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A novel non-invasive method to assess aortic valve opening in HeartMate II left ventricular assist device patients using a modified Karhunen-Loève transformation

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BACKGROUND: Thrombus formation on or near the aortic valve has been reported in HeartMate II (Thoratec, Pleasanton, CA) left ventricular assist device (LVAD) patients whose aortic valves do not open. With an akinetic valve, thrombogenesis is more likely. Thrombus formation may lead to neurologic events, placing the patient at greater risk. Aortic valve stenosis and/or regurgitation have also been observed with akinetic aortic valves. Assessing aortic valve opening is crucial when optimizing rotations per minute (rpm) to minimize embolic risk and aortic valve stenosis but presently relies solely on echocardiography, intermittent decreases in rpms to force aortic valve opening, and monitoring of pulse pressure. We hypothesized the electrical current waveforms of the HeartMate II would reveal whether the aortic valve was opening due to pressure changes in the left ventricle to allow for continuous monitoring and control of aortic valve opening ratios.
METHODS: Electrical HeartMate II current waveforms of patients from 2008 to 2009 that were recorded at the time of echocardiograph procedures were analyzed using a modified Karhunen-Loève transformation with a training set of electrical waveforms from 8,860 HeartMate II electrical current recordings from 2001 to 2009.
RESULTS: The study included 6 patients. The electrical current magnitude of the projection of the electrical current waveforms onto the training set's eigenvectors was statistically significantly greater in 4 of the 6 patients when the aortic valve was closed, confirmed by echocardiography. The 2 patients who did not have a large increase in the magnitude had mild aortic valve regurgitation.
CONCLUSION: Electrical current analysis for rotary non-pulsatile pumps is a means to develop a physiologic feedback algorithm for an auto-mode, which currently does not exist. Constant regulation and optimization of rotary non-pulsatile LVADs would minimize patients' risk for neurologic events and aortic valve stenosis.
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Heart failure is one of the world's leading causes of death, affecting more than 4.5 million people in the United States. The prevalence of heart failure is expected to increase 10% to 15% by the year 2020.[1] In severe cases, heart failure conditions cannot be medically managed, and the patient's only option is to receive a heart transplant; however, there is a tremendous shortage of transplantable hearts worldwide. Patients now have an additional option of receiving a left ventricular assist device (LVAD), which is used for bridging patients to heart transplantation or as destination therapy (implanting the LVAD indefinitely).

The LVAD decreases the workload of the LV by producing both pressure and volume unloading of the heart.

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First-generation LVADs were made to pump blood in a pulsatile manner because the manufacturing companies believed that pulsatility was optimal for the circulatory system. These pulsatile LVADs have bearings and moving parts that limit the durability and life of the pump. To overcome durability issues, LVADs with fewer moving parts were designed. These second- and third-generation LVADs, which are continuous-flow rotary LVADs that contain no bearings, now have an estimated life of 6 to 8 years. Patient outcomes are not adversely affected by the lack of pulsatility.[2]

However, when the non-pulsatile LVADs operate at rotations per minute (rpms) that are too high, most or all of the blood that enters the LV exits through the inflow conduit of the LVAD and essentially no blood volume flows through the aortic valve (AV), its native route. When blood pressure or volume in the native heart is decreased, the LV cannot generate enough pressure to open the AV. This may lead to adverse neurologic events,[3] including transient ischemic attacks and cerebrovascular accidents due to thrombus formation because of an akinetic AV.[4–8] In addition, fusion may occur when the AV is not opening, resulting in stenosis and/or regurgitation, which further promotes disturbances in blood flow.[9]

When LVAD rpms increase and decrease, the apparent native heart contractility decreases and increases, respectively. There is a balance between the degree of LVAD mechanical circulatory support and the LVAD's rpms. The rpms need to be low enough that the AV is opening, but high enough that the patient receives adequate systemic circulation and unloading of the native heart. A current method of assessing this balance is to perform echocardiograms at regular intervals every few months after LVAD implantation.

Frazier et al[10] has shown that when the pulse pressure is $<$ 15 mm Hg, there is a 24% probability the AV is opening with the Jarvik 2000 continuous-flow pump (Jarvik Heart Inc, New York, NY), whereas that probability jumps to 65% when the pulse pressure is $>$ 15 mm Hg.[10] This method is advantageous in determining what rpms are necessary to minimize the risk of complications. However, this method of measuring blood pressure and interfacing the LVAD circuitry for automation would prove difficult in terms of size constraints and extraneous wires. In addition, a Jarvik controller is capable of increasing the probability of AV opening by intermittently dropping the rpms. This is feasible but continuous control of the AV opening ratios would be superior.

This proof of concept article for continuous regulation of rpms describes a novel approach to determine whether the AV is opening to control the AV opening ratios by analyzing the LVAD's electrical current.

Methods

The Karhunen-Loève transform, also known as principal component analysis (PCA), was performed on 6 HeartMate II (Thoratec, Pleasanton, CA) patients using their electrical current waveforms. To train the PCA algorithm to teach the system what consistency is in electrical waveforms, 8,860 electrical waveforms recorded for HeartMate II patients from 2001 to 2009 at our large single-center institution were used. With 8,860 electrical training data samples from our patients, the calculation accuracy in detecting change is greatly improved.

Recording electrical current waveforms

Electrical current waveforms for the HeartMate II LVAD were recorded using Thoratec's external display modules. All electrical current waveform files were saved in *.tci format. To extract the *.tci files' data, we used MinGW (Minimalist GNU for Window), a Minimal SYStem (MSYS) console, and C++ code. The MSYS console pointed the desired *.tci file into the C++ code to output a *.dat file which was then loaded into MatLab (The MathWorks Inc, Natick, MA) and analyzed.

The analysis was begun by calibrating the unscaled *.dat file values, which are proportional to current, into values with units of amps by a multiplication factor of 0.00146. This amp calibration factor was determined by comparison of the known pre-determined Thoratec amp values calculated from Thoratec's Current Waveform Viewer application. The application's output is unfiltered current data in amps. This current data must be intercepted at an earlier stage in order to collect actual values for each data point, thus the need to calibrate before our analysis. An expanded schematic of the electrical current collection phase is shown in Figure 1.

Fast Fouriér transform analysis

The 10-second current waveform shown in Figure 2 is the electrical current in amps after the comparison-calibration. The current was filtered using a low-pass filtering fast Fouriér transform until a single waveform capitulated the overall morphology.

Subsequently, the derivative of the filtered current waveform was analyzed to determine when the ventricular contraction (systolic interval) began. A ventricular contraction was detected when a slope of 1.5e-4 amps/msec was sustained in any given 225-msec current interval for 125 msec. These values were determined by maximizing the number of detected systolic intervals that were complete while rejecting the partial systolic intervals recorded at the beginning and the end of the recording interval. When the first systolic data point was skewed due to its position in the recording cycle, it was discarded to avoid calculation errors. Once the beginning of the full recorded systolic intervals was found, the subsequent 600 msec of current data were extracted.

Data organization

These systolic intervals, from the initialization of the heart contraction to 600 msec after initialization, were stored into