INTRAMYOCARDIAL INJECTIONS ARE SAFE

Studies of intracoronary stem-cell injection after acute myocardial infarction (MI) have provided conflicting results. However, as Korff Krause from Asklepios Clinic St George, Hamburg, Germany, comments, "it is important to use the best delivery route for cell treatment to evaluate whether stem cells or other cells really can improve heart function." Indeed, left ventricular electromechanical mapping allows precise injection into regions of the heart that are less well perfused than others, and preclinical studies have shown that cells delivered by intramyocardial injection have better cell distribution than those delivered through an intracoronary route. Krause and colleagues have demonstrated that intramyocardial delivery of mononuclear stem cells after acute MI is safe and feasible.

Observational feasibility studies of patients with chronic ischemic heart disease and no option for revascularization have demonstrated a safe and positive effect of intramyocardial delivery of stem cells, guided by the electromechanical mapping system NOGA® (Cordis Corporation, Miami Lakes, FL), on left ventricular heart function. On the basis of this result, and given that preclinical trials have indicated that cell distribution is better after intramyocardial injection than after intracoronary injection, Krause and colleagues embarked on a phase I safety and feasibility study of NOGA® -guided intramyocardial delivery of mononuclear stem cells after acute MI.

Patients who had undergone an acute MI with subsequent glycoprotein IIb/IIIa blockade, coronary reperfusion and stenting were eligible for enrollment in this single-center study. Enrolled patients (18 men, 2 women) received a total of ~20×10^7 bone-marrow-derived mononuclear cells via 20 injections into the low-voltage (at-risk) area of their MI—as identified using the NOGA® system—10.5 ± 5 days after their acute MI.

No patients developed sustained ventricular tachycardia, pericardial effusion, stroke, MI, myocarditis, endocarditis, or died as a result of the procedure or at any stage in the 12-month study. At the 12-month follow-up appointment, no patient demonstrated worsened NYHA classification compared with that seen at time of hospital discharge 48 h after cell injection. Indeed, at the 6-month follow-up, electromechanical mapping showed a decrease in the extent of at-risk area in the MI of the 15 patients who underwent invasive diagnostic testing (5 refused to undergo invasive diagnostic testing because they had not experienced any adverse symptoms). Additionally, at both the 6-month and 12-month follow-up appointments, transthoracic echocardiography demonstrated increased left ventricular ejection fractions in the 20 enrolled patients, from 41% at time of cell injection, to 47% at the follow-up appointments. However, although these results are encouraging, the authors emphasize that "this study was a safety and feasibility trial and not set up to prove efficacy due to the small number of patients and the lack of a randomized control group." Furthermore, the authors highlight that the study is also limited by the lack of intramyocardial sham injections.

Krause and colleagues are now studying the effects of intramyocardial delivery of stem cells in patients after acute MI, compared with matched control patients. According to Krause, "a head-to-head study of intracoronary versus intramyocardial cell injections would also be helpful to evaluate this technique."

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Original article Krause, K. *et al.* Percutaneous intramyocardial stem cell injection in patients with acute myocardial infarction. First-in-man study. *Heart* doi:10.1136/hrt.2008.155077