

in CRT. We sought to determine if the HN would attenuate HF progression in patients with stable symptomatic chronic systolic HF implanted with CRT. **Methods:** Prospective Evaluation of Elastic Restraint to LESSen the effects of Heart Failure (PEERLESS-HF) is a randomized trial comparing the HN plus optimal medical and device therapy versus optimal medical and device therapy alone. Here we report on the long-term outcomes of a subset of 104 patients with CRT (min. duration 3m, mean 1.5 y; LVEF= $23 \pm 5.5\%$) out of the total cohort of 210 Stage C HF patients. An independent CEC comprised of HF cardiologists and cardiac surgeons adjudicated causes of deaths and of hospitalizations. **Results:** The demographics are (T/C): Age:56/56, NYHA III: 36/50%, NI:70/67%, HF duration 8.9/6.9y. None of the observed differences were statistically significant. The Hazard Ratio and significance levels for important outcomes are presented in the table below.

Hazard Ratios for HF outcomes

Endpoint	HR T/C	p value
CV Death, MCP, HFH	0.45	0.06
MCP	0.25	0.039

Conclusions: In CRT recipients, HN reduced a composite endpoint of CV mortality, MCS/OHT and HFH rates, suggesting a synergistic effect of CRT and HN. 2) These favorable effects may be due to HN device's ability to reduce global myocardial stress.

133

The Impact of Technology Dependency on Device Acceptance and Quality of Life in Persons with Implantable Cardioverter Defibrillators

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Method: A sample of all 161 ICD recipients from one hospital device clinic were mailed self-administered questionnaires including the Dependency on Technology Scale (DOTS), Brief Illness Perceptions Questionnaire (BIPQ), Florida Shock Anxiety Scale (FSAS), Florida Patient Acceptance Survey (FPAS), and SF-12 as a measure of quality of life (QOL). Hierarchical multiple regressions and ANOVAs were performed. **Results:** A response rate of 63% resulted in a sample of $n=101$. Mean age was 68 ± 13 , 74% male, 99% Caucasian, and 70% had a primary prevention ICD indication. Most had a diagnosis of heart failure (55%). Thirty percent reported receiving at least one shock with an average number of shocks of 0.9 ± 2.9 . Eighty percent reported positive attitudes towards technology dependency, 14% neutral and 6% negative (DOTS). Mean BIPQ scores showed slightly positive illness perceptions (34.5 ± 12.6). Mean FSAS scores showed mildly elevated shock anxiety (16.5 ± 6.6), yet device acceptance (FPAS) was good ($m=75 \pm 17$). The mean SF-12 indicated lower QOL scores in the physical component (PCS) (38.9 ± 11.1), and moderate QOL scores in the mental component (MCS) (50.9 ± 10.2). Attitudes towards technology dependency contributed significantly to the variance in device acceptance beyond age, gender, number of shocks, illness perceptions and shock anxiety by 5.9% ($p=.001$). The full model accounted for 57.1% ($p<.001$) of the variance. Attitudes towards technology dependency did not significantly account for the variance in PCS, however, it contributed significantly to the variance in MCS beyond age, gender, number of shocks, illness perceptions and shock anxiety by 4% ($p=.04$). The full model accounted for 21.3% ($p<.001$) of the variance. Significant differences were seen in device acceptance between those with negative and neutral attitudes ($p=.001$) and those with negative and positive attitudes towards technology dependency ($p<.001$) and in shock anxiety and MCS between those with negative and positive attitudes ($p<.001$). **Conclusions:** Attitudes towards technology dependency is a significant predictor of psychological outcomes in ICD recipients. Degree of positivity towards technology dependency influences device acceptance, shock anxiety, and mental health QOL. These attitudes may account for the psychological distress experienced by some ICD recipients. Further research evaluating attitudes towards technology dependency and testing of tailored psychosocial and educational interventions focusing on these attitudes is warranted.

134

Persistent Anemia in Patients Supported With the Total Artificial Heart: Hemolysis and Ineffective Erythropoiesis

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Objectives: The CardioWest Total Artificial Heart (TAH) replaces the entire heart with two pneumatic pumps and four tilting disk mechanical valves and is an effective way to bridge dying patients to heart transplantation (HT). We hypothesized that patients with a TAH have anemia from pump-related hemolysis which improves after HT. **Methods:** We evaluated patients who received a TAH as a bridge to HT. Data were abstracted from the medical records. **Results:** Thirty-six patients (age 47 ± 13 years) were supported with a TAH for median of 83 days (IQR: 43,115). When compared to baseline, hematocrit (HCT) was decreased after TAH implantation at 2 weeks (34 ± 6 g/dL vs 20 ± 2 g/dL, $p<0.001$), 4 weeks (22 ± 3 g/dL, $p<0.001$), 6 weeks (22 ± 4 g/dL, $p<0.001$), and 8 weeks (23 ± 4 g/dL, $p<0.001$).

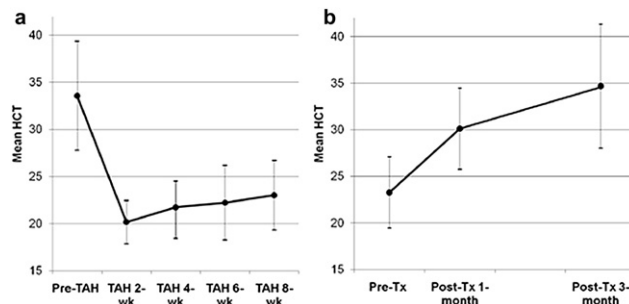


Fig. 1. (A) HCT (g/dL) plot after TAH. (B) HCT (g/dL) Plot after HT.

However, HCT increased significantly at 4 weeks after the device was removed for HT (23 ± 4 g/dL vs 30 ± 4 g/dL, $p<0.001$). Laboratory data obtained while on TAH support suggested ongoing hemolysis including an undetectable haptoglobin in 96% of assessments, increased lactate dehydrogenase (1128 ± 384 units/L) in all samples, and elevated plasma free hemoglobin that was detectable in 40% of measurements (mean of 21 ± 15 mg/dL in those with detectable levels). The mean reticulocyte production index value was decreased (1.6 ± 0.6) indicating ineffective erythropoiesis. Inflammatory markers were elevated: high sensitivity c-reactive protein (52 ± 50 mg/dL) was elevated in all cases and ferritin (745 ± 703 ng/mL) was increased in 62% of evaluations. **Conclusion:** Patients implanted with the total artificial heart have persistent anemia that corrects after heart transplantation. Laboratory data suggests that in addition to hemolysis from the four mechanical heart valves, there is ineffective erythropoiesis and an increased inflammatory state.

135

Predictors of Worsening Renal Function in Patients With Decompensated Heart Failure Treated With Ultrafiltration

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Background: Ultrafiltration (UF) is used to treat patients with diuretic-resistant, decompensated heart failure; however worsening renal function (WRF) is a common complication. The aim of this study was to identify the clinical, laboratory, and echocardiographic predictors of WRF during UF. **Methods:** From 1/2008 to 4/2011, 81 patients (age 65 ± 13 years, 58% men) underwent UF at the University of Nebraska Medical Center. All patients were on optimal heart failure medical therapy. Average intravenous dose of furosemide before UF was 199 ± 194 mg/day. WRF was defined as a rise in serum creatinine level > 0.3 mg/dL. Patients were divided into WRF and control groups based on changes in serum creatinine during UF. **Results:** In the whole study population, BUN increased from 48.9 ± 20.8 mg/dL to 59.9 ± 28.0 mg/dL ($p < 0.001$), creatinine increased from 1.9 ± 0.7 mg/dL to 2.3 ± 1.1 mg/dL, ($p < 0.001$), and WRF developed in 35 (44%) of patients. Uric acid (UA) level decreased from 9.7 ± 2.8 mg/dL to 9.1 ± 2.1 mg/dL ($p=0.02$). Female gender (18 (51%) vs. 15 (14%) $p=0.045$) and treatment with an aldosterone antagonist (AA) (13 (37%) vs. 6 (13%) $p=0.015$) was associated with increased risk of WRF by univariate analysis. There was no difference between groups in other baseline demographic, laboratory, or hemodynamic characteristics. Echocardiography at admission showed smaller left ventricular end diastolic volume (LVEDV) 127 ± 51 mL vs. 165 ± 57 mL, $p=0.04$), larger right ventricular diameter (RVD) 43.3 ± 6.4 mm vs. 38.4 ± 7.5 mm, $p=0.02$), and lower E' (5.6 ± 1.6 m/s vs. 7.2 ± 2.4 m/s, $p=0.01$) by univariate analysis in the WRF group. The peak UF rate (170 ± 65 mL/h vs. 139 ± 47 mL/h, $p=0.04$) was higher in the WRF group; however duration of UF, liters of fluid removed, and change in patients weight were not statistically different. After multivariate analysis, peak UF rate ≥ 150 mL/h (OR 2.36, CI 1.06 - 4.82, $p=0.04$), treatment with AA (OR 3.5, CI 1.01-2.16, $p=0.02$), RVD (OR 1.1, CI 1.01-1.86, $p=0.04$), LVEDV (OR 0.88, CI 0.75-0.98, $p=0.012$) were independently associated with higher risk of WRF during UF. **Conclusion:** WRF occurred frequently in patients treated with UF. UF rate > 150 mL/h and treatment with an AA during UF were associated with increased risk of WRF. Cardiac remodeling indices on echocardiography at hospital admission can identify patients at increased risk for developing WRF. Overall, UA levels decreased during ultrafiltration treatment.

136

Powering a Ventricular Assist Device over Meter Distances Wirelessly: The Free-Range Resonant Electrical Energy Delivery (FREE-D) System

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Background: Technological innovation of smaller, frictionless, single moving part has an advantage over earlier large pulsatile Ventricular Assist Devices (VAD) prone

to mechanical failure. Drivelines limits the potential of newer pumps and act as source for infection, increased morbidity, and re-hospitalizations. Older TETS based technologies are hampered by power delivery over few millimeters, mis-alignment and poor efficiency. The Free-range Resonant Electrical Energy Delivery (FREE-D) wireless power system uses magnetically coupled resonators to efficiently transfer power. We previously demonstrated the efficiency of such system. In the current investigation we have vastly improved the distances to a room sized transmission of electrical energy wirelessly. **Methods:** The axial pump was set at 9600rpm. The experimental set-up (Fig 1) consisted of a single turn drive loop and multi-turn spiral coil as a transmitter (Tx) and receiver coil (Rx) attached to the hardware and software for a close wavelength tuning. To achieve a seamless wireless delivery in any room size, we introduced a third relay coil. This relay coil can be installed throughout a room (walls, beds, couches, chairs, etc.), while a single relay coil could be built into a jacket worn by the patient, which would always be within range of the Rx coil implanted in the patients body. **Results:** The power was delivered over a one meter distance without interruptions or fluctuations (Fig 1) with coil, rectifier and regulator efficiency over 80% and overall system efficiency of 54%. The axial pump worked well throughout the 8 hours of continuous operation. The distance can be doubled by having same set-up on the opposite side.

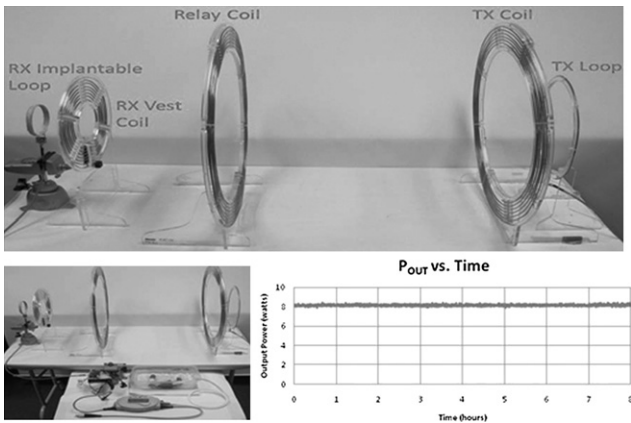


Fig. 1. Above: set-up of coils over a meter distance, bottom left: axial pump in operation, bottom right: power output vs time over eight hours.

Conclusion: A tether free operation of a VAD can be easily achieved by FREE-D system in room size distances. Besides improving quality of life it has the potential to make the VAD therapy more acceptable from the patient perspective.

137

Predicting Acute Cardiac Allograft Rejection Using Donor and Recipient Gene Expression
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Background: The occurrence of acute allograft rejection in cardiac transplant patients is still a contributing factor to the limited survival of the implanted heart. Currently, there are no biomarkers in clinical use that can predict, at time of transplantation, the likelihood of post-transplantation acute rejection. Therefore, the Biomarkers in Transplantation (BiT) initiative set out to discover biomarkers that could predict, before transplantation, the risk of rejection in order to allow for a more personalized clinical management of transplant patients. **Methods:** As a first step, seven clinical variables measured pre-transplantation were investigated for their power to predict post-transplantation rejection in a larger cohort of patients. A subset of these subjects had recipient whole blood collected pre-transplantation and donor heart tissue collected during transplantation. These samples were analyzed using Affymetrix Human Genome U133 plus 2.0 chips. In the next step, the biomarker discovery was focused on genes from whole blood and biopsy in this subset of patients. Furthermore, statistical analysis was performed to discover classifiers that combine genes from whole blood and biopsy as well as clinical variables measured pre-transplantation. **Results:** Biomarker panels containing clinical variables or genes from either blood or biopsy or genes from blood and biopsy were identified. The Area Under the Receiver Operating Characteristic Curve (AUC) of the genomic and/or clinical biomarkers ranged between 0.30 and 0.90. **Conclusions:** The BiT team discovered novel biomarker panels for predicting, at time of transplantation, which patients will develop acute rejection post-transplantation. Based on this study, a biomarker combining 25 genes from the donor biopsy and 18 genes from the recipient blood provides the best, clinically relevant, prediction power (AUC=0.90). This biomarker,

if validated in a separate patient cohort, may help in personalizing immunosuppressive treatment and frequency of acute rejection monitoring.

138

Treatment of Functional Mitral Regurgitation by Percutaneous Annuloplasty Results in Durable Clinical Efficacy through 18 Months

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Introduction: Functional mitral regurgitation (FMR) contributes to both morbidity and mortality of patients with systolic heart failure. Percutaneous mitral annuloplasty is feasible in these patients. Whether the therapy results in durable efficacy is unknown. **Hypothesis:** The reduction of FMR and associated left ventricular reverse remodeling associated with percutaneous mitral annuloplasty will result in a durable clinical benefit as measured by exercise capacity. **Methods:** Patients with NYHA II-IV heart failure and stable medical therapy, six minute walk distance (6MWD) 150-450 meters, moderate to severe FMR, and LVEF <40% underwent percutaneous mitral annuloplasty. Echo assessments of efficacy (degree of FMR and LV dimensions) were assessed thru 12 months. Clinical measures of efficacy including NYHA and 6MWD were collected through 18 months. **Results:** At baseline, 94% of patients were NYHA III, EF was 28.4%, and LVEDD was 70mm. Permanent device placement was achieved in 36/53 patients. The major adverse event rate at 30-days for all 53 attempted patients was 1.9%. There were no device related adverse events through 18 months. Between baseline and 12 months for the implanted cohort, the regurgitant volume was reduced from 34.1 ± 9.9 to 17.4 ± 12.4 (N=25, p<0.001) and the left ventricular end systolic volume decreased from 149.1 ± 61 to 120.7 ± 43 (N=24, p=0.02). The changes in 6MWD through 18 months are detailed in the table below.

Change in 6MWD and NYHA in 6 month intervals thru 18 months

	Baseline	6 months	12 months	18 months
6 MWD (m)	302.5 ± 74	429.9 ± 209	406.0 ± 180	387.7 ± 112
	(N=36)	(N=27, P=0.007)	(N=23, P=0.007)	(N=17, P=0.010)
NYHA Class	3.06 ± 0.23	2.10 ± 0.62	2.08 ± 0.64	2.32 ± 0.67
	(N=36)	(N=29, P<0.001)	(N=25, P<0.001)	(N=19, P<0.001)

Conclusion: Percutaneous treatment of FMR is associated with significant reduction in FMR and LV dimensions at 12 months. These hemodynamic results are associated with durable clinical efficacy through 18 months.

139

Effect of QRS Morphology on Clinical Event Reduction With Cardiac Resynchronization Therapy: Meta-Analysis of Randomized Controlled Trials
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Background: Cardiac resynchronization therapy (CRT) is effective in reducing clinical events in systolic heart failure patients with a wide QRS. Previous retrospective studies suggest that only patients with QRS prolongation due to a left-bundle branch

