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The Helical Infusion Catheter: First Clinical Evaluation for Local Intramyocardial Delivery of Therapeutics

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Background: Therapeutic cells and genes delivered locally to the myocardium are currently in clinical trials for treatment of ischemic and nonischemic cardiomyopathy. To enable these efforts, a percutaneous intramyocardial delivery (IMD) system that provides for fixation and delivery through a 27-gauge hollow helical needle has been developed and rigorously tested in preclinical studies. This first human study intends to show the safety of the system in patients with coronary artery disease.

Methods: Patients (N = 3) suffering from chronic myocardial ischemia in regions not treatable with conventional revascularization approaches were enrolled. A deflectable tip 9Fr percutaneous guide catheter was advanced retrograde across the aortic valve and into the left ventricle (LV) over a guidewire. The 5Fr IMD catheter was advanced through the guide to the endocardial surface of the LV. After fluoroscopic confirmation of position, the helix is rotated to advance it 5 mm into the tissue. A separate radio opaque contrast infusion lumen provided additional means to confirm the position and depth of helix penetration. IMDs of 0.2 mL of phosphate-buffered saline or diluted contrast were completed at 5 separate sites within each untreatable region. Patients were monitored for hemodynamics and LV function during infusions. After the procedure, blood was sampled for creatine kinase (CK)-MB and troponin levels, and echocardiography was performed.

Results: IMD of 0.2 mL of solution at 5 sites per ventricle was well tolerated by all patients. Total procedure time was <10 minutes. No persistent arrhythmia or hemodynamic instability occurred during or after the infusions. Postprocedural CK, CK-MB, troponin levels, and predischarge echocardiograms were all within normal limits.

Conclusion: Percutaneous intramyocardial infusion of agents with a helical-tipped infusion catheter is well tolerated in patients with coronary artery disease. The use of an anchoring catheter system allows control over rate of injection and provides the ability to confirm position before delivery. The additional lumen for radiopaque contrast fluid allowed visualization of ventricular location, as well as depth of penetration under standard dual-plane fluoroscopy. This approach promises to be safe in routine clinical use. Investigations are ongoing.

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