## ABSTRACTS •

## **2010 Internal Medicine Clinical Research Symposium Integrating Clinical Research Into Medical Practice**



Acute Renal Insufficiency Induced by Diuretics in a Sample of Patients with Congestive Heart Failure Treated at the Cardiovascular Center of Puerto Rico and the Caribbean

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**Objective**: The use of loop diuretic therapy in patients with congestive heart failure (CHF) may result in acute renal insufficiency (ARI). We assessed the factors that contributed to the development of ARI in patients with CHF treated with loop diuretics in a sample of patients hospitalized at the Cardiovascular Center of Puerto Rico and the Caribbean (CCPRC) in 2008.

Methods: Medical records of 102 patients admitted to the CCPRC between January 1, 2008 and December 31, 2008 with CHF (ICD-9 code 428) and who received furosemide during the hospitalization were reviewed. Diagnosis of CHF, based on symptoms (fatigue, dyspnea or orthopnea) and clinical signs (elevated jugular venous pressure, chest rales, S3 gallop, or edema), was confirmed by echocardiography. Twelve patients with significant valvular disease were excluded from the study. Hospital course was evaluated until diuretic therapy was discontinued or until patient was discharged from the hospital. Left ventricular (LV) systolic dysfunction was defined as an ejection fraction < 50% and LV diastolic dysfunction was defined as an ejection fraction > 50% in the presence of LV hypertrophy and an abnormal mitral inflow pattern. ARI was defined as a 25% increase in serum creatinine level after the start of diuretic therapy. The study sample was categorized in two groups: patients who developed ARI and those who did not. Univariate analysis was performed to characterize the demographic, lifestyle and clinical characteristics of the study sample. Comparison of categorical values by ARI status was performed using chi-square or Fisher's exact tests. Independent-sample t-test was used to compare means for continuous variables. Generalized estimating equations were fitted to estimate prevalence odds ratios with 95% confidence intervals to define these relationships. Variables associated with ARI (p < 0.05) in the bivariate logistic regression models were included in the multivariate logistic regression models. All study procedures were reviewed and approved by

the Institutional Review Board of the University of Puerto Rico Medical Science Campus.

Results: Of 102 patients studied, 40 (39.2%) patients developed ARI. Of patients who developed ARI, 37 (92.5%) patients had LV systolic dysfunction. In the bivariate logistic regression models, diuretic doses, baseline creatinine, type of CHF, and the use of digitalis were significantly associated (p<0.05) with ARI. However, in the multivariate logistic regression models, only higher doses of furosemide therapy (>120 mg/day) were significantly associated (p<0.05) with ARI. Baseline creatinine level was marginally associated (p=0.09) with ARI.

**Conclusion**: Analysis of our data shows that higher doses of furosemide therapy were significantly associated with ARI in patients with CHF. This study highlights the importance of monitoring doses of diuretic therapy during the hospitalization of CHF patients.

## Response to Antiretroviral Treatment in HIV Elderly Patients from Puerto Rico

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**Objective:** The epidemiology of the HIV-infected population is changing with more middle aged and older patients affected. The percentage of all HIV cases in patients aged 50 years or older has increased to over 17% in the most recent US CDC statistics. In Puerto Rico this increasing trend is also notorious, 20% of the total HIV/AIDS cumulative cases reported until August 2009 are represented by patients  $\geq$  50 years. With the introduction of highly active antiretroviral therapy (HAART), the prognosis for older patients has changed. However, there are controversies regarding their response to HAART. Given the limited information about the response to HAART in the Puerto Rican HIV population, this study aimed to compare the epidemiological and clinical characteristics, and the response to HAART in HIV patients  $\geq$  50 years versus younger HIV patients.

**Methods**: Sixty-five antiretroviral naïve subjects who initiated HIV treatment from January 1, 2004 to December 31, 2008 in the Puerto Rico Community Network for Clinical Research on AIDS (PR CONCRA) were included in the study. Only

subjects ≥ 21 years of age were included in the study. Pregnant women were not included. Medical charts were reviewed to obtain demographic and clinical characteristics including gender, education level, annual family income, type of health care coverage, risk factors for HIV transmission, data of the first available HIV test, HIV status, date of AIDS diagnosis, AIDS-defining diseases, antiretroviral therapy, presence of adverse metabolic events, failure to treatment and date of death. Data collected from laboratory included percentage of CD4 and HIV RNA viral load. The review period for each selected record was done for 0, 3, 6, 9, 12, 15 and 18 months. The date of the first HAART prescription was used as a baseline. The study sample was categorized in two groups: HIV patients that started HAART at 50 years of age or older (group 1), and HIV patients that started HAART between 21 and 50 years of age (group 2). Frequency distributions were computed to describe demographic, lifestyle and clinical characteristics of the study group. Comparison between groups was examined using a Fisher's exact test for categorical variables and nonparametric Wilcoxon rank-sum test for continuous variables. Significant values were considered if p-value was < 0.05. All study procedures were reviewed and approved by the Institutional Review Board of the UPR Medical Sciences Campus.

Results: Medical charts of 65 patients were selected, 22 patients from group 1 (63.6% male vs. 36.4% female) and 43 patients from group 2 (69.7% male vs. 20.2% female). The mean age in group 1 was  $58.1 \pm 6.8$  years while the mean age in group 2 was  $36.5 \pm 7.7$  years. No significant differences (p>0.05) were observed by sex, education level, annual family income, type of health care coverage, and co-infection with hepatitis B, hepatitis C and STD in both groups. However, significant differences were observed in the HIV transmission mode (63.6% of heterosexual contact in group 1 vs. 65.1% men sex with men in group 2) and HIV classification at time of study (50.0% classified with AIDS-CD4 criteria in group 1 vs. 45.2% classified with HIV-not AIDS in group 2). No significant differences were observed through time regarding immunological response and virological response. Also, no significant differences were observed in the first HAART regimen and regimen failure. No deaths were recorded for both groups.

**Conclusion**: The present study showed that the response to HAART in this sample of the HIV population of Puerto Rico was similar in the elderly group ( $\geq$  50 years) and younger group (<50 years).

Validation of a Gastroesophageal Reflux Disease (GERD) Questionnaire for its use in Puerto Rico

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**Objective:** Gastroesophageal reflux disease is a common condition that develops when the reflux of stomach contents causes troublesome symptoms and/or complications. The pathophysiology of GERD is multifactorial. Individuals with the disease suffer from typical and atypical symptoms causing impairments in their quality of life. Diagnosis of GERD is based on clinical presentation, radiographic or endoscopic findings, and/or positive gold-standard 24-hours pH monitoring test. Despite all these methods, medical literature has highlighted the importance of self-administered questionnaires to assess GERD clinically and as an aid in the diagnosis. The goal of this study was to develop and validate a GERD Questionnaire for its use in Puerto Rico. Once validated, it could be used to assess the prevalence of GERD in Puerto Rico.

**Methods**: A new questionnaire was designed and consisted of 14 questions grouped in three sections addressing heartburn, regurgitation and extra-esophageal symptoms of GERD. The new instrument's feasibility was evaluated by its administration to 16 patients. Study participants were asked to suggest changes to ease its understandability. After the feasibility phase, the reliability of the questionnaire will be measured by a test-retest procedure in 30 additional patients. Concurrent validity will be assessed by comparing findings from a physician interview, with self-questionnaire report data from 60 patients with a diagnosis of GERD and 60 patients unaware of having GERD. Patients newly diagnosed with GERD will be referred to primary physicians and contacted four weeks later. Those patients started on a therapeutic regimen will complete the questionnaire again; this will be done to assess the questionnaire's discriminant validity.

Results: A total of 16 outpatients were enrolled in the feasibility phase; 10 (62.5%) were women and 6 (37.5%) were men. Age ranged from 10 to 82 years, with a mean of 42.3 years of age. All participants reported Spanish as their native/first language. In our sample, one participant had primary school education; six had had secondary school education; three had some college education, one had a bachelor degree, one had a master's degree, and one had a doctoral education completed. We found that the instrument needed some qualitative changes to ease its understandability. Participants recommendations included: to increase the instrument's font size, to clarify the questionnaire's instructions, and to include other type of symptoms. However, in our sample, the most prevalent suggestion was to explain/define some medical wording; such as, "gastroesofágicas" and "gastrointestinales". After completing the feasibility phase, suggestions were evaluated by the expert panel. Questionnaire's instructions were shortened and some questions are re-structured. Medical wording was modified and a more colloquial wording was used instead.

**Conclusion**: A new instrument to assess GERD in Puerto Rico has been developed. After the feasibility phase, the questionnaire was amended and will continue to the next phase of validation.