

CLINICAL TEST STUDIES PERFORMED IN LANZHOU, P.R.C., JANUARY, 1989 TO DECEMBER, 1992 (BACKGROUND AND DETAILED RESULTS EDITED BUT UNCHANGED)

Bu-Nao-Gao in the treatment of 23 patients of motor neuron disease (including 13 cases of ALS patients)

1. General information

This clinical trial was carried out between January 1989 and December 1992 at the Provincial Hospital of Chinese Medicine, Lanzhou, GanSu Province. P. R. China. The trial was summarized by July 1994 (**ref. 1**).

Total cases: 23 cases

- 20 cases hospitalized,
- 3 cases outpatient

Age: Range 24 to 68 years of age (average 44 years)

- 4 cases (20-29 years of age),
- 2 cases (30-39 years of age),
- 7 cases (40-49 years of age),
- 8 cases (50-59 years of age),
- 2 cases (over 60 years of age).

Stage of progression:

- 2 cases mild (muscle strength grade III⁺~V⁻, no bulbar syndromes).
 - 8 cases moderate (muscle strength grade II⁺~III, no bulbar syndromes).
 - 13 cases Severe (muscle strength grade 0~II or with bulbar syndromes).
- 11 out of the 23 patients had bulbar syndromes. Most cases had been treated elsewhere before being included in the Bu-Nao-Gao trial.

Duration of illness:

- 4 cases < 1 year
- 9 cases 1-3 years
- 4 cases 3-5 years
- 3 cases 5-7 years
- 2 cases 7-10 years,
- 1 case > 10 years.

EMG: 20 cases were tested for EMG, and all suggested damage of neuronal origin.

Clinical Diagnosis:

Amyotrophic lateral sclerosis: 13 cases

7 cases without bulbar syndromes,
6 cases with bulbar syndromes.

Primary lateral sclerosis: 8 cases

4 cases without bulbar syndromes,
4 cases with bulbar syndromes.

Progressive muscular atrophy: 2 cases

1 case without bulbar syndromes,
1 case with bulbar syndromes.

Complications and concomitant conditions:

3 cases with coronary heart disease,
1 case with cerebral infarct,
1 case with hepatitis B,
4 cases with lung infection,
1 case with respiratory palsy.

ECG: 20 cases tested

10 cases normal,
4 cases with insufficient coronary blood supply,
3 cases right heart enlargement
1 case incomplete right-bundle block
2 cases incomplete left-bundle block
(frontal branch)

Lingual diagnosis: (a diagnostic technique by observing the texture, color and moisture of the coating and the substance of the tongue)

Substance of tongue:

4 cases pinkish (Dan Hong);
4 cases red (Hong);
3 cases dark red (Hong An);
6 cases dark plain (Dan An);
6 cases plain (Dan);

Tongue coating:

- 16 cases white coating (Bai);
- 1 case white glossy coating (Bai Ni);
- 3 cases yellow coating (Huang);
- 3 cases yellow glossy coating (Huang Ni).

Pulse:

- 16 cases fine pulse (Xi Mai)
- 6 cases stringy pulse (Xuan Mai)
- 1 case rapid pulse (Shu Mai)

2. Treatment Strategy

Bu-Nao-Gao alone, taken orally 2 cubes/day.

- 7 cases- finished 30-day treatment
- 5 cases- finished 60-day treatment
- 4 cases- finished 90-day treatment
- 7 cases- finished over 90-day treatment

Due to the often fast-deteriorating nature of this disease and the ethical issues involved, no control group was set up for this study.

3. Criteria for therapeutic efficacy

Due to the already well-established course of development for this disease, efficacy of the treatment is evaluated based on patients' pre-treatment conditions and the trend of deterioration.

- 1) Clinically cured: disappearance of bulbar palsy, muscle strength improved to grade V.
- 2) Notable effect: bulbar palsy significantly improved, muscle strength improved more than 2 grades.
- 3) Effective: bulbar palsy improved, muscle strength improved more than 1 grade.
- 4) No effect: bulbar palsy continue to exist, no improvement of muscle strength or improvement was less than 1 grade.
- 5) Deteriorated: continuous deterioration of symptoms or death.

4. Results

Therapeutic efficacy of Bu-Nao-Gao on motor-neuron diseases (23 cases)

	mild	moderate	severe
Total	2	8	13
<i>cured</i>		1	
<i>notable</i>		3	2
<i>effective</i>	2	3	8
no effect		1	2
deteriorated			1
total effective	2/2	7/8	10/13

In this study, to the one ALS patient who died during the period of our evaluation, a 3-cubes/day dosage was used at the late stage in an effort to get his conditions under control, and some positive effects were observed even at the very late stage. This patient had been repeatedly treated by Bu-Nao-Gao during the 8-year period after the initial diagnosis (before the cube form was available, liquid concoction was used), and he made improvements in prior episodes of Bu-Nao-Gao treatment. This patient belonged to the fast-deteriorating type. According to the inventor's experience, if untreated, this patient's natural course of disease may be 2-3 years. This patient appeared to have a family history of similar disorders.

In our experience, the 2-cubes/day dosage was adequate for most patients. When this dosage failed to get the condition under control, a 3-cubes/day dosage (1.5 times of the daily dosage) was used. As soon as the patient's condition was stabilized, the dosage was reduced to the usual 2-cubes/day dosage. Although no side effect had been seen with the 3-cubes/day dosage, patients were not advised to go on this high dosage unnecessarily.

5. Strategy for longer-term treatment

After the clinical evaluation during the stated periods, patients were discharged from the hospital when considered clinically safe. Most patients took 0.5-1 year's supply of Bu-Nao-Gao for continued treatment as outpatients.

Every three-month treatment was considered as one cycle. Patients were advised to take a one-week break after each three-month cycle to avoid any potential side effects (on the condition that the disease was in a reasonably stable condition). After taking Bu-Nao-Gao for 3-6 months, if the disease showed no sign of comeback after Bu-Nao-Gao was stopped, these patients could stop taking Bu-Nao-Gao. However, patients were advised to be back on Bu-Nao-Gao immediately as soon as there was a concern (or any signs) suggesting a comeback of the disease.

Some patients remained stable for many years without continuously taking Bu-Nao-Gao; some patients had to be back on Bu-Nao-Gao for more cycles of treatment when the problems resurfaced. Due to the lack of an effective follow-up mechanism for this disease in our system, long-term follow-up data is not yet available, and this information may become available at a later date.

All patients were advised to avoid stressful situations of all kinds, physical exercise was not recommended for muscle strengthening in this disease.

6. Examples of typical cases

In addition to the above-summarized report, the following cases reports gave more detailed description of changes in patients with this type of disease.

Case #1 (Amyotrophic lateral sclerosis) (ref. 2)

Patient: A 50-year-old female (Administration number #69834). Progressive upper limbs weakness for approximately 9 months, was admitted to the hospital on Sept. 18, 1992 with the diagnosis of amyotrophic lateral sclerosis (ALS). The patient begun feeling upper limb weakness without any known reason, later experienced difficulty of raising arms and were unable to unbutton her clothes, and also felt weakness on both lower limbs. EMG (done at other hospital): muscle abnormality of neuronal origin, all nerves tested showed abnormalities of different extents; Diagnosis by other hospital: amyotrophic lateral sclerosis (ALS); After failed all other regular treatments of both Chinese and Western Medicines, and with a progressively worsening condition, the patient was admitted to our hospital. Upon hospitalization: the patient showed weakness of all four limbs, could not raise her upper limbs above shoulder, both hands could not do gripping and stretching, could not unbutton her clothes, difficulty of lifting her feet while walking with a feeling of rigidity, could only go up and down stairs by holding onto railing, could see muscle jumping all over her body.

Tongue: pink red, with a thin white coat, fine pulse.

Physical exam: Cranial nerves (normal); obvious atrophy of thenar muscles interosseous muscles and forearm muscles and fasciculation, and muscle strength III⁻; no muscle atrophy in the lower limbs, and muscle strength III⁺; muscle tone of four limbs (low); reflexes of ankle –jerk, Biceps-jerk, Triceps-jerk and Knee-jerk are all hyperactive; Unable to induce pathological reflexes. No abnormalities of bladder control and bowel movement; No abnormality in sensory. Diagnosis according to Western Medicine: amyotrophic lateral sclerosis (ALS). Diagnosis according to Chinese Medicine: Wei Zheng (belong to insufficiencies of liver and kidney, and insufficiencies of Qi and blood), therefore the treatment strategy require nourishment of liver, kidney, Qi and blood. Treatment given: Bu-Nao-Gao (two cubes/day) alone. Two weeks after Bu-Nao-Gao: increased muscle strength in four limbs, could raise upper limbs above head but could not stretch straight; reduced rigidity in the lower limbs and reduced muscle jumping in whole body. One month after Bu-Nao-Gao: could raise upper limbs above shoulder and could stretch straight, could do up and down stairs more freely than before. Two months after Bu-Nao-Gao, all five fingers of both hands could stretch out and could unbutton clothes, could go up and down stairs easily, muscle strength III⁺-V⁻. After being considered to have made a notable improvement, the patient was discharged from the hospital.

Case #2 (Amyotrophic lateral sclerosis) (ref 3.)

Patient: A 25-year-old male (Administration number #73819). Weakness of four limbs for approximately one year was admitted to the hospital on Aug. 7, 1993 with the diagnosis of amyotrophic lateral sclerosis (ALS). Upon hospitalization: the patient showed weakness of all four limbs, weak gripping (only 5 Kg), obvious muscle atrophy of four limbs and both hands, twitching of both both upper limbs, unsteady walking (could only manage 100 meters), difficulty of walking up and down stairs. Tongue: red, with white coat, fine pulse. Physical exam: Lung and heart (-), muscle strength of four limbs (grade III), muscle tone (normal), tendon reflex (hyperactive), Babinski sign on both sides (+), Hoffmann sign on both sides (+); EMG: injury of neuronal origin. Diagnosis according to Chinese Medicine: Wei Zheng (liver and kidney weakness); Diagnosis according to Western Medicine: amyotrophic lateral sclerosis (ALS). Treatment strategy: Bu-Nao-Gao (two cubes/day) alone. 20 days after Bu-Nao-Gao: slightly enriched muscle volume, walking more steadily than before, gripping of both hands increased from 5Kg to 20Kg, could walk by himself for 2-3 hours, could walk up and down stairs by himself rather easily, muscle strength of four limbs V-. After one-month treatment with Bu-Nao-Gao, significant improvement was observed and the patient was discharged.

Case #3 (Primary lateral sclerosis) (ref. 4)

Patient: A 51-year-old male with a 6-month history of weakness in four limbs and lower limb rigidity, and was diagnosed by neurologists of other hospitals as “lateral sclerosis”. His symptoms worsened continuously despite all the treatments with both Chinese and Western medicines before being admitted to our hospital.

Diagnosis: Primary lateral sclerosis.

After treatment with a decoction modified from “Fu Shou San”, the patient showed improved in muscle strength after 15 day’s treatment, and can climb stairs without the need for aid (still had difficulty of going downstairs) after 20 day’s treatment; he can walk freely (still with some weakness) after 35 day’s treatment. After 80 day’s treatment, the patient’s muscle strength reach grade V (still slight weakness), could walk up and down stairs easily and had normal gait. His pathological reflexes disappeared, and physiological reflexes of four limbs were only slightly active.

This patient was treated with a decoction when the cube form of Bu-Nao-Gao (or the consensus formulation) was not yet invented, nevertheless this report reflected one of the early attempts by the inventor to define a therapeutic rule (or consensus formulation) for treating this type of disease.

7. Potential side effects

Due to the rather rapidly deteriorating nature of motor neuron disease (particularly ALS), and the potential of a long-term repeated use of Bu-Nao-Gao for these patients, the following advice and precautions were given to patients: This formulation was designed to be used alone without anticipating further combination with other drugs or supplements without proper medical supervision. Furthermore, people with certain medical conditions may put themselves at risk by using this formulation: i.e. (a) people with hypertension with blood pressure above 150/90mmHg may put themselves at risk by taking this formulation without first lowering their blood pressure to a clinically safe level; (b) people with problems with blood clotting (i.e. bleeding tendency) may put themselves at risk by taking this formulation due to the anti-coagulating effect of this formulation; (c) Women in pregnancy or lactation should not use this formulation.

The only known side-effect of this formulation in people with suitable medical conditions (according to the experience of more than 25 years) has been an increased bowel movement, a problem which will usually resolve by itself within the first one or two weeks’ usage. Despite the anti-coagulation effect of the formulation, no bleeding tendency has so far been reported from our long-term experience. For longer-term usage, a one-two weeks’ break after every three-months usage is recommended.

8. Conclusion

Most patients treated by Bu-Nao-Gao has failed conventional treatment elsewhere (both Chinese and Western medicines). Bu-Nao-Gao has shown to be effective for treating motor-neuron disease with a total effective rate of 82.6% during the period of our evaluation. During the follow-up period (though incomplete), some patients (including some ALS patients) remained stable for many years without continuously using Bu-Nao-Gao; some other ALS patients experienced the comeback of the disease several times. In every occasion of the disease comeback, Bu-Nao-Gao had demonstrated its beneficial effect on slowing, stabilizing or reversing of the disease progression.

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