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Percutaneous Endocardial Versus Selective Coronary Venous Cellular Delivery: Comparisons of Transplant Efficiency, Distribution, and Efficacy in Reducing Infarct Size and Improving Myocardial Function

Erik T. Price, Fumiaki Ikeno, Ralph C. Fenn, Pauline Chu, Jennifer K. Lyons, Peter J. Fitzgerald, Alan C. Yeung, Paul G. Yock, Mehrdad Rezaee

Stanford University Medical Center, Stanford, CA

Background: Cellular transplantation is an emerging option for the treatment of ischemic cardiomyopathy. Percutaneous endocardial delivery (PED) and percutaneous coronary venous delivery (PCVD) offer potential advantages in safety, transplant efficiency, and targeted distribution for preservation of myocardium.

Methods: A total of 22 swine were studied: 6 PED and 4 PCVD for acute feasibility arm; and 4 PED, 4 PCVD, and 4 combined controls for chronic efficacy arm (LAD infarct by balloon occlusion). Porcine fibroblasts labeled with iron nano-particles were used for transplantation.

Between $2-2.5 \times 10^6$ cells were injected into the infarct area either by PED using a BioCardia(tm) helical infusion catheter, or by PCVD using a single high-pressure (100-200 mmHg) injection through a balloon-tipped catheter in the anterior interventricular vein (AIV). Ejection fraction (EF) was measured at infarct induction (day 0), cell delivery (day 7), and sacrifice (day 28). Horizontal cross-sections of the left ventricle were stained with tetrazolium for infarct size, then with H&E and Prussian Blue for cell identification. A linear computational model was used to estimate transplant efficiency.

Results: Acute studies demonstrated safe, targeted transplantation using both modalities. In infarcted animals, PED and PCVD resulted in $17.3 \pm 24.3\%$ and $15.7 \pm 11.6\%$ of fibroblasts identified after 21 days. PED resulted in 98.4% of cells in the antero-septal walls, with 95.8% localized to the endocardial half, at an average depth of 3.4 ± 3.9 mm. PCVD resulted in 97.6% of cells in the antero-septal walls, a radial 21.8 ± 7.9 mm from the AIV, with 60.1% localized to the endocardial half. With both modalities >96.0% of cells were within 5 mm of the infarct zone. Both PED and PCVD trended in reduced infarct size compared to the controls (3.9 ± 1.6 and 7.9 ± 6.0 , vs. 13.9 ± 10.8 , $p=0.12$ and $p=0.37$ respectively), and improved EF (26.0 ± 3.2 and 26.8 ± 12.6 vs. 17.0 ± 9.8 , $p=0.13$ and $p=0.27$ respectively).

Conclusions: PED and PCVD provide comparable efficiency and targeted distribution. As anticipated, PCVD provides regional delivery, and PED a more local distribution. Studies are underway to further establish the efficacy of both modalities.