ORIGINAL ARTICLE

Clinical Effect of Maixuekang Capsule (脉血康胶囊) on Long-Term Prognosis in Patients with Acute Coronary Syndrome after Percutaneous Coronary Intervention

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ABSTRACT  Objective: To study the changes of adenosine diphosphate (ADP)-induced platelet aggregation rate, and evaluate the effects of Maixuekang Capsule (脉血康胶囊, MKC) on platelet aggregation rate and long-term prognosis of patients with acute coronary syndrome after percutaneous coronary intervention (PCI). Methods: A total of 236 patients with acute coronary syndrome, who received successful PCI, were randomly assigned to a trial group (116 cases) and a control group (120 cases) according to random numbers; treatment allocation occurred when the participants met the inclusion criteria and signed the informed consent forms. In the trial group, the patients were treated with MKC combined with routine medication, and in the control group the patients were treated with routine medication. The therapeutic course for the two groups was 12 months and the follow-up was 12 months. The levels of ADP-induced platelet aggregation rate and serum high-sensitive C-reactive protein (hs-CRP) were determined before PCI, 12 h and 30 days after PCI. In the meantime, the incidence of cardio-/cerebrovascular events was recorded during the 12-month follow-up. Results: Compared with before PCI, the levels of ADP-induced platelet aggregation rate and serum hs-CRP were significantly higher at 12 h after PCI (P<0.05). There were significantly reduced after 30-day-treatment of MKC, showing statistical differences when compared with those in the control group (P<0.05). During the 12-month follow-up, the incidence of cardio-/cerebrovascular events was significantly lower in the trial group than in the control group (6.9% vs. 12.5%, P<0.01). Conclusions: ADP-induced platelet aggregation function was significantly elevated after PCI, MKC improved the prognosis of patients with acute coronary syndrome, possibly through inhibiting the platelet aggregation, fighting against inflammation, and protecting the vascular endothelial function.

KEYWORDS acute coronary syndrome, platelet aggregation inhibitors, percutaneous coronary intervention, Maixuekang Capsule

Percutaneous coronary intervention (PCI) has become the preferred treatment for most patients with coronary heart disease; it not only improves quality of life of patients, but also ameliorates the long-term prognosis. However, stent treatment is a "double-edged sword", the application of drug-eluting stents just partially resolved stents stenosis, but caused incidence of in-stents thrombus to increase obviously. Once stents thrombus has formed, it performances as acute coronary syndrome (ACS), and the prognosis of patients is poor.¹ The mechanisms involve endothelial injury, platelet activation, inflammation, and blood at hypercoagulable states.

Recent treatment of coronary heart disease emphasizes treatment based on syndrome differentiation. The fact that standardizing and optimizing integrative medicine treatment eventually reduce adverse cardio-/cerebrovascular events is increasingly recognized in the treatment of coronary heart disease. Chinese medicines for activating blood circulation and removing blood-stasis have unique advantages of preventing restenosis and thrombosis and improving the prognosis of patients.² Three previous studies have indicated that Maixuekang Capsule (脉血
METHODS

Diagnostic Criteria of ACS

2007 American College of Cardiology (ACC)/American Heart Association (AHA) guideline for management of patients with unstable angina/non-ST-elevation myocardial infarction (NSTEMI) was adopted. (5)

ST-Elevation Myocardial Infarction Diagnostic Criteria

(1) Typical ischemic chest pain, duration time more than 30 min, chest pain cannot be eased through resting or taking nitroglycerin; (2) ECG showed that two or more contiguous limb leads have ST-segment elevation more than 0.1 mV, two or more contiguous chest leads have ST-segment elevation 0.2 mV; (3) MB isoenzyme of creatine kinase (CK-MB, the normal spectrum is 0 to 3.6 ng/mL) or troponin I (TnI, the normal spectrum is 0 to 0.05 ng/mL) ≥ twice of the upper normal limit.

NSTEMI Diagnostic Criteria

Patients with typical myocardial infarction symptoms, ECG shows ischemia, but no ST-segment elevation and dynamic evolution of ST-T, CK-MB or TnI > 2 times the upper normal limit.

Unstable Angina Diagnosis Criteria

Typical chest pain, ECG shows ischemia, but no ST-segment elevation, CK-MB less than twice of the normal.

Diagnostic Criteria of Chinese Medicine Syndrome

Chinese medicine symptom scores and blood-stasis syndrome scores were diagnosed with reference to the diagnostic criteria documented by Committee of Cardiovascular Disease and Committee of Activating Blood Circulation, and Chinese Association of Integrated Traditional Chinese and Western Medicine. (6, 7)

Inclusion Criteria

(1) Patients met the diagnostic criteria; (2) normal coagulation function; (3) age between 40 to 80 years; (4) no experience in other clinical intervention trial, one month prior to the recruitment; (5) patients should receive the treatment voluntarily and sign informed consents.

Exclusion Criteria

Patients (1) with abnormal coagulation function, bleeding tendency; (2) with any history of heart valve diseases, cardiomyopathy; (3) with chest wall and mediastinum disease, pleurisy, plural tumors, pneumothorax, hemothorax; (4) with central nervous system diseases; (5) with serious diseases such as tumor, heart failure, liver and kidney diseases, or hematopoietic system diseases; (6) with congenital or acquired immune deficiency; (7) participating in other clinical intervention research; (8) allergic to treatment drugs.

Baseline Characteristics

Totally 236 patients with ACS after successful PCI in Beijing Anzhen Hospital, Beijing, China from July 2008 to June 2010 were randomly assigned to a trial group (116 cases) and a control group (120 cases) using consecutively numbered envelopes and the randomization sequences were blinded for clinical investigators. The trial group and the control group had similar baseline characteristics (P > 0.05, Table 1). The study protocol was approved by the ethics committee of our institution.

Quality Control

The present study was a prospective, randomized, and parallel controlled clinical trial. Quality control personnel trial was responsible for reviewing any documentation in this clinical trial. All data were inputted and statistically analyzed by a specialized person who did not participate in the clinical trial.

Medication

The control group: after successful PCI, patients with ACS were given conventional Western medicine treatment including anti-ischemic therapy [nitrates, β blockers, calcium antagonists, angiotensin converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB)], anti-platelet therapy (clopidogrel plus aspirin or aspirin alone), anti-coagulant therapy