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Weekly Periodicity in Device-Based Diagnostics in Heart Failure Patients

Harriette F, Verwey¹, Sander G, Molhoek¹, Kelly Schatz², Saskia van der Leden-Blaauw¹, Karin Froidcourt³, Bernd Schubert³, Martin J. Schalij¹; ¹Cardiology, Leiden University Medical Center, Leiden, Netherlands; ²Guidant Corporation, St Paul, MN; ³Guidant Clinical Research EMEAC, Diegem, Belgium

To provide insight into the onset of heart failure decompensation, Leiden University Medical Center is monitoring patients with RENEWAL® family CRT-D devices for 12 months. Prior to using the data to assess the health status of the patient in a patient management system, it is necessary to understand the periodicities that exist in device-based diagnostics in order to ensure the most accurate interpretation of the data. Methods: Twenty patients receiving CRT-D devices (mean 11.3 months, range 3.3 to 27.5) were enrolled and monitored for up to 52 weeks (mean 49). The device Activity Log recorded patient activity each day as the % of the day above a fixed threshold. For each patient, daily %Activity values during the study were averaged by weekday. A peak-to-peak weekday difference was calculated as a percentage of the weekly mean. For each patient, the minimum and maximum weekday values were compared using paired t-tests. Autocorrelations were performed on the de-trended daily %Activity values for each patient to detect periodicities in patient activity. **Results:** Peak-to-peak weekday differences were significant (P < 0.05) in 19 of the 20 patients, and the average difference was 25.2% ± 10.1 with a range of 13.3% to 49.6%. The average (across patients) autocorrelation of the %Activity showed a peak at a seven day shift, indicating a weekly periodicity. The autocorrelation peak at a 7-day shift in conjunction with the average peak-to-peak weekday difference of 25% indicates the presence of a weekly infradian rhythm for %Activity. Conclusions: The overwhelming majority of patients exhibited a weekly rhythm in %Activity. Such periodicities in the daily %Activity diagnostic in these CRT-D patients may be due to work schedules, environmental and physiological factors. In a patient management system, it is essential to acknowledge this periodicity in order to distinguish between changes detected in %Activity caused by a decline in patient health status and those due to a natural weekly periodicity. Detecting the presence of periodicities in patient diagnostics will allow more accurate interpretation of the health status of the patient, and more insight into changes in this diagnostic over time.

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Nesiritide Is Effective for Patients with Diastolic Dysfunction with and without Associated Right Ventricular Failure and Significantly Improves Renal Function Ramzan M. Zakir¹, Rajiv J. Patel², Muhamed Saric², Robert L. Berkowitz¹, ¹Medicine, Hackensack University Medical Center/UMDNJ-New Jersey Medical School, Hackensack, NJ; 2Medicine, UMDNJ-New Jersey Medical School, Newark, NJ

Background: The prevalence of heart failure (HF) with preserved systolic function or diastolic dysfunction is increasing and is present in nearly 50% of patients diagnosed with acute decompensated heart failure (ADHF). The incidence of secondary right ventricular failure, clinical presentation, and treatment strategies are poorly defined. **Methods:** We evaluated the medical records of 10 consecutive patients (mean age 69.4 ± 12.1 ; 60 % males) admitted to Hackensack University Medical Center with a diagnosis of ADHF with a LVEF \geq 50%, 2 or more admissions for ADHF in the last six months, and who were resistant to intravenous diuretics requiring the use of nesiritide. The presenting symptoms, echocardiographic parameters, BNP levels, serum creatinine, LFTs were analyzed and outcomes were reviewed. A paired, one tailed T test was used to compare serum creatinine levels at presentation and discharge. **Results:** The mean LVEF was 54%, LA size 4.7 cm, LV thickness 1.3 cm and PA systolic pressure 52.3 mmHg. Right ventricular dilation and hypokinesis was present in 6 of the 10 patients in this cohort. These 6 patients with biventricular failure (LV diastolic/RV systolic) presented with gastrointestinal symptoms (abdominal pain, nausea, vomiting) in addition to dyspnea and had severe volume overload with hepatic congestion. Total bilirubin (mean 2.1 mg/dl) was also elevated. BNP was significantly elevated in all 10 patients (mean BNP 1666 pg/mL). Serum creatinine was elevated in 9 of the 10 patients (mean creatinine 2.1 mg/dl.) and did not differ based on the presence of RV failure. When nesiritide was added to IV furosemide, a profound diuresis occurred with resolution of symptoms along with improvement in BNP (mean 566 pg/mL) and discharge creatinine (mean 1.8 mg/dl) (p = 0.045). In the 6 patients with RV failure, total bilirubin levels were also reduced at discharge $(mean\ 0.85\ mg/dl)$. There were no in-hospital deaths and no readmissions or mortalities at 6 months. **Conclusion:** In patients with diastolic heart failure who present with ADHF that is resistant to intravenous diuretics, right ventricular failure is a common associated finding. Nesiritide use is associated with profound diuresis, symptom resolution and a significant improvement in serum creatinine in these patients.

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Demographic Characteristics and Clinical Outcomes of Minority Female Patients Admitted with Acute Decompensated Heart Failure Giancarlo Speziani, Carlos Arrieta, Javier Jimenez, Shen Biing, Stephen Mallon;

Medicine/Cardiology, University of Miami Jackson Memorial Med. Ctr., Miami, FL

Background: Little is know of the characteristics of minority female pts admitted with decompensated heart failure (HF). Socioeconomic and racial factors may influence the outcomes in these pts. Purpose: To determine the clinical characteristics, in-hospital outcomes and 6 month follow-up of female pts admitted to the hospital with a diagnosis of heart failure. **Methods:** Female pts admitted to a tertiary inner city hospital with a primary diagnosis of HF were enrolled in the study. Baseline characteristics and clinical data were recorded. Pts were administered questionnaires including Borg Scale, Minnesotta Quality of Life and a Beck Depression Scale. At 6 months pts were contacted by telephone for follow-up. **Results:** From July 2004 to March 2005, 115 female pts were enrolled in the study 52(45%) were African American (AA), 43(37%) were Hispanics (H)and 20(17%) were Caucasians (C). There was no difference is underlying ischemic cardiomyopathy etiology, DM, dyslipidemia, CRI or Body Mass Index. AA females were more likely to be hypertensive 83% vs. H 70% and C 45%, p=0.006 and had a history of stroke/CVA 29% vs. H 2%, C 10%, p=0.001. C 43%, p = 0.000 and had a history of stroke/C \sqrt{A} 29% vs. H 2%, C 10%, p = 0.01. H females were more likely to have history of atrial fibrillation 30%, vs. AA 17% and C 25%, p = 0.05 and hypothyroidism 35% vs. AA 13% and C 20%, p = 0.04. AA females were more likely to be single mothers (p = 0.06). Most patients had a household income of < \$25,000. No difference in education, mode of tranportation and number of children was found among the different ethnic groups. The Borg (p = 0.03), Beck (p = 0.001) and Minnessota Scales (p = 0.003) were worse among AA females. There were 59 (51%) attempts for follow-up; of those 32 (54%) were contacted. Follow-up data is shown below. **Conclusion:** Inner city female minority patients admitted with HF show similar baseline social characteristics, however the perception of level of exertion, quality of life and depresion was more severe among AA females. Although at the time of the abstract the follow-up was limited, there were significant readmission rates, dietary and medical non compliance among all minority groups

Six-month follow-up

| Variable | African Americans (n = 14) | Hispanics (n = 14) | Caucasians (n = 4) | p value |
|--------------------------|----------------------------|-----------------------|-----------------------|---------|
| Any hospitalization | 63% | 66% | 0% | 0.92 |
| Any emergency room visit | 36% | 50% | 0% | 0.76 |
| Medical non-compliance | 27% | 25% | 0% | 0.14 |
| Dietary non-comliance | 63% | 95% | 0% | 0.22 |
| Cardiac Transplant | 7% | 0% | 75% | 0.002 |
| Death | 14% | 14% | 0% | 0.72 |
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Automated Detection of Hemodynamic Changes Associated with Heart Failure **Decompensation Events**

Philip B. Adamson¹, Mark F. Aaron², William T. Abraham³, Juan M. Aranda⁴, Yong K. Cho⁵, Robert Taepke⁵, Susan Madden⁵, Tom Bennett⁵, Robert C. Bourge⁶; ¹College of Medicine, University of Oklahoma; ²St. Thomas Heart Institute; ³Ohio State University; ⁴University of Florida Shands; ⁵Medtronic, Inc; ⁶University of Alabama

Background: Continuous right ventricular (RV) pressure monitoring with the Chronicle implantable hemodynamic monitor provides ability to quantify day-to-day hemodynamic changes in patients (pts) with heart failure (HF). Automated detection of hemodynamic changes may provide early warning of potential cardiac decompensa-tion. This study evaluated the performance of an automated method for detecting hemodynamic changes associated with HF hospitalization events. **Methods:** Data from 67 pts in the COMPASS-HF trial (a randomly selected subset of the control, whose data were not used to manage HF) were studied. RV systolic, diastolic, and estimated pulmonary arterial diastolic pressure (ePAD) were continuously monitored for 171 ± 38 days (mean ± SD). During the monitoring period, a total of 42 HF hospitalizations occurred in 25 pts. The detector calculated the cumulative sum of differences between the daily median hemodynamic value and a reference value, and compared it to a threshold. Detector performance was evaluated for sensitivity of predicting HF hospitalization events, and for false positive rate. Results: Hemodynamic changes were statistically significant (p < 0.0001) from baseline to peak pressure associated with HF hospitalization, and from the peak to recovery during hospitalization (see Table). Based on a single variable analysis using ePAD, the method correctly detected filling pressure changes preceding 38 of 42 HF hospitalization events (sensitivity = 86%) with a median early warning of 20 days (range 1 to 89 days). The detector also reported false positive detections not associated with a documented HF hospitalization or diuretic change, at a rate of 2.2 times per one-year of a patient monitoring. Other hemodynamic variables also resulted in comparable performance.

| | Baseline (mmHg) | Peak Pressure (mmHg) | Recovery (mmHg) |
|-----------|--------------------|-------------------------|-----------------|
| Systolic | 46.5 ± 11.3 | 59.5 ± 12.3* | 45.6 ± 10.2 |
| ePAD | 25.2 ± 6.0 | $34.0 \pm 8.1*$ | 25.4 ± 7.6 |
| Diastolic | 12.9 ± 4.9 | $21.1 \pm 6.9*$ | 13.9 ± 7.1 |

^{*} p < 0.0001 vs. Baseline and Recovery

Conclusion: The automated method detects pressure changes associated with HF hospitalization events with a high sensitivity in these Chronicle pts. With advanced information about potential HF decompensation, the automated detection of hemodynamic changes may improve chronic management of HF.