Revivent™ for heart failure with left ventricular scar

TECHNOLOGY

Revivent™ is a device developed by BioVentrix for reshaping and reducing the volume of the left ventricle in patients with symptomatic heart failure and left ventricular scarring due to myocardial infarction (heart attack). Revivent™ has been developed for open surgery and is being developed for delivery by catheter.

Heart attacks can damage heart muscle leading to progressive enlargement of the left ventricle causing the symptoms of heart failure – fatigue, shortness of breath and fluid accumulation. Both versions of Revivent™ use paired anchors to reshape and reduce left ventricular volume. One anchor rests in the right ventricle against the septum, the other rests on the left ventricular surface. The anchors are then opposed to exclude the area of damaged left ventricle.

The first system to be launched is the Revivent™ Myocardial Anchoring System. This is delivered through an open chest procedure which can be done on or off cardiopulmonary bypass as a stand-alone procedure or combined with other open chest procedures. The anchor pairs are sited using a needle and introducer through the left ventricular wall. Multiple anchors can be aligned end to end along the length of the scar. A force gauge is used to oppose the anchors at the end of the procedure.

Revivent™ Myocardial Anchoring System was CE marked in December 2012 and is now commercially available in the UK. Phase I studies are being followed up and Phase II recruitment is ongoing. The first Revivent procedure was performed in the UK in August 2013.
The second product under development is for delivery by catheter - Revivent TC™ Transcatheter Ventricular Restoration System. This is intended as a less invasive approach for the same patient groups as Revivent™.

It is a joint procedure performed by a cardiovascular surgeon and interventional cardiologist using the same anchoring system and principles as the open procedure. Revivent TC™ Transcatheter Ventricular Restoration System is not yet CE marked and is currently planned for UK launch in 2014.

**POTENTIAL FOR IMPACT**

Heart failure is a common disease affecting approximately 900,000 people in the UK and adversely affects quality of life for patients and carers. Incidence and prevalence increase with age. The prognosis is poor, 30-40% of patients die within the first year, although this has improved over the past decade. Heart failure accounts for 2% of all NHS bed days and 5% of emergency admissions. With an ageing population the burden of heart failure on NHS services is projected to rise. NICE guidance for chronic heart failure was updated in 2010. Standard treatment includes a range of drugs such as beta blockers and ACE inhibitors. Some patient groups can benefit from invasive procedures such as coronary artery bypass grafting, valve surgery and cardiac resynchronisation therapy. According to the European Society of Cardiologists, the value of surgical ventricular reconstruction is uncertain. These techniques and devices are not currently recommended for routine use. Other devices for ventricular reshaping have been developed, including CorCap™ and Parachute® (see previous NIHR HSC Alert).

Revivent™ is intended to be used in addition to current pharmacotherapy. The company state that Revivent™ is less invasive than existing technologies for left ventricular restoration as it can be done off bypass and does not require cutting into the ventricle. They suggest that the transcatheter version, Revivent TC™ will further capitalise on these benefits as it does not require sternotomy. BioVentrix claim that both systems can be deployed more rapidly, with reduced risk and provide more controlled and consistent reshaping than alternative approaches. This less invasive approach may mean reduced recovery times and shorter in patient stays. The company also claim that the technology will reduce readmissions. Development and trials are ongoing. If clinical and cost effectiveness can be demonstrated, Revivent™ may offer an additional treatment option for select patients with heart failure and left ventricular scars.

**EVIDENCE**

**PUBLISHED PAPERS AND ABSTRACTS**

Teerlink JR. Prospective study of the revivent myocardial anchoring system for less invasive treatment of ischaemic cardiomyopathy (CONFIGURE-HF), Phase I, Oral presentation. European Society of Cardiology, Heart Failure May 2013 Conference.
ONGOING STUDIES


INFORMATION FROM

This Alert is based on information from the company and a time-limited internet search.