

Validation and Clinical Utility of a Simple In-Home Testing Tool for Sleep-Disordered Breathing and Arrhythmias in Heart Failure: Results of the Sleep Events, Arrhythmias, and Respiratory Analysis in Congestive Heart Failure (SEARCH) Study

Sleep-disordered breathing (SDB) is a condition marked by nocturnal episodes of apnea and hypopnea of either obstructive (increased airway resistance) or central (depressed respiratory effort) origin. Observations from the Sleep Heart Health Study¹ demonstrate a correlation between SDB and the subsequent development of a variety of forms of cardiovascular (CV) disease, including hypertension, stroke, and heart failure (HF). Moreover, SDB is a common comorbidity in patients with established HF. The prevalence of SDB in HF patients is approximately 40%–60%, a rate higher than that seen in patients with CV disease (30%) and in the general population (5%).^{2–11} Of note, HF patients with SDB have an increased risk for arrhythmias and higher cardiac mortality.^{3,11–15} Normalization of airway patency and arterial oxygen saturation with continuous positive airway pressure and/or oxygen therapy has the potential to improve cardiac function in these patients. Correction of SDB improves sleep quality and CV function, including improvement in end-systolic dimension, stroke volume, and left ventricular ejection fraction.^{16–21} Correction of SDB also has the potential to prolong transplant-free survival in HF, reduce overall CV mortality, and improve quality of life.^{19,22–24}

Despite these potential clinical and prognostic benefits associated with the identification and management of SDB in patients with HF, the diagnosis is rarely made, because testing is infrequently carried out routinely in

Fifty patients with New York Heart Association class III systolic heart failure were enrolled in this prospective multicenter study that compared the diagnostic accuracy of a home-based cardiorespiratory testing system with standard attended polysomnography. Patients underwent at least 2 nights of evaluation and were scored by blinded observers. At diagnostic cutoff points of ≥ 5 , ≥ 10 , and ≥ 15 events per hour for respiratory disturbance severity, polysomnography demonstrated a sleep-disordered breathing prevalence of 69%, 59%, and 49%, respectively. Compared with polysomnography, the cardiorespiratory testing system demonstrated predictive accuracies of 73%, 73%, and 75%, which improved to 87%, 87%, and 83%, respectively, when analysis of covariance suggested reanalysis omitting one site's data. The system accurately identified both suspected and unsuspected arrhythmias. The device was judged by 80% of patients to be easy or very easy to use, and 74% of patients expressed a preference for the in-home system. Therefore, this system represents a reasonable home testing device in these patients. (CHF. 2006;12:241–247) ©2006 Le Jacq

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this population. The failure to diagnose and treat SDB in HF may be due to a number of factors, including the challenges of performing large-scale screening using a complete polysomnography (PSG) assessment in this population. Referral for PSG, sometimes requiring multiple nights, has substantial expense and can place

large demands on the patient. Patient access to PSG may be limited.^{25,26} A simple and inexpensive SDB detection device would afford a more practical and needed screening tool to help identify HF patients who have SDB.

Recently, a home-based cardiorespiratory testing system (ClearPath System [CPS] Nx-301; Nexan Inc,

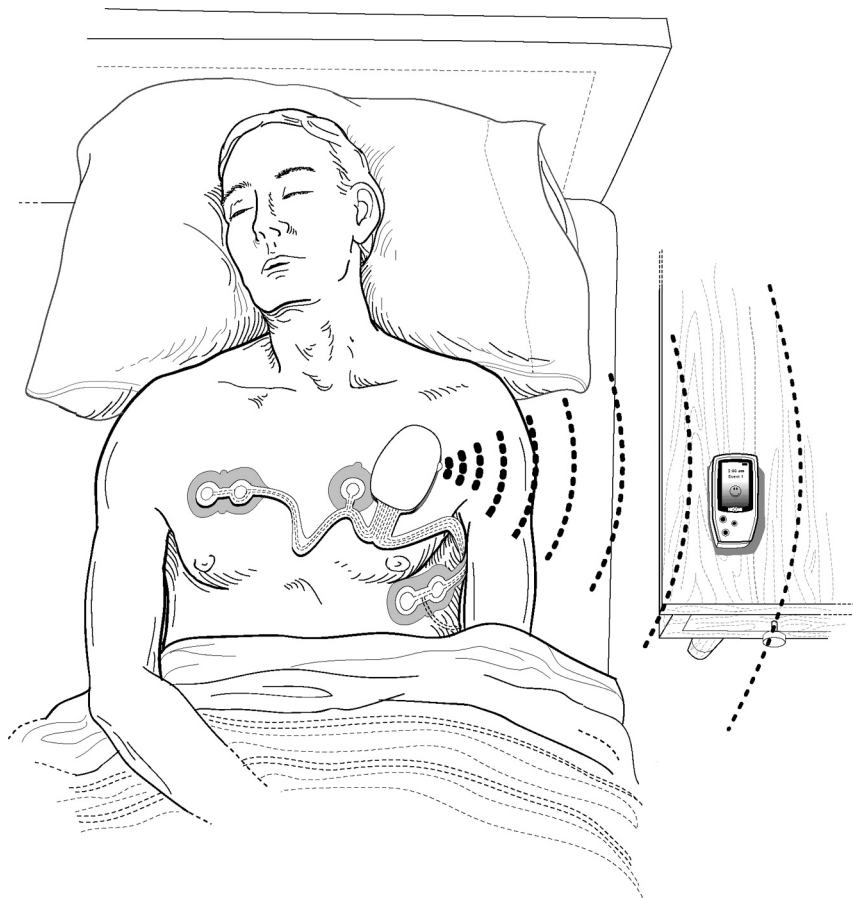


Figure. Illustration of the components of the ClearPath System Nx-301 (Nexan Inc, Alpharetta, GA). Electrodes (sensors) are positioned on the anterior chest region as shown. The sender unit collects the impedance, oximetry, and electrocardiographic information and transmits data to the partner, the data storage device. After testing, the partner is loaded into a specially configured workstation and interrogated for data retrieval, long-term storage, and analysis.

Alpharetta, GA) was introduced. This device records 2 leads of an electrocardiogram (ECG), pulse oximetry, and respiratory impedance. If this device is accurate in detecting SDB, its ease of use and lower cost compared with PSG could allow for screening more HF patients for SDB. The Sleep Events, Arrhythmias, and Respiratory Analysis in Congestive Heart Failure (SEARCH) study, reported here, represents the first direct comparison of a home-based SDB screening system with PSG in the diagnosis of SDB in patients with New York Heart Association (NYHA) class III HF.

Materials and Methods

Objective. This study was designed to assess the accuracy and reliability

of the CPS in identifying SDB in NYHA class III systolic HF patients when evaluated in different sleep center laboratories with PSG and in the home. The CPS device's ease of use was also determined, using a patient-completed questionnaire.

Materials. The CPS uses multiparameter sensors that include a 2-lead ECG and thoracic impedance sensor applied to the chest. Each sensor transmits physiologic data via a sender device attached to the sensors that transmits wirelessly to a data storage and transfer unit that can fit in the palm of the hand (Figure). A peripheral pulse oximeter is attached to the transmitter for retrieval of pulse oximetry data. After collection, the data

are transferred to and evaluated by a computer system with proprietary data editing, analysis, and presentation software. For this study, both credentialed ECG and sleep technician readers further edited and fully analyzed the CPS data and provided a report that was reviewed and approved by a qualified sleep medicine physician.

The CPS's diagnostic accuracy was compared with attended PSG performed at sleep laboratories. PSG equipment included the ALICE 3 or ALICE 4 (Respironics, Murrysville, PA), Sandman (Mallinckrodt, Phillipsburg, NJ), and Embla (ResMed, Poway, CA) devices. The choice of PSG as the comparator test was based on its widespread use as a benchmark for SDB diagnosis. The potential for investigator- and technology-variable diagnoses was accounted for by standardizing scoring criteria and analysis settings for all sites. PSG scoring was conducted manually by trained and sleep medicine registered polysomnographers.

Patient Population. Fifty subjects identified in outpatient clinics, aged 19–90 years, who were diagnosed with stable NYHA class III systolic HF (left ventricular ejection fraction $\leq 35\%$) at 3 clinics in the United States and 1 clinic in the United Kingdom were enrolled in the SEARCH study. Stable HF was defined as no change of medication (except for diuretic adjustments) for at least 2 weeks before entry, no change of diuretics during the first week, and no anticipated need to change medication during the study period. All subjects provided written informed consent.

Exclusion criteria included the presence of cerebrovascular, neuromuscular, or terminal disease and severe chronic obstructive pulmonary disease (forced expiratory volume in 1 second < 2 L and forced expiratory volume in 1 second/forced vital capacity ratio $< 55\%$). Other exclusion criteria included the presence of a known dermatologic condition or allergy (eg, contact dermatitis, eczema) that might interfere with application of

the sensors or an allergy to medical adhesives. In addition, subjects with a documented myocardial infarction within 6 weeks were excluded. The study conformed to the Declaration of Helsinki and was approved by each local institutional review board.

Methods. At each center, an HF specialist enlisted patients for inclusion in the study. On entry, demographic data including age, gender, race, body weight, height, body mass index, blood pressure, smoking history, concurrent medications, and medical history information were recorded in case report forms. Patients also completed the Epworth Sleepiness Scale, Minnesota Living With Heart Failure, and ClearPath questionnaires, which evaluated daytime sleepiness,²⁷ health-related quality of life specific to HF patients,²⁸ and the ease of use and tolerability of the CPS, respectively.

All subjects underwent 2 overnight testing procedures (sessions I and II) occurring ≤ 3 nights apart. During session I, subjects were tested in the sleep laboratory with simultaneous monitoring by attended PSG and CPS. Session II required a brief presentation at the study site for application of the CPS, followed by testing in the home with instructions to follow the same sleep schedule as in session I. The CPS was applied in the clinic by nurses trained in the application and setup of the CPS system. Subjects were provided instructions on managing the CPS system at home. On awakening, subjects were instructed to remove the system and return all components to the center, either in person or via an overnight carrier.

With PSG testing, total sleep time respiratory disturbance index (TST RDI) is the diagnostic parameter most commonly used to identify SDB and is based on a montage of 11 physiologic parameters including the electroencephalogram, degree of oxygen saturation, and the number of abnormal breathing events. While the CPS does not include electroencephalogram recordings to assess sleep stage, a similar but distinct measure—total

Table I. Baseline Demographics and Patient Characteristics

CHARACTERISTIC	No.	MEAN	SD	RANGE
Sex, M/F	34/16			
Age, y	50	55.5	12.8	23–78
Height, in	50	68.3	3.8	59–76
Weight, lb	50	213.7	49.3	133–366
Body mass index, kg/m ²	50	32.6	6.5	19–48
SBP, mm Hg	50	120	17.9	88–160
DBP, mm Hg	50	73.9	8.7	60–94
Pulse, bpm	50	77.4	15.7	55–111
MLWHF score	50	61.7	21.6	20–102
ESS score	46	10.6	4.4	1–23

M/F indicates male/female; SBP, systolic blood pressure; DBP, diastolic blood pressure; MLWHF, Minnesota Living With Heart Failure (Quality of Life); and ESS, Epworth Sleepiness Scale.

recording time in bed (“lights off to lights on”)—was used as the denominator for calculation of the device-specific RDI (CP RDI). The total number of respiratory events associated with a 3% oxygen desaturation in the cohort was summed, and the CP RDI was calculated by dividing by the number of hours in the total recording time in bed. Also, PSG testing differentially diagnoses an episode of obstructive apnea by an absence of airflow in the presence of rib cage and abdominal excursions for at least 10 seconds, while central apnea was diagnosed by an absence of rib cage and abdominal excursions and the absence of airflow for at least 10 seconds. Although CPS data were evaluated for central and obstructive events, all apnea events were totaled to compare the CPS with PSG and, therefore, the diagnostic accuracy of CPS vs PSG in differentiating central and obstructive events was not analyzed.

PSG data from the 4 study sites were compared with CPS data as evaluated by 3 off-site certified respiratory readers. Data from the CPS were blinded to avoid evaluator bias by eliminating subject identifiers during all readings and assigning new identification numbers for each report. Respiratory events were recognized when oxygen desaturation was $\geq 3\%$. Events were classified as central apnea, obstructive apnea, mixed apnea, obstructive hypopnea, or central hypopnea based on standard criteria.²⁹ When it was not possible to distinguish obstructive

and central hypopneas, the groups were combined and given a value for all hypopneas with and without oxygen desaturation $\geq 3\%$.

ECG abnormalities observed at each session were recorded and tabulated. In addition, any findings indicating intolerance or method hazard were documented under safety assessments. Treatment of adverse events was initiated at the investigator’s discretion. Subjects found to have a TST RDI (by PSG) or CP RDI (by CPS) of ≥ 15 during session I were determined to have clinically significant SDB and were referred for therapy.

Statistical Analyses. Data were tabulated and compared at the 3 thresholds of TST RDI (PSG-based) and CP RDI (CPS-based): ≥ 5 , ≥ 10 , and ≥ 15 events per hour, which correspond with mild, moderate, and severe SDB, respectively. Sensitivity, specificity, positive and negative predictive values, and total predictive accuracy were determined by comparing CPS with PSG at the 3 thresholds. Analysis of covariance (ANCOVA), factored for site and reader and adjusted for RDI, was used to identify any significant site effects. The Pearson coefficient was determined to statistically compare the similarities of the 2 techniques.

Results

Subject Demographics and Baseline Characteristics. A total of 50 subjects entered the study, 39 at the 3 US study

Table II. Predictive Accuracy of CPS for PSG Diagnosis of SDB During Session I Using 4 or 3 Sites (After ANCOVA)

EVENTS/H	FOUR SITES			THREE SITES		
	SENSITIVITY	SPECIFICITY	PREDICTIVE ACCURACY	SENSITIVITY	SPECIFICITY	PREDICTIVE ACCURACY
Five	20/21 (92)	12/23 (52)	32/44 (73)	16/16 (100)	10/14 (71)	26/30 (87)
Ten	15/17 (88)	17/27 (63)	32/44 (73)	13/15 (87)	13/15 (87)	26/30 (87)
Fifteen	8/12 (67)	25/32 (78)	33/44 (75)	7/11 (64)	18/19 (95)	25/30 (83)

Data are presented as the number of patients at each threshold determined by ClearPath System Nx-301 (Nexan Inc, Alpharetta, GA) (CPS)/the number of patients at each threshold determined by polysomnography (PSG), and (percentage). SDB indicates sleep-disordered breathing; ANCOVA, analysis of covariance.

Table III. Arrhythmia Detection With the CPS Monitoring System

ARRHYTHMIAS, No. (%)	SESSION I (N=45)	SESSION II (N=46)
Atrial fibrillation/flutter	6 (13)	4 (9)
Supraventricular tachycardia	3 (7)	1 (2)
Multifocal PVCs	20 (44)	18 (39)
More than 30 PVCs/h	17 (38)	12 (26)
Ventricular couplets	17 (38)	16 (34)
Ventricular bigeminy/trigeminy	8 (18)	10 (22)
Ventricular tachycardia	5 (11)	3 (7)
Sinus pauses	1 (2)	2 (4)
First-degree atrioventricular block	6 (13)	5 (11)
Bundle branch block	3 (7)	3 (7)

CPS indicates ClearPath System Nx-301 (Nexan Inc, Alpharetta, GA); PVC, premature ventricular contraction.

sites and 11 in the United Kingdom (Table I). The group included 44 white, 5 African American, and one Native American subject. The etiology of HF was classified as ischemic (n=23), dilated (n=21), hypertrophic (n=2), and viral (n=1). The baseline characteristics were as expected for this population of subjects with NYHA class III HF (Table I). The mean left ventricular ejection fraction (\pm SD) of 36 patients, as documented over the previous year, was $26.4 \pm 13.5\%$. The 7 UK patients (who were categorized as having mild, moderate, or severe systolic HF) all fell into the moderate category. Symptoms of HF included fatigue (n=37), shortness of breath (n=37), paroxysmal nocturnal dyspnea (n=17), dyspnea on exertion (n=21), angina (n=9), orthopnea (n=2), dizziness (n=1), and lower extremity edema (n=2). The Minnesota Living With Heart Failure Questionnaire score was consistent with an NYHA class III HF population,²⁸ and the Epworth Sleepiness mean score of 10.6 indicat-

ed a population with borderline daytime sleepiness. Baseline medications were typical for NYHA class III HF patients and included diuretics (96% of subjects), β -blockers (76%), angiotensin-converting enzyme inhibitors (64%), and other CV drugs (74%).

Holter monitoring data during the prior year were available for 14 subjects and identified the following arrhythmias: atrial fibrillation/flutter (n=5), multifocal premature ventricular contractions (n=1), bundle branch block (n=4), left anterior fascicular block (n=1), T-wave changes (n=2), voltage criteria for left ventricular hypertrophy (n=1), old anterior myocardial infarction (n=1), and paced beats (n=1).

Forty-nine subjects completed the trial. One subject could not tolerate the PSG equipment during session I and withdrew from the study with no evaluable data.

Comparison of PSG and CPS Data.

To be valid, there had to be comparable data from the PSG and CPS

systems for a minimum of 5 hours and pulse oximetry data for 90%–100% of the session. Valid data were tabulated from a total of 44 of 50 subjects in session I and 47 of 49 subjects in session II. The invalid sessions during the first testing period (session I) resulted from technical errors with CPS (n=3), severe pacemaker interference (n=1), and premature patient withdrawal (n=1). The 2 invalid sessions in session II were due to technical errors.

Sensitivity and Specificity. There was a wide range of RDI measures in session I, from normal (RDI=0) to severe SDB (RDI=92.3). Among the 44 subjects with valid PSG data from session I, 34 (77%) had ≥ 5 events per hour, 29 (66%) had ≥ 10 events per hour, 24 (54%) had ≥ 15 events per hour, and 13 (29%) had ≥ 30 events per hour. The data from the CPS system were compared with the PSG data using the 3 different thresholds for positive and negative outcome, as shown in Table II. Predictive accuracy for the 3 cutoff points ranged from 73% to 75%.

Between-Site Effects. While PSG is the most widely used method for the diagnosis of SDB, there were no completely uniform definitions of events due to differing methodologies and technologies between systems. Therefore, we conducted an ANCOVA analysis, modeled with factors for site and reader plus adjustment for TST RDI, to assess between-site differences. There was a statistically significant difference between one site and the other 3, and reanalysis was conducted with data from the outlier site removed. When the data from the remaining 3 sites

were reanalyzed, the sensitivity and specificity at all 3 event thresholds improved substantially, and predictive accuracy for the 3 cutoff points ranged from 83% to 87% (Table II). The agreement between the CPS and PSG had a Pearson correlation of $r=0.90$.

False-Positive/False-Negative Reports.

During Session I, false-positive and false-negative findings were infrequent and, in many cases, were the result of borderline measures. For instance, 3 of the 4 false positives at the 10 events per hour threshold were borderline, with RDIs of 9.9, 10.3, and 10.8, respectively. Similarly, 3 of 5 incorrect reports at the 15 events per hour threshold were associated with borderline measures of 13.6, 14.3 (false-negative), and 15.5 (false-positive) events per hour.

Session II Analysis. Analysis was performed to compare the CPS sleep laboratory data (session I) and the at-home data (session II) correlated with PSG. Data were available for 42 patients with valid data for both session I and session II. The same RDI event rates were observed for the 3 cutoff points in 69%–80% of sessions between sessions I and II. There was a slightly greater identification of RDI during sleep laboratory testing when compared with the CPS data. When data were tabulated using only subjects from the 3 sites with comparable PSG readings ($n=30$), the 5 events per hour threshold analysis was consistent in detecting 22 (73%) of subjects, and the 10 and 15 events per hour thresholds were in agreement in 24 (80%) and 23 (77%) of subjects, respectively.

Holter ECG Data. ECG monitoring indicated a range of arrhythmias during study sessions I and II. Documented events were similar in sessions I and II and included recordings of multifocal premature ventricular contractions, >30 premature ventricular contractions per hour, ventricular couplets, ventricular bigeminy/trigeminy, and first-degree atrioventricular block that were evident in >10% of subjects

during both sessions (Table III). Other reported arrhythmias included atrial fibrillation/flutter, ventricular tachycardia, supraventricular tachycardia, sinus pauses, ventricular tachycardia, and bundle branch block, all findings typical of this population of NYHA class III HF subjects. There were no obvious differences in event rates between sessions I and II. Of note, more atrial fibrillation and flutter events were recorded as the severity of diagnosed SDB worsened. Using data from session I, atrial fibrillation and flutter was observed in no (0%) subjects with an RDI <5 events per hour, 1 (2%) with RDI ≥ 5 events per hour, 2 (4%) with RDI ≥ 10 events per hour; and 4 (7%) with RDI ≥ 15 events per hour.

ClearPath Questionnaire. The ClearPath Questionnaire evaluated acceptance and clinical utility of the home-based CPS system with a range of questions based on ease of application, ease of removal, comfort, and irritation. Among the 50 subjects questioned, 88% reported no difficulties in applying the sensor or sender (including 18% citing it as very easy and 62% as easy); 86% indicated no difficulties with removing the devices (including 20% reporting it as very easy and 58% as easy); and 86% reported that the system was comfortable to wear (8% very comfortable and 62% comfortable).

A tolerability assessment found that skin irritation (including skin redness) on removal of the system was infrequent, with only 1 subject reporting very red skin after removal of the sensors—56% reported no redness, 20% reported minimal redness, and 16% reported some redness associated with use of the CPS system. Similarly, itching did not cause intolerance to the system, with 78% of subjects reporting no itching from the sensor, 84% reporting no itching from the sender, and 12% and 6%, respectively, indicating some itching that did not necessitate removal of the devices. Detachments were infrequent, with only 2 subjects (4%) reporting partial

detachment of the sensor. A total of 37 of the 50 subjects (74%) preferred home testing to an overnight evaluation in the sleep laboratory.

Discussion

This study demonstrates the utility of a home-based diagnostic system for evaluating HF patients for SDB. It validates, for the first time, a simple and inexpensive approach to screening such patients with accuracy nearly comparable to that seen with PSG. Importantly, the sensitivity of the CPS was very high and the false-negative rate was low, indicating that few HF patients with SDB would be falsely reassured of a negative diagnosis and not referred to the sleep laboratory for confirmation of diagnosis and treatment. Based on the high prevalence of SDB in HF patients, such screening seems warranted. Javaheri and colleagues⁹ reported a prevalence of central sleep apnea of about 40% among 81 ambulatory patients with stable HF due to systolic dysfunction, and Chan and associates³⁰ found that 55% of a population of patients with diastolic HF or isolated diastolic dysfunction alone had significant SDB. Other studies have reported a prevalence of SDB in HF patients of $\approx 40\%$.^{2–11} Recently, the CPS was used to screen consecutive patients seen in an outpatient HF program and successfully identified >40% as having SDB despite receiving optimal medical and device therapy for their HF.¹⁰

SDB may have a profound negative impact on the prognosis of HF patients.^{13,31–33} In HF patients, SDB contributes to the decline in cardiac structure and function that characterizes the disease and to the poor prognosis.³¹ The negative CV impact of SDB in patients with HF is believed to be mediated by hypoxia and hemodynamic alterations during respiratory events. Respiratory events lead to increases in blood pressure, heart rate, and sympathetic activation, resulting in an additional mechanical load placed on an already challenged heart.³² Recurrent episodes of sleep apnea and

hypopnea impair sleep quality and may result in hypoxemia and repeated respiratory effort-related arousals and induce large negative deflections in intrathoracic pressure.^{14,34} Over the long term, this situation can worsen left ventricular function and further increase the risk for CV morbidity and mortality.^{3,35–39} In this regard, SDB therapy has the potential to reduce CV morbidity and mortality associated with HF.^{14,33,40}

The failure to routinely test HF patients for SDB is likely due to multiple factors, including poor physician awareness of the association between HF and SDB, the dissociation between primary care or cardiology practices and sleep centers, the view that SDB therapy is poorly tolerated, the limited accessibility of sleep centers (particularly for high-volume screening), the complexity and demands on both patients and clinicians associated with scheduling and performing overnight SDB testing with PSG, and the high expense of PSG that discourages its use in large-scale screening. Furthermore, PSG is often delayed due to scheduling issues and backlogs at many centers. Timely, routine diagnosis and management of SDB has the potential to benefit HF patients.²¹ This study demonstrates the feasibility of CPS to easily and inexpensively screen and identify SDB in such patients.

Based on the CPS data, the prevalence of SDB was 69% for subjects with ≥ 5 events per hour, which is within a range established by other investigators. As mentioned above, the sensitivity of the CPS at 95% suggests with a high level of confidence that a negative result would not necessitate referral to a sleep laboratory for diagnostic evaluation in most patients. Patients with negative CPS results and ongoing symptoms of SDB could still be referred for sleep laboratory-based PSG testing.

Although accepted as a gold standard, use of PSG as the comparator was complicated by a lack of rigorous evaluation of the most commonly

used methods and systems for evaluating SDB.²⁹ While PSG is the most widely used method for SDB diagnosis, there are varied definitions of events based on differing methodologies and technologies that makes comparison between PSG systems difficult. To limit the differences between the PSG systems, the criteria and methodology of scoring were standardized as far as possible, but significant site-specific differences were apparent by ANCOVA. These could be attributed to technical differences, patient selection, or interpretation subjectivity. We did not attempt to fully control for these potential differences, since the intent was to derive a comparison of CPS and PSG that was relevant to real-world practice. For PSG, various systems and means of interpretation are used in practice, and the CPS proved to be reliable when compared with a number of these systems.

Moreover, with a concordance rate in the range of 73%–80% at the ≥ 5 , ≥ 10 , and ≥ 15 events per hour diagnostic thresholds between sessions I and II, the reliability of the CPS monitoring system appeared to suggest that SDB findings generated in the home setting correspond well with the results expected from PSG performed in a sleep laboratory. Variability between sessions I and II could be explained by expected night-to-night RDI variation, as previously observed with PSG.⁴¹

As added value in this group of patients, the CPS allowed for the documentation of supraventricular and ventricular arrhythmias. This feature is significant since it is well known that patients with HF have a high degree of serious arrhythmias, such as atrial fibrillation, non-sustained and sustained ventricular tachycardia, and sudden death. In this regard, one might hypothesize a connection between SDB and the high incidence of nocturnal sudden death seen in the HF population. The ability to document such arrhythmias at night and in potential association with SDB with CPS may greatly

enhance the diagnosis and management of these disturbances.

Equally compelling was the finding that patient acceptance of the CPS was high. Most patients preferred to be tested at home and reported greater satisfaction with the simplicity, unobtrusiveness, and tolerability of the CPS as compared with in-laboratory PSG. There were few technical problems with the CPS and very few complaints about application, removal difficulty, or discomfort during the test. This is an issue of greater importance since patient reluctance toward PSG testing has been notable, due to reluctance to attend overnight sleep testing in a laboratory and facing other PSG-associated hardships. Thus, CPS acceptance may be an important factor in making sleep testing a useful clinical tool.

There are some limitations of the present work. As previously noted, while PSG was used as the gold standard, different PSG systems were used and there was no core laboratory to analyze all data in a blinded manner. This allowed for differences in PSG analysis and interpretation to occur between sites. Such differences were identified with ANCOVA and caused an underestimation in the accuracy of CPS to reproduce PSG results. The CPS may not fully differentiate central from obstructive apneic events, and this may have important implications for clinical management. Thus, the CPS should be viewed as a screening device and PSG may still be required to prescribe appropriate management to patients.

In summary, quality of life and prognosis for patients with HF may be improved by identification and treatment of SDB. This study describes the diagnostic accuracy of the CPS compared with PSG, demonstrating that CPS screening is accurate and easy to use. With the ability to provide 2-lead ECG, oxyhemoglobin saturation, and thoracic impedance (respiratory) data, the CPS appears to be a useful system for testing patients with HF and, perhaps, other CV diseases.

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CME Questions

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INSTRUCTIONS FOR COMPLETING THIS FORM: Read the selected paper and answer *all* the questions that follow. After each question there is a series of possible correct answers. Please select the one best answer for each and place your selection on the answer grid. **YOU MUST ALSO COMPLETE THE CME EVALUATION SECTION** and return the form within 6 months of the paper's publication to receive credit. Letters of credit will be mailed to participants biannually.

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OBJECTIVE AND TARGET AUDIENCE: All health care practitioners are eligible to receive credit. At the conclusion of this activity, participants should be able to: (1) summarize the important points discussed in the paper reviewed, (2) identify patients to whom the paper is relevant, (3) modify management practices as new information is learned, and (4) identify deficiencies in their knowledge base.

Please Select the One Best Answer for Each and Place Your Selection on the Answer Grid.

1. The Sleep Heart Health Study has determined that there is a relationship between sleep-disordered breathing (SDB) and the development of all of the following except:
 - A. Heart failure
 - B. Pulmonary fibrosis
 - C. Stroke
 - D. Hypertension
2. Correction of SDP in heart failure patients does not improve:
 - A. Right ventricular ejection fraction
 - B. Stroke volume
 - C. End-systolic dimension
 - D. Sleep quality
3. Attended polysomnography:
 - A. Is expensive
 - B. Isn't always available to these patients
 - C. Is disruptive to lifestyle
 - D. All of the above
4. A home-based cardiorespiratory system does not monitor:
 - A. Electrocardiographic data
 - B. Oximetry
 - C. Sleep cycle
 - D. Respiratory impedance
5. Study subjects were excluded if they had:
 - A. Any history of thoracic surgery
 - B. Severe chronic obstructive pulmonary disease
 - C. A history of tobacco use
 - D. Any history of myocardial infarction



CME answers are available on the *Congestive Heart Failure* page at www.lejacq.com

CME Answer Grid

Answer the questions from the previous page by selecting the best choice of A, B, C, or D.

Questions: 1. __ 2. __ 3. __ 4. __ 5. __

CME Evaluation

	Agree			Disagree
1. My knowledge was enhanced by this activity.	1. __	2. __	3. __	4. __ 5. __
2. The activity helped to clarify issues specific to heart failure patients.	1. __	2. __	3. __	4. __ 5. __
3. The information obtained from this exercise will have an impact on my care of patients.	1. __	2. __	3. __	4. __ 5. __
4. The format of the exercise was useful.	1. __	2. __	3. __	4. __ 5. __
5. Suggestions for future topics:				

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