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INTRACORONARY AUTOLOGOUS CD34+ STEM CELL THERAPY FOR INTRACTABLE ANGINA

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Objectives A large number of patients with coronary artery disease experience angina that is not suitable for revascularisation and is refractory to conventional medical therapy. Laboratory and preclinical studies have provided evidence for the safety and potential efficacy of autologous CD34+ stem cell therapies as treatment for angina. Clinical studies investigating intramyocardial transplantation of autologous CD34+ stem cells by catheter injection for patients with refractory angina show that this is safe and feasible. It remains unclear whether intracoronary infusion of CD34+ stem cells exerts beneficial effects in patients with angina as well. We addressed this question with a controlled clinical trial by enrolling 112 patients with refractory angina. Previous trials have investigated the safety and beneficial effects of CD34+ cells isolated from granulocyte colony-stimulating factor-mobilised peripheral blood; in our trial, we isolated CD34+ cells directly from the patient's bone marrow.

Methods One hundred and twelve patients with diffuse triple-vessel disease and Canadian Cardiovascular Society class III or IV angina were enrolled in a double-blind, randomised (1: 1), placebo-controlled study. Patients received optimal medical treatment but were not candidates for mechanical revascularisation (percutaneous coronary intervention or coronary artery bypass grafting). Fifty-six patients (27 women and 29 men aged 42–80 years) were enrolled in the treatment group, and 56 patients (28 women and 28 men aged 43–80 years) who received optimal medical treatment and intracoronary saline injections were enrolled in the placebo control group. Bone marrow was collected from all enrolled patients at a volume of 120–150 ml each in both groups. Selections of CD34+ cells were performed by a CE-marked device approved by the Security, Food and Drug Administration of China. Coronary angiography had been performed before enrolment in this study.

Results No myocardial infarction was observed during intracoronary infusion. The intracoronary infusion of cells or saline did not result in cardiac enzyme elevation, cardiac perforation or pericardial effusion. No arrhythmia, such as ventricular tachycardia or ventricular fibrillation, was induced by intracoronary infusion. No serious adverse events occurred in either group. The reduction in the frequency of angina episodes per week 3 and 6 months after infusion was significantly higher in the treatment group (–14.6 8 4.8 at 3 months and –15.6 8 4.0 at 6 months) than in the control group (–4.5 8 0.3 and –3.0 8 1.2, respectively; $p < 0.01$). Other efficacy parameters such as nitroglycerine usage, exercise time and the Canadian Cardiovascular Society class also showed an

improvement in the treatment group compared to the control group. A significant improvement in myocardial perfusion was noted in the treatment group compared to the control group, as measured by single-photon emission CT.

Conclusions This randomised trial investigating intracoronary infusion of autologous CD34+ cells in patients with intractable angina shows the safety and feasibility of this therapy and provides evidence for efficacy.



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