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Interatrial decompression device to for left atrial decompression to prevent lung congestion

Left atrial pressure is an important hemodynamic determinant of the symptomatology in patients with congestive heart failure. In patients with systolic (HF with reduced EF) or diastolic heart failure (HF with normal EF) left atrial pressure tends to increase excessively leading to pulmonary congestion and occasionally pulmonary edema. These observations were made with hemodynamic measurements obtained invasively in patients with severe heart failure and presented in multiple studies in the medical literature. Significant progress have been made in Pharmacotherapy and device based therapy for systolic heart failure but there is a need for more modalities. Moreover, for patients with diastolic heart failure the therapeutic measures are very limited.

V-wave develops a device that will effectively reduce left atrial pressure when excessive. The concept is simple and is based on the physiologic observation that left atrial pressure (LAP) is higher than right atrial pressure (RAP). In pts with heart failure either systolic or diastolic the difference is excessive and when a shunt device is implanted in the interatrial septum the LAP to RAP difference will result in flow from LA to RA that will decompress the LA and prevent pulmonary congestion. The device can be implanted in a transcatheter approach. The device was implanted to the interatrial septum of animals with chronic HF and compared to control. All shunts after 12-20 weeks were patent and there were no adverse events and no deterioration in hemodynamic parameters recorded. The shunts were highly effective in ameliorating HF animals whereas marked deterioration was observed in controls. Hemodynamic and echocardiographic studies performed serially over time proved the hemodynamic and clinical benefit of the device with marked improvement of animal survival. This led to the first in Human clinical trial where 38 patients with severe heart failure either systolic or diastolic were implanted with the device. The study was performed in Canada, Spain and in Israel with very promising results. The procedure was successfully performed in all patients without significant complications and the procedure time was 72 minutes. The number of adverse events related to the device or protocol were minor. There was marked improvement in NYHA class over 12 months of follow up, marked improvement in the quality of life and improvement in 6 minute walk test and no worsening of RV function. The company will start soon the Relieve - HF randomized control pivotal trial with 500 pts in NYHA class 3 or ambulatory 4 with HFREF and HFPEF, elevated BNP or proBNP, on optimal medical and device based therapy. There will be comparisons for effectiveness - mortality, transplant/LVAD, HF hospitalization, 6 MWT.

In summary: A pressure difference exists between LA and RA in health and disease. This can be harnessed to create flow between LA and RA and decompress LA. A decompression device can be inserted percutaneously and lead to remarkable improvement in outcome. The concept, the device, animal data and initial human implantation data will be presented.

Biography

Gad Keren is the Head of the Department of Cardiology at Tel Aviv Medical Center and is a Professor of Cardiology at the Sackler School of Medicine.

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