Aortic Pacemaker (Hadasit)

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David Planer, Hadassah Ein Kerem, Cardiology
Amos Cahan, Hadassah Ein Kerem

Need:

Heart failure is a major cause of death and disability in both developed and developing countries. Major clinical conditions associated with heart failure include: 1) End-stage chronic heart failure (including ischemic and non-ischemic cardiomyopathy), 2) Acute decompensated heart failure, and 3) Acute myocardial infarction, including cardiogenic shock. Currently practiced management of these conditions includes medications, coronary revascularization, assist devices (both temporary and chronic), CRT and heart transplantation. The aorta is a viable organ that behaves under normal physiologic conditions as an energy capacitor in order to maintain perfusion pressure to the tissues during cardiac diastole. The aortic arterial wall consists of elastic fibers and smooth muscle circular and longitudinal layers that have the potential to contract in response to electrical stimulation. Despite various therapeutic options, patients with end-stage heart failure have a poor quality of life and a very high mortality rate due to inherent limitations of current therapies and limited organ supply for heart transplant candidates. Modalities such as left ventricular assist device (LVAD) are extremely costly, involve a major operation and are associated with reduced quality of life and severe complications. Cardiac resynchronization therapy (CRT) does not have a substantial clinical benefit in the majority of patients and is not indicated in patients with heart failure who have a normal duration QRS complex. Device-based therapy for heart failure as a bridge to transplantation or as destination therapy are limited either because of the high rate of complications (e.g. infection, thrombosis), dependency on external source of energy (ventricular assist device) and limited efficacy due to exhausted heart (CRT, inotropes). Progressive pump failure and ventricular tachyarrhythmias are common causes of death in these patients despite optimal therapy.

Innovation:

The proposed unique aortic pacemaker will be used as an adjunctive therapy to improve end-organ perfusion in patients with acute and chronic heart failure. It will be used in outpatients as well as hospitalized patients. The aortic pacemaker causes augmentation of the physiologic elastic recoil of the aorta by electric stimulation of the arterial wall smooth muscle layer. The invention is based on the concept that by synchronous directional contraction of smooth muscle cells, a peristaltic wave will ensue that will decrease cardiac after-load, improve diastolic coronary flow and result in improved hemodynamic and organ perfusion pressure. A chain of electrodes connected to the aorta will be used to create a coordinated activation impulse, generating organized and directional aortic contraction. This technology may also be used to treat other clinical conditions such as aortic valve insufficiency and aortic aneurysm.

Indications/Applications:

The aortic pacemaker will have several applications such as in acute myocardial infarction, intractable angina pectoris, cardiogenic shock, congestive heart failure and aortic regurgitation.

Competitive Advantages:

- Uses low energy to activate smooth muscle contraction – no dependency on external source of energy
- Utilizes a healthy organ
- Totally implantable - no external lines and cables

Contact for more information:
Ariel Rabin ✉, VP Business Development, Medical Devices, +972-2-6777906

Hadasit Medical Research Services & Development Ltd
Mother & Child Pavilion, Hadassah Ein Kerem, Jerusalem , 91120 Israel
Phone: +972-2-6778757, Fax: +972-2-6437712, E-mail: skimhi@hadassah.org.il