

Women with Heart Failure in the CardiAMP Cell Therapy Trial

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CardiAMP CELL THERAPY TRIAL (NCT 02438306)

- NYHA Class II / III; left ventricular ejection fraction 20-40%
- Chronic ischemic LV dysfunction after an MI (>6 months)
- 250 patients
- Prescreen patients for bone marrow quality (e.g. CD34+)
- Collect 60 ml autologous bone marrow
- Point of care concentration of bone marrow with CardiAMP CS device
- Helical needle delivery with high cell retention
- Transendocardial delivery of concentrated cells
- See CTR-009 on Clinical Trials Row for more details

Introduction

More than half of the newly diagnosed HF patients in the U.S. each year are women. Women are more symptomatic than men, with HF having a larger impact on quality of life¹. Despite similar need for treatment, women represent only ~20% of patients enrolled in HF clinical trials². The ongoing CardiAMP Cell Therapy HF trial employs a novel personalized approach to cell-based management of NYHA class II-III ischemic HF. Prior to inclusion the trial and treatment with concentrated autologous bone marrow cells, an important screening criterion consists of a cell “potency” assay (CPA), whereby prospective subjects must demonstrate sufficient bone marrow quality, characterized by a minimum concentration of CD34+ and other cell types. The purpose of this study was to compare CPA results of female and male patients in the trial.

¹ Walsh, et. al., J. of the American College of Cardiology 2019;73(1)

² Lindenfeld, et. al., JACC 1997;30(6):1417-9

Methods

CPA bone marrow cell concentrations were determined using a biomarker panel by flow cytometry. Of the 166 patients screened thus far, 18 (11%) are women. CPA results were tabulated with age as a co-variate since older age is suspected to be associated with reduced cell counts.

Conclusions: Women continue to be under enrolled in this HF trial. Preliminary results suggest that women may be more likely than men to meet the CPA criterion for study eligibility. Additional analyses are underway to evaluate other demographic measures that may be associated with bone marrow quality for autologous treatment of heart failure. While the trial continues to enroll, the importance of including more women into this and other HF research programs is vital to understand and improve outcomes for all patients.

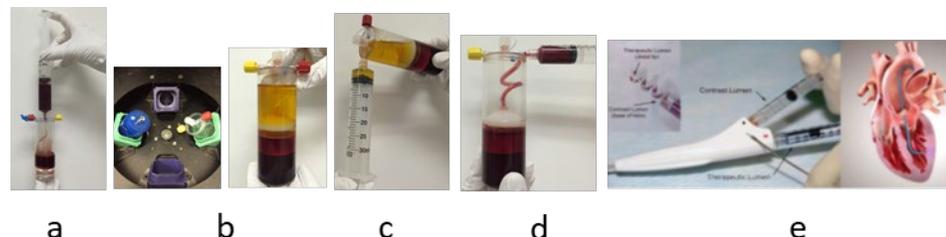
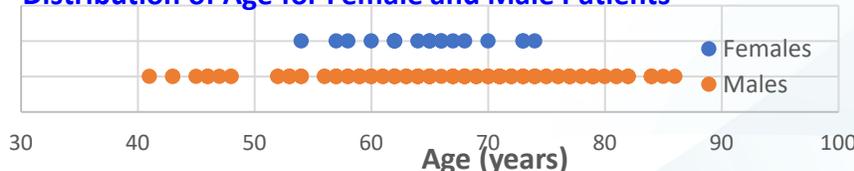


Figure 1. (a) Bone marrow aspirate is aspirated and transferred into the CardiAMP CS, (b) centrifuged and (c) the cell poor plasma layer is removed. (d) Concentrated cells are drawn into 1 mL syringes for transendocardial injections. (e) The Helix catheter has a helical shaped needle with a distal lumen to administer the cell therapy and a more proximal lumen for injection of dilute contrast, which is used to verify transendocardial catheter engagement (left image). The Helix catheter is telescoped within the steerable Morph guide (right image). Both devices are positioned retrograde across the aortic valve into the left ventricle for transendocardial therapeutic injections under fluoroscopy.

Distribution of Age for Female and Male Patients



Results

Concentration of CD34+ cells did not differ significantly between males and females (p=0.279; Table 1). Females tended to meet the CPA criterion at a higher rate than males (83% vs 67%). For both sexes, younger patients met the CPA criterion at a higher rate (Table 2).

Table 1: CPA Analysis

	Female	Male
n	18	148
Age (mean±SD)	64.8 ±5.6	66.9 ±11.4
CD34+ Concentration (k/ml)		
mean±SD	451±248	381±301
median	445	309
Cell Potency Assay Result		
# eligible	15/18	99/148
% eligible	83%	67%

Table 2: CPA Eligibility Stratified by Age

Female			
Age (years)	n	# eligible	eligibility rate
40-64	8	7	88%
65+	10	8	80%
total	18	15	83%
Male			
Age (years)	n	# eligible	eligibility rate
40-64	53	42	79%
65+	95	57	60%
total	148	99	67%