

TREATMENT OF LOW BACK PAIN WITH ACUPUNCTURE

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THERE HAS BEEN A GREAT DEAL OF INTEREST recently in acupuncture as a form of treatment for chronic pain syndromes not amenable to conventional forms of treatment. This paper attempts to evaluate the effect of acupuncture in the therapy of low back pain since this is a common problem sometimes not effectively treated by ordinary means available to the Western trained physician.

METHOD

Patient selection

Patients were chosen by one of us (A.G.) after a complete orthopedic investigation. Conventional therapy including bed rest, analgesics, heat, and physiotherapy was undertaken. When improvement did not occur in the expected interval, they were referred to the acupuncturist (G.E.). These patients were felt to have disc disease which could not be surgically improved. The patients were randomly distributed into two groups: the first group to receive true acupuncture, that is needles were placed into the acupuncture points used for the treatment of low back pain in the People's Republic of China,¹ the second group to receive sham acupuncture, that is needles randomly placed in areas not considered to have any bearing on low back pain. All patients gave informed consent in writing and the experiment was approved by the University of Toronto Human Research Committee.

NEEDLING TECHNIQUE

Real Acupuncture

Needles were inserted under sterile techniques into acupuncture points *Ta-ch'ang-yü bilaterally and Ch'êng-san bilaterally*. *Ta-ch'ang-yü* is 3.6 cm lateral to the midline at a level between the fourth and fifth lumbar vertebrae. *Ch'êng-san* is at the distal margin of the gastrocnemius muscle, between its medial and lateral heads. The needles were manipulated until *Te Chi* was elicited. This is a sensation of numbness, tingling, heat or distension at the site of needle insertion. The needles were then attached to electrical stimulator G6805 and set to stimulate at a frequency at 3–10 HZ with an intensity (current) which the patients felt they could tolerate. The needles were electrically stimulated for 30 minutes and then removed.

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This treatment was undertaken at two-day intervals where possible for three treatments. Occasionally, in order not to inconvenience the patients or the acupuncturist, the interval between treatments varied, although no interval was longer than one week. At the end of the treatment period the patients were referred back to the orthopedic surgeon for re-evaluation.

Sham Acupuncture

Four needles to correspond to the number of needles used in the real acupuncture group were inserted. Two were inserted at the level of L4-5 bilaterally 15 cm lateral to the mid-line. There are no classic acupuncture points in this area. A needle was also inserted into each leg 10 cm below the popliteal fossa, 6 cm lateral to the mid-line. Again this area is devoid of classic acupuncture points. Te Chi was not searched for. The needles were attached to the electrical stimulator as before and the subsequent treatment proceeded as with the real acupuncture group. All patients were referred back to the orthopedic surgeon for re-evaluation.

Patient Evaluation

All patients were evaluated by the referring orthopedic surgeon without knowledge of whether the patient was in the real or the sham group. They were placed into two groups according to subjective improvement in the back and/or leg pain and objective improvement as measured by increased range of spinal movement, improvement in tests for nerve root tension and objective improvement in neurological signs. The groups were designated no improvement and significant improvement. The acupuncturist had no knowledge of the findings on this examination until the experiment had been completed.

RESULTS

The results are summarized in Table I and Table II. The sample is quite small and there is no statistical significance between the two groups. There seemed to be no difference in either the subjective or objective changes between the two

TABLE I

Total Patients	Improvement	No improvement
Real (15)	7	8
Sham (15)	6	9

TABLE II

Total Patients	Subjective Improvement	Objective Improvement	Both
Real (15)	7	6	6
Sham (15)	6	5	5

groups. Every patient, except one in each group, who had subjective improvement also exhibited objective improvement.

DISCUSSION

Any experiment attempting to evaluate the efficacy of the treatment of pain is extremely difficult because of the multitude of factors affecting the interpretation of painful stimuli.² These include anxiety, fear, diversion of attention, relief from impending danger, hope, cultural and home environment, etc.³ Our experiment was designed with several goals in mind. The first was that the person evaluating the response to therapy did not know which therapy the patient received, eliminating observer bias. Secondly, the acupuncturist did not know during the course of the experiment whether there was a difference between the two groups until the experiment had been completed, therefore he was uninfluenced by this factor. No attempt was made to obtain this information from the patients although many volunteered some information about their progress. The acupuncturist's impression during the course of the study was that the two groups appeared not to differ in their improvement. Thirdly, the patients had no idea whether they were receiving real or sham acupuncture. The nature of the experimental consent form was such that the patients knew they would be placed in either of the two groups but they were not informed which group. The similarity of the methods in the two groups was such that we believe the patients did not in fact know whether they had received real or sham acupuncture. Therefore we feel justified in this experimental design to establish the sham acupuncture group as a control. The problem, of course, is that a pure control group should have no treatment whatever; but this would have changed the patients' outlook immediately. We were unable to conceive a control group that would be untreated and yet perceive itself to have been treated by acupuncture. The results show that there is no real difference between a group treated for low back pain with acupuncture and a control group receiving sham acupuncture. There is 40 per cent improvement in the sham group and 46 per cent improvement in the real group, which falls into the realm of the placebo effect.⁴ This incidence is less than that quoted by others using acupuncture in a clinical setting^{5,6} where between 65 per cent⁵ and 85 per cent⁶ of patients are said to have had improvement with acupuncture. There are several possible explanations for this difference. First, this study was controlled, with the evaluation of improvement being made by an unbiased observer. Secondly, the acupuncturist in our study may not have been as skilled as the acupuncturist reporting better results. This factor is, of course, difficult to evaluate. Thirdly, the patients in our study, although willing to undergo acupuncture, did not see the referring physician with this in mind and may not have been as well motivated as other groups of patients. Fourth, we gave the patients only three treatments, whereas others have used many more. However, it did not appear that the results we obtained warranted further treatment, since no difference between the two groups appeared. Nevertheless, with these limitations we should point out that we were unable to differentiate any benefit of acupuncture for low back pain in excess of the placebo

effect and suggest that much of the improvement in pain syndromes associated with acupuncture may be on the basis of placebo effect.

RÉSUMÉ

Ce travail a cherché à mesurer l'efficacité de l'acupuncture dans le traitement des douleurs dorso-lombaires chroniques résistant aux autres formes de traitement. Ces malades, la plupart porteurs de lésions discales considérées non chirurgicales, étaient référés à l'acupuncture après une période de repos au lit, de physiothérapie, de prise d'analgésiques, etc.

On a partagé les sujets en deux groupes, l'un recevant l'acupuncture aux points traditionnels, l'autre en des points choisis au hasard; le partage se faisant à l'insu des malades.

Résultats: il n'apparaît aucune différence entre les deux groupes (40 à 46 pour cent respectivement), chacun montrant une amélioration subjective et objective comparable.

Des résultats meilleurs ont été publiés d'autres et les auteurs avancent comme explications possibles différents facteurs: évaluation de leur groupe de sujets par un observateur neutre, inexpérience de l'acupuncturiste, (difficultés évidentes de mesurer l'influence de ce facteur); d'autre part les sujets se sont vu proposer l'acupuncture, ils n'y venaient pas par eux-mêmes et finalement ils n'ont reçu que trois séances de traitement.

Malgré ces considérations, les auteurs avouent que leur expérience ne leur a pas permis d'éliminer l'effet placebo comme cause de l'amélioration chez leurs sujets.

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