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## Is an Automatic Control Algorithm Necessary for Centrifugal Pumps?

Gerry O'Driscoll

*University of Notre Dame Australia*, [godriscoll@nd.edu.au](mailto:godriscoll@nd.edu.au)

Dan Tamez

Neil Voskoboynikov

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multiple sites also reveal HF information and may expand HF monitoring to pacemaker patients.

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**LVAD, Transplantation or Optimal Medical Therapy for Advanced Heart Failure? A Decision Analysis**

Ronald S. Freudenberger<sup>1</sup>, Isaac Tawfik<sup>2</sup>, Johnny Kim<sup>3</sup>, Frank A. Sonnenberg<sup>2</sup>; <sup>1</sup>Center for Advanced Heart Failure, Lehigh Valley Hospital and Health Network, Allentown, PA; <sup>2</sup>Medicine, Robert Wood Johnson Medical School, New Brunswick, NJ; <sup>3</sup>Medicine, Yale University School of Medicine, New Haven, CT

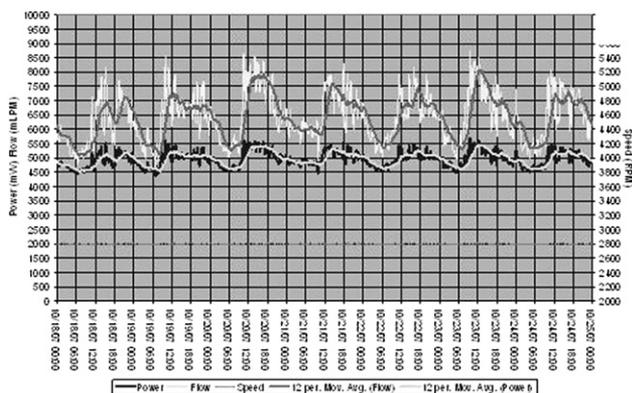
**Background:** The survival benefit of heart transplantation (HT) compared to current optimal medical therapy (OMT) or Ventricular Assist Device (VAD) implantation in heart failure has never been assessed directly. **Methods:** We created a decision analytic model that simulates a randomized clinical trial of OMT versus HT versus VAD for New York Heart Association (NYHA) class I-IV heart failure (HF). The model simulates average life expectancy. The following assumptions were made for OMT annual mortality: class I confers no excess mortality; class II and III mortalities are based on Sudden Cardiac Death in Heart Failure Study (SCD-HeFT) and assumed to be 4.4% and 13.2% per patient year of follow-up respectively. Class IV annualized mortality for OMT is based on Scientific Registry of Transplant Recipients (SRTR) data for Status 1A and 1B patients (class 4A and 4B) listed for transplantation and assumed to be 53.6% for status 1A and 32.6% for Status 1B. HT mortality rates were based on survival curves for HT 1982–2001 from the International Society of Heart and Lung Transplantation. VAD mortality was 41% per year based on information from later enrolled Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure REMATCH trial patients. **Results:** Destination therapy for LVAD had an expected survival of 17 months regardless of preceding heart failure class and was not favored over OMT or HT for any class. For Classes I and II, OMT was the favored strategy with gains over HT of 108 months and 29 months respectively and with gains over LVAD of 211 months and 128 months respectively. For Classes III, IV-A and IV-B, HT was favored with gains over OMT of 31, 61 and 54 months, respectively and gains over LVAD of 58, 8 and 25 months, respectively. For Class IV-A, mortality following LVAD placement would have to decrease by 33% (to 0.028 monthly) for LVAD to equal OMT. For Class IV-B, mortality following LVAD placement would have to decrease by 67% to 0.014 monthly for LVAD to equal OMT. **Conclusions:** Our model predicts that currently, OMT is superior to HT or VAD for classes I & II, but HT is superior to both OMT and VAD for class III and IV. However, future advances in OMT, VAD or HT may change the relative benefits of these treatment modalities.

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**Is an Automatic Control Algorithm Necessary for Centrifugal Pumps?**

O'Driscoll Gerry<sup>1</sup>, Dan Tamez<sup>2</sup>, Neil Voskoboinikov<sup>2</sup>; <sup>1</sup>Advanced Heart Failure & Cardiac Transplant Service, Royal Perth Hospital, Perth, WA, Australia; <sup>2</sup>Heartware Inc., Miramar, FL

**Background:** In order to meet physiologic changes in LVAD patients, VAD manufacturers have been developing automatic control algorithms for rotary blood pumps. However, whether an automatic control algorithm is required for normal physiological functioning is unknown. Physiological patterns may be monitored by analyzing daily VAD parameter data (Speed, Power, and Estimated Flow) as acquired by the HeartWare<sup>®</sup> LVAS Controller. **Experiment:** Log files from patients supported on the HeartWare<sup>®</sup> LVAS which contained VAD parameter data (logged at 15 minute intervals) were analyzed for daily performance under various physiological conditions while a constant VAD Speed was maintained. A 12-point moving average of Estimated Flow was calculated to eliminate erratic deviation in flow and provide a visual reference of circadian rhythm. Resulting data was analyzed and presented in a weekly viewable time frame.



**Results/Discussion:** Each patient's VAD parameters exhibited a distinct daily periodical pattern corresponding to a circadian cycle. VAD flow fluctuated by an average of  $\pm 2$  L/min corresponding with a decrease in flow demand typically observed in the evening hours followed by an increase in flow during a patient's waking hours. **Conclusion:** HeartWare<sup>®</sup> LVAS parameters may be used to extract individual circadian rhythms of each patient by analyzing the daily estimated flow. This data contains distinct periodical patterns related to each patient as reflected in daily fluctuations in flow, corresponding to daily physiological processes and activity levels within a circadian cycle. Although preliminary, this initial data set may signify that the HeartWare<sup>®</sup> LVAS sensitivity to activity and hemodynamic changes may negate the need to develop an automatic algorithm.

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**Safety and Efficacy of Late Conversion to Sirolimus Based Immunosuppression, in Heart Transplant Recipients**

B. Kamoga Gilbert-Roy<sup>1</sup>, Sherry LaForest<sup>1</sup>, Parag Kale<sup>1</sup>, James Fang<sup>1</sup>; <sup>1</sup>Internal Medicine - Cardiology, Case Western Reserve University, Cleveland, OH

**Introduction:** Sirolimus (SBI) based immunosuppression has been used to slow the progression of renal insufficiency and allograft coronary artery disease in heart transplantation (HT). We hypothesized that SBI improves renal function independent of when it is started post HT. **Methods:** We studied all HT recipients who had undergone conversion from CNI to SBI therapy, and evaluated their outcomes based on time to conversion post HT. They were divided into Early (less than 12 months) and Late (more than 12 months) converters. We assessed significant rejection (3A or 2R), initiation of dialysis and discontinuation of sirolimus. We also evaluated renal function (expressed as serum creatinine) from pre-conversion to 6 months post-conversion in both groups. **Results:** 16 patients in this series were converted to SBI. Mean age at HT was 49 years (range 22–63). Indications for conversion included arteriopathy 31% (5), renal dysfunction 44% (7), and MMF intolerance 25% (4). Median starting Sirolimus dose was 2 mg/day and target blood levels were 6–12ng/ml. Mean baseline serum creatinine for all patients was  $1.94 \pm 0.52$  mg/dl and for those patients converted for renal dysfunction,  $2.73 \pm 0.48$  mg/dl.

Outcomes for Early Vs Late Converters

Outcome	Early (n = 5)	Late (n = 11)
Mortality (%)	2 (40)	1 (9)
Significant Rejection (%)	2 (40)	3 (27)
Dialysis Post-conversion (%)	2 (40)	2 (18)
Discontinuation of Sirolimus for adverse effects (%)	0 (0)	3 (27)

At 6 months post-conversion the renal function among the patients converted early showed a negative trend while those converted late had a positive trend regardless of indication for conversion. Mean serum creatinine increased from 1.34 mg/dl to 1.90 mg/dl ( $p > 0.05$ ) in the early group and decreased from mean of 2.11 mg/dl to 1.47 mg/dl ( $p > 0.05$ ) in the late group. In addition, there was improvement in renal function among those patients converted for renal dysfunction in both groups; mean serum creatinine decreased from  $2.73 \pm 0.48$  mg/dl at baseline to  $1.8 \pm 0.23$  mg/dl at 6 months. **Conclusion:** A strategy for conversion to SBI more than 12 months after HT leads to improved outcomes regardless of indication for change in therapy. Although eligible patients were few, this result is hypothesis generating and could be explored further in larger trials.

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**Implantation of Biventricular Circulatory Support with the Levitronix CentriMag in Patients with Acute ST-Elevation Myocardial Infarction (STEMI) and Refractory Cardiogenic Shock**

Jeffrey A. Morgan<sup>1</sup>, Tariq M. Naseem<sup>1</sup>, Faisal H. Cheema<sup>1</sup>, Andrea Mignatti<sup>2</sup>, Tessa Scripps<sup>1</sup>, Gabriel Sayer<sup>2</sup>, Minoru Tabata<sup>1</sup>, Michael Argenziano<sup>1</sup>, Katherine Leitz<sup>2</sup>, Yoshifumi Naka<sup>1</sup>, Ulrich P. Jorde<sup>2</sup>; <sup>1</sup>Division of Cardiothoracic Surgery, Columbia Presbyterian Medical Center, New York, NY; <sup>2</sup>Division of Cardiology, Columbia Presbyterian Medical Center, New York, NY

**Purpose:** Mortality of subjects with STEMI and cardiogenic shock refractory to maximal therapy including inotropes, pressors, IABP, and early revascularization (ERV) approaches 100%. We have expanded the usual treatment paradigm for such patients with implantation of a biventricular circulatory support system that completely unloads both ventricles. Here we report our early experience with this approach. **Methods:** From February 2007 through December 2007, 9 patients underwent implantation of a CentriMag (Levitronix LLC, Waltham, Mass) biventricular