Medical Device Daily™
The Daily Medical Technology News Source
Thursday, August 15, 2013 Vol. 17, No. 157 Special Reprint

BioVentrix goes LIVE with heart failure device in Germany

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PARIS — "The patient was critically ill and had exhausted all other available treatment options," explained cardiologist Ralph Haberl, MD, a cardiologist at the **University of Munich** in Germany.

A diagnostic imaging exam showed the 54-year old man, suffering for two years from advanced heart failure, demonstrated an ejection fraction of only 12% and significant cardiac damage.

He was expected to live only a few more weeks.

An interdisciplinary team at the Schön Klinik Vogtareuth near Munich decided to put the patient on a fast track to receive an innovative procedure developed by **BioVentrix** (San Ramon, California).

It was a first use of the novel device outside of a clinical trial, a very modest step for sales, but a significant indication of the readiness of surgeons to adopt this new procedure for the large population of 14 million people in Europe diagnosed with heart failure.

BioVentrix's Revivent system was successfully placed using a less-invasive ventricular enhancement (LIVE) procedure, said Albert Schütz, MD, chief of Heart Surgery at the 400-bed clinic who led the team.

"The entire procedure was uncomplicated, the patient was extubated the same day and he continues to do very well," he reported.

It was only in June, 2013 that the results of an 11-patient Phase I trial using the BioVentrix technology were published in the European Journal of Cardio-Thoracic Surgery, showing a sustained 39.6% improvement in heart function at one year.

The LIVE procedure creates a gentler surgical intervention that aims to reshape and restore left ventricle size and function using the Revivent myocardial anchoring system.

Unlike the current practice of surgical ventricular restoration (SVR), the BioVentrix system does not require stopping the beating heart and supporting it with cardiopulmonary bypass, nor does it require any incisions into the heart muscle.

"Those are two actions that can have very deleterious effects for the patient," said David Schickling, VP of sales and marketing.

"The SVR procedure has lost favor among surgeons because of this risk and difficulty," he said, adding, "We are introducing a technology that makes it a consistent, easily performed operation."

"It is well-documented and acknowledged by all clinicians in heart failure that medical therapy may prolong life, but it does not stop the disease process and patients ultimately become so sick they end up with a heart transplant or a ventricular assist device," said Schickling, which are both tremendously expensive and invasive therapies.

"Our fit in the heart failure paradigm is that we actually impede or arrest the disease process, reduce the cascade of events, and do it in a relatively less invasive manner and at significantly lower cost," he said.

Thanks to the SVR procedure, BioVentrix will benefit from established procedure coding and reimbursement, a distinct advantage for a novel device facing Europe's fragmented payer landscape.

Next step: transcatheter delivery

Before the end of the year the company expects to perform a first-in-man procedure using a trans-catheter device in a closed-chest intervention within the framework of a clinical trial.

More than a next-generation, Schickling called the new Revivent-TC device a next step for a heart team that is practiced in the open chest technology.

"Once surgeons at a center understand how the remodeling technique and the device work, they can move to a yet-more beneficial transcatheter intervention where they will need to rely on imaging technology rather than direct vision," he said.

While designed for use in a interventional catheterization lab, the new procedure requires a mini-thoracotomy, and like a transapical, transcatheter aortic valve implantation (TAVI), it reinforces the role of the heart surgeon.

The lessons of TAVI development in Europe have not been lost on BioVentrix, which preaches the new gospel of the Heart Team pioneered by Californian colleague, **Edwards LifeSciences** (Irvine, California).

Schickling said the introduction of a transcatheter device greatly expands the eligible population for ventricular remodeling as many patients can not tolerate the risk of a surgical intervention.

The company will be speaking about the opportunity at the congress for the **European Society of Cardiology** (Sophia Antipolis, France) in Amsterdam at the end of this month and Schickling said he is confident it will be introduced to interventional cardiologists at EuroPCR in May, 2014.

The first clinical use this week of the LIVE procedure with the Revivent system were outside of a clinical trial but within the company's clinical development program as it precipitated the launch of a registry trial for Germany called BRAVE.

"We are using a center of excellence strategy in Germany were we have recruited eight of the top academics centers so far to serve as our focus and for our training model going forward," he said.

"Our entire focus is on Europe at this moment and we are active in many countries with a primary focus to collect clinical data and further substantiate the effectiveness of our device," he said.

The first-in-man for the first generation device was performed in Eastern Europe at heart centers in Vilnius, Lithuania and Kraków, Poland.

As BioVentrix gained momentum and confidence with the results of the Phase I trial, Schickling explained the company has moved with deliberate focus to reference centers in Western Europe, including Austria, France, Italy, Portugal, Spain, and the UK.

The multi-center, adjudicated Phase II PLICATH trial is designed to evaluate the safety and efficacy of the BioVentrix PliCath HF System for left ventricular volume restoration in patients with ischemic cardiomyopathy, assessing as a primary endpoint the overall rate of serious adverse device effects through 12 months.

Despite the starting block advantage of reimbursement codes for SVR, "there remains a lot of work to do regarding reimbursement," said Schickling.

Germany offers the clearest path toward eventual reimbursement of the disposable Revivent device that adds cost to the SVR procedure thanks to the NUB Innovation clause (Neue Untersuchungs und Behandlungsrichtlinien).

"As with most medical devices Germany is the most promising and lucrative market, but the SVR procedure is well reimbursed with a well established coding processes throughout most of Europe," he said.

"Having an existing code is a good stepping stone to what we are going to need for the transcatheter device," he added.

"The beauty of this opportunity for BioVentrix is that there has not been an effective surgical therapy for heart failure patients, and we offer a technology that not only assures optimal clinical outcomes but improves the quality of life for heart failure patients," said Schickling.