

## Clinical Observations

### Depressive Neurosis Treated by Acupuncture for Regulating the Liver —A Report of 176 Cases

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**Objective:** To observe therapeutic effect of acupuncture for regulating the liver on depressive neurosis.

**Methods:** In a multi-center randomized controlled trial, 440 patients were divided into 3 groups: Acupuncture group for regulating the liver (Acup., 176 cases) was treated by acupuncture at Siguan Points, i.e. bilateral Hegu (LI 4) and Taichong (LR 3), Baihui (GV 20) and Yintang (EX-HN3) plus ear-acupuncture, Prozac group (P., 176 cases) by oral administration of Prozac, and Non-acupoint needling group (NAN, 88 cases) by acupuncture at non-acupoints as acupuncture placebo. Self-rating Depression Scale (SDS) was examined before treatment, and one month, two and three months after treatment respectively to evaluate therapeutic effect, and Rating Scale for Side Effects (SERS) was used to evaluate the safety. **Results:** After one month of treatment, SDS scores in Acup. Group were significantly lower than that in P. Group ( $P<0.05$ ) and than that in NAN Group ( $P<0.01$ ), and SDS scores in P. Group were lower than that in NAN Group ( $P<0.05$ ), showing the SDS scores in Acup. Group  $<$ P. Group  $<$ NAN Group. After 2 months of treatment, SDS scores in Acup. Group were also significantly lower than that in P. Group ( $P<0.01$ ) and than that in NAN Group ( $P<0.01$ ), and SDS scores in P. Group were also lower than that in NAN Group ( $P<0.05$ ), showing the SDS scores in Acup. Group  $<$ P. Group  $<$ NAN Group. After 3 months of treatment, SDS scores in Acup. Group were also significantly lower than that in P. Group ( $P<0.01$ ) and than that in NAN Group ( $P<0.01$ ), and SDS scores in P. Group were also lower than that in NAN Group ( $P<0.01$ ), showing the SDS score in Acup. Group  $<$ P. Group  $<$ NAN Group. After treatment, SERS scores were  $0.16\pm 0.95$ ,  $6.51\pm 5.09$  and  $0.23\pm 1.36$  in Acup. Group, P. Group and NAN Group respectively. A significant difference existed between Acup. Group and P. Group ( $P<0.05$ ), but no significant difference between Acup. Group and NAN Group ( $P>0.05$ ), showing the SERS scores in Acup. Group  $<$ NAN Group  $<$ P. Group. No side effect was found in Acup. and NAN groups. **Conclusion:** The therapeutic effect of acupuncture on depressive neurosis is better than or similar to that of Prozac but with less side effect.

**Key words:** depression; regulating the liver; acupuncture therapy; investigation

Depressive neurosis is a kind of mental disorder manifested by complete or almost complete loss of

interest in any activities or entertainment. Depressive neurosis accounts for 5% to 10% of all outpatients in

psychiatric department,<sup>1</sup> for 3.11% in China.<sup>2</sup> In the very multi-center randomized controlled trial, the authors treated it by acupuncture for regulating the liver with TCM syndrome differentiation and achieved good therapeutic effect. A report follows.

## CLINICAL MATERIALS

### General data

The outpatient 440 cases from the Acupuncture Department or Psychology Department of Guangdong Hospital of TCM, the 2nd People's Hospital of Zhaoqing City, Shenzhen TCM Hospital, and the 1st Affiliated Hospital of Guangzhou University of Chinese Medicine were treated from October 2004 to December 2006. They were randomized into 3 groups: Acupuncture group for regulating the liver (Acup., 176 cases), Prozac group (P., 176 cases), and non-acupoint needling group (NAN, 88 cases).

Of 176 in Acup. Group, 67 cases were males and 109 were females aged  $41.87 \pm 12.29$  with disease duration of  $4.59 \pm 3.00$  years, including 3 cases having family history, 30 cases having taken western medicine, and 20 cases having accepted psychological treatment. Of 176 in P. Group, 54 cases were males and 122 were females aged  $39.88 \pm 11.04$  with the course of disease  $3.91 \pm 2.38$  years, including 0 case having family history, 54 cases having taken western medicine, and 9 cases having accepted psychological treatment. Of 88 in NAN Group, 28 cases were males and 60 were females aged  $43.51 \pm 11.43$  with disease duration of  $4.59 \pm 2.83$  years, including 0 case having family history, 14 cases having taken western medicine, and 3 cases having accepted psychological treatment. There were no differences in age, duration of disease, sex and family history among the 3 groups ( $P > 0.05$ ), being comparable. But there were significant differences in history of medication and psychological treatment ( $P < 0.05$ ), they should be considered as affective factors in statistical analysis.

### Diagnostic criteria

Referred to *Chinese Classification and Diagnostic Criteria of Mental Disorders (CCMD)* and *Criteria*

*for Diagnosis and Therapeutic Effect of Diseases and Syndromes in Traditional Chinese Medicine*,<sup>3-4</sup> depressive neurosis was classified as: 1) stagnation of liver-qi, manifested as deprementia, fullness in chest and hypochondrium, epigastric stuffiness, frequent belching, frequent sighing, irregular menses, thin white coating, and wiry pulse; 2) transformation of depressed qi into fire, manifested as impatience and irritability, thoracic oppression and hypochondriac distention, headache and conjunctival congestion, bitterness in the mouth, gastric upset and acid regurgitation, constipation and yellow urine, red tongue with yellow coating, and wiry and rapid pulse.

### Inclusion

1) Hamilton Depression Scale (HAMD) scores  $\geq 20$ , consciousness, no aphasia and intellectual disturbance, above primary education, understanding the contents in HAMD, and cooperating the treatment; 2) accorded with criteria for the syndrome of stagnation of liver-qi or stagnated qi transforming into fire; 3) aged 18–65 years; 4) without taking antidepressant in recent 2 weeks; and 5) agreed and signed the medical informed consent document.

### Exclusion

1) Schizophrenia or any organic and physical somatic that may induce it; 2) below the age of 18 and over the age of 65; 3) with severe complications of cardio- and cerebral-vascular, hepatic, nephritic diseases, diseases of hemopoietic system, and pregnancy; 4) unable to cooperate needling or take medicine as the way asked; 5) taking antidepressant in recent 2 weeks.

### Setting of blinded method

1) Patients were aware whether they received drug treatment or acupuncture, but those accepted acupuncture were not aware of whether acupoints were punctured or non-acupoint; 2) the evaluators evaluating therapeutic effect were not involved in treatment process.

## METHODS

### Acupuncture group

1) Siguan points, i.e. Bilateral Hegu (LI 4) and

Taichong (LR 3), Baihui (GV 20) and Yintang (EX-HN3). Needles were perpendicularly inserted into Siguan points to a depth of 0.5 *cun*, obliquely with 30° to the scalp into Baihui (GV 20) to a depth of 0.5 *cun*, and subcutaneously into Yintang (EX-HN 3) to a depth of 0.5 *cun*. Needle twirling was not stopped until needling sensation was achieved in the patient. During retaining of needles for 30 min the patient was asked to take deep nasal respiration. 2) Ear points acupuncture: The thumbtack-type needles were intracutanously embedded in ear points, Liver and Heart, and kept for 3 days. Two ears were used in alternation. The above-mentioned treatment was given twice a week for 3 months.

#### Prozac group

Prozac produced by Eli Lilly and Company, was orally administered to the patients in a dose of 20 mg once daily after breakfast, 3 months.

#### Non-acupoint needling group

1) Acupuncture was applied with the same insertion and manipulation but to those 0.5 cm laterals to the body points of Acup. Group. The patient was also asked to do deep nasal respiration. 2) Ear points, corresponding areas of Liver and Heart on the back of ear. The intradermal thumbtack needles were embedded and kept for 3 days. Two ears were used in alternation. The above-mentioned treatment was given twice a week for 3 successive months.

#### Other measures

Explanation was made to comfort and encourage the patients, and 1–2 mg of estazolam was orally administered temporarily to the patients with obvious sleep disorder in the early stage of treatment just before going to bed.

#### Items and time for observation and statistical analysis

Self-rating Depression Scale (SDS) and Asberg's Rating Scale for Side Effects (SERS) were examined before treatment, and one month, two and three months after treatment respectively and severe side effects were recorded. Double logging data was done by two investigators to assure the integrality and accuracy of the data. SPSS11.0 software was used for statistical analysis. Because it was a multi-center randomized controlled trial, central effect was taken into consideration, for which PEMS3.1 software was also used for Meta analysis.

### RESULTS

#### Comparison of SDS scores of 3 groups (Table 1)

After one month of treatment, SDS scores in Acup. Group were obviously lower than those in P. Group ( $P<0.05$ ) and than those in NAN Group ( $P<0.01$ ), and SDS scores in P. Group were lower than those in NAN Group ( $P<0.05$ ), showing the SDS score in Acup. Group  $<$ P. Group  $<$ NAN Group.

After 2 months of treatment, SDS scores in Acup. Group were also obviously lower than those in P. Group ( $P<0.01$ ) and than those in NAN Group ( $P<0.01$ ), and SDS score in P. Group were also lower than those in NAN Group ( $P<0.05$ ), showing the SDS score in Acup. Group  $<$ P. Group  $<$ NAN Group.

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Table 1. Comparison of scores in SDS of 3 groups ( $\bar{x} \pm s$ )

Group	<i>n</i>	Before treatment	1 Month After	2 Months After	3 Months After
Acup.	176	67.06±12.01	56.68±10.81* <sup>△</sup>	48.97±10.10 <sup>△□</sup>	43.18±9.38 <sup>△□</sup>
P.	176	67.06±12.01	59.29±11.37 <sup>▲</sup>	53.23±12.85 <sup>▲</sup>	46.99±12.67 <sup>△</sup>
NAN	88	68.45±11.15	62.84±10.71	56.83±10.17	52.90±12.94

Notes: \* $P<0.05$ ; <sup>□</sup> $P<0.01$ , compared with P. Group; <sup>△</sup> $P<0.01$ ; <sup>▲</sup> $P<0.05$ , compared with NAN Group.

### Comparison of SERS scores of 3 groups

After treatment, SERS score were  $0.16\pm 0.95$ ,  $6.51\pm 5.09$  and  $0.23\pm 1.36$  in Acup. Group, P. Group and NAN Group respectively. A significant difference existed between Acup. Group and P. Group ( $P<0.05$ ), but no significant difference between Acup. Group and NAN Group ( $P>0.05$ ), showing the SERS score in Acup. Group  $<$  NAN Group  $<$  P. Group. No side effect was found in Acup. and NAN groups.

### DISCUSSION

In terms of pathogenesis, depressive neurosis is closely related to stagnation of liver-qi. In applying acupuncture for regulating the Liver, needling Baihui (GV 20), Yintang (EX-HN3) and Siguan Points was used as the main treatment measure, which was combined with ear point embedding. Located at the vertex where the Liver Meridian and Governor Vessel are convergent, Baihui (GV 20) is to regulate the flow of qi, soothe the liver and activate mental activity. Located at the forehead, through where the Governor Vessel passes and crosses with the Liver Meridian, Yintang (EX-HN3) is used to function dredging. As the Yuan-source point of the Liver Meridian, Taichong (LR 3) is removing fullness in chest and hypochondrium to relieve sighing. Combined with Siguan Points, it is to calm the mind, soothe the liver, and stop wind. Together with deep breathing exercise and ear point embedding, acupuncture functions to regulate the stagnated flow of qi. In addition, ear needle embedding consolidates the therapeutic effect well.

It was found that scores in Acup. Group were lower than those in group on 1, 2 and 3 months after treatment, however, this does not mean that acupuncture for regulating the liver is affirmatively in therapeutic Prozac, because 1) all patients were treated in TCM hospitals, their psychological accepting of western medicine is lower; 2) longer duration of acupuncture procedure than oral administration of Prozac promotes communication between patient and doctor, which serve as psychological treatment. Therefore, it is concluded that therapeutic effect of acupuncture for regulating the liver on depressive neurosis may be better than Prozac or similar to that of Prozac, but it is safer than Prozac based on the results of SERS.

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