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A preliminary study on application of portable monitoring for diagnosis of obstructive sleep apnea

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Abstract

Portable monitoring (PM) for diagnosis of obstructive sleep apnea has developed recently. Many studies were performed in the laboratory setting, with simultaneous polysomnographic recordings or required technical assistance in the home setting. And the data were automatically analyzed. In this study, we attempted to evaluate whether PM could be useful in fully unattended home setting, and whether the auto analysis of the data is reliable. Home setting examination by Stardust II, a novel PM device, was performed unattendedly on consecutive 62 patients who complained of snoring. The questionnaire survey on the difficulty of fitting and operation, and the discomfort was conducted by visual analog scale. Automatically and manually analyzed results were compared. The examination was successfully performed by all subjects. The difficulty of fitting and operation, and the discomfort were 2.9 ± 1.9, 1.8 ± 1.2 and 3.6 ± 2.1, respectively. Auto analysis differed significantly from manual analysis not only in apnea/hypopnea index (AHI), but also in the construction of sleep disordered respiratory events. Although AHI in automatic and manual analysis had a good correlation ($r = 0.949$; $P < 0.001$), their agreement was poor, especially in mild and moderate cases. However, setting AHI = 50 as a cut-off point in auto analysis, sensitivity and specificity could reach 100% and 92.5%, respectively. Accordingly, PM is useful to identify obstructive sleep apnea in an unattended home setting condition. Considering the significant difference between automatic and manual analysis, we suggest that the data analysis should be performed manually.

Keywords: Obstructive sleep apnea; Portable monitoring; Stardust II device; Polysomnography; Diagnostic tests

1. Introduction

Obstructive sleep apnea (OSA) is attacking 2–4% of the middle-aged population [1]. Untreated OSA is an important contributor to many sequential diseases, such as cardiovascular diseases, psychoneural disorders, and so on [2,3]. A qualitative and quantitative examination is the first but the most important step for treatment. Nocturnal polysomnography (PSG) is applied for this purpose and is accepted as the standard for diagnosis of OSA. However, considering the higher prevalence of OSA, laboratory-based and technician-dependent PSG is not feasible for all cases as the first step toward diagnosis.

Many convenient devices were developed for primary screening and diagnosis of OSA [4,5], such as nocturnal oxymeter [6] or other multichannel recording systems [7–13]. Four levels of sleep respiratory examination were described according to the Standards of Practice Committee of the American Sleep Disorders Association (ASDA) in 1994 [14], and modified portable sleep apnea testing was defined as level III. Although this kind of device cannot detect sleep stage as standard PSG can, it is able to distinguish disordered respiratory pattern and assess the

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severity of OSA by apnea/ hypopnea index (AHI), which makes it much available than nocturnal oxymeter [14]. Recently, level III devices were developed [15,16–18]. Evaluation and guideline for the application of portable monitoring (PM) were renewed lastly in 2004 by the American Thoracic Society (ATS), the American College of Chest Physicians (ACCP) and the American Academy of Sleep Medicine (AASM) [19].

Type 3 portable monitoring, defined as the level III testing by ASDA in 1994, was applied in the laboratory setting or required technical assistance in the home setting [10–12,16]. Meanwhile, some of the studies directly used automatic analyzed results [10–12,16–18], without knowing how much difference there is between auto and manual analysis. In order to make the best use of the type 3 device we attempted to evaluate if it could be useful in the situation of unattended home setting, and if the automatic analysis of data is reliable. Stardust II (Respironics Inc., USA), a novel kind of type 3 PM device, was employed in this study.

2. Materials and methods

2.1. Subjects

Sixty two patients (45 males and 17 females) complained of snoring were enrolled in this study consecutively from April to September of 2003. The age ranged from 2 to 85 years (45.6 ± 18.2 years, mean $\pm$ S.D.). Body mass index (BMI) varied within 13.0–42.7 kg/m^2 (26.1 ± 6.4 kg/m^2).

2.2. Device setting

An unattended home setting examination by Stardust II was performed consecutively as the first step towards diagnosis. Stardust II device detects oronasal airflow and snoring signals by a pressure sensor simultaneously. Ribcage or abdominal movement is measured by inductance plethysmography through a belt around the chest or abdomen. Arterial oxygen saturation and pulse rate are measured by an attached pulse oxymeter. Body position is detected by the device itself. There is another channel for input of continuous positive airway pressure or for real time output.

The device was lent to the patients after a thorough explanation of usage so that a quality home setting examination could be conducted well by the patients themselves. Patients were asked to fit the apparatus before going to bed. The record of data began from when patients were ready to sleep till right after they woke up in the next morning. When waking up during the monitoring, such as for toilet, and when ready for sleep again, the patients were asked to press a button in the device to signal the time of awaking.

The device was collected the next day, and then questionnaire survey of visual analog scale (VAS) was given to adult subjects on difficulty of fitting, difficulty of operation, and discomfort of usage.

2.3. Data analysis

Automatic and manual analysis of the data recorded by Stardust II was compared. Apnea/hypopnea event was scored after the criteria of AASM [20]. Apnea was defined as reduction of airflow >80% for 10 s or longer. Hypopnea (H) was considered as reduction of airflow >50% or clear amplitude reduction with an oxygen desaturation of $\geq$3%, for 10 s or longer. AHI was calculated based on time in bed (TIB). Statistical analysis was conducted using a SPSS10.0J. Bland and Altman Plot [21] was applied for agreement checking.

3. Results

3.1. VAS survey, record time and sleep position

The examination was successfully conducted in unattended home setting by all patients. The difficulty of fitting and operation, and the discomfort of usage by VAS were 2.9 ± 1.9, 1.8 ± 1.2 and 3.6 ± 2.1, respectively.

Record time of TIB ranged from 151 to 546 min (428.0 ± 88.7 min). Supine TIB was much less than no-supine TIB in most of the subjects (71.0%; $P < 0.05$; U-test) with mean of the supine TIB percentage was 40.1 ± 24.8%.

3.2. Difference in event scores between auto and manual analysis

Automatic analysis over-scored disordered events in comparison with manual analysis (Table 1). The mean difference was 73.3 ± 55.3 events ($P < 0.001$; t-test). In details, overscore of central apnea (CA), mixed apnea (MA) and hypopnea, and underestimation of obstructive apnea (OA) were recognized in auto analysis ($P < 0.001$; t-test). However, no difference was found for the total apnea events between two analysis methods ($P > 0.05$; t-test). Furthermore, the proportion of CA, MA, OA and H differed significantly ($P < 0.001$; t-test), and so did their constituent ratio ($P < 0.005$; χ^2-test).

3.3. Correlation and discrepancy of AHI between auto and manual analysis

Significantly higher AHI and hypopnea index (HI) were suggested ($P < 0.001$; t-test) in auto analysis. Apnea index (AI) differed little between two analysis methods, as the total apnea events were rightly counted.

Fig. 1 illustrated that the manual AHI (mAHI) and auto AHI (aAHI) were highly correlated ($r = 0.949$; $P < 0.001$). The correlationship was also considered high between auto