

## A Controlled Trial of Acupuncture in Psoriasis: No Convincing Effect

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Several uncontrolled studies have suggested that acupuncture is an effective treatment for psoriasis. To test this hypothesis, 56 patients suffering from long-standing plaque psoriasis were randomized to receive either active treatment (electrostimulation by needles placed intramuscularly, plus ear-acupuncture) or placebo (sham, 'minimal acupuncture') twice weekly for 10 weeks. The severity of the skin lesions was scored (PASI) before, during, and 3 months after therapy. After 10 weeks of treatment the PASI mean value had decreased from 9.6 to 8.3 in the 'active' group and from 9.2 to 6.9 in the placebo group ( $p < 0.05$  for both groups). These effects are less than the usual placebo effect of about 30%. There were no statistically significant differences between the outcomes in the two groups during or 3 months after therapy. The patient's own opinion about the results showed no preference for 'active' therapy. It was also clear from the answers that the blinded nature of the study had not been discovered by the patients. In conclusion, classical acupuncture is not superior to sham (placebo) 'minimal acupuncture' in the treatment of psoriasis. *Key word: alternative therapy.*

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In Sweden acupuncture has been officially recognized for more than 10 years for the relief of pain, and basic knowledge of the physiological effects in painful states is accumulating (1). Since 1993 indications for acupuncture in other conditions have officially become recognized as any other form of treatment and have to be based on scientific evidence and clinical experience. In certain other countries, however, traditional Chinese medicine, including acupuncture, has for a number of years become established as a legitimate part of medicine (2). Many controlled studies have been made in non-psoriatic conditions, and meta-analysis of over 90 of them has recently been performed by Ter Riet et al. (in Dutch) and critically assessed (3). Effects of acupuncture on psoriasis have been reported either sweepingly without substantial evidence (4, 5) or without proper controls (6), or have been described in journals difficult to get hold of (7, 8).

Our interest in acupuncture for psoriasis was stimulated by a retrospective analysis of 37 patients who had been treated by an approved acupuncturist for an average of 24 sessions with classical Chinese acupuncture, complemented with topical needling of the psoriatic lesions, ear acupuncture and an oral Chinese herbal remedy. Seven of these patients (19%) had cleared completely and 17 (46%) showed  $\geq 75\%$  improvement (unpublished observation). The results prompted us to perform

a prospective, placebo-controlled study of standardized acupuncture in a larger group of patients with plaque psoriasis.

### MATERIAL AND METHODS

#### Patients

The great majority of patients were recruited by an advertisement in the local newspaper. Inclusion criteria were: stable plaque psoriasis, age 18–75 years, no change in treatment during the previous 3 months, and no ongoing treatment with oral anti-psoriatic drugs, UV-therapy, or extensive use of topical corticosteroids. The patients should not previously have been treated with acupuncture and there should be no contraindications to electroacupuncture, e.g. certain heart conditions, presence of metallic implants such as clips or orthopaedic prostheses.

The patients received both oral and written information about the trial before consenting to participate.

#### Sample size

Consultation with a statistician resulted in the following requirements. A theoretically positive response to placebo treatment of 30% and to active therapy of 70%, with a statistical power of 80% and with randomization of 2 patients to the active series against one to the control series. This would require a total of 54 patients for a significant result. There would inevitably be some dropouts, and a sample of 60 patients was therefore aimed at.

#### Design of study

The trial consisted of a 10-week treatment period with either active or placebo therapy twice weekly (see below), followed by a 3-month observation period. The first group of 30 patients were to receive treatment during the autumn of 1994, and the remaining 30 patients were to be treated in the spring of 1995. The skin state was assessed by the size of the psoriasis area and severity index, i.e. the PASI score (9), on two occasions 3 weeks apart before the study, after 5 and 10 weeks of treatment, and at the end of the study (3 months after therapy). All examinations were performed by the same doctor (B.J.), without access to previous protocols or PASI scores. Only if the patient's PASI score remained reasonably constant before therapy was he or she allowed to enter the treatment phase.

The patients were randomized to the active or placebo groups by being allowed to pick one of a number of identical envelopes, each containing a pair of sealed envelopes with coded protocols. One envelope was kept sealed at the clinic with the patient's name on it, and the other was given to the patient to present to the acupuncturist. The only non-blinded person involved in the study was the acupuncturist.

The patients were also asked after 10 and 20 sessions to state which category of treatment they thought they had received, and to give their own assessment of the results. Any change in ongoing treatment was recorded. The treatments were performed outside the department of dermatology at the acupuncturist's private rooms<sup>†</sup>. It was agreed that active treatment should consist of deep intramuscular insertion

<sup>†</sup> The acupuncturist is a registered nurse with approved training as acupuncturist, who initially approved of the design of the study but later declined to appear as co-author of this paper. We have not yet been able to obtain detailed description of the technique she used.

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of the needles according to traditional Chinese principles, at about 20 named points, plus ear acupuncture with needles on the outer aspect of one of the auricles (a standardized version of the technique applied to the retrospectively analysed group of patients – see Introduction). All needles were attached to an electrostimulator and given appropriate stimulation at 10–20 Hz for about 20 min. Patients in the placebo series were handled in a similar fashion, but needles were inserted superficially in the subcutaneous tissue ca 1 cm outside the classical points, and with only one needle on the medial aspect of the earlobe. Needles were attached to the stimulator, the index lamp being switched on but with no electric tension initiated.

The plan of the trial was approved by the hospital ethics committee and the patients were given written and oral information before consenting to the study.

#### Statistical evaluations

The statistical significance of differences was evaluated by Student's *t*-test using either paired or unpaired comparisons. A probability level of  $<0.05$  was considered significant. The Gaussian distribution of the values was ascertained.

## RESULTS

Fifty-six patients entered the study. Two were excluded in the final evaluation: one patient did not show up at the last control, and another received oral corticosteroid therapy for bronchial asthma at the end of the acupuncture phase. Of the remaining 54 patients, 35 received active treatment and 19 placebo, which was in accordance with the plan. Table I shows that there was no difference between the groups with respect to age of the patients or duration and severity of psoriasis, but there were rather more men in the placebo group. Although patients recruited in the spring usually had severer skin symptoms than those starting in the autumn (data not shown), the results for both cohorts are combined in the following evaluation.

Immediately before the start of treatment the mean PASI values were almost identical to the screening values obtained 3 weeks previously (compare Tables I and II) and were similar in the two groups. Table II shows a slight improvement in skin symptoms during treatment of both groups; thus, after 20 treatments the mean PASI scores had decreased from 9.6 to 8.3 in the active group and from 9.2 to 6.9 in the placebo group ( $p < 0.05$  for both). Three months after therapy the PASI scores were slightly further reduced, although in the active group this was partially due to exclusion of two high values (see footnote, Table II). Note that unpaired comparisons revealed no statistically significant differences between the groups at any of the check points.

The patients were asked at the end of the treatment sessions whether or not they found themselves helped by the treatment. Table III shows that in both groups a majority experienced slight or marked improvement. However, there was no difference between the groups in this respect.

Table I. Some demographic data

Treatment group	No. of subjects men/women	Mean age (yrs)	Duration of psoriasis (yrs)	Disease severity <sup>a</sup> (PASI score)
Active	19/16	44 ± 13 <sup>b</sup>	20 ± 12	10.1 ± 5.3
Placebo	12/7	48 ± 13	20 ± 11	9.1 ± 2.8

<sup>a</sup> At screening 3 weeks before start of the study. <sup>b</sup> Mean ± SD.

Table II. PASI scores in patients before and after receiving active or "placebo" treatment

Treatment group	Baseline	After 10 treatments	After 20 treatments	3 months after completed therapy
Active	9.6 ± 4.8 (35) <sup>a</sup>	8.6 ± 3.9 (35)	8.2 ± 4.5* (35)	7.3 ± 3.2 (33) <sup>b</sup>
Placebo	9.2 ± 2.7 (19)	7.9 ± 2.7 (19)	6.9 ± 3.1* (19)	6.6 ± 2.0 (19)

\*  $p < 0.05$  compared to baseline value.

<sup>a</sup> Number of patients. <sup>b</sup> Two patients with high PASI values had to start other treatments for their psoriasis after completing the acupuncture treatment.

The patients were also asked to guess whether they had received active or placebo therapy. Table IV shows that, although initially there had been a slight tendency for the patients to discern the blinded nature of the study, after 20 treatments most of the actively treated patients believed that they were in fact receiving placebo therapy.

## DISCUSSION

It is generally accepted that a placebo-controlled trial of acupuncture is exceedingly difficult to set up with confidence. Sham acupuncture, placing needles outside the classical points, has been recommended, but might itself have some clinical effects (10). We decided to use a sort of sham minimal acupuncture as placebo, inserting the needles superficially and outside the classical points (11), without electrostimulation and without achieving 'deqi', a specific sensation which is described as numbness, heaviness and radiating paraesthesia (1). Active treatment consisted of deep insertion of the needles intramuscularly, which is considered to be a prerequisite for optimal effects, at the classical points, and with electrostimulation aiming at achieving 'deqi'. At the request of the acupuncturist, traditional ear acupuncture was also given to the active group, while the placebo group received a similar sham procedure. Aiming at a standardized procedure, local insertions in psoriasis plaques were excluded. In order to make it easier to recruit patients, the study was designed to give a 66.6% rather than 50% probability of receiving active treatment.

Analysis of the blinded data showed no impressive results (individually or by average) in either series. If anything, the results were better in the placebo-treated patients, but none of the groups attained the 'usual' placebo-induced improvement of about 30% (12). Our previous, retrospective analysis of a slightly different type of acupuncture treatment in 37 patients showed impressive results (see Introduction), and similar good results have been reported from all sorts of un-controlled treatments of psoriasis. It is also a fact that identical treatments may give different results in different studies; e.g. complete clearance after therapy ranged from 10% in one report to 80% in another (12). It is evident that the placebo effect in psoriasis and many other conditions may be quite considerable (13) – an effect worth aiming for in any medical practice (14).

Patients with chronic dermatological disorders quite often turn to alternative medical approaches, including acupuncture, often with poor results (15). It seems that younger Chinese doctors and younger Chinese patients are becoming increas-

Table III. Patients' blinded opinions about the effects of completed therapy

Treatment group	"Much worse"	"Slightly worse"	"No change"	"Slightly better"	"Much better"	Total
Active	2	1	7	13	10	33 <sup>a</sup>
Placebo	1	1	6	3	8	19

<sup>a</sup> Reports were not available for 2 of the patients in this group.

Table IV. Patients' blinded opinions about which therapy they were receiving

No. of treatments	De facto active treatment			De facto placebo treatment		
	"Active"	"Placebo"	"Don't know"	"Active"	"Placebo"	"Don't know"
10	15	11	7	7	11	1
20	11	19	5	9	9	1

ingly sceptical about this traditional approach (16), and the current attitude in China regarding application of acupuncture for psoriasis seems to be rather vague: 'Psoriasis can be improved to a certain extent by acupuncture treatment in some cases' (17). We conclude that classical acupuncture with electrostimulation combined with ear acupuncture has no effect on psoriasis vulgaris. Whether or not an individualized type of acupuncture combined with e.g. oral herbal remedy is more effective remains to be investigated.

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