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 words: alternative therapy. (Accepted October 14, 1996.)

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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 ≥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*. It was agreed that active treatment should consist of deep intramuscular insertion

*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.
of the needles according to traditional Chinese principles, at about 20
together with treatment points, plus ear acupuncture with needles on the outer aspect
of one of the auricles (a standard technique 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
group were handled in a similar fashion, but needles were inserted
superficially in the subcutaneous tissue at 1 cm outside the classical
points, and with only one needle on the auricle of the earlobe.
Nails were attached to the stimulator, the index lamp being switched on
but with no electric current 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 $p<0.05$ 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
treatment, and another received 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 symp-
toms 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 compari-
sions 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 differ-
cence between the groups in this respect.

Table I. Some demographic data

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>No. of subjects</th>
<th>Mean age (yrs)</th>
<th>Duration of psoriasis (yrs)</th>
<th>Disease severitya (PASI score)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active</td>
<td>19/16</td>
<td>44.2 ± 33b</td>
<td>20 ± 12</td>
<td>10.1 ± 5.3</td>
</tr>
<tr>
<td>Placebo</td>
<td>12/7</td>
<td>48 ± 13</td>
<td>20 ± 11</td>
<td>9.1 ± 2.8</td>
</tr>
</tbody>
</table>

a At screening 3 weeks before start of the study. b Mean ± SD.

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

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>Baseline</th>
<th>After 10 treatments</th>
<th>After 20 treatments</th>
<th>3 months after completed therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active</td>
<td>9.6 ± 4.8 (35)</td>
<td>8.6 ± 3.9 (35)</td>
<td>8.2 ± 4.5* (35)</td>
<td>7.3 ± 3.2 (35)</td>
</tr>
<tr>
<td>Placebo</td>
<td>9.2 ± 2.7 (19)</td>
<td>7.9 ± 2.7 (19)</td>
<td>6.9 ± 3.1* (19)</td>
<td>6.6 ± 2.0 (19)</td>
</tr>
</tbody>
</table>

*p<0.05 compared to baseline value.

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,
have 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 electrostimula-
tion aiming at achieving ‘deqi’. At the request of the acu-
puncturist, 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 insert-
sion 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

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>&quot;Much worse&quot;</th>
<th>&quot;Slightly worse&quot;</th>
<th>&quot;No change&quot;</th>
<th>&quot;Slightly better&quot;</th>
<th>&quot;Much better&quot;</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active</td>
<td>2</td>
<td>1</td>
<td>7</td>
<td>13</td>
<td>10</td>
<td>33</td>
</tr>
<tr>
<td>Placebo</td>
<td>1</td>
<td>1</td>
<td>6</td>
<td>3</td>
<td>8</td>
<td>19</td>
</tr>
</tbody>
</table>

* Reports were not available for 2 of the patients in this group.

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

<table>
<thead>
<tr>
<th>No. of treatments</th>
<th>De facto active treatment</th>
<th>De facto placebo treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&quot;Active&quot;</td>
<td>&quot;Placebo&quot;</td>
</tr>
<tr>
<td>10</td>
<td>15</td>
<td>11</td>
</tr>
<tr>
<td>20</td>
<td>19</td>
<td>11</td>
</tr>
</tbody>
</table>

interestingly 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.

ACKNOWLEDGEMENTS

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REFERENCES

8. Zhao F, Wang P, Hua S. Treatment of psoriasis with acupuncture and cupping therapy. Chinese Acupuncture and Moxibustion 1991; 11(2): 16–19. (The same message as in ref. 7. It is quoted in ref. 6 but is not available in libraries in the Nordic countries.)