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## **Transendocardial Autologous Bone Marrow in Chronic Myocardial Infarction using a Helical Needle Catheter, Two Year Follow-up in an Open-Label, Non-Randomized, Pilot Study (the TABMMI study)**

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**Aims:** Cell therapy has shown benefit in preclinical and clinical studies, although debate continues on the mechanism of action and the most appropriate methods for performing such therapies. We assessed the hypothesis that helical needle transendocardial delivery of autologous bone marrow (ABM) mononuclear cells around regions of hypo or akinesia in chronic post-myocardial infarction (MI) patients would be safe and possibly improve ejection fraction (EF).

**Methods:** 17 stable post-MI ischemic heart failure patients with an EF <40% were enrolled. ABM cells were aspirated from the iliac crest and the ABM mononuclear cells were delivered percutaneously with a transendocardial helical needle catheter. 2D echo left ventricle EF measurements, 24 hour Holter, and exercise tolerance testing were performed at baseline, day of procedure, 1 and 12 weeks, 6, 12, and 24 months.

**Results:** In the first ten patients, 86 million cells were injected into  $7.1 \pm 3.1$  sites around the infarct to target the peri-infarct zones. In the next seven patients 100 million cells were delivered to 10 sites similarly selected. There were no adverse events associated with the catheter based cell transplantation procedure in any of 17 patients treated to date. For the first ten patients, baseline EF ( $35.2 \pm 4.6\%$ ) rose in a statistically significant fashion at each time points: 6 months ( $40.8 \pm 4.5$ ,  $p=0.003$ ), 12 months ( $42.3 \pm 5.1$ ,  $p=0.0001$ ) and 24 months ( $42.3 \pm 6.1$ , at 12 months,  $p=0.0001$ ).

**Conclusion:** ABM cells delivered with the helical needle transendocardial catheter was safe in this small uncontrolled study in patients with chronic MI. Increased ejection fraction and other positive data trends support continued development of this therapeutic strategy in larger controlled trials.