Clinical study comparing acupuncture, physiotherapy, injection and oral anti-inflammatory therapy in shoulder-cuff lesions

H. Berry, D.M., M.R.C.P.,
L. Fernandes, M.R.C.P.,
Brenda Bloom, B.A.,
R. J. Clark,* M.B., B.S., M.B.Ac.A., and
E. B. D. Hamilton, B.Chir., F.R.C.P.

Department of Rheumatology, King's College Hospital, London, England

Curr. Med. Res. Opin., (1980), **7**, 121.

Received: 5th June 1980

Summary

In a single-blind trial, five treatments for painful stiff shoulder were compared for a 4-week assessment period in 60 patients. The treatments were acupuncture, steroid injection with placebo and with active tolmetin sodium, physiotherapy in the form of ultrasound and 'placebo' physiotherapy with placebo tolmetin sodium. Objective assessment was gained by use of goniometer readings to monitor shoulder abduction. Pain was measured by visual analogue scales and by a 4-point scale. Comparative assessment was also recorded and at the end of the study a success or failure was recorded for each patient's treatment. With very few exceptions all patients improved markedly, both in terms of the subjective and objective parameters. No differences between the treatments were detected. The incidence and severity of side-effects was low. It is suggested that the results show that the painful stiff shoulder may be a self-limiting condition and that any beneficial effect was really due to natural recovery. This is an important consideration because patients do not always receive immediate attention when referred to an out-patient department and the use of physiotherapy and acupuncture in such cases, perhaps, should be critically examined.

Key words: Tolmetin – acupuncture – ultrasonic therapy – shoulder joint

Introduction

The painful stiff shoulder presents a common, though often difficult therapeutic challenge, since there is no agreement on the most effective forms of treatment. Physiotherapy, steroid injections, manipulation under anaesthesia and analgesics[2] have all been recommended, but treatment is generally unsatisfactory because of lack of controlled data. Even in studies using adequate controls, there are conflicting reports on the relative merits of different treatments.[5]

In view of this, we decided to evaluate the efficacy of acupuncture – a much publicised therapeutic aid for pain relief[4] – and compare it with steroid injection, physiotherapy and the non-steroidal anti-inflammatory drug, tolmetin sodium.†

*Acupuncturist in Private Practice, London

†'Tolectin', trade mark Ortho

Patients and methods

The patients selected for inclusion in the study were males or females attending King's College Hospital out-patients department, following a doctor's referral. They had pain arising from the shoulder due to a rotator-cuff lesion. For the purpose of this study it was defined as 'pain on resisted movements of the shoulder, with loss of passive movement, mainly abduction'. Many of these patients had the painful arc syndrome and those with a 'frozen shoulder' were specifically excluded. Other exclusion criteria were the presence of underlying fracture, associated inflammatory arthritis, known renal or hepatic disease, haemopoietic disorder, malignancy, any mental disorder likely to interfere with the course or assessment of the disease process, a history of severe indigestion, peptic ulceration, or any significant gastro-intestinal condition likely to affect drug absorption. Women who were pregnant or at risk of pregnancy were also excluded.

After obtaining their informed consent to participate, the patients were treated in one of five groups: (i) *acupuncture*. This was administered once a week by a medically qualified doctor using classical Chinese acupuncture with moxibustion. The practitioner is a member of the British Acupuncture Association, and a recognized teacher at the College of Acupuncture; (ii) *steroid injection plus placebo tolmetin sodium*. The injections consisted of 40 mg methyl prednisolone with 2 ml of 2% lignocaine, given by the same person using the anterior approach to the shoulder joint. (Placebo tolmetin sodium was given at the dosage of 2 tablets 3-times daily); (iii) *steroid injection plus active tolmetin sodium*. The steroid was administered as above, and tolmetin sodium was given at a dosage of 1200 mg daily in 3 equally divided doses of 2 × 200 mg tablets; (iv) *physiotherapy in the form of ultrasound*. A standardized treatment programme was used by a qualified therapist consisting of 8 sessions of 10 minutes each; and (v) *placebo tolmetin sodium plus 'placebo' ultrasound*. The latter was administered by the physiotherapist who sat the patient in front of the machine without switching it on.

Each group contained 12 patients who were allocated treatment according to a random code. Paracetamol was prescribed for use throughout the trial period as a rescue analgesic to be taken as required up to 8 tablets per day; all other analgesics were excluded. If other conditions, present at the start of the study, required drug therapy the medication was prescribed at a stable dose throughout the study.

All patients had an X-ray of the affected shoulder and the following indices were recorded by a blind, external observer at the start of the study and at 2 and 4 weeks: (a) pain using a 100 mm visual analogue scale[1] and a 4-point scale for none, mild, moderate and severe pain, (b) shoulder abduction using a goniometer, (c) comparative assessment by patient and assessor scored as 'much better', 'better', 'same', 'worse' or 'much worse', (d) success or failure of treatment at the end of 4 weeks, being defined in the opinion of the assessor as the need for a steroid injection, and (e) adverse effects in response to the question "Has the treatment upset you in any way?"

Results

Sixty patients were admitted to the study. There were no differences between the

five groups in terms of age, sex and duration of symptoms. The admission data are summarized in Table I.

Table I. Admission data for 60 patients included in the trial

Data	Acupuncture	Steroid injection/ placebo tolmetin sodium	Steroid injection/ active tolmetin sodium	Physiotherapy	'Placebo' physiotherapy/ placebo tolmetin sodium
No. patients	12	12	12	12	12
Sex: Male	8	6	4	5	6
Female	4	6	8	7	6
Age (yrs): Mean	52.3	54.1	51.2	55.1	56.2
S.D.	10.8	16.7	14.6	12.7	11.2
Duration of disease (weeks):					
Mean	20.3	23.6*	28.3	16.3	27.5
S.D.	16.9	27.9	15.2	14.5	35.0

*Excluding 1 patient with a disease duration of 10 years

Pain

Visual analogue scale. There were no differences between the groups in terms of their initial pain when measured by the visual analogue pain scales (Table II). All groups showed a statistically significant improvement during the 4 weeks of the study (Wilcoxon rank sum test for paired samples). However, the differences between the groups showed no statistical difference when analyzed using the Wilcoxon rank sum test for unpaired samples.

Table II. Visual analogue scale readings (min) for pain before and after treatment: mean (±S.D.) values

Treatment	Week 0	Week 2	Week 4
Acupuncture	41.3±33.2	38.6±26.7	34.1±27.2
Steroid injection/ placebo tolmetin sodium	39.0±26.3	20.6±20.5	26.6±22.5
Steroid injection/ active tolmetin sodium	39.1±27.3	26.2±21.3	29.2±24.3
Physiotherapy	48.2±29.9	33.7±34.0	41.2±36.6
'Placebo' physiotherapy/ placebo tolmetin sodium	52.2±26.0	29.4±23.6	22.0±28.6

Four-point scale. All patients assessed their pain as at least 'mild' on admission to the study and 75% admitted to pain of moderate to severe intensity. After 4 weeks, one-third had pain of moderate intensity and none had severe pain. There were no differences between the treatment groups.

Shoulder abduction

The goniometer readings for shoulder abduction are summarized in Table III. There were no statistically significant intergroup differences at the start of the study and all groups improved markedly ($0.01 > p > 0.001$ using paired t-test). There were no differences between the effects of the various treatments on shoulder abduction (unpaired t-test).

Table III. Goniometer readings of shoulder abduction: mean (±S.D.) values

Treatment	Week 0	Week 2	Week 4
Acupuncture	78.8±15.2	95.5±27.6	103.5±36.6
Steroid injection/ placebo tolmetin sodium	85.6±30.4	107.2±34.5	100.6±37.7
Steroid injection/ active tolmetin sodium	80.2±15.2	95.2±22.9	93.2±25.7
Physiotherapy	79.3±15.7	96.3±34.2	95.6±37.1
'Placebo' physiotherapy/ placebo tolmetin sodium	91.8±18.1	107.3±25.1	120.8±30.1

Comparative assessment

There was a good correlation between the comparative assessments by both patient and physician, at least half the cases showing an improvement. The physician assessed 3 patients as being worse, 2 in the acupuncture group and 1 in the steroid injection/placebo tolmetin group.

Success or failure?

The ratings for success and failure of the various treatments are given in Table IV. Although more successes were recorded for the 'placebo' physiotherapy/placebo tolmetin sodium group the rate was not statistically different from that found in the other four groups.

Table IV. Success and failure rates after treatment: number of patients

Treatment	Success	Failure
Acupuncture	5	7
Steroid injection/ placebo tolmetin sodium	6	6
Steroid injection/ active tolmetin sodium	5	7
Physiotherapy	6	6
'Placebo' physiotherapy/ placebo tolmetin sodium	9	3

Emergent conditions

The number of emergent conditions was low; a summary is given in Table V. They

were of a mild, self-limiting nature and none necessitated withdrawal from the trial. Six patients reported side-effects whilst taking placebo tolmetin sodium and 4 whilst taking the active drug.

Table V. Details of side-effects reported during treatment in the groups receiving oral drug treatment

Side-effects	Placebo tolmetin sodium	Active tolmetin sodium
Heartburn	2	
Nausea		1
Indigestion	1	1
Constipation	1	1
Diarrhoea		1
Dizziness	1	
Drowsiness	1	
Blurred vision	1	1
Total no. reports	7	5
No. patients reporting	6	4

Discussion

This was basically a small trial and was intended to be a pilot study, as we only studied 60 patients, 12 in each group. However, there were clearly no trends in any direction except perhaps in favour of no treatment at all. The reason for this is hard to ascertain, one possibility being that we are taking patients already on the road to recovery. The argument against this is that not all the patients did respond to their treatment. Another possibility is that the physiotherapist, by her charming and persuasive personality, was more effective than the acupuncturist in exerting a therapeutic influence on the patients!

What this study has shown, in our opinion, is that there does not seem to be any definite advantage of any particular treatment for the painful shoulder. Most patients improved, irrespective of treatment, and it is possible that the beneficial effects from therapy were really due to natural recovery. This is a very important consideration because most patients who have these problems do not get immediate treatment, but have to remain on a waiting list before they are seen. Even at King's College Hospital, where our waiting list is no more than 2 or 3 weeks, this must nevertheless make such treatment of questionable value. In particular, physiotherapy needs to be more critically assessed to avoid unnecessary wasting of the therapist's valuable time.[6]

As far as the use of acupuncture is concerned, it did not seem to confer any particular benefit on the patients over either injection or physiotherapy and, therefore, the case for acupuncture in chronic shoulder pain will have to be proven. Controlled studies by other workers support our negative findings.[3] It would seem to us that a beautiful girl is probably a more effective treatment than either of the different forms of beautiful needles!

References

1. Berry, H., and Huskisson, E. C., (1972). Treatment of rheumatoid arthritis: a trial of meprothixol. *Clin. Trials J.*, **9**, 13-15.
2. Hazleman, B. L., (1972). The painful stiff shoulder. *Rheumatol. Phys. Med.*, **11**, 413-421.
3. Moore, M. E., and Berk, S. N., (1976). Acupuncture for chronic shoulder pain. An experimental study with attention to the role of placebo and hypnotic susceptibility. *Ann. Intern. Med.*, **84**, 381-384.
4. Plotz, C. M., Plotz, P. H., and Lamont-Havers, R. W., (1974). Workshop on the use of acupuncture in the rheumatic diseases. *Arthritis Rheum.*, **17**, 939-943.
5. Richardson, A. T., (1975). The painful shoulder. *Proc. R. Soc. Med.*, **68**, 731-736.
6. Sheldon, P. J. H., (1972). A retrospective survey of 102 cases of shoulder pain. *Rheumatol. Phys. Med.*, **11**, 422-427.