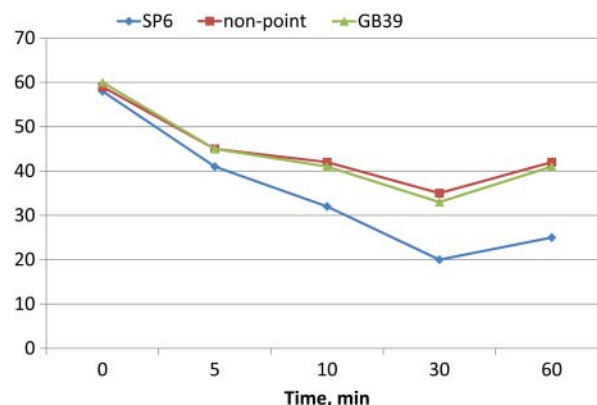


Figure 7 Dysmenorrhoea visual analogue scale. Based on *J Altern Complement Med* 2013;19:43–9.

Methods

This was a TCM pattern analysis of the data from a multicentre, randomised, controlled trial. A total of 501 participants from 6 hospitals diagnosed as having primary dysmenorrhoea were randomly divided into 3 treatment groups with 30 min or EA at 3 bilateral sites: SP6, or GB39, or an adjacent non-point. Participants were diagnosed using TCM patterns before the treatment. The improvement of pain was measured with a 100-mm VAS before the intervention, at 5, 10 and 30 min during the intervention, and at 30 min after the completion of this intervention.

Results

Three TCM patterns (n=320) were eligible for analysis, including the ‘Cold and Dampness Stagnation’ pattern (n=184), ‘Qi and Blood Stagnation’ pattern (n=84) and ‘Qi and Blood Deficiency’ pattern (n=52). In the Cold and Dampness Stagnation pattern, the SP6 group had a significant reduction in VAS scores compared with the GB39 group (mean difference –7.6 mm) and the non-point group (mean difference –8.2 mm), respectively, as shown in figure 7. There was no difference between the latter two groups and no group differences in VAS scores in the other two patterns.

Comments

This suggests that the TCM pattern, whose main feature is that the abdominal pain is ‘cold’ and alleviated by warmth rather than ‘distending’ and alleviated by pressure, might have a limited influence on acupuncture to SP6. It is difficult to see any meaningful physiological correlation.

SYSTEMATIC REVIEW

Style of acupuncture

► Hao XA, Xue CC, Dong L, *et al.* Factors associated with conflicting findings on acupuncture for tension-type headache: qualitative and quantitative analyses. *J Altern Complement Med* Published Online First: 17 October 2012. doi:10.1089/acm.2011.0914

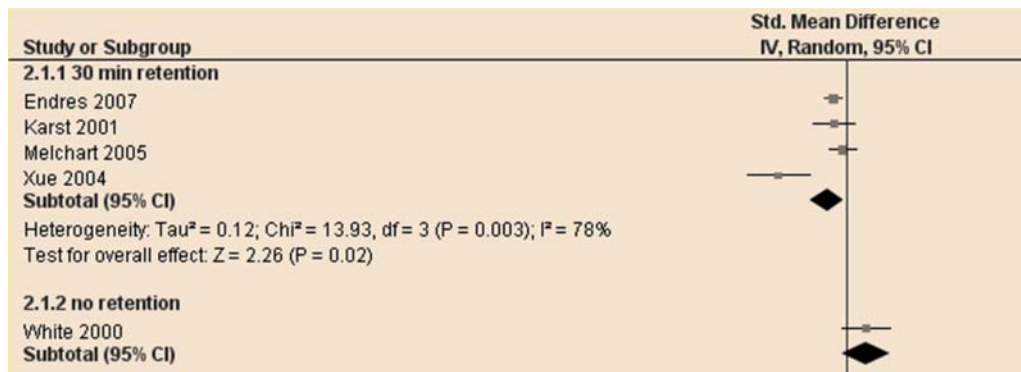


Figure 8 Effect of needle retention on days with headache. Based on *J Altern Complement Med* 2013;19:43–9.

Meta-analysis on whether study results vary according to type of acupuncture.

Methods

Out of 43 possible studies, only 5 studies of high methodological quality were included. The studies were grouped according to the treatments, and compared.

Results

Electroacupuncture (standard mean difference (SMD) -1.60 ; 95% CI -2.33 to -0.88) was more efficacious than manual acupuncture (SMD -0.13 ; 95% CI -0.41 to 0.14); needle retention for 30 min (SMD -0.46 ; 95% CI -0.87 to -0.06) was better than no needle retention (SMD 0.45 ; 95% CI -0.11 to 1.01), as shown in figure 8; and treatment twice a week (SMD -0.46 ; 95% CI -0.87 to -0.06) was better than treatment once a week (SMD 0.45 ; 95% CI -0.11 to 1.01). It made no difference whether the study was multicentre or single centre.

Comments

Various reviewers have tried to look in different ways at whether the results of acupuncture studies differ

because of the type of acupuncture. This simple analysis seems to imply that EA, needle retention over 30 min and treatment twice a week were more effective treatments. However a major problem exists with the study: the groups of studies were very small—often only one study—and the groups differed in more than one variable (for example, the number of points treated, or type of sham used), so the results are likely to be confounded.

Although one might want to believe the results, they are unreliable since this is not a strong study: a multivariate analysis would be preferred.

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