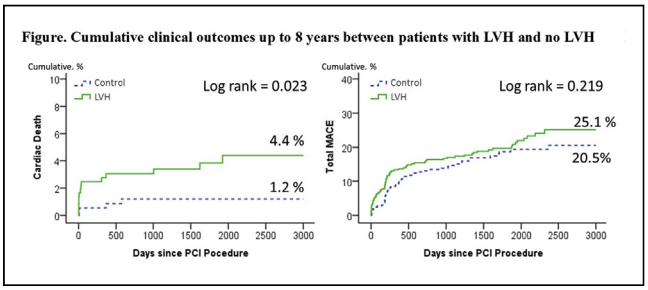


CRT-400.09

Early Transendocardial Autologous Bone Marrow Injection of Bone Marrow Derived Mononuclear Cells Following Ischemic Myocardial Events (the Alster - Helix Phase I Study)

Martin W. Bergmann,[1] Christian Heeger,[2] Kai Jaquet,[2] Christoph Boosfeld,[3] Peter Altman[3]
[1]Cardiologicum Hamburg, Hamburg, Germany; [2]Abt. Kardiologie, Ak StGeorg, Hamburg, Germany; [3]BioCardia, San Carlos, CA

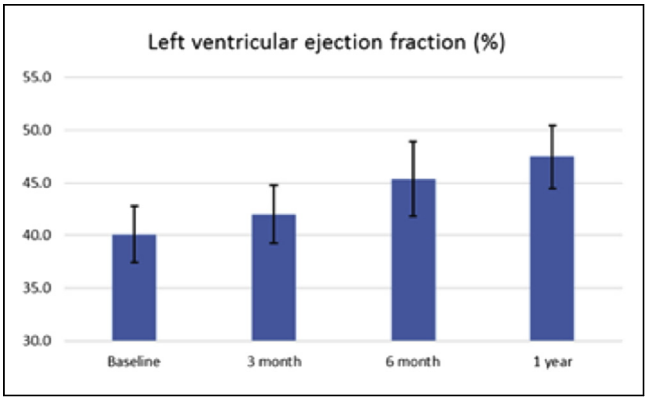
BACKGROUND There has been no clinical experience in an acute setting reported using a fluoroscopically guided system for intramyocardial delivery of cell therapy.

OBJECTIVES To assess safety and efficacy of fluoroscopically guided intramyocardial transendocardial delivery of cell therapy less than 45 days after onset of acute myocardial infarction.

METHODS Patients with symptomatic heart failure following myocardial infarction (NSTEMI, STEMI) received transendocardial application of autologous bone marrow-derived mononuclear cells (BMC) 2-4 weeks after the acute event.

RESULTS Patients (n=9) with LV ejection fraction (EF) of 40.1± 8.0% and NYHA Class ≥II had autologous bone marrow cell preparation performed on site employing a closed-loop system. Cells delivered were 1.3 ± 1.3% CD34+, 1.68 ± 1.58 CD117+, 0.24 ± .16 CD133+, and 0,28 ± 0.40 CD90+. Each patient received Helix transendocardial injection of BMC into the infarction border zone 28±13 days following successful interventional revascularization. Delivery procedure took 32.1±11.7 minutes to perform 9 ± 2 deliveries of in total more than 1.5x108 cells/patient around the infarcted zone; There were no treatment emergent adverse events, no MACE, no pericardial effusions, and no arrhythmias in any procedure. Endpoints derived from comparisons of baseline vs. twelve month follow-up showed improvements of NYHA class (2.6±0.5 to 1.3 ± 0.5, p = 0.0002), BNP levels (362.1 ± 340.4 to 58.9 ± 45.9 ng/l, p = 0.036), and LV EF transthoracic echocardiography measurements (40.1±8.0 to 47.4 ± 9.0%, p = 0.02).

CONCLUSIONS Results support that transendocardial intramyocardial injection of BMC using Helix can be used safely in patients with symptomatic heart failure following acute ischemic events.



CRT-400.10

Real-time MRI Guidance Improves the Diagnostic Yield of Endomyocardial Biopsy Compared With X-ray Fluoroscopy

Toby Rogers, Kanishka Ratnayaka, William H. Schenke, Jonathan R. Mazal, Adrienne Campbell-Washburn, Ozgur Kocaturk, Anthony Z. Faranesh, Robert J. Lederman
NHLBI, National Institutes of Health, Bethesda, MD

BACKGROUND The diagnostic yield of endomyocardial biopsy is low because X-ray fluoroscopy cannot distinguish abnormal from normal myocardium. We hypothesized real-time MRI guidance could improve the yield.

METHODS Under X-ray fluoroscopy guidance, 3mL of fluorescent microspheres (NuFlow Hydrocoat, 15μm diameter, 5 million spheres/mL) was infused to a branch coronary artery followed by 2mL of 100% ethanol to create a single focal endomyocardial lesion. Animals were survived for minimum 14days, before undergoing in the same procedure MRI guided biopsy using a custom-built active visualization MR-conditional bioptome (Figure 1) and X-ray guided biopsy using a commercial steel bioptome. Specimens were analysed using a dissecting microscope under ultraviolet light with a 400-480nm band pass filter to determine the proportion of 'on-target' specimens containing fluorescent microspheres.

RESULTS 5 swine with mean bodyweight 51kg underwent both MRI and X-ray guided biopsy. After administration of systemic gadolinium contrast, the lesion was visible using late gadolinium enhancement MRI. A total of 77 specimens were collected in MRI, and 87 in X-ray. Examination of the specimens under ultraviolet light revealed fluorescent microspheres in 63/77 (81.8%) specimens obtained under MRI guidance compared with 49/87 (56.3%) specimens obtained under X-ray fluoroscopy guidance (Figure 2).

CONCLUSIONS Real-time MRI guidance can improve the diagnostic yield of endomyocardial biopsy in an animal model of focal myocardial disease.

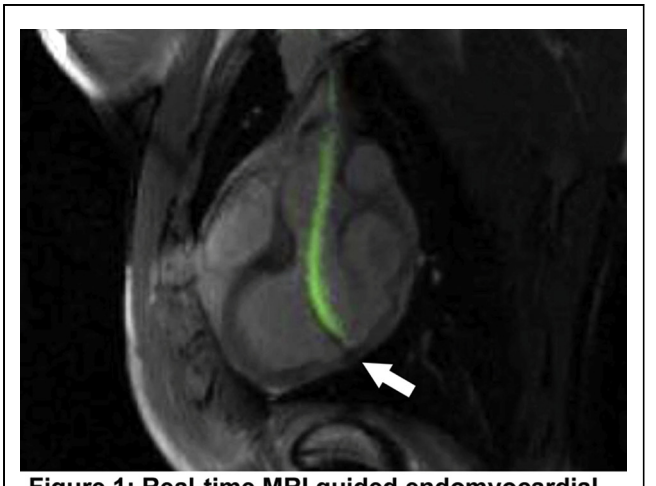


Figure 1: Real-time MRI guided endomyocardial biopsy using an active visualization bioptome