

**The Clinical Research of 30
Cases Before the Administration
of Pegasus "Cardio Guard" Ginsenosides
From North American Ginseng**

With the Pharmaceutical, pharmacological and toxicological test results of Pegasus "Cardio Guard" Formula Ginsenosides of North American Ginseng being taken into account, this preliminary clinic test is conducted on 30 chosen testees on the basis of toxicity and safety.

Clinical Data

1. The Choice of Testees

There are altogether 30 testees and 18 of them are male and 12 female. The mean age is $54 \pm SD 8$ years (41-65 years old). 16 of these testees are suffering from coronary heart disease, 10 cerebralarteriosclerosis and 4 cerebral sequela. The 16 patients suffered from coronary heart disease are counted as the hypofunction of heart and spleen and deficiency in heart -yin in the "deficiency in origin" of traditional Chinese medicine science according to "The Dialectical Criterion of Traditional Chinese Medicine Science against Coronary Heart Disease and Angina Pectoris" (See Submission Document 18 ,Attachment 1). The disease is, at the same time, diagnosed in accordance with 'Some Advice on the Name of Coronary Heart Disease and Its Diagnosis Criterion' put forward at the 1980 National Internal Medicine Academic Conference. Among these 16 cases there are 12 coronary heart disease cases, 4 coronary heart disease accompanied with hypertension, 14 tired angina pectoris and all the above are mild stable

tiredness cases. In addition, 2 are remote myocardial infarction, 14 are suffering from high triglycerides (TG) ($> 1.21\text{mmol/L}$), 15 high total cholesterol (TC) ($> 4.5\text{mmol/L}$), and 8 high lipoprotein ($> 4.5\text{mmol/L}$).

2. Instructions

4 granules each time of "Cardio Guard" Formula Capsules (50mg/granule), twice a day for four consecutive weeks. No other drugs permitted one week prior to taking the product. Take a record of symptoms, heart rate, cardiac rhythm, blood pressure and side reaction before and after the treatment. Examine the ECG. Determine the blood-lipid, liver and kidney function, blood routine and others while empty stomach in mornings. The diet, living habits and physical activities are as usual during the treatment period.

3. Evaluation of the therapeutic effect

The effect is valued in line with "Evaluating Criteria on the curative Effect of Coronary Heart Disease, Angina Pectoris and ECG" at the 1979 Forum of Treating Coronary Heart Disease, Angina Pectoris and Arrhythmia by Combining Chinese and Western Medicinal Science (See Submission Document 18, Attachment III).

Results

1. Clinical Therapeutic Effects

After 30 testees have taken the "Cardio Guard" Capsules, the symptoms like tired vitality and weakness, aching pain and fragility in waist and knee are relieved. The patients feel more vigorous, better appetites, physical fitness enhanced and are of high-quality sleep.

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No adverse reactions appeared. 10 cases in these 16 coronary heart disease patients are effectual, which is 62.5%; 4 cases (25%) are improved, and 2 cases (12.5%) ineffective. As to ECG, 4 cases are effectual, which is 25%; 7 are improved, 43.7%; and 5 are ineffective, 31.3%.

2. Effects on the blood pressure and blood-lipid

Although the "Cardio Guard" Capsules exerts no evident effect on those with normal blood pressure, it can decrease that of the seven testees with hypertension, whose systolic pressure varies significantly from 22.1 ± 1.3 KPa to 19.3 ± 2.0 KPa ($P < 0.01$) in the treatment; The diastolic pressure changes from 12.8 ± 1.1 KPa to 11.7 ± 0.8 KPa ($P < 0.20$) with little difference.

The "Cardio Guard" Capsules will not change the normal blood-lipid greatly, however, it can lower much of the high blood-lipid. 14 high TG patients' blood-lipid reduced from 2.14 ± 0.47 mmol/L (before taking) to 1.54 ± 0.58 mmol/L (after taking). The effect is obvious ($P < 0.02$). 15 high TC patients' blood-lipid slides from 5.58 ± 0.67 mmol/L down to 3.86 ± 0.75 mmol/L. The effect is evident ($P @ 0.001$). 8 high lipoprotein patients' blood-lipid varies from 5.10 ± 0.75 mmol/L to 3.97 ± 0.70 mmol/L, which is evident, too ($P < 0.01$).

3. Others

While determining 12 testees' platelet aggregation (Attractant ADP, Platelet Aggregator manufactured by Beijing Biochemical Instrument Factory) the aggregation rate is lowered from 63% to 32% ($P < 0.02$). 14 testees' plasma 6-Keto-PGF_{1a} and TXB₂, 6-Keto-PGF_{1a} increases evidently from 88 ± 88 pg/ml to 254 ± 90 pg/ml ($P < 0.01$). 14 testees' plasma lipid peroxide (TBA Approach) markedly reduced from 5.1 ± 1.2 pg/mi

to 3.5 ± 1.2 nmol/ml (P <0. 05).

Conclusion

1. While taking the Comfort Capsule in 400mg/d, the testees feel good and there are no adverse reactions. Therefore, this indicates that this dosage is tolerant and the product is safe.
2. It is extremely good for chest paralysis patients (the mild coronary heart disease patients) suffering from hypofunction of the heart and spleen, deficiency in the heart-yin in "deficiency in origin".
3. It has been essentially proved in clinical cases that the Pegasus "Cardio Guard" Capsules can lower the blood pressure, adjust blood -lipid level and thus can prevent and treat coronary heart disease effectively.
4. It is found from the testees that the Pegasus "Cardio Guard" Capsules can inhibit platelet aggregation, enhance plasma 6-Keto-PGF_{1a}, decrease plasma TXB₂, and reduce plasma lipid peroxide, therefore, help prevent and treat coronary heart disease.