Clinical and Experimental Observation on Treatment of Sensorineural Deafness with Bushen Conger Tablet (补肾聪耳片)

Lin Wensen (林文森), Shi Zhixing (石志兴), Ma Enming (马恩明)
Chen Jie (陈 洁)

Department of Otorhinolaryngology, Nankai Hospital, Tianjin (300100)

Wu Xiaoxian (伍孝先), Zhou Wenluo (周文洛), Yuan Hongda (袁洪达)

Institute of Acute Abdomen of Integrated TCM-WM, Tianjin

ABSTRACT Objective: To observe the effect of Bushen Conger (BSCE) tablet, a pure Chinese herbal medicine for reinforcing Kidney, removing blood stasis and opening apertures, in treating sensorineural deafness. Methods: Three hundred and ten patients were treated by BSCE tablet and the effects were observed. At the same time the effects of BSCE tablet on hearing, SOD, LPO, etc. were also assayed in guinea pigs. Results: The clinical total effective rate of BSCE tablet was 71.9 %. Animal experiment proved that the drug was effective in preventing and treating toxic deafness induced by aminoglycoside antibiotics. Conclusion: BSCE tablet could cure sensorineural deafness through adjusting the cochlear cyclic nucleotides as well as its SOD level, reducing the LPO level, and raising the thyroid and sexual glandular functions.

KEY WORDS Bushen Conger tablet, sensorineural deafness, toxic deafness model

From 1986, the authors treated 310 patients of sensorineural deafness (SND) by Bushen Conger (BSCE) tablet with good effect, at the same time relevant experiment was also adopted. The work were reported as following.

CLINICAL STUDY

Clinical Materials

Enrolled in the study were 310 cases, 186 males and 124 females, aged 5 – 60 years, 24.6 years in average. Their degree of hearing loss was 31 cases of mild (threshold of speech frequency, TSF, was 20 – 40 dB), 79 of moderate (TSF was 41 – 60 dB), 148 of severe (TSF 61 – 90 dB) and 52 of complete loss (TSF > 90 dB). All were bilateral deafness, hearing loss in two ears occurred simultaneously in 259 cases, and one after the other in 51 cases. Two hundred ninety six cases (95.5 %) had a history of aminoglycoside antibiotics injection, and 96 cases (31.0 %) were injected with two kinds of aminoglycoside antibiotics in combination. Blood immune criteria were assayed in 112 cases and abnormal data were found in 52 cases in circulatory immune complex, complement, immunoglobulin, etc. Before treatment in this study, all the patients had been treated by routine therapy with traditional Chinese or Western medicines, but the effects were unsatisfactory.

Methods

1. Treatment

BSCE tablet (supplied by the Tianjin Institute of Acute Abdomen of Integrated Traditional Chinese and Western Medicine, consisting of Herba Epimedium, Radix Polygonum Multiflorum, Rhizoma Polygonatum, Rhizoma Ligusticum Wallichii and Magnetitum, etc.), containing extract of 2 g crude drug in each tablet of 0.5 g, was given orally 4 – 6 tablets in each time, three times a day. Besides, vitamin E 10 mg, vitamin B1 10 mg and zinc gluconate 75 mg were given simultaneously, 3 times per day orally. Forty days constituted one therapeutic course. Hearing function of the patients was measured every ten days in the period of treatment and efficacy was assayed after two course of therapy.

For the 36 cases with multiple abnormal immune criteria, 1.5 – 2.0 mg/kg of prednisone was given daily, the dosage would be reduced by halves every 10 days.
2. Hearing Measurement

Pure tone audiometry and impedance audiometry were measured with Madsen type OB-822 and Madsen type ZO-174 audiometer respectively. Evoked potential of auditory nerve was measured with Madsen type EAR-2250 brain stem evoked potentiometer. The measurement was carried out in a sound proof room by specialized experts.

3. Method of Statistic Analysis

- **t-test was adopted.**

**Results**

1. Standard of Effects Assessment

- **Cured:** 125 - 8000 Hz audio-threshold reached normal scope, i.e. within 20 dB;
- **Markedly effective:** speech frequency audio-threshold (500 - 2000 Hz) improved for more than 30 dB;
- **Effective:** speech frequency audio-threshold improved for more than 15 dB;
- **Ineffective:** the above-mentioned standard not attained.

2. Clinical effects

Eight cases of the 310 (2.6%) were cured, 127 (41.0%) markedly effective, 88 (28.4%) effective, 87 (28.1%) ineffective, the total effective rate being 71.9%. Among them, 19 of the 36 cases (52.8%) treated with BSCE tablet combined with prednisone markedly effective, 10 (27.8%) effective and 7 (19.4%) ineffective.

3. Relationship between effect and age

The therapeutic effect was negatively correlated with the age of patients, the younger the patients are, the better the result would be. Effective rate of patients aged below 5 years was 76.0%, while that of patients over 40 years was 42.3%, the difference between them was significant, $P < 0.01$.

4. Relationship between effect and duration of disease

The total effective rate in patients with duration of disease < 1 year was 83.3%, for those of 1 - 5 years was 80.0%, for 5 - 10 years 60.0% and for >10 years 45.6%. The above results showed that the therapeutic effect dropped along with the protracting of the disease.

5. Follow-up effects

Follow-up study has been done in 103 effective cases for 1 - 2 years, the hearing of the patients was found to be stable, and no relapse was found.

**EXPERIMENTAL STUDY**

**Materials**

Hybrid guinea pigs, normal, 4 months old, weighing 250 - 300 g and 30 months old hybrid guinea pigs weighing 400 - 500 g, were provided by The Animal Department of Tianjin Medical University.

**Effect of BSCE Tablet on SOD and LPO Levels in Old Guinea Pigs**

1. Methods

Sixty old guinea pigs, 30 male and 30 female, with normal auricular sound reflex and normal tympanic membrane, were divided randomly into 3 groups, 20 in each group. The experimental group was perfused with concentrated BSCE liquid 2 - 4 ml (each milliliter containing 1.5 g of crude drug, that was corresponding to 15 times the dosage for human adult); the vitamin E (VE) group was treated with VE suspension 2 - 4 ml (each milliliter containing 2.50 - 2.75 mg of VE) and the control group with normal saline in equal volume. All three groups were treated for 1 month. Blood of the animals was collected by decapitation 3 days after stopping medication, and heparin was added in the blood for anticoagulation. Kidney, adrenal gland and tissue of cochlear membrane were taken and ground into tissue homogenate for superoxide dismutase (SOD) and lipid peroxidase (LPO) measurement instantly. The TBA method was adopted in LPO measurement and NBT method for SOD measurement.

2. Results

The SOD, LPO contents of various organs of the three groups were listed in detail in table 1.