

Sleep apnea in 81 ambulatory male patients with stable heart failure. Types and their prevalences, consequences, and presentations

Javaheri S, Parker TJ, Liming JD, Corbett WS, Nishiyama H, Wexler L, Roselle GA: Sleep Disorders Laboratory, Department of Veterans Affairs Medical Center, Cincinnati, Ohio, USA

Circulation 1998 Jun 2; 97(21):2154-2159

BACKGROUND: Heart failure is a highly prevalent disorder that continues to be associated with repeated hospitalizations, high morbidity, and high mortality. Sleep-related breathing disorders with repetitive episodes of asphyxia may adversely affect heart function. The main aims of this study were to determine the prevalence, consequences, and differences in various sleep-related breathing disorders in ambulatory male patients with stable heart failure.

METHODS AND RESULTS: This article reports the results of a prospective study of 81 of 92 eligible patients with heart failure and a left ventricular ejection fraction < 45%. There were 40 patients without (hourly rate of apnea/hypopnea, 4 +/- 4; group 1) and 41 patients with (51% of all patients; hourly rate of apnea/hypopnea, 44 +/- 19; group 2) sleep apnea. Sleep disruption and arterial oxyhemoglobin desaturation were significantly more severe and the prevalence of atrial fibrillation (22% versus 5%) and ventricular arrhythmias were greater in group 2 than in group 1. Forty percent of all patients had central sleep apnea, and 11% had obstructive sleep apnea. The latter patients had significantly greater mean body weight (112 +/- 30 versus 75 +/- 16 kg) and prevalence of habitual snoring (78% versus 28%). However, the hourly rate of episodes of apnea and hypopnea (36 +/- 10 versus 47 +/- 21), episodes of arousal (20 +/- 14 versus 23 +/- 11), and desaturation (lowest saturation, 72 +/- 11% versus 78 +/- 12%) were similar in patients with these different types of apnea.

CONCLUSIONS: Fifty-one percent of male patients with stable heart failure suffer from sleep-related breathing disorders: 40% from central and 11% from obstructive sleep apnea. Both obstructive and central types of sleep apnea result in sleep disruption and arterial oxyhemoglobin desaturation. Patients with sleep apnea have a high prevalence of atrial fibrillation and ventricular arrhythmias.

Effects of continuous positive airway pressure on cardiovascular outcomes in heart failure patients with and without Cheyne-Stokes respiration

Sin DD, Logan AG, Fitzgerald FS, Liu PP, Bradley TD: Sleep Research Laboratory of the Toronto Rehabilitation Institute, Department of Medicine at the Toronto General Hospital (University Health Network), University of Toronto, Ontario, Canada.

Circulation 2000 Jul 4; 102(1):61-66

BACKGROUND: Continuous positive airway pressure (CPAP) improves cardiac function in patients with congestive heart failure (CHF) who also have Cheyne-Stokes respiration and central sleep apnea (CSR-CSA). However, the effects of CPAP in CHF patients without CSR-CSA have not been tested, and the long-term effects of this treatment on clinical cardiovascular outcomes are unknown.

METHODS AND RESULTS: We conducted a randomized, controlled trial in which 66 patients with CHF (29 with and 37 without CSR-CSA) were randomized to either a group that received CPAP nightly or to a control group. Change in left ventricular ejection fraction

(LVEF) from baseline to 3 months and the combined mortality-cardiac transplantation rate over the median 2.2-year follow-up period were compared between the CPAP-treated and control groups. For the entire group of patients, CPAP had no significant effect on LVEF, but it was associated with a 60% relative risk reduction (95% confidence interval, 2% to 64%) in mortality-cardiac transplantation rate in patients who complied with CPAP therapy. Stratified analysis of patients with and without CSR-CSA revealed that those with CSR-CSA experienced both a significant improvement in LVEF at 3 months and a relative risk reduction of 81% (95% confidence interval, 26% to 95%) in the mortality-cardiac transplantation rate of those who used CPAP. CPAP had no significant effect on either of these outcomes in patients without CSR-CSA.

CONCLUSIONS: CPAP improves cardiac function in CHF patients with CSR-CSA but not in those without it. Although not definitive, our findings also suggest that CPAP can reduce the combined mortality-cardiac transplantation rate in those CHF patients with CSR-CSA who comply with therapy.

Prognostic value of nocturnal Cheyne-Stokes respiration in chronic heart failure

Lanfranchi PA, Braghiroli A, Bosimini E, Mazzuero G, Colombo R, Donner CF, Giannuzzi P: Division of Cardiology, Department of Bioengineering, Salvatore Maugeri Foundation, IRCCS, Veruno, Italy.

Circulation 1999 Mar 23; 99(11): 1435-1440

BACKGROUND: Nocturnal Cheyne-Stokes respiration (CSR) occurs frequently in patients with chronic heart failure (CHF), and it may be associated with sympathetic activation. The aim of the present study was to evaluate whether CSR could affect prognosis in patients with CHF.

METHODS AND RESULTS: Sixty-two CHF patients with left ventricular ejection fraction $\leq 35\%$, in NYHA class II to III, underwent clinical evaluation, Doppler echocardiography, ergospirometry, phenylephrine test, Holter recording, and a sleep study to evaluate the occurrence of CSR, expressed as percentage of periodic breathing, and apnea/hypopnea index (AHI) (ie, the number of apneas and hypopneas per hour of recording). During a mean follow-up of 28 ± 13 months, 15 patients died of cardiac causes. Nonsurvivors were in a higher NYHA functional class than survivors ($P < 0.001$) and had a more depressed left ventricular ejection fraction ($P < 0.03$), a shorter deceleration time of early filling ($P < 0.05$), larger left and right atria ($P < 0.05$ and $P < 0.02$, respectively) and a lower peak $V(O_2)$ ($P < 0.05$). Nonsurvivors also spent a greater percentage of the night in periodic breathing ($P < 0.01$) with a greater AHI ($P < 0.03$) and showed lower values of diurnal baroreflex sensitivity ($P < 0.05$) and of heart rate variability (sdNN: $P < 0.01$). Multivariate analysis revealed the AHI (χ^2 , 10.4; $P < 0.01$), followed by left atrial area (χ^2 , 5.7; $P < 0.01$), as the only independent and additional predictors of subsequent cardiac death. Patients at very high risk for fatal outcome could be identified by an AHI $\geq 30/h$ and left atria $\geq 25 \text{ cm}^2$.

CONCLUSIONS: The AHI is a powerful independent predictor of poor prognosis in clinically stable patients with CHF. The presence of an AHI $\geq 30/h$ adds prognostic information compared with other clinical, echocardiographic, and autonomic data and identifies patients at very high risk for subsequent cardiac death.

Pathophysiologic and therapeutic implications of sleep apnea in congestive heart failure

Bradley TD, Floras JS: Department of Medicine of the Toronto Hospital, Ontario, Canada.

J Card Fail 1996 Sep; 2(3): 223-240

Obstructive and central sleep apnea are common in patients with congestive heart failure (CHF). These sleep-related breathing disorders are characterized by two pathophysiologic features that could have important implications for disease progression in CHF: sympathetic nervous system activation, and adverse changes in cardiac loading conditions. In patients with obstructive sleep apnea, blood pressure is frequently elevated as a result of excessive sympathetic nervous system activity elicited by the combination of apnea, hypoxia, and arousals from sleep. The generation of exaggerated negative intrathoracic pressure during obstructive apneas further increases left ventricular afterload, reduces cardiac output, and may promote the progression of pump failure. Increased afterload and hypoxia can also predispose such patients to myocardial ischemia and arrhythmias. In patients with CHF, abolition of coexisting obstructive sleep apnea by nasal continuous positive airway pressure improves left ventricular function. Central sleep apnea (i.e., Cheyne-Stokes respiration) is also characterized by apnea, hypoxia, and increased sympathetic nervous system activity and, when present in CHF, is associated with increased risk of death. Recent medium-term trials involving small numbers of patients have demonstrated that nocturnally applied continuous positive airway pressure in patients with CHF and central sleep apnea alleviates central sleep apnea, improves left ventricular function, reduces sympathetic nervous system activity and improves symptoms of CHF. These studies emphasize the importance of considering obstructive and central sleep apnea in the differential diagnosis of conditions that could contribute to the development or progression of CHF. They also suggest that continuous positive airway pressure is a promising nonpharmacologic adjunctive therapy for patients with CHF and coexisting sleep-related breathing disturbances that warrants further investigation.

Effects of Nasal O2 on Sleep-Related Disordered Breathing in Ambulatory Patients with Stable Heart Failure

Shahrokh Javaheri MD, Maqbool Ahmed MD, Thomas J. Parker MD, with assistance of Candice R. Brown BA: Sleep Disorders Laboratory, Department of Veterans Affairs Medical Center, and Department of Medicine, University of Cincinnati, College of Medicine, Cincinnati, Ohio

SLEEP, Vol. 22, No. 8, 1999

OBJECTIVE: The purpose of this study was 1) to determine the effects of nasal O₂ on periodic breathing, arterial oxyhemoglobin desaturation and nocturnal ventricular arrhythmias in patients with heart failure and 2) determine the characteristics of patients whose periodic breathing will be reversed by O₂ administration; our hypothesis was that patients with more severe periodic breathing and desaturation, will respond more favorably to oxygen.

DESIGN: Prospective study

SETTING: Referral sleep laboratory of a Department of Veterans Affairs Medical Center.

PARTICIPANTS: 36 ambulatory male patients with heart failure whose initial polysomnograms showed periodic breathing with fifteen or more episodes of apnea (A) and hypopnea (H) per hour (AH index, AHI) were treated with nasal O₂ during the subsequent full night polysomnography.

INTERVENTIONS: Oxygen

MEASUREMENTS AND RESULTS: Arterial blood gases and hydrogen ion concentrations were measured, and cardiac radionuclide ventriculography, Holter monitoring, and polysomnography were done. The studies were scored blindly. Treatment with O₂ resulted in a significant reduction in AHI (49 ± 19 vs 29 ± 29 , means \pm SD), central apnea index (28 ± 23 vs 13 ± 18 per hour), and the percent of total sleep time below an arterial oxyhemoglobin saturation of 90% ($23 \pm 21\%$ vs $0.8 \pm 2.3\%$). In spite of virtual normalization of saturation with O₂ therapy, the number of ventricular arrhythmias during sleep did not change significantly. In 39% of the patients (14 out of 36), O₂ therapy resulted in reversal of central sleep apnea (defined by a reduction in AHI to less than 15/hr). In this group, the AHI decreased by 78% which was significantly ($p=0.0001$) more than improved (22%) in AHI of the remaining patients ($n=22$). The main differences between baseline characteristics of the two groups was a significantly higher mean PaCO₂ in patients who did respond fully to O₂ (39.3 ± 5.4 vs 36.1 ± 4.2 mm Hg, $p=0.03$). In both groups, however, O₂ administration resulted in significant and similar improvement in arterial oxyhemoglobin saturation (saturation $<90\%$, percent total sleep time $0.1 \pm 0.3\%$ vs $1 \pm 3\%$).

CONCLUSION: In patients with stable heart failure, administration of nasal O₂ significantly improves periodic breathing and virtually eliminates clinically significant arterial oxyhemoglobin desaturation. The beneficial effects of O₂, however, may be modulated by the level of arterial PCO₂. Acute O₂ therapy has important benefits on sleep apnea and nocturnal arterial oxyhemoglobin desaturation in heart failure patients. Long term benefits of O₂ therapy in heart failure and sleep apnea need to be determined.

Effects of continuous positive airway pressure on sleep apnea and ventricular irritability in patients with heart failure

Javaheri S: Sleep Disorders Laboratory, Department of Veterans Affairs Medical Center, and Department of Medicine, University of Cincinnati College of Medicine, Cincinnati, Ohio

Circulation 2000 Feb 1; 101(4): 392-397

BACKGROUND: Patients with heart failure and systolic dysfunction may develop disordered breathing during sleep. Repeated episodes of apnea and hypopnea may result in desaturation and arousals, which could adversely affect left ventricular function. The purpose of this study was to determine the short-term effects of continuous positive airway pressure (CPAP) on sleep-disordered breathing and its consequences in heart failure patients.

METHODS AND RESULTS: The author prospectively studied 29 male patients whose initial polysomnograms showed 15 or more episodes of apnea and hypopnea per hour (apnea-hypopnea index, AHI). Twenty-one patients had predominately central and 8 patients obstructive sleep apnea. All were treated with CPAP during the subsequent night. In 16 patients, CPAP resulted in virtual elimination of disordered breathing. In these patients, the mean AHI (36 ± 12 [SD] versus 4 ± 3 per hour, $P=0.0001$), arousal index due to disordered breathing (16 ± 9 versus 2 ± 2 per hour, $P=0.0001$), and percent of total sleep time below saturation of 90% ($20 \pm 23\%$ to $0.3 \pm 0.7\%$, $P=0.0001$) decreased, and lowest saturation ($76 \pm 8\%$ versus $90 \pm 3\%$, $P=0.0001$) increased with CPAP. In 13 patients who

did not respond to CPAP, these values did not change significantly. In patients whose sleep apnea responded to CPAP, the number of hourly episodes of nocturnal premature ventricular contractions (66 ± 117 versus 18 ± 20 , $P=0.055$) and couplets (3.2 ± 6 versus 0.2 ± 0.21 , $P=0.031$) decreased. In contrast, in patients whose sleep apnea did not respond to CPAP, ventricular arrhythmias did not change significantly.

CONCLUSIONS: In 55% of patients with heart failure and sleep apnea, first-night nasal CPAP eliminates disordered breathing and reduces ventricular irritability.

A mechanism of central sleep apnea in patients with heart failure

Javaheri S: Veterans Affairs Medical Center, Department of Medicine, University of Cincinnati College of Medicine, OH

N Engl J Med 1999 Sep 23; 341(13): 949-954

BACKGROUND: Breathing is controlled by a negative-feedback system in which an increase in the partial pressure of arterial carbon dioxide stimulates breathing and a decrease inhibits it. Although enhanced sensitivity to carbon dioxide helps maintain the partial pressure of arterial carbon dioxide within a narrow range during waking hours, in some persons a large hyperventilatory response during sleep may lower the value below the apneic threshold, thereby resulting in central apnea. I tested the hypothesis that enhanced sensitivity to carbon dioxide contributes to the development of central sleep apnea in some patients with heart failure.

METHODS: This prospective study included 20 men who had treated, stable heart failure with left ventricular systolic dysfunction. Ten had central sleep apnea, and 10 did not. The patients underwent polysomnography and studies of their ventilatory response to carbon dioxide.

RESULTS: Patients who met the criteria for central sleep apnea had significantly more episodes of central apnea per hour than those without central sleep apnea (mean [\pm SD], 35 ± 24 vs. 0.5 ± 1.0 episodes per hour). Those with sleep apnea also had a significantly larger ventilatory response to carbon dioxide than those without central sleep apnea (5.1 ± 3.1 vs. 2.1 ± 1.0 liters per minute per millimeter of mercury, $P=0.007$), and there was a significant positive correlation between ventilatory response and the number of episodes of apnea and hypopnea per hour during sleep ($r=0.6$, $P=0.01$).

CONCLUSIONS: Enhanced sensitivity to carbon dioxide may predispose some patients with heart failure to the development of central sleep apnea.

Improvement of exercise capacity with treatment of Cheyne-Stokes respiration in patients with congestive heart failure

Andreas S, Clemens C, Sandholzer H, Figulla HR, Kreuzer H: Department of Cardiology and Pneumology and Department of General Practice, Georg-August University, Göttingen, Germany.

J Am Coll Cardiol 1996 May; 27(6): 1486

OBJECTIVES: The aim of this study was to determine the impact of nasal nocturnal oxygen therapy on respiration, sleep, exercise capacity, cognitive function and daytime symptoms in patients with congestive heart failure and Cheyne-Stokes respiration.

BACKGROUND: Cheyne-Stokes respiration is common in patients with congestive heart failure and is associated with significant nocturnal oxygen desaturation and sleep disruption with arousals. Oxygen desaturations and arousals cause an increase in pulmonary artery pressure and sympathoneural activity and therefore may reduce exercise capacity. Oxygen is an effective treatment of Cheyne-Stokes respiration and should improve exercise capacity in these patients.

METHODS: The study was designed as a randomized crossover, double-blind, placebo-controlled trial: 22 patients were assigned to 1 week each of nocturnal oxygen and room air. After each week, polysomnography, maximal bicycle exercise with expiratory gas analysis and trail-making test were performed, and a health assessment chart was completed.

RESULTS: Nocturnal oxygen significantly reduced the duration of Cheyne-Stokes respiration (162 +/- 142 vs. 88 +/- 105 min [mean +/- SD]; $p < 0.005$). Sleep improved as evidenced by less stage 1 sleep and fewer arousals (20 +/- 13 vs. 15 +/- 9/h total sleep time; $p < 0.05$) as well as more stage 2 and slow-wave sleep; nocturnal oxygen saturation also improved. Peak oxygen consumption during exercise testing increased after oxygen treatment (835 +/- 395 vs. 960 +/- 389 ml/min; $p < 0.05$). Cognitive function evaluated by the trail-making test improved, but daytime symptoms in the health assessment chart did not improve significantly.

CONCLUSIONS: Successful treatment of Cheyne-Stokes respiration with nocturnal nasal oxygen improves not only sleep, but also exercise tolerance and cognitive function in patients with congestive heart failure.

The effect of oxygen on respiration and sleep in patients with congestive heart failure

Hanly PJ, Millar TW, Steljes DG, Baert R, Fraiss MA, Kryger MH: University of Manitoba, Winnipeg, Manitoba, Canada.

Ann Intern Med 1989 Nov 15;111(10):777-782

STUDY OBJECTIVE: To determine the effect of supplemental oxygen on Cheyne-Stokes respiration, nocturnal oxygen saturation (SaO₂), and sleep in male patients with severe, stable congestive heart failure. **DESIGN:** Randomized, single-blind, placebo-controlled crossover study.

SETTING: Patients referred from outpatient cardiology clinics of two teaching hospitals.

PATIENTS: Sequential sample of nine outpatients with severe, stable congestive heart failure.

INTERVENTIONS: For each patient, sleep studies (after an adaptation night) from two consecutive randomized nights were compared; one study was done while the patient breathed compressed air and the other while the patient breathed oxygen (O₂). Compressed air and oxygen were both administered through nasal cannulae at 2 to 3 L/min.

MEASUREMENTS AND MAIN RESULTS: Cheyne-Stokes respiration, defined as periodic breathing with apnea or hypopnea, was found in all patients. Low-flow oxygen significantly reduced the duration of Cheyne-Stokes respiration (50.7% +/- 12.0% to 24.2% +/- 5.4% total sleep time), mainly during stage 1 NREM (non-rapid eye movement) sleep (21.3% +/- 7.1% to 6.7% +/- 2.3% total sleep time) with no significant change during stage 2 sleep, slow-wave sleep, or REM (rapid eye movement) sleep. Although patients had normal SaO₂ (96.0% +/- 1.7%) while awake, severe sleep hypoxemia was common; breathing oxygen reduced the amount of time that SaO₂ was less than 90% from 22.3% +/- 8.0% to 2.41% +/- 1.93% of total sleep time. Sleep, disrupted to a variable extent in all patients, improved with oxygen therapy: There was an increase in total sleep time from 275.3 min +/- 36.6 to 324.6 min +/- 23.3; a reduction in the proportion of stage 1 sleep (27.6% +/- 5.8% total sleep time to 15.2% +/- 2.6% total sleep time); and a reduction in the number of arousals (30.4/h +/- 8.0 to 13.8/h +/- 1.9). The apnea-hypopnea index was reduced from 30.0 +/- 4.7 to 18.9 +/- 2.4 with oxygen breathing.

CONCLUSION: In severe, stable congestive heart failure, nocturnal oxygen therapy reduces Cheyne-Stokes respiration, corrects hypoxemia, and consolidates sleep by reducing arousals caused by the hyperpneic phase of Cheyne-Stokes respiration. Correction of nocturnal hypoxemia and sleep disruption may improve the clinical status of these patients.

HFSA 6th Annual Scientific Meeting

Filename: 550103 Contact Author: William T Abraham MD, FACP, FACP
Department/Institution: Cardiology, University of Kentucky, College of Medicine Address: 740 South Limestone St. City/State/Zip/Country: Lexington, KY, 40536-0284, United States Phone: 859-323-5843 Fax: 859-323-6475 E-mail: wtabra2@pop.uky.edu
Presentation Format: Any Category: Clinical trials Awards: Please do not consider my abstract for an award Disclosure: There is no relationship to disclose.

Authors: 1 William T Abraham, MD, 2 Barbara Phillips, MD, 3 Brian Foley, MD, 4 Susan Harding, MD, 5 Peter Schofield, MD, FRCP, 5 John Shneerson, MA, DM, FRCP, 6 Thomas Di Salvo, MD, M. Sci. and 7 Douglas Johnson, MD. 1College of Medicine, University of Kentucky, Lexington, Kentucky; 2Sleep Disorders Center, Samaritan Hospital, Lexington, Kentucky; 3, University of Alabama, Birmingham, Alabama; 4Sleep/Wake Disorders Center, University of Alabama, Birmingham, Alabama; 5, Papworth Hospital, Papworth Everard, Cambridge, United Kingdom; 6, Massachusetts General Hospital, Boston, Massachusetts and 7Spaulding Sleep Center, Spaulding Rehabilitation Hospital, Boston, Massachusetts.

Title: Sleep Disordered Breathing in Heart Failure Patients: First Night Treatment Response from a Multicenter International Study

Body:

Background: Recent studies in single centers have shown a high prevalence of Sleep Disordered Breathing (SDB) in patients with heart failure (HF). We undertook a multicenter international trial to compare a new, wireless, ambulatory monitoring system (ClearPath) to conventional polysomnography (PSG) during the diagnostic and treatment sessions of HF patients with SDB. This report focuses on the treatment phase of this trial.

Methods: Fifty NYHA Class 3 or 4 heart failure patients with an EF of less than 35 % were enrolled at four sites. Patients underwent a simultaneous diagnostic PSG and **ClearPath** sleep study. ClearPath provides 2 lead ECG, pulse oximetry and respiratory impedance. Local technicians and physicians scored PSG traces for hypopneas with an associated 3% oxyhemoglobin desaturation and apneas. The PSG apnea-hypopnea index (AHI) was equal to all apneas plus hypopneas divided by the total sleep time and determined therapy.

Patients with a PSG AHI greater than 15 per hour were referred for an overnight treatment titration. Patients with predominately central events were treated with oxygen and patients with predominantly obstructive events were treated with CPAP. Responders were patients with AHI under 15 events per hour during the treatment session.

Results: Forty-nine patients completed the diagnostic overnight session while one patient could not tolerate the PSG. Twenty-four patients had an AHI of greater than 15 and were treated during a separate overnight session. Fourteen received CPAP and 10 received oxygen. Seventy-five percent of treated patients had an AHI below 15 events per hour; 25 % had an AHI below 5 events per hour; and 63 % of the treated patients dropped to an AHI of less than 50 % of their baseline.

Conclusion: In 75% of patients with heart failure and SDB, first night CPAP or oxygen reduces abnormal respiratory events to less than 15 per hour. The response rates for CPAP and oxygen are similar and both are over 70 % on the first night of therapy. Heart failure patients treated for SDB in this trial responded well to first night therapy with a significant decrease in AHI.

| SLEEP DISORDERED BREATHING TREATMENT RESPONSE | | | |
|--|-----------------|-------------------|-------------------|
| TREATMENT CATEGORY | PATIENTS | RESPONDERS | PERCENTAGE |
| CPAP | 14 | 10 | 71% |
| OXYGEN | 10 | 8 | 80% |
| TOTALS | 24 | 18 | 75% |

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Filename: 550063 Contact Author: Donald E Jansen Department/Institution: Nexan
 Address: 4555 Mansell Road, Suite 110 City/State/Zip/Country: Alpharetta , GA , 30022 ,
 United States Phone: 770-360-9090 Fax: 770-521-9080 E-mail: donald.jansen@nexan-
 inc.com Presentation Format: Any Cate gory: Clinical Care/Management Strategies Awards:
 Please do not consider my abstract for an award Disclosure: There is a relationship(s) that
 could represent or be perceived to represent a conflict of interest.

Authors: 1 Donald E Jansen, 1 Cherie L Kunik, 2 Priya Patel, 2 Wendy Maddox and 2
 Stephen C Frohwein. 1, Nexan, Inc , Atlanta, GA and 2, Atlanta Cardiology Group, Atlanta,
 GA.

Title: Sleep Disordered Breathing in Heart Failure Patients with and without Atrial Fibrillation

Body:

Introduction: The mortality rate for heart failure (HF) patients is 50% at five years and the presence of atrial fibrillation (AF) increases that risk. Previous studies also support that the pathophysiologic consequences of sleep disorder breathing (SDB) exacerbate HF. While limited data suggests that AF is more common in HF patients with SDB, the occurrence of SDB in HF patients with established AF has not been previously studied. This study compares the frequency of SDB in HF patients with AF to patients with sinus rhythm (SR).

Methods: We selected 20 known HF patients with an EF of less than 40%. Ten HF patients had an underlying rhythm of AF while the other 10 HF patients had an underlying rhythm of SR. After obtaining informed consent, patients underwent placement of an outpatient-monitoring device (ClearPath System) that collects thoracic impedance, SpO2 data and two-lead ECG data. A registered sleep and ECG technician scored the data for respiratory events, oxygen desaturations and cardiac arrhythmias with a physician over read. Respiratory events were defined as apneas and hypopneas with an associated 3% desaturation. A respiratory disturbance index (RDI) was calculated by dividing the total number of respiratory events by the estimated time in bed.

Results: The overall occurrence of moderate to severe SDB (greater than 5 respiratory events per hour) in this study group was 65%. The mean RDI for the AF patients was 10.8 versus 7.9 for the SR patients (p-value = .17). While 30% of the HF patients with AF had mild events, 50% of the AF patients had severe SDB. In contrast, 40% of the HF patients with sinus rhythm (SR) had mild events, and only 10% of HF patients with SR had severe SDB.

Conclusion: This study illustrates the high frequency of SDB in an outpatient HF population. In addition, the data demonstrates a trend of increased RDI values for HF patients whose underlying rhythm is AF. Half the patients with AF had an RDI greater than 15 events per hour. HF patients with AF may be at greater risk for developing more severe SDB, thus increasing this group's morbidity and mortality.

| Frequency of Sleep Disordered Breathing | | | |
|--|------------------------------|--|-----------------------------------|
| Events Category | RDI (events per hour) | Patients with Atrial Fibrillation | Patients with Sinus Rhythm |
| Mild | Less than 5 | 4 | 3 |
| Moderate | 5-15 | 1 | 6 |
| Severe | Greater than 15 | 5 | 1 |
| Totals | | 10 | 10 |

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Filename: 550081 Contact Author: William T Abraham MD, FACP, FACC
 Department/Institution: Cardiology, University of Kentucky Address: 740 South Limestone Street City/State/Zip/Country: Lexington , KY , 40536-0284 , United States Phone: (859) 323-5843 Fax: (859) 323-6475 E-mail: wtabra2@pop.uky.edu Presentation Format: Any
 Category: Clinical Care/Management Strategies Awards: Please do not consider my abstract for an award Disclosure: There is a relationship(s) that could represent or be perceived to represent a conflict of interest.

Authors: 1 William T Abraham, MD, FACP, FACC, 1 Sumant Lamba, MD, 1 Julia Osborne, RN, 1 Shelly Selby, RN, 1 Peggy Hardesty, MSN, RN, ARNP, 2 Donald E Jan sen, MPH, MD, 2 Cherie L Kunik, MSN, RN, CS and 1 Robin J Trupp, MSN, RN, ARNP. 1Cardiology, University of Kentucky, Lexington, KY and 2, Nexan, Inc ., Alpharetta, GA.

Title: A Prevalence Study of Sleep Disordered Breathing in Consecutive Patients from a Heart Failure Clinic

Body:

Introduction: Sleep disordered breathing (SDB) is frequently associated with chronic systolic heart failure (HF). Such patients may be at increased risk for HF morbidity and mortality. However, screening for SDB in HF patients is under-utilized.

Methods: Three consecutive days in a Heart Failure Clinic at a large academic center were randomly selected. All patients (n=45) that were seen on these days were invited to participate and were not pre-screen for SDB. Seven patients declined, and the remaining 38 had an outpatient-monitoring device (ClearPath System) applied. The ClearPath System collects thoracic impedance, SpO2 and two-lead ECG data. Thirty-seven of the total 38 patients had interpretable monitoring data for SDB. A registered sleep and EKG technician scored the data for respiratory events, oxygen desaturations and cardiac arrhythmias with a physician over-read. Respiratory events were defined as apneas and hypopneas with an associated 3% desaturation. A respiratory disturbance index (RDI) was calculated by dividing the total number of respiratory events by the estimated hours in bed.

Results: This study group had a mean age of 53.4 years old and a mean body mass index(BMI) of 31.35. 55% of patients had mild events while 42% percent of patients had moderate or severe SDB. All sixteen patients with an RDI >5 events per hour were referred to a sleep lab for a full polysomnography (PSG) to confirm the diagnosis of SDB and for treatment.

Conclusion: Over 40% of consecutively studied patients in an outpatient HF clinic for SDB had significant respiratory events. The high prevalence rate was not clinically suspected in this group and would have gone otherwise undiagnosed. Most if not all patients presenting to a heart failure clinic should be considered for SDB evaluation.

| Sleep Disordered Breathing Prevalence | | | | |
|--|-----------------------|-----------------|----------|----------|
| Events Category | RDI (events per hour) | PATIENTS (n=37) | Mean Age | Mean BMI |
| Mild | Less than 5 | 21 (56.7%) | 50.8 | 30.9 |
| Moderate | 5-15 | 12 (32.4%) | 59.5 | 30.4 |
| Severe | Greater than 15 | 4 (10.8%) | 48.5 | 36.1 |

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Filename: 550083 Contact Author: William T Abraham MD, FACP, FACC Department/Institution: Cardiology, University of Kentucky Address: 740 South Limestone St. City/State/Zip/Country: Lexington , KY , 40536-0284 , United States Phone: 859-323-5843 Fax: 859-323-6475 E-mail: wtabra2@pop.uky.edu Presentation Format: Any Category: Clinical trials Awards: Please do not consider my abstract for an award Disclosure: There is a relationship(s) that could represent or be perceived to represent a conflict of interest.

Authors: William T Abraham, MD, Barbara Phillips, MD, Brian Foley, MD, Susan Harding, MD, Peter Schofield, MD, FRCP, John Shneerson, MA, DM, FRCP, Thomas Di Salvo, MD, M. Sci and Douglas Johnson, MD. 1, University of Kentucky College of Medicine, Lexington, Kentucky; 2Sleep Disorders Center, Samaritan Hospital, Lexington, Kentucky; 3, University of Alabama, Birmingham, Alabama; 4Sleep/Wake Disorders Center, University of Alabama, Birmingham, Alabama; 5, Papworth Hospital; Papworth Everard, Cambridge, United Kingdom; 6, Massachusetts General Hospital, Boston, Massachusetts and 7Spaulding Sleep Center, Spaulding Rehabilitation Hospital, Boston, Massachusetts.

Title: Sleep Disordered Breathing in Heart Failure Patients: A Multicenter International Study

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Background: Recent studies in single centers have shown a high prevalence of Sleep Disordered Breathing (SDB) in patients with heart failure (HF). We undertook a multicenter international trial to compare a new, wireless, ambulatory monitoring system (ClearPath) to conventional polysomnography (PSG) during diagnostic and treatment sessions of HF patients. This report focuses on the diagnostic phase of this trial.

Methods: Fifty NYHA Class 3 or 4 heart failure patients with an EF of less than 35 % were enrolled at four sites. Patients underwent simultaneous PSG and ClearPath sleep studies. ClearPath provides 2 lead ECG, pulse oximetry and respiratory impedance. Local technicians and physicians were blinded and then scored PSG and ClearPath data for hypopneas and apneas with an associated 3% oxyhemoglobin desaturation. The apnea-hypopnea index (AHI) for PSG was equal to all apneas plus hypopneas divided by the total sleep time and confirmed SDB diagnosis. The respiratory disturbance index (RDI), defined as all apneas plus hypopneas divided by time in bed, was compared between the two systems.

Results: Forty-nine patients completed the overnight session while one patient could not tolerate PSG. The PSG AHI ranged from 0 to 92.3 and reflected the full spectrum of SDB. Forty-nine percent had severe SDB with an AHI of 15 events or greater per hour. Twenty-seven percent had an AHI of 30 events or greater per hour. Applying an AHI threshold of five or greater, 69% of the patients would require evaluation for treatment.

Using the RDI time in bed comparison for valid data sessions, the ClearPath data compared to PSG demonstrated sensitivity of 100% and specificity of 71% for a RDI greater than 5. Using a RDI greater than 10, the sensitivity and specificity were both 87%.

Conclusion: This multicenter trial further illustrates the high prevalence of SDB in heart failure patients. Nearly half the patients required treatment for severe SDB. Further, the comparative data between ClearPath and PSG demonstrated an excellent sensitivity and specificity for this new ambulatory system.

| SLEEP DISORDERED BREATHING FREQUENCY | | | |
|---|----------------------------------|-----------------|-------------------|
| EVENTS CATEGORY | PSG AHI (events per hour) | PATIENTS | PERCENTAGE |
| MILD | Less than 5 | 15 | 31 |
| MODERATE | 5-15 | 10 | 20 |
| SEVERE | Greater than 15 | 24 | 49 |
| TOTALS | | 49 | 100 |