Therapeutic Effect of Berberine on 60 Patients with Non-Insulin Dependent Diabetes Mellitus and Experimental Research

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ABSTRACT The effects of berberine on 60 cases with non-insulin dependent diabetes mellitus and experimental research results were observed in this study. The results suggest berberine has significant effects on non-insulin dependent diabetes mellitus patients and experimental diabetes in animals in the reduction of blood glucose levels. The clinical symptoms basically disappeared and the level of serum insulin rose. The total effective rate was up to 90 percent and there were no significant side-effects. It was found that berberine has an effect on the recovery of pancreas islet ß-cells through pathological examination on the animal subjects.

KEY WORDS berberine, non-insulin dependent diabetes mellitus, animal model

It was found by accident that berberine had the therapeutic effect on the decrease of blood glucose when the authors used berberine to treat diarrhea for inpatients who suffered from diabetes. Therefore, berberine was used to treat non-insulin dependent diabetes mellitus (NIDDM) during 1983 to 1987. And a better effect was obtained.

CLINICAL STUDY

METHODS

Subjects
According to two diagnosis standards [the diagnosis standard for diabetes by World Health Organization (WHO) and the domestic diagnosis standard and classification system adopted by WHO in 1980] presented by the National Diabetes Study Enlargement Conference held in Beijing in February 1982, 60 cases were diagnosed to suffer from non-insulin dependent (type II) diabetes mellitus. Among them, 36 cases were male and 24 female. They ranged in age from 37 to 69 years (average 54 years). The duration of illness was from 2 months to 5 years. They were all in good nutritional condition. Eighteen cases were classified as obese, 8 cases were overweight, and 34 cases were at a standard. Insulin was not used in the treatment and ketosis had not occurred. Twelve cases suffered from serious diabetes (fasting blood glucose > 13.9 mmol/L), 38 from moderate diabetes (8.33 ~ 13.9 mmol/L) and 10 from mild diabetes (< 8.33 mmol/L). Twelve cases were complicated with hypertension, 2 cases with coronary heart disease and 1 case with cor pulmonale. Forty-five cases showed no clear complication. Sixty cases whose blood glucose was normal were used as the control group in order to observe if berberine has a double adjustable effect and the side-effect of hypoglycemia.

Therapeutic Method
A self-control method was used for 60 patients. Dietary therapy was used for one month prior to the study. If the therapeutic effectiveness was not significant, i.e., the levels of blood glucose and urine glucose were not reduced by 4 times. Berberine was administered orally at 0.3 ~ 0.5 g three times daily. Each dosage was properly adjusted periodically in terms of the level of fasting blood glucose determined before meals. Less than 8.33 mmol/L (150 mg/
dl) dosage of 0.3 g was taken each time, 8.33–13.9 mmol/L dosage of 0.4 g and more than 13.9 mmol/L (250 mg/dl) 0.5 g. During this period, activity was the same as during dietary therapy. The course of treatment was 1 to 3 months. The course of treatment of 5 cases that had an effect after 40 days was extended to 3-month therapy and the courses were the same as mentioned above for 60 cases of normal blood glucose.

**Method of Observation**

Before and after treatment, symptoms and signs were recorded, fasting blood and urine glucose, blood and urine glucose 2 hours after meals were determined (method of oxidase) once a week. Twenty-four hour determinations of quantity for glucose in urine, blood-lipid and serum insulin were made once two weeks (30 outpatient cases). The determination of blood pressure was made once a week for patients complicated with hypertension. T-test was used for the statistical process.

**RESULTS**

**The Standard for Therapeutic Effect**

The standards used to determine a good therapeutic effect were the standards for the cure and improvement of clinical diseases (z).

**The Therapeutic Effect of Lowering Blood Glucose**

The effect was determined after dietary therapy and combined with berberine treatment. The fasting blood glucose of 60 cases was 6.6±1.4 mmol/L, and was much lower than the 11.6±2.9 mmol/L level noted before treatment (pure dietary therapy. P<0.01).

After the treatment of 30 cases, their serum insulin was 21.93±3.46 μu/L and was evidently increased compared with 16.0±2.68 μu/L (before treatment. P<0.01).

The fasting blood glucose levels after treatment of 36 cases were less than 6.105 mmol/L (110 mg/dl. ideal control standard); 14 cases between 6.105～7.215 mmol/L (110～130 mg/dl. controlled better); 4 cases 7.215～8.325 mmol/L (130～150 mg/dl. generally controlled); and 6 cases >8.325<11.1 mmol/L (200 mg/dl).

The fasting blood glucose of 54 cases was up to generally controlled levels, with the total effective rate reaching 90%. Two hours after meals, 12 cases were up to ideal control standards (<130 mg/dl): 16 cases were at controlled better levels (<150 mg/dl): 12 cases were generally controlled (<180 mg/dl). Although the blood glucose after meals in 16 of the remaining 20 cases (2 cases not examined) was not up to the standards mentioned above, decreased an average of 5.988 mmol/L, compared with before treatment. Another 2 cases decreased by less than 3.33 mmol/L. The fasting urine glucose of 8 cases was (+), 8 cases (−+) and the remaining (−). On 24 hours, quantitative tests for glucose in urine, 36 cases reached ideal control standard (<5 g); 4 cases reached normal (<100 mg): 8 cases reached better control (<10 g); and 4 cases reached generally controlled (<15 g). The remaining 8 cases were decreased by an average of 39.25 g. Compared with previous treatment, in 60 cases of cholesterol in blood obviously lowered with an average of 76 mg/dl. and β-lipoprotein, triglyceride also had lowering tendencies.

The time necessary to lower blood glucose after administering the medicine: Ranged from 2 weeks in 30 cases. 3 weeks in 14 cases. to 1 month in 14 cases (40 days for 5 cases). The fasting blood glucose in 36 cases was up to ideal control standards 2 months later.

For 60 cases with normal blood glucose (control group), the fasting blood glucose before the treatment was x̄=4.8 mmol/L (86.35 mg/dl), while after the treatment.