Absorbable matrix does not prevent cardiac remodelling

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An investigational material known Bioabsorbable Cardiac Matrix (BCM) that is injected through the coronary artery to prevent cardiac remodelling in heart attack patients had no significant effect compared to a saline placebo, according to results of the PRESERVATION I trial.

The Hot Line findings announced today at ESC Congress 2015 were "somewhat surprising and disappointing", said study investigator Uwe Zeymer, MD, from Institut für Herzinfarktforschung, in Ludwigshafen, Germany.

"Based on encouraging results in experimental studies and a previous pilot trial in humans, which showed a preservation of left ventricular dimensions after heart attack, we had expected to find a reduction in left ventricular enlargement and an improvement in clinical symptoms compared to saline control," said Professor Zeymer.

BCM is a liquid mixture of sodium alginate and calcium gluconate that can be injected into the coronary artery during percutaneous coronary intervention (PCI) in heart attack patients.

The liquid flows into the heart, where it reacts with ionized calcium that collects in damaged heart muscle, forming an absorbable gel. This gel acts as flexible scaffold, or "matrix", that supports the heart during repair and then dissolves, explained Professor Zeymer.

Previous studies have shown that injection of BCM prevents remodelling

of the heart - which is changes to the shape, size and structure of cardiac muscle that occur after a heart attack, and the deployment procedure has been shown to be safe without any difference in ischemic or arrhythmic events compared to placebo, he noted.

The study included 303 subjects (from Australia, Belgium, Canada, France, Germany, Israel, Poland, Spain, and USA) who were randomised to receive an intracoronary injection of the investigational substance or a saline control.

For the primary endpoint, change from baseline in left ventricular end diastolic volume index (LVEDVI) - an echocardiographic measurement of remodelling assessed at 6 months – there was no significant difference between the two groups.

In addition, the groups showed no significant difference in any secondary endpoints including Kansas City Cardiomyopathy Questionnaire (KCCQ),

Six minute walk test (6MWT), NYHA functional classification, time to cardiovascular death or non-fatal heart failure events or cardiovascular hospitalisations, or time to first rehospitalisation due to any CV event.

The dropout rate was similar between those treated with the investigational substance and placebo (4% versus 6%) and there were no significant differences in serious adverse events between groups.

Professor Zeymer said there are several possible explanations for why the study did not show better outcomes with the investigational material. "Potential reasons include selection of a patients with too large an infarct without any chance to prevent remodelling, or timing of the intervention- which might have been done too late. Therefore further studies are necessary to determine the optimal timing and target population for this

innovative therapy."

Provided by European Society of Cardiology