Research reviews

This section is designed to give a synopsis of some of the latest research published in Medline listed journals over the last year or so. It will concentrate on controlled trials and systematic reviews, but will also include other papers that may be of interest to the readership. Some papers will be reviewed in more detail than others. If summaries and comments are based on an abstract only, this will be indicated. The main reviewer in this section is Mike Cummings, London. Other reviewers are indicated after the relevant review.

RCTs

Acupuncture during recovery from arthroscopic acromioplasty (n=40)


Summary

Acupuncture may alleviate acute and chronic shoulder pain. Yet it has not been determined whether acupuncture is useful following musculoskeletal surgery. The aim of this study was to determine whether, compared to sham acupuncture, arthroscopic acromioplasty subjects who received real acupuncture would manifest significantly better recovery as demonstrated by: UCLA shoulder scale, improved range of motion, diminished pain, decreased need and duration of analgesic use, and enhanced patient satisfaction. Forty arthroscopic acromioplasty patients were randomised to real or sham acupuncture. UCLA shoulder scale scores, pain intensity, analgesic use, range of motion, and quality of life were monitored for four months. Data were analysed with the general linear model ANOVA for repeated measures. Thirty-five subjects completed the study. Real acupuncture subjects scored significantly better on UCLA shoulder scale (p<0.000); pain intensity (p<0.022); self-reported analgesic use (p<0.008); angles of abduction (p<0.046); and six of eight health status questionnaire components. The authors concluded that following arthroscopic acromioplasty, real acupuncture compared to sham acupuncture offered significantly greater improvement via: (1) lower pain level, (2) reduced analgesic use, (3) range of motion, and (4) patient satisfaction.

Comment

This is an interesting study that shows a positive effect for real acupuncture despite using a penetrating sham in the control group and having a relatively small number of subjects. The real acupuncture was individualised and involved needle insertion at points located anatomically and ‘confirmed’ by the presence of low skin resistance. Some needles were stimulated electrically, and auricular points were also used. The sham acupuncture involved needle insertion at points that ‘definitely did not have electrical characteristics similar to true acupuncture points’. In this group, two needles were inserted into the operated limb, and these were connected to a deactivated EA device. Needles were also inserted in both lower limbs.

The main disadvantage of using such an individualised approach is that the investigation cannot easily be repeated with an identical acupuncture intervention by another group. It also makes it difficult to determine the physiological differences between the groups. All that can be inferred from the report is that the real acupuncture group probably had more intense sensory stimulus to deep tissues in the area of the surgery, but this is by no means clear.
Auricular acupuncture for drug use in prison inmates (n=163)


Summary
This study tested the viability of auricular acupuncture in prisons for alleviating inmates’ symptoms of psychological and physical discomfort and reducing their drug use. The experimental NADA-Acudetox protocol was compared with a non-specific helix control protocol in a randomised trial. Over a period of 18 months, a 4-week, 14-session auricular acupuncture treatment program was offered in two prisons to 163 men and women with self-reported drug use. Among treatment completers, no differences by method were found in self-reported symptoms of discomfort. Drug use occurred in the NADA group but not in the helix group. In contrast, confidence in the NADA treatment increased over time while it decreased for the helix treatment. No significant negative side effects were observed for either method. Participants in both groups reported reduced symptoms of discomfort and improved night-time sleep. Future research should compare auricular acupuncture to a non-invasive control in order to attempt to disentangle active effects from placebo.

Comment
This is a relatively large trial comparing two different varieties of needling of the pinna. Needling the helix of the ear was developed as a sham control procedure when missing real points by a few millimeters in early trials of the NADA protocol failed to give positive results. The first study using this control gave a positive result in cocaine addicts, however, a much larger subsequent trial (n=620) showed no effect for either NADA protocol acupuncture or helix (sham) acupuncture over a relaxation control. This reviewer is intrigued by the persistence of research groups in testing the NADA protocol, and other forms of manual auricular acupuncture, in addictions. These interventions have proved singularly unimpressive in large and rigorous randomised controlled trials. Perhaps it is time to start trying other methods with a greater physiological stimulus, such as electroacupuncture, as was used by Wen and Cheung, who made the first observations of acupuncture effects on opiate withdrawal symptoms. It will be hard, however, to change the path of a whole industry of acupuncture practice and teaching, which has developed around the NADA protocol.

Reference list

Acupuncture relieves pelvic and low back pain in late pregnancy (n=72)


Summary
This study was designed to evaluate the analgesic effect and possible adverse effects of acupuncture for pelvic and low back pain during the last trimester of pregnancy. Following individual informed consent, 72 pregnant women reporting pelvic or low back pain were randomised during pregnancy weeks 24-37 to an acupuncture group (n=37) or to a control group (n=35) at three maternity wards in southern Sweden. Traditional acupuncture points and local tender points (TP) were chosen according to individual pain patterns and stimulated once or twice a week until delivery or complete recovery in acupuncture patients. Control patients were given no sham stimulation.
Throughout the study period each patient made weekly visual analog scale (VAS) evaluations of maximal and minimal pain intensity as well as three-point assessments of pain intensity during various activities. During the study period, VAS scorings of pain intensity decreased over time in 60% of patients in the acupuncture group and in 14% of those in the control group (P<0.01). At the end of the study period, 43% of the acupuncture patients were less bothered than initially by pain during activity compared with 9% of control patients (P<0.01). No serious adverse effects of acupuncture were found in the patients, and there were no adverse effects at all in the infants. The authors concluded that acupuncture relieves low back and pelvic pain without serious adverse effects in late pregnancy.

**Comment**

This was an open study, and so the effects measured cannot necessarily be attributed entirely to the specific effect of acupuncture needling; however, in all other respects the study performed well. The acupuncture treatment used in the study was robust. Periosteal stimulation was used ‘when possible’, and the authors describe an approach that started with local ‘tender points’, and progressed if there was insufficient response, to inclusion of the distal points BL60 and SI13, or a variety of techniques around the pelvis and back. Patients were treated for at least three weeks, with twice weekly treatment for the first two weeks and weekly thereafter. At the first session, *de qi* was stimulated at up to eight different acupuncture or trigger points, and the needles removed. At subsequent treatments *de qi* was stimulated twice at each point, with needle manipulations separated by 30 to 60 seconds. The needles were then removed and the patient left to rest for 10 minutes. Two of the 44 patients in the acupuncture group withdrew because they found the acupuncture treatment unpleasant.

The study suffered a dropout rate of about 28%, but the authors had allowed for 30% dropout, and the observed difference between groups was substantially greater than had been estimated for the purposes of the power calculation.

So far most of the work in this area has been performed in Sweden, perhaps it is time for other groups in other countries to get involved, and try to repeat the good results.

**Acupuncture does not help spasticity following stroke (n=25)**


**Summary**

The objective of this study was to determine whether needle acupuncture may be useful in the reduction of leg spasticity in a chronic state. The design was a single-blind, randomised, placebo-controlled trial. The setting was a neurologic outpatient department of a medical school in Germany. Twenty five patients (14 women) suffering from chronic poststroke leg spasticity with pes equinovarus deformity (Modified Ashworth Scale [MAS] score ≥1), aged 38 to 77 years (mean ± standard deviation 58.5±10.4 years), were enrolled in the study. The mean time from stroke to inclusion in the study was approximately 5 years (mean 65.4±48.3 months; range 7-180 months). Participants were randomly assigned to placebo treatment (n=12) by using a specially designed placebo needling procedure, or verum treatment (n=13). The main outcome measures were MAS score of the affected ankle, pain (visual analogue scale), and walking speed. There were no demonstrated beneficial clinical effects from verum acupuncture. After four weeks of treatment, mean MAS score was 3.3±0.9 in the placebo group versus 3.3±1.1 in the verum group. The neurophysiologic measure of H-reflex indicated a significant increase of spinal motor neurone excitability after verum acupuncture (H-response/M-response ratio: placebo 0.39±0.19; verum 0.68±0.41; P<0.05). The authors concluded that the measured effect might be explained by afferent input of A delta and C fibres to the spinal motor neurone. The results from this study indicate that needle acupuncture may not be helpful to patients with chronic poststroke spasticity. However, there was neurophysiologic evidence for specific acupuncture effects on a spinal (segmental) level.
Research reviews

Involving nociceptive reflex mechanisms.

**Comment**

This was a controlled trial using a non-penetrating sham device, thus any relevant physiological effect of the control procedure was minimal. The acupuncture treatment could have been more robust, since the report does not describe *de qi* being stimulated, nor the use of electroacupuncture. Up to 15 needles were left in place for 30 minutes at each session, and eight sessions were performed in a four week period.

Acupuncture had no significant effect in any of the clinically relevant outcome measures. The fact that there was a significant difference at the 5% level in one measure is not terribly remarkable given the low numbers and the fact that there were more than 10 separate measures taken (each having a 1:20 chance of a type 1 error at the 5% level).

It is not surprising that acupuncture appears to have no effect in spasticity since its effects (as determined so far) are mediated through peripheral afferent stimulation and the resulting central neuromodulation. These effects are unlikely to have significant impact on conditions characterised by upper motor neurone deficits, or other central nervous system disorders.

**Other clinical papers**

**Peripheral afferent nerve stimulation – electroacupuncture to SP6 (n=51)**


**Summary**

The objective of this study was to assess the efficacy of posterior tibial nerve stimulation for treatment of lower urinary tract irritative symptoms (urgency, frequency, urge incontinence and pelvic pain). Fifty one female patients with a mean age of 55 years were enrolled in the study. The patients presented with the following symptoms: frequency/urgency 26 patients (50.98%), urge incontinence 22 (43.13%) and interstitial cystitis three patients (5.88%). The technique consists in administering low voltage electric stimulation via a 3-5cm needle placed above the tibial malleolus. Patients received weekly stimulations of 30 minutes for a 10-week period. Quality of life questionnaires and voiding diaries before and after treatment were completed. Moreover, the results were evaluated by patients. The variables analysed included: daytime and night-time voiding frequency, daytime and night-time voiding volume, daytime and night-time leakage episodes and hypogastric pain. A statistically significant improvement was seen in all variables, especially remarkable in relation to frequency/urgency, impact on women’s quality of life and hypogastric pain, being less marked in relation to leakage episodes and voiding volume. The authors concluded that afferent nerve stimulation offers an alternative treatment for managing lower urinary tract irritative symptoms, but it would be advisable to confirm the results obtained by means of long-term randomised, follow-up studies.

**Comment**

This is a cohort study that used the Stoller Afferent Nerve Stimulator (SANS) device. The device is named after Marshall Stoller, a urologist from California. SANS consists of a small electrical stimulus generating unit, like a TENS machine, and a single cable that divides to attach to a TENS pad and a needle. The needle is placed at SP6 (or thereabouts), and the TENS pad is placed on the medial aspect of the foot (although this location is probably unimportant). It effectively delivers electroacupuncture to SP6. Under the name of UroSurge Percutaneous SANS (Stoller Afferent Nerve Stimulator) Device, it was approved by the FDA in 2000, and classified under the generic name ‘non-implanted, peripheral nerve stimulator for pelvic floor dysfunction’.

This reviewer has little doubt that high intensity somatic stimulation in the bladder segments will be shown to have specific effects on bladder activity and symptoms, but the same levels of evidence of efficacy should be required of ‘peripheral afferent nerve stimulation’ as are required for acupuncture techniques.
Non-clinical papers

Statistical reanalysis of four recent acupuncture trials


Summary

Acupuncture has been promoted for the treatment of chronic pain. Though many randomised trials have been conducted, these have been criticised for deficiencies of methodology, acupuncture technique, and sample size. Somewhat less emphasis has been placed on methods of statistical analysis. This paper describes four recent randomised trials of acupuncture for musculoskeletal or headache pain. Each trial used statistical methods that did not adjust for baseline pain scores and were thus of suboptimal power. The objective of this study was to reanalyse the trials using analysis of covariance (ANCOVA). Raw data for the four trials were obtained from the original authors. Data were reanalyzed by ANCOVA. For two trials - acupuncture versus placebo for chronic headache and acupuncture versus transcutaneous electric nerve stimulation for back pain - reanalysis did not change the conclusion of no difference between groups, but showed that clinically significant differences between groups could not ruled out. Reanalysis of a trial of acupuncture versus placebo for shoulder pain slightly strengthened the evidence of acupuncture effectiveness. Reanalysis of the fourth trial, which compared acupuncture to placebo acupuncture and massage for neck pain, reversed the results of the original paper: reanalysis found acupuncture to be effective and that its effectiveness could not be ascribed to a placebo effect. Future trials of acupuncture and other modalities for pain should use efficient statistical methods. ANCOVA is more efficient than unadjusted analysis where used appropriately.

Comment

Why is it important to take into account baseline differences in pain scores? In most trials, baseline and post-intervention scores are used to calculated the change score (usually an improvement), and these are compared between groups to see whether there is a difference in the effects of the interventions. If change scores are used, then surely baseline differences are accounted for? But as Vickers points out, using change scores does not account for ‘regression to the mean’ – the tendency for greater change in subjects with higher baseline scores. ANCOVA takes account of any effect of differences in baseline scores by fitting the data to regression lines with the same slope in all groups. The technique is only valid if this can be done. A bonus of using this method is that the statistical power of the trial is increased by between 10 and 15%.

A good summary of ANCOVA (with very useful graphical illustrations) can be found at: http://www.uccs.edu/~lbecker/psy590/ancova2.htm (accessed on 21/11/04).