

BRIEFING PAPER No 1

Migraine and Acupuncture

The evidence for effectiveness



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The Evidence Series of Briefing Papers aims to provide a review of the key papers in the literature, which provide evidence of the effectiveness of acupuncture in the treatment of specific conditions. The sources of evidence will be clearly identified ranging from clinical trials, outcome studies and case studies. In particular this series of briefing papers will seek to present, discuss and critically evaluate the evidence.

MIGRAINE AND ACUPUNCTURE: THE EVIDENCE FOR EFFECTIVENESS

Summary

Acupuncture has been much used in the treatment of migraine and episodic tension headache both in China and the West. This paper assesses the quantity and quality of the evidence for the use acupuncture in treating this condition. Our conclusion is that there is some evidence that acupuncture has a significant therapeutic effect on symptoms such as pain and frequency in migraine attacks.

Introduction

Migraine is described as the most frequently encountered condition treated in the NHS, which does not lead to disability or death, and costs £20 million per annum. It affects about 20% of the UK population of which 60% to 70% are women. It also has dramatic effects on the functioning of the economy, for example in the UK an estimated 60% of sufferers lose time from work (Tukmachi 1994).

Migraine is defined as "a complex constellation of symptoms effecting the nervous system, gastrointestinal tract and vascular systems" (Lewith 1996).

The highly debilitating nature of recurrent migraine attacks and the limited effectiveness of medications, all of which can give rise to unpleasant side effects (Shaikh 1986), bring many patients to acupuncture for treatment. A recent article reported that it is the 6th most common condition presenting to acupuncturists (Wadlow 1996). In a study of student doctors in Norway, 63% said they would refer patients with migraine for acupuncture (Norheim 1993). Thus both public and professionals are becoming aware of the benefits of this form of treatment.

Literature Search

A search was made on the specialist acupuncture database, ARRCBASE, using the term 'migraine' and 'acupuncture' and 73 references were found. ARRCBASE is a composite database which has been built up by the Acupuncture Research Resources Centre and it incorporates relevant articles from the British Library's AMED and the US Medline databases.

Most of these articles were not trials and were excluded from this study. Based on a review of these articles and their citations, we present here the evidence from 12 trials for migraine where the primary treatment was with acupuncture. Of the 12 trials, 6 were uncontrolled outcome studies, and 6 were classified as randomised controlled trials.

Outcome Trials

In the 6 trials falling into this group, results are mostly given in terms of a 'global assessment' of improvement derived either from the patients or practitioner. All these trials were outcome studies which followed a group of patients treated by acupuncture. Outcomes were arrived at either through posing a simple question on perceived change to patients (Tukmachi 1994, Junnila 1986) or from the practitioner's assessment (Laitinen 1975). In some cases the mechanism for assessing outcome was not clear, and only the studies by Baischer(1995) and Boivie & Brattburg (1987) utilised more detailed outcome measures.

The results ranged from 81% responding positively to treatment (Shaikh 1986) to 84% (Tukmachi 1984) and as high as 92% (Laitinen 1975). Baischer (1995) reported 69% of patients improving 'more than 33%', with 58% maintaining this improvement at a 3 year follow up.

A long term study of 115 patients from Finland found 77% responded to treatment, with a 81% reported reduction in pain levels maintained over 2 years and a 55% reduction in frequency and duration of episodes at 10 months post treatment (Junnila 1986). In this study 75% of patients reduced their drug intake by at least half.

While outcome studies are useful indicators of *effectiveness*, randomised controlled trials are generally considered more rigorous (Richardson & Vincent 1986). An evaluation of *efficacy* takes place where a randomised controlled trial is designed to assess the specific effect of acupuncture intervention while excluding the other non-specific effects of treatment generally.

Controlled Trials

Of the 6 randomised controlled trials, 5 involved control groups who received a placebo treatment such as sham acupuncture, and one compared the effectiveness of acupuncture with medication.

The evaluation of outcomes from these randomised controlled studies usually incorporate measures of intensity, duration and frequency of migraine attacks. Some researchers have devised indices based on these factors (Tavola et al 1992, Vincent 1989) and many also took note of decreases in use of prophylactic and analgesic medications (Vincent 1989, Tavola et al 1992, Hesse et al 1994).

Vincent (1989) observed that after 6 weekly treatments a reduction in weekly pain scores of 43% and a 38% reduction in medication were achieved and maintained at a 1 year follow up. This study is noteworthy in that it tested the credibility of the sham treatment used; an

introduction to good design that was not repeated until a study in 1996 (White et al 1996). This was a small pilot study with no follow up which showed that those having active treatment had significantly more weeks free from headache although it failed to show a significant difference in mean weekly headache scores between the two groups.

In another study, Tavola et al (1992) devised a headache index from patient diary recordings and found at the end of the 8 week treatment period that the index had decreased 58% in the group receiving active acupuncture, a highly statistically significant change in relation to the sham group. Frequency of attacks was reduced by 44% with acupuncture (also a statistically significant change) and analgesic intake had reduced by 58% in this group compared to 22% in the sham group. Results were well maintained at the 6 and 12 month follow-ups.

In an early trial by Dowson et al (1985) a small (20%), non-significant superiority of acupuncture over the placebo of mock TENS treatment was recorded when measuring average pain scores. One of their conclusions was that because all those improving reduced intake of analgesics, this could well be used as a clear measure of success or failure in future studies.

A trial with a "crossover" design (Loh et al 1984) was carried out with a population of severely affected migraineurs, those referred to a neurologist. In this study a global improvement of 59% was attributed to acupuncture by patients but a high proportion (45% of patients) were not helped by either acupuncture or the alternative of various medications .

A trial carried out in Denmark (Hesse et al 1994) compared the effects of trigger point acupuncture and placebo pills with sham acupuncture and metoprolol (a prophylactic medication for migraine). Both treatment regimes had a significant effect in reducing frequency and duration of migraine attacks, although neither proved statistically superior to the other. An important conclusion of this study was that acupuncture was particularly valuable because of the lower incidence of side effects.

Discussion

Migraineurs are a highly heterogeneous group in acupuncture terms and the use of simple formulaic acupuncture is unlikely to be an appropriate protocol for treatment (Birch 1998, Blackwell 1991). From the perspective of traditional acupuncture, treatments should be able to be individualised in at least two dimensions: the choice of points to match the patient, and changes in point prescriptions over time. Other aspects of treatment given as standard, such as lifestyle advice or moxibustion, also need to be included.

The use of a control group that receives a placebo treatment in the form of sham acupuncture should be expected to offer more reliable measure of the benefits of the acupuncture itself. However it appears that the use of sham acupuncture is unsatisfactory as it *"seems to have either an intermediate effect between that of placebo and 'real' acupuncture points or effects similar to those of real acupuncture points"* (NIH 1997). As a result, the controlled trials that use sham acupuncture as a control will systematically underestimate the therapeutic gain (Vincent & Lewith 1995).

Conclusion

All the uncontrolled trials demonstrated that acupuncture is highly effective, often helping over 80% of patients. This is considerably more effective than a likely placebo response which has been estimated to be from around 30% to as high as 50% (Tavola et al 1992). In all the controlled studies, treatment was shown to be more effective in at least one measure(i.e. pain intensity or frequency of attacks), with statistical significance reached in two studies (Vincent 1989, Tavola et al 1992). In the comparative study (Hesse et al 1994), acupuncture performed as well as the standard therapy with the added benefit of a lower incidence of side effects. Overall the evidence supports the hypothesis that acupuncture is effective in the treatment of migraine.

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Migraine studies: a summary of the evidence

Study	Sample size	Control	Stats	Outcome Measures	Form of Acupuncture reported	Number of treat's	Results	Follow up
Baischer 1995	26	X	X	Diary (IDF,Med)	Indiv	6-13	68% improved > 33% of whom 58% maintained this for 3 yrs	3yrs
Boivie 1987	25 (severe chronic cases)	X	Yes	Diary (IDF,Med) index. Base:GH q'aire etc	8-15 local pts	5-10	t1and t2 index improved. p=0.01 28% free of migraine for 9mths 44% no benefit	9mths Also 3mth run in
Dowson 1985	39	mock TENS	Yes	Diary (IDF, Med, symps) with scales	Indiv.10 mins with deqi	6	<20% better than placebo. Almost all >33% better. Decreased analgesic use	24wks. Also 4 wks prior
Hesse 1994	77	Comp. Metoprolol 100mgs & placebo acup	Yes	Diary (IDF, Med) + global score of 1-3)	Trigger points in neck	6-8	Frequency dec for both groups p=0.01 No sig diffs between groups. Acup better because fewer side effects. Decreased analgesic use	No 4 week run in
Junnila 1986	121	X	X	?self report on IDF and medication use	?some indiv from a selection of points	3-6	81% dec pain maintained over 2years 55% dec F&D at 10mths	56% followed over 6yrs
Laitenen 1975	39	X	X	Dr evaluation	2 points BI2,LI4	Av 5	92% improved.54% relapsed after 6mths	6mths
Loh 1984	48 (many severe)	Crossover, with prophylactic drugs	X	Diary plus patient scale of effects: interviews. Also, Becks depression and Eysenek's personality tests	Min 6 points for 2 mins. inc LI4,Liv3	?	59% improved with acup: 25% with medication. 29 changed tx, most preferred acup. Analgesic levels cut. 45% no effect from either treatment	3mths crossover and 6 mths.

Shaikh 1986	105	X	X	? patient or Dr evaluation	Formula from GV20,P6,Liv3,He7,L14	X	81% 'positive' response. 48% complete relief. 33% F&D dec. 5% no response	X
Tavola 1992	30	sham, shallow close to points	Yes	Diary (ID, med) + baseline GH	Indiv	8	Means, at $p=0.001$. t tests and Anova. index 58% dec acup: 28% sham medication 58% dec acup: 22% sham, (well maintained) Frequency 44% dec acup: 21% sham	2mths and 12 mths.
Tukmachi 1994	46	X	X	1-4 scale for patients report	6+ needles, some indiv + electro	? av 8wks	84% migraines either disappeared or showed marked improvement.	8wks and 1 yr
Vincent 1989	30	sham, light, shallow at non-points	Yes.	Diary (I, med). Also Psych tests and credibility. Index compiled	8 points. Formula, Liv3, Taiyang GB20/BI10 and local	6	Sig diffs between groups pain dec 43% acup: 14% sham. 38% dec in medication , maintained at 1 yr Analysis of Variance	6wks + 4 mths + 1yr. 4wk run in
White 1996	9	cocktail stick on surface		Diary (IDF) after Tavola. Mean weekly index	Brief needling of 2-6 tender local points, +L14	6	Overall a significant change in number of weeks free of headache. No sig diffs between groups	X 3 wk run in.