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Original Article

Comparison of in-laboratory and home diagnosis of sleep apnea using a cordless portable acoustic device

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ABSTRACT

Background and Objectives: Sleep apnea (SA) is a common, serious, but underdiagnosed condition. There is a need for more accessible and economic means of diagnosing SA in the home. The aim of this study was to test the validity of a cordless acoustic portable device (BresoDx™) for home diagnosis of SA compared with standard polysomnography (PSG).
Methods: A total of 135 subjects underwent full overnight PSG and simultaneous recording of breath sounds by BresoDx in the sleep laboratory. Acoustic data extracted from BresoDx were analyzed using validated computer acoustic algorithms. The PSG-derived apnea–hypopnea index (AHI-p) and the acoustic AHI (AHI-a) were calculated and compared. A subset of 100 subjects used the device in a subsequent night in their home from which home AHI (AHI-h) was determined.
Results: The correlation between AHI-a and simultaneous AHI-p was 95.2% and diagnostic accuracy of BresoDx ranged between 88.9% and 93.3% around AHI cutoffs of 5–15. In the home, AHI-h did not differ significantly from AHI-p ($p = 0.60$). Using an AHI-p cutoff ≥ 10 BresoDx's accuracy was 81%. Of the 100 subjects, 81 (81%) had low inter-night variability measured by a difference between home AHI-h and PSG AHI-p < 10 event/h, while 19% had higher inter-night variability.
Conclusion: AHI determined using BresoDx was in excellent agreement with simultaneous AHI-p. The majority of patients had a consistent AHI in their subsequent home study with very good overall diagnostic accuracy. We conclude that BresoDx is a reliable device for diagnosing SA that can be used by subjects, unattended in their own homes.

1. Introduction

Sleep apnea (SA) is characterized by recurrent cessation of breathing during sleep. The two main types of SA are obstructive sleep apnea (OSA) and central sleep apnea (CSA). OSA is the most common type and is associated with hypersomnolence that increases the risk of motor vehicle accidents [1]. OSA also increases the risk of developing cardiovascular diseases including hypertension, heart failure, and stroke [2,3], and of death from cardiovascular diseases [4]. Patients with untreated OSA consume twice as many health-care resources for treatment of cardiorespiratory diseases as subjects without OSA [5]. However, treating OSA alleviates hypersomnolence, improves cardiovascular function, and lowers blood pressure in patients with hypertension or heart failure [6–10]. Therefore, widespread diagnosis and treatment of OSA could have a significant beneficial medical and public health impact [11]. Although CSA is far less common than OSA in the general population, in heart failure patients, CSA is common and its prevalence has been reported to be between 15% and 37% [12]. In such patients, CSA is associated with increased mortality [13].

Although SA is common and affects approximately 7% of adults [14,15], the majority of patients (approximately 85%) remain undiagnosed [16], corresponding to approximately 18,000,000 patients in Canada and the US alone. This low rate of diagnosis is partly attributable to the lack of accessibility to polysomnography (PSG), the

Study Location: The work was performed at the Sleep Research Laboratories of the University Health Network Toronto Rehabilitation Institute and Toronto General Hospital Toronto ON Canada.

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standard test for SA diagnosis, which is expensive and inconvenient, because it requires attachment of multiple electrodes as well as overnight monitoring in a sleep laboratory [11]. Therefore, there is an increasing demand for developing reliable yet simple instruments to diagnose SA that are more accessible and less expensive than PSG.

We have developed a new acoustic device for home monitoring of SA, BresoDx™ (previously known as ApneaDx), as a means to increase access to accurate, economical, and timely diagnosis of SA [17,18]. The device consists of an open face frame with an embedded microphone in front of the nose and mouth as demonstrated in Fig. 1. The frequency of apneas and hypopneas per hour (apnea–hypopnea index, AHI) identified by BresoDx has been validated against AHI determined by simultaneous PSG [17]. The latest version of the device has been further developed to become self-contained, battery operated, and with no external wires in order to facilitate the use by patients in their homes without the need for an external power source. Indeed, patients ranked ease of use as "excellent" in a previous study [18]. However, the device has not yet been validated for accuracy in detecting SA in the home settings against in-laboratory PSG. Therefore, the aim of this study was to compare the AHI detected by BresoDx in the home against the AHI measured during in-laboratory PSG as well as simultaneously assessed AHI by BresoDx.

2. Methods

2.1. Subjects

We recruited consecutive subjects at least 18 years of age referred for PSG due to a history suggestive of OSA including at least two of the following symptoms: a history of loud habitual snoring, restless sleep, morning headaches, or excessive daytime sleepiness. Exclusion criteria were breath sound recording using BresoDx <3.5 h or sleep efficiency <30% on the PSG. A subset of those subjects agreed to undergo overnight breath sound recordings in their homes using the BresoDx device.

The protocol was approved by the research ethics board of the University Health Network-Toronto Rehabilitation Institute, and subjects provided written informed consent before participation.

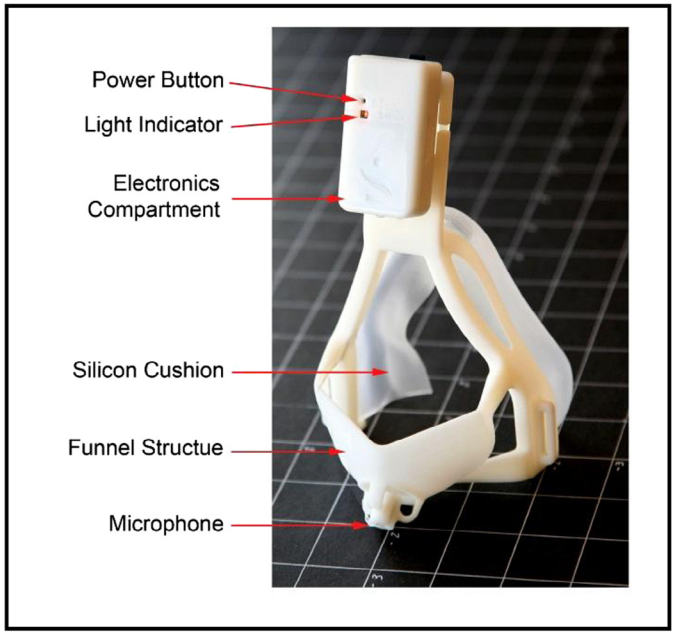

Fig. 1. Illustration of the device used in this study.

2.2. Polysomnography

Subjects initially underwent overnight PSG using standard techniques and scoring criteria for sleep stages and arousals from sleep [19,20]. Thoracoabdominal movements and tidal volume were measured by respiratory inductance plethysmography (Respitrace, Ambulatory Monitoring Inc). Airflow was measured by nasal pressure cannulae (Binaps, Salter Labs) and arterial oxyhemoglobin saturation (SaO_2) by oximetry (Nellcor, N-200 pulse oximeter, Nellcor Inc). PSG signals were recorded on a computerized sleep scoring system (Sandman, Nellcor Puritan Bennett Ltd). Respiratory events were scored according to the 2012 American Academy of Sleep Medicine Criteria [21]. Apnea was defined as a reduction in the respiratory signal, by ≥90% lasting ≥10 s and hypopnea as a reduction by ≥30–90% lasting ≥10 s and accompanied by a ≥ 3% desaturation or an arousal. Obstructive and central apneas and hypopneas were defined as previously described [22].

PSG-derived AHI (AHI-p) was first evaluated according to the recording time (i.e., time in bed) rather than sleep time. This was done to investigate its ability to identify respiratory events regardless of sleep status and to allow comparison with home recordings by BresoDx, which did not measure sleep time. In addition, we compared AHI-a against AHI-p per hour of sleep to investigate the effect of this limitation on its performance.

2.3. Portable breath sound recordings

Breath sounds were captured by BresoDx (BresoTec Inc., Toronto, Ontario, Canada) [17]. It consists of an open lightweight face frame with an embedded electronic module and a microphone as shown in Fig. 1, the technical details of which have been described previously [18]. Breath sounds and airflow from the nose and mouth were stored continuously on an onboard microSD card for up to 8 h. Upon the completion of overnight studies, data stored on the microSD card were transferred to a central server and analyzed using our acoustic analysis algorithms, for determination of the AHI as previously described [17].

2.4. Protocol

During PSG, simultaneous breath sound recordings were made with BresoDx from which the acoustically determined AHI was calculated (AHI-a). After completion of PSG, subjects were offered the opportunity to take the portable device home and perform an overnight recording in their own bed. Those who agreed were given the portable device and an instruction guide on how to wear it, turn it on, and conduct the overnight test unattended in their home. After completing the home test, subjects mailed the device back to the clinic using a prepaid box provided to them. The contents of the microSD card were then downloaded onto a computer, from which the home study AHI (AHI-h) was determined.

2.5. Inter-night variability

The AHI can vary considerably from night to night in any given subject [23,24]. While assessing the performance of BresoDx in the home against PSG, the inter-night variability in AHI should be taken into account. In this study, the AHI was considered to be consistent if it varied by <10 on any 2 nights, and variable if it varied by ≥10 between any 2 nights as previously used in the literature [23].

2.6. Statistical analysis

We assessed the agreement between AHI-a and the simultaneous AHI-p from the PSG by Pearson correlation and Bland-Altman limits of agreement. The receiver operating characteristics curves