Heart separation device improves 3 year outcomes in heart failure patients - ESC Press Release - ESC Congress 2012

A novel non-invasive device which separates healthy and damaged heart muscle and restores ventricle function improves 3 year outcomes in patients with ischemic heart failure, according to research presented at the ESC Congress 2012. The findings were presented by Professor William T. Abraham at an ESC press conference on 25 August and by Dr Marco Costa at an ESC Congress scientific session on 27 August.

Heart failure is a common, debilitating, and potentially deadly condition in which the heart is unable to supply sufficient blood flow to meet the needs of the body. Symptoms of heart failure negatively impact quality of life and include shortness of breath, persistent coughing or wheezing, buildup of excess fluid in body tissues (edema), fatigue, lack of appetite or nausea, impaired thinking, and increased heart rate. More than 20 million people around the world are affected.

Many heart attack survivors experience enlargement of the heart, causing a decrease in cardiac output that results in heart failure symptoms such as fatigue and shortness of breath. The healthy portion of the heart not affected by the heart attack has to compensate for the loss in output and becomes overloaded over time. Current treatment options for patients whose hearts have enlarged are limited.

The Parachute Ventricular Partitioning Device is the first minimally invasive treatment for patients with heart failure caused by damage to the heart muscle following a heart attack. The Parachute device is implanted in the left ventricle through a small catheter inserted in the femoral artery.

“The device creates a barrier between the non-functioning, damaged segment of heart muscle and the healthy, functional segment of heart muscle,” said Dr Costa. “This decreases the overall volume of the left ventricle chamber and restores its optimal geometry and function. The procedure is performed in the catheterization laboratory under conscious sedation.”

Two-year clinical data presented at the EuroPCR conference earlier this year demonstrated improved overall cardiac function and quality of life for patients treated with the Parachute device.

The current study included 31patients treated in the US and Europe with the Parachute system. The New York Heart Association (NYHA) Functional Classification of 1 (mildest) to 4 (most severe) was used to define the severity of heart failure at 1, 2 and 3 years after treatment.

The average NYHA class at baseline was 2.6. This improved to 1.6 ($p<0.001$) at 1 year, 1.9 ($p<0.01$) at 2 years and 1.8 ($p<0.0001$) at 3 years post treatment. Dr Costa said: “This shows that the severity of heart failure maintained its improvement over time after treatment with the Parachute device.”

The proportion of patients who were hospitalized due to worsening heart failure increased from 29.7% at 2 years to 33.2% at 3 years after treatment. “This small increase could be because the Parachute is specifically targeting the structural heart problem by excluding the scar caused from a heart attack which initiated the negative ventricle remodeling,” said Dr Costa.

The low cardiac death rate of 6.5% at 2 years remained unchanged at 3 years. “This suggests that percutaneous ventricle restoration with the Parachute system results in a plateau of the progression of heart failure in these patients,” said Dr Costa. “These outcomes compare favorably with current medical therapy in a similar high-risk patient population.”

“These results are compelling,” said Professor Abraham. “The sustained improvements in functional capacity and plateauing effect seen in outcomes three years after treatment with the Parachute device are particularly encouraging, showing that we may be able to slow the progression of heart failure – a very exciting prospect.”

“We were already very excited about the two-year clinical data presented at the EuroPCR conference earlier this year,” said Dr Costa. “Our three-year results in this high-risk population reinforce our initial enthusiasm and fuel our motivation to start a large randomized trial later this year.”

Dr Costa concluded: “In these two first-in-man studies we have shown that the Parachute device is safe and leads to sustained improvements in symptoms, heart function, and clinical outcomes over three years. This points to a potentially historical turning point in the treatment of heart failure caused by a heart attack.”

ENDS

Notes to editors

The Parachute Ventricular Partitioning Device received CE Mark in 2011. In the US, the Parachute system is an investigational device limited by federal law to investigational use only and is not available for sale.

Please note that picture and CV from the author, abstract, picture and CV from spokesperson can be found here http://www.escardio.org/about/press/esc-congress-2012/press-conferences/Pages/new-approaches-heart-failure-diagnosis-therapy.aspx

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The European Society of Cardiology (ESC) represents more than 75,000 cardiology professionals across Europe and the Mediterranean. Its mission is to reduce the burden of cardiovascular disease in Europe.

About ESC Congress 2012
The ESC Congress is currently the world’s premier conference on the science, management and prevention of cardiovascular disease. ESC Congress 2012 takes place 25-29 August at the Messe München in Munich. The scientific programme is available here.
More information is available from the ESC Press Office at press@escardio.org.

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