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EDITORIAL

Left-to-Right Interatrial Shunting: A Novel Treatment for Heart Failure in Ischemic Cardiomyopathy

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Despite recent advances in pharmacologic and device-based therapies, heart failure with reduced ejection fraction remains an important clinical problem that is associated with poor quality of life, frequent hospital admissions and high mortality rates. The clinical deterioration and symptoms of these patients are directly related to volume overload and increased left atrial filling pressures with pulmonary congestion. This concept forms the basis for the hypothesis that unidirectional left-to-right interatrial shunting could provide a novel therapy for chronic systolic heart failure by reducing left atrial pressures.[1,2]

In this issue of *Structural Heart*, Eigler and colleagues report their findings using a novel interatrial shunt device (V-Wave implantable shunt; V-Wave Ltd., Israel) in an ovine model of ischemic cardiomyopathy.[3] The V-wave device comprises an hourglass-shaped Nitinol frame with a polytetrafluoroethylene polymer coating on the left atrial side and a valve with porcine pericardial leaflets on the right atrial side to prevent paradoxical embolism and right-to-left shunting. The initial V-Wave device utilized a bi-leaflet valve, whereas the later generation device that was also used for human implants used a tri-leaflet valve. The diameter of the narrowest portion of the shunt device is 5.1 mm, which is small enough to prevent right-sided volume overload and subsequent right heart failure.

The authors utilized a microembolization model that leads to rapidly developing heart failure. Prior to the shunt implantation, animals underwent on average two microembolization procedures to the left circumflex coronary artery, which were separated by a week. The average left ventricular ejection fraction across all animals was reduced to 35.8% after injection of the microspheres. Fourteen sheep were implanted with the V-Wave device and seven additional sheep served as sham controls. Animals were followed for 12 weeks with serial hemodynamic and echocardiographic assessments. This study represents the first evaluation of this device in a large animal model of ischemic cardiomyopathy and the authors made several important observations. Left-to-right interatrial shunting led to reduced left atrial pressures, enhanced left ventricular function and improved survival at 3 months. In addition, there was evidence for a reduction in adverse remodeling in the treatment group. Three out of seven animals in the sham control group died during follow-up, whereas only one out of 14 animals died in the shunt group. Interestingly, in the shunt group not only did the animals have lower filling pressures than controls, but they also experienced an improvement in LVEF over time while systolic function in the control animals continued to decline.

Recently, a publication reported the initial clinical experience with the V-Wave device in a single center study in 10 patients with reduced ejection fraction.[2] This first-in-human experience demonstrated excellent procedural safety with successful implantation in all patients and without device- or procedure-related complications during follow-up. Device patency was assessed at 1 month by transesophageal echocardiography and at 3 months by transthoracic echocardiography and demonstrated persistent left to right shunting. One patient died during follow up from incessant ventricular tachycardia. Patients were anticoagulated after the procedure and one patient was admitted for gastrointestinal bleeding 1 month after device implantation. In these patients who had persistent heart failure symptoms despite optimal guideline-directed medical therapy, interatrial shunt implantation was associated with a significant reduction in pulmonary capillary wedge pressure in the absence of deleterious effects on right-sided filling pressures or pulmonary hypertension. In contrast, NT-pro BNP levels remained unchanged 3 months after V-Wave implantation. Further, there was no change in LVEF during follow-up. The reduction in left atrial pressures was associated with significant improvements in several clinical performance metrics including NYHA class, quality-of-life scores and 6-minute walk test distance. While these data are intriguing, one must keep in mind that clinical data from open-label, non-randomized studies, and in particular those with small sample sizes, are subject to a number of biases. The persistence of the shunt long term, and the effect of any design iterations (as invariably happens with first generation devices) will also need to be assessed. In addition, clinical differences were mostly observed in soft outcomes and subjective parameters. As evidenced by the example of inotropic agents, beneficial short-term hemodynamic alterations do not always translate into favorable long-term effects on outcome. Randomized clinical trials with longer-term outcomes need to be performed to confirm the above findings and to evaluate the effect of interatrial shunting in patients with heart failure with reduced ejection fraction, on cardiovascular mortality and hospital readmissions.

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The findings of the preclinical study by Eigler and colleagues are consistent with the clinical proof-of-principle trial, in that left-to-right interatrial shunting decompressed left atrial pressures and there was no evidence of adverse effects on right ventricular pressures or function as well as on pulmonary artery pressure. However, in the animal model, left ventricular function deteriorated rapidly and left ventricular remodeling occurred precipitously. As a result the mortality rate in this model was very high (43%) within just a few months. This is in contrast to the stable chronic heart failure patients treated in the study by Del Trigo and coworkers.[2] Furthermore, animals did not receive any heart failure medications or resynchronization therapy and it is unclear how much the treatment effect of the study device would be altered in the presence of guideline-directed heart failure therapy. Of course, the short duration of follow up was also a significant limitation of the study.

Despite the limitations delineated above, the authors should be congratulated for this exciting proof-of-principle study. The results of this study suggest that left-to-right interatrial shunting in heart failure with reduced ejection fraction not only promotes the decompression of the left atrium but it also reduces adverse left ventricular remodeling. Future studies will be needed to determine the optimal shunt size and to assess the effects of the V-wave device on RV and LV remodeling in greater detail. If the concept of left-to-right interatrial shunting holds up in randomized controlled clinical trials, and the data support improvements in cardiac remodeling and reduced heart failure admissions, then this technology might alter our approach to heart failure therapy.

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