OMICS Group Conferences
Accelerating Scientific Discovery
3rd World Congress on
Cell Science & Stem Cell Research
November 20- 22, 2013 DoubleTree by Hilton Baltimore-BWI Airport, USA

The clinical trial experience in cellular cardiomyplasty

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Introduction: Heart failure (LV dysfunction) is the leading cause of death in most countries of the world. The present mode of treatment primarily involves medicinal therapy, interventional methods such as angioplasty or surgery. However, when a considerable portion of the heart muscle is significantly affected, then the patient may require a Left ventricular assist device (LVAD) or heart transplant. This has disadvantages such as surgical complications, the perils of immuno-suppression drugs, lifelong expenditure and paucity in donor graft availability. Such tribulation cues the necessity for other modalities of therapy. Cellular cardiomyoplasty for myocardial damage appears promising as it might replace damaged myocytes by stimulating neo-angiogenesis and regeneration.

Methodology: The Granulocyte colony stimulating factor (GCSF) induced Peripheral blood derived CD34+ Endothelial progenitor cells (EPCs) and iliac crest bone marrow derived mononuclear cells (MNCs) were collected from 70 patients suffering from ischemic/dilated cardiomyopathy (mean age group: 42) (autologus EPCs: 26 cases, autologus MNCs: 43 cases, allogenic paternal EPCs: 1 case) with the approval from Clinical trial registry, Govt of India (Clinical trial number: CTRI/2009/091/000590). The bone marrow were processed by closed vial method using RBC sedimentation technique. The isolated MNCs were subjected to a battery of tests such as flowcytometry to analyze the presence of CD34+ & CD45+, total cell viability and cell count, microbial sterility check and endotoxin analysis. The route of cell delivery was trans-coronary for 52 patients and epicardial for 18 patients. The patients were injected with total cell yield approximately 6x108 cells/ml of 99.5% viable cells.

Results: The Ischemic cardiomyopathy patients (20/36) had shown significant improvement in Ejection fraction (55.5%), whereas dilated cardiomyopathy patients (6/20) had an improved cardiac output (33.3%) during a average follow up of 2 years. 10 patients in either group lost the follow up. Four patients (25%) had expired during the follow up due to other complications.

Conclusion: The autologus cellular cardiomyoplasty with EPCs and MNCs is more safe and effective therapy for Left ventricular dysfunction. However, many refinements are required to standardize the dosage and route of cell delivery for appropriate homing of stem cells.

Biography

Balasundari Ramesh, M.Sc., Ph.D. is a Senior Research Scientist in the Frontier lifeline pvt ltd, Dr.K.M.Cherian heart foundation in India. Doctorate in Biomedical Science from MAHER University, India in 2012. Teaching Faculty in the stem cells and tissue engineering dept. for PG diploma courses in stem cell technology- Madras University. she is currently responsible for tissue engineering of xenografts for clinical use and cellular Cardiomyoplasty clinical trial held at frontier lifeline Pvt ltd. Her research efforts have resulted in about 4 grants from Govt. of India (TDB, SBIRI, ICMR, DBT) with 10 national/ international publications. Reviewer for 4 journals.