Clinical Observation of Kaixin Capsule in Treating Type 2 Diabetes Mellitus Complicated with Abnormal Lipidemia

XUE Jun (薛军) and CHEN Jing-he (陈镜合)

ABSTRACT Objective: To observe the clinical efficacy of Kaixin Capsule (KXC, 开心胶囊), a Chinese compound preparation, in treating type 2 diabetes mellitus (DM) complicated with abnormal lipidemia. Methods: Seventy-two DM inpatients were medicated on the basis of administering conventional hypoglycemics, and KXC was orally taken. They were compared with those patients only taking hypoglycemics to observe the change of blood lipid before and after treatment. Results: The total cholesterol of KXC combined with hypoglycemics group had their blood lipid lowered by 14% after treatment and triglyceride lowered by 36%, HDL-C raised by 11%, and LDL-C lowered by 24%. Compared with only hypoglycemics treatment, there was significant difference (P<0.01). Conclusion: KXC has good blood lipid regulating effect on DM complicated with abnormal lipidemia.

KEY WORDS Kaixin Capsule, type 2 diabetes mellitus, abnormal lipidemia, clinical efficacy

DM is a series of endocrine-metabolic disorders mainly shown as glucose metabolic disturbances due to absolutely or relatively shortage of insulin secretion, and easy to be complicated with lipid metabolic disturbance. Hyperlipidemia is closely related to DM complicated vascular lesion occurrence, which may seriously affect the prognosis of DM patients. Therefore in treating DM vascular lesion, particular emphasis should be laid on the adjusting of lipid metabolic disturbances. But either western medicine treatment or surgical operation has indispensable side-effects and limitations, and furthermore cannot definitely prevent or treat the vascular complications. Therefore using integrative Chinese and western medicine approach to treat it is the first choice of elevating clinical efficacy in treating DM vascular complication. The authors supplemented conventional hypoglycemics, with a self-formulated pure Chinese medicine preparation called Kaixin Capsule (KXC, 开心胶囊) to treat 40 type 2 DM patients complicated with abnormal lipidemia from May to December 2000, the efficacy was remarkable, and now the results are reported as follows.

METHODS

Clinical Data

Seventy-two patients enrolled were inpatients of our hospital, the diagnosis of type 2 DM conformed to the standard for DM diagnosis of WHO. The diagnosis standard of abnormal lipidemia referred to Chinese “Suggestions on Preventing and Treating Abnormal Lipidemia” (1). Hypolipidemic medication was ceased for 2 weeks before observation; fasting serum total cholesterol (TC≥5.72 mmol/L), or triglyceride (TG≥1.7 mmol/L), or high density lipoprotein-cholesterol (HDL-C ≤ 0.91 mmol/L) were examined twice. Those who conformed to one or more of the above-mentioned items were chosen, and those were ruled out who had familial hyperlipidemia as well as hyperlipidemia induced by liver, biliary and thyroid disorders or those who suffered from severe DM complicated keto-acidosis, hyperosmotic coma, serious infection, acute myocardial infarction, cerebrovascular accident, etc.

Seventy-two patients conformed to above-mentioned standards, male 30 and female 42; ages 38 - 73 years, mean 58.46 ± 8.49 years; illness course 3 months to 15 years, mean 6.2 ± 4.73 years. The patients were randomly divided into the treated group (KXC combined with hypoglycemics) and the control group (treated with hypoglycemics only). In the treated group were male 16 and female 24, ages 38 - 71 years, mean 57.58 ± 9.37 years; the control group: male 14 and female 18; age-
es 38 - 73 years, mean 58.64 ± 9.52 years. Statistical analysis of age, gender, illness course, blood glucose and blood lipid before treatment showed that there were no significant differences between the two groups.

**Therapeutical Methods**

All the patients were given low fat diet, orally taken glilazide (80 mg per tablet, products of Tianjin Huajin Pharmaceutical Factory, batch No. 00203) 80 mg, twice a day, or Ruiyining (5 mg each tablet, Pfizer Pharmaceutical Company, Ltd., batch No. 991109) 5 mg per day, taken during breakfast. The treated group was supplemented with KXC (American ginseng, lilyturf, nutgrass flatsedge, Chinese atracylodes, ligusticum, cape jasmine, safflower, cat-tail pollen, trogopterus dung, hawthorn, etc. made by Preparation Department, the First Affiliated Hospital, Guangzhou University of TCM, 0.45 g crude drug for each capsule) orally taken, 6 capsules each time, 3 times a day. They were consecutively medicated for 30 days as one treatment course, altogether 2 courses.

**Observation Parameters**

Using oxidase method to measure fasting blood glucose (FBG), enzyme method to detect serum TC, TG, HDL-C, low density lipoprotein-cholesterol (LDL-C), with all the parameters done by the laboratory of the First Affiliated Hospital, Guangzhou University of TCM.

**Statistical Analysis**

Measurement data is expressed by mean ± standard deviation (x ± s), before and after treatment coupled t test is used, and enumeration data expressed by χ² test.

**RESULTS**

**Clinical Efficacy Assessment Standard**

The efficacy assessment standard refers to "Guiding Principle on Drugs for Clinical Study" (trial) issued by the Ministry of Health in July 1993: (1) Markedly effective: TC lowered by ≥20%, or TG lowered by ≥40%, or HDL-C raised by ≥0.26 mmol/L; FBG < 7.2 mmol/L, post-breakfast glucose (PBG) < 8.3 mmol/L. (2) Effective: TC lowered by 10% - 20%, or TG lowered by 20 - 40%, or HDL-C raised by 0.1 - 0.25 mmol/L, FBG < 8.3 mmol/L, PBG < 10 mmol/L. (3) Ineffective: the parameters failed to reach the level for being effective. (4) Aggravated: TC elevated by ≥10%, or TG raised by ≥10% or HDL-C lowered by ≥0.1 mmol/L.

**Clinical Efficacy**

After 60 days treatment, the total effective rate in TC lowering of the treated group was 78.6%, that of TG lowering, of HDL-C raising, of LDL-C lowering was 81.4%, 54.5% and 88.9% respectively. Z² test shows that these figures mean significant difference when compared with the control group (P < 0.01).

**Blood Lipid Change before and after Treatment**

See Table 1. The results showed that TC, TG, LDL-C of the treated group before and after treatment had significant difference, they were lowered by 14%, 36% and 24% respectively (P < 0.01), although HDL-C after treatment elevated by 11% compared with that of before treatment, but statistical analysis indicated that no significant difference existed (P > 0.05). The changes of TC, TG, HDL-C and LDL-C had no significant difference before and after treatment in the control group (P > 0.05).

**Comparison of FBG between the Two groups**

The result shows that in both groups after treatment the FBG was markedly improved. Before treatment, the blood glucose of the treated group and the control group was 12.26 ± 0.57 mmol/L and 12.18 ± 0.54 mmol/L respectively, but they lowered to 7.89 ± 0.38 mmol/L and 8.09 ± 0.34 mmol/L respectively after treatment, statistical analysis indicated significant difference P < 0.01. But before and after treatment, comparison of the blood glucose between the two groups showed insignificant difference, P > 0.05.