A single-blind, controlled and randomised clinical trial to evaluate the effect of acupuncture in the treatment of trapezio-metacarpal osteoarthritis

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Summary

A single-blind, controlled, randomised trial was undertaken to evaluate the effect of acupuncture on trapezio-metacarpal (TMC) joint osteoarthritis (OA).

Patients were randomised to treatment (acupuncture) or placebo (mock TNS) group and received 6 sessions of either procedure over a two week period. Assessments were undertaken blind to treatment:- i) at recruitment ii) after treatment and iii) during follow-up.

This study was undertaken in partial fulfilment of the requirements for Masters degree for which 5 months were available for data collection. Despite undertaking a 2 centre trial, only 12 patients completed the full course thus reducing its statistical power. Indeed the acupuncture group gained a 76.01% pain reduction and the mock TNS group 20%; but this difference was only statistically significant within and not between groups.

However, the trial provides further validation of the acupuncture versus mock TNS study model as an effective method of evaluating acupuncture in a controlled manner.

Introduction

Acupuncture has been extensively researched since its revival in the West in 1972, and this has provided much evidence to validate its analgesic effects [1 2].

Here acupunture is mainly used in the treatment of chronic pain, a symptom commonly caused by osteoarthritis (OA). Functional capacity may also be affected by OA and this is particularly evident with trapezio-metacarpal (TMC) joint involvement. However, few studies have been undertaken to establish the efficacy of acupuncture specifically for OA [3].

Treatment for TMC joint OA is aimed at relieving pain and maintaining/improving function. Drugs and physical therapy are commonly utilised and surgery is undertaken in severe cases. However, both pharmacological and surgical therapies carry higher risks of complications and side effects than physical therapy [4] and surgery is not always a feasible option [5]. Conversely physical therapy, although varied and widely used, has received little scientific investigation.

Hence this trial was undertaken to:- a) investigate the physical therapy modality of acupuncture in the treatment of TMC joint OA and b) test the following hypothesis:-

Acupuncture is more effective than mock transcutaneous electrical nerve stimulation (TNS) in alleviating the pain and disability associated with osteoarthritic trapezio-metacarpal joints.

Methodology

The model chosen to test the hypothesis was mock TNS versus acupuncture in a single-blind, randomised, controlled trial. This format was selected in view of the proposal that sham acupuncture (ie needle insertion in non-acupuncture points), elicits a response that is greater than the placebo alone [6]. Thus using sham acupuncture, ineffective versus real acupuncture would be tested rather than placebo versus real acupuncture. Furthermore, to achieve statistical power a larger patient population would be required with sham acupuncture than with mock TNS. This was not feasible within the time constraints of the MSc course.

The trial was undertaken at Queen Alexandra Hospital, Portsmouth and Southampton General Hospital.

Patients were admitted if:-

a) Clinical diagnosis of TMC joint OA was radiologically confirmed.

b) There was no other site of significant chronic pain.

c) There was no previous operative intervention or fracture involving the thumb.

d) They had received no previous TNS or acupuncture treatment.

e) They had received no steroid therapy in the previous 6 months.

f) They were not pregnant.

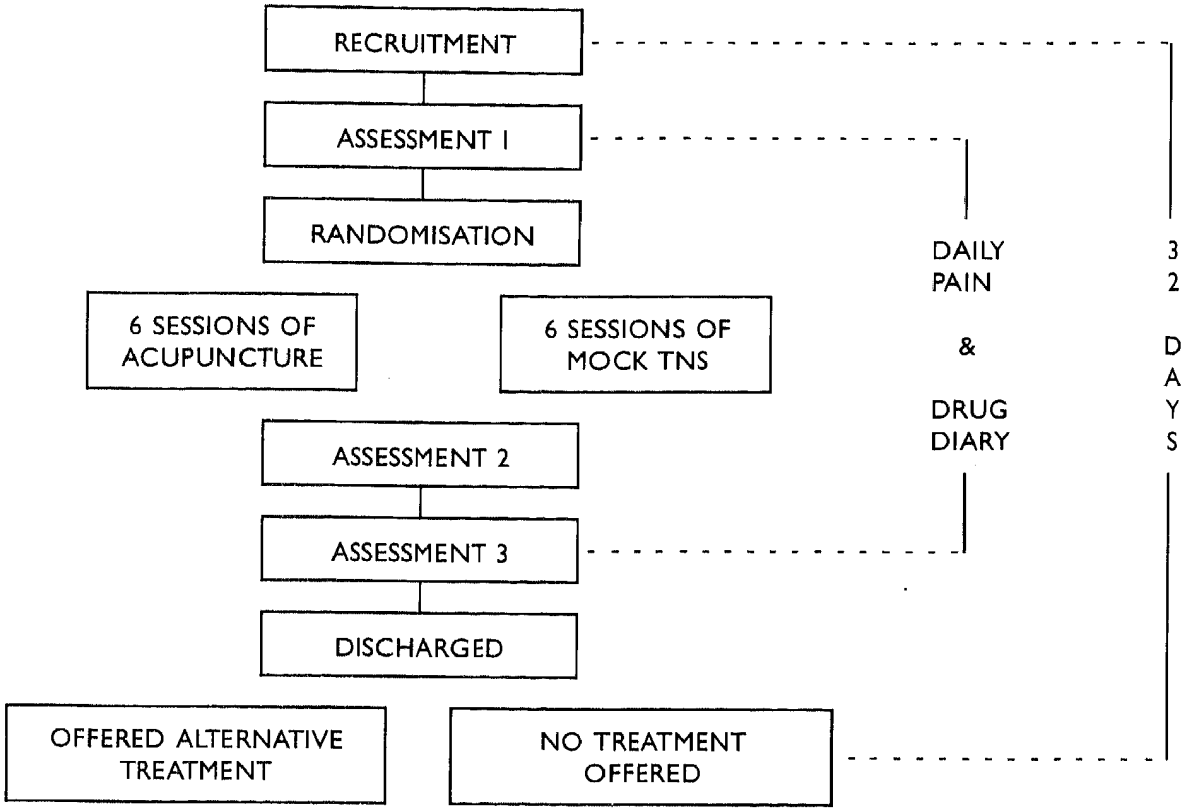
Recruited patients were randomised to either treatment or control group. Randomisation was performed by a computer programme from which treatment cards were placed into envelopes and sealed. This was stratified for centre.

Each patient received 6 sessions of either procedure over a 2 week period and kept a daily diary of thumb pain (on a visual analogue scale) and drug intake throughout the trial. The investigator administered both treatment procedures.

Assessments were undertaken blind to treatment and included a combination of subjective and objective measures: functional capacity, pinch grip, joint tendernesss, sleep disturbance and verbal rating of improvement. Assessments took place:-

1. 1 week prior to the commencement of treatment.
2. At the end of treatment.
3. 2 weeks after treatment had ceased.

Flow chart: Summary of procedure



Results

Patient population

13 patients were recruited and 12 completed the trial. Of these 12, 7 were female and 5 male.

1 mock TNS patient experienced pain in his untreated hand following treatment. He remained concerned despite reassurance and was therefore discharged from the study.

7 patients received acupuncture and 5 mock TNS. The 2 treatment groups were comparable in age, sex and duration of symptoms (See Table 1), therefore differences in outcome were assumed to be a treatment effect.

Subject measures

1. PAIN:- Three periods of the 5 week visual analogue scales (VAS) were considered:- A) Baseline week, B) Second week of treatment C) Second week of follow-up.

The group results were analysed using the Wilcoxon test for non-parametric statistics (See Table 2a & b). This revealed that acupuncture patients experienced a significant percentage pain reduction between periods A and B p= 0.02 (95% CI -76.14, -32.77) and A and C p=0.04 (95% CI -90.54, -28.37). In the mock TNS group these changes were not significant p=0.10 (CI 95% -8.01, 0.00) and p=0.06 (95% CI -8.01, 0.00) respectively.

Table 1: Summary of the patient population.

Variable	Acupuncture group	Mock TNS group	Total
No. patients	7	5	12
No. women	4	3	7
No. men	3	2	5
Q. A. H.	4	4	8
S. G. H	3	1	4
Age range	48-77 years	52-69 years	48-77
Mean age	59 (SD 8.91)	59.2 (SD 6.46)	/
Mean women	61 (SD 12.03)	60.3 (SD 8.5)	/
Mean men	56.3 (SD 1.53)	57.5 (SD 3.54)	/
Range pain	1-5 years	2-5 years	
Mean	3.2 (1.68)	3.2 (1.3)	

NB. Numbers in brackets are standard deviations.

Table 2a: Acupuncture group.

Periods compared	Median	Wilcoxon test results
A and B	−69.22	p=0.02 (95% CI −76.14, −32.77)*
A and C	−76.10	p=0.04 (95% CI −90.54, −28.37)*
B and C	−10.00	p=0.27 (95% CI −24.16, 12.77)

Table 2b: Mock TNS group.

Periods compared	Median	Wilcoxon test results
A and B	−73.00	p=0.10 (95% CI − 8.01, 0.00)
A and C	−20.00	p=0.06 (95% CI −90.16, −2.39)
B and C	1.70	p=0.59 (95% CI −17.11, 60.00)

- Denotes pain reduction.
* Denotes result significant at the 5% level.

Table 2: Within group analysis of VAS changes.,g,+

The percentage pain reduction between periods A and C in the acupuncture group was 76.10% and the mock TNS group 20.01%. However despite this large actual difference, with the small patient population statistical significance at the 5% level was not achieved p= 1.0 (CI 95% -69, 28).

2. VERBAL RATING OF IMPROVEMENT:- 85.7% of acupuncture patients and 40% of mock TNS patients reported improvement. But again with the small patient population this difference was not statistically significant p=0.15 (1 d.f. 1 tailed test).

3. FUNCTION:- All 7 acupuncture patients and 3 mock TNS patients recorded improvement in function and the 2 remaining mock TNS patients reported no change. Analysis of within group changes (See Table III), revealed that the only significant improvement occurred in the acupuncture group between assessments 1 and 3 p0.02 (CI 95% 1, 7). However, between groups, differences were not statistically significant at the 5% level for any comparison.

Table 3: Within group analysis of changes in functional scores

Assessment comparison	Wilcoxon test results					
	Acupuncture group			Mock TNS group		
	Median	p-value	95% CI	Median	p-value	95% CI
1 and 2	1	p=0.09	(0, 6)	2	p=0.10	(0, 7)
1 and 3	2	p=0.02	(1, 7)*	1	p=0.10	(0, 7)
2 and 3	1	p=0.10	(0, 2.5)	0	p=1.00	(−, 0)

4. DRUG INTAKE:- Only 7 patients were taking drugs prior to trial entry (3 acupuncture and 4 mock TNS).
Of these, 1 acupuncture and 2 mock TNS patients were drug-free after treatment. The remaining 4 had maintained their intake.

5. SLEEP DISTURBANCE:- The 2 patients reporting sleep disturbance as a result of their thumb pain, both received acupuncture and reported 'no disturbance' at final assessment.

Objective measures
1. PINCH GRIP:- Both groups recorded increasing pinch grip from assessment 1-3, although the acupuncture group recorded a more rapid and substantial increase.

2. JOINT TENDERNESS:- Analysis revealed decreased joint tenderness from assessment 1-3 in the mock TNS group. However, the acupuncture group, after an initial decrease, recorded an increase to above the pre-treatment level.

Statistical analysis did not reveal any significant differences either within or between groups on either objective measure p> 0.11.

Discussion

The results suggest that acupuncture is more effective than placebo treatment in reducing the pain and disability associated with TMC joint OA; some of the results relating to pain being statistically significant. Therefore the hypothesis can be tentatively accepted. They also support the results of previous studies, although to produce more statistically significant results, larger patient numbers would be required.

Pinch grip did not increase as significantly as expected in view of the pain relief achieved. However, this may reflect the influence of the deformity and instability associated with TMC joint OA. Joint tenderness results for the acupuncture group were interesting as a number of patients reported joint soreness as a result of needle insertion. It could be assumed that this objective measure reflected subjective reports, although examination of individual scores does not confirm this. It may be that these two objective measures were not adequate for the trial. Indeed for some subjective outcome measures, insufficient data was available with which to make any firm conclusions about treatment efficacy.

This study was undertaken in partial fulfilment of the requirements for Masters degree for which 5 months were available for data collection. Despite undertaking a 2 centre trial, only 12 patients completed the full course thus reducing it statistical power. However, despite this the methodology is sound and effective and provides further validation of the mock TNS (placebo) versus acupuncture model as a method of evaluating the clinical effectiveness of this technique.

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