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A wrist-worn oximetry in the detection of obstructive sleep apnea in stroke patients

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Abstract

Objective: To assess the accuracy of a Dehaier wrist pulse oximeter DHR998 Plus to detect obstructive sleep apnea (OSA) in stroke patients. *Methods:* One hundred and fifty-one ischemic stroke patients simultaneously completed a standard polysomnogram (PSG) and wore the Dehaier wrist pulse oximeter DHR998 Plus and another finger-worn oximetry Pulsox-300i during a nocturnal recording. PSG sleep and apnea-hypopnea index (AHI) were scored according to AASM criteria. Dehaier wrist pulse oximeter DHR998 Plus and Pulsox-300i data were analyzed with an automated computerized algorithm which calculated the amount of oxygen desaturation events with a 4% decline from baseline lasting more than 3 seconds per hour. This yielded an oxygen desaturation index 4% (ODI4). Agreement analysis and receiver operator characteristic curve analysis were used to measure the diagnostic reliability of Dehaier wrist pulse oximeter DHR998 Plus compared with AHI and Plusox-300i. *Results:* Among the 151 patients, 14 cases were without OSA (AHI<5), 25 cases were diagnosed with mild OSA (AHI:5-14.9), 29 cases were diagnosed with moderate OSA (AHI:15-29.9) and 83 cases were diagnosed with severe OSA (AHI≥30). There was a significant correlation between Dehaier wrist pulse oximeter DHR998 Plus derived ODI4 and AHI (r=0.74, P<0.01). The agreement between Dehaier wrist pulse oximeter DHR998 Plus derived ODI4 and Pulsox-300i derived ODI4 was moderately good, with interclass correlation coefficient (ICC) values of 0.83 (95% CI, 0.78-0.88, P<0.01). To assess sensitivity and specificity of Dehaier wrist pulse oximeter DHR998 Plus, we constructed receiver operator characteristic curve by various AHI threshold values (5, 15, 20 and 30). Optimal combinations of sensitivity and specificity for the various thresholds were 0.88/0.71, 0.88/0.69, 0.93/0.65, 0.74/0.9, respectively.
Conclusions: Wrist-worn Dehaier wrist pulse oximeter DHR998 Plus can detect OSA with reasonable reliability as Gravel V2, especially for severe OSA in stroke patients.

Keywords: Obstructive sleep apnea, stroke, oximeter, polysomnography

INTRODUCTION

Obstructive sleep apnea (OSA) is a common disorder with a prevalence ranging from 5% to 15% among the general population.[1,2] It has been demonstrated that OSA is associated with obesity, fatigue, high blood pressure, diabetes.[3,4] It has been widely accepted that OSA is an independent risk factor for cardiovascular and stroke, current guidelines have emphasized the potential benefits of screening for OSA.[5] The gold standard for the diagnosis of OSA is attended laboratory PSG. However, the complex screening method, considerable burden of cost and long waiting lists from PSG generates a barrier for physicians to detect OSA. As a result, OSA remains unrecognized and underdiagnosed.[6]

It is commonly assumed that new cost-effective technologies might have the potential effectiveness in diagnosis OSA. The utility of portable monitoring devices has increased for detecting OSA. Utility of a device based on photo-plethysmography (PPG) to detect OSA is attractive. It is convenient and simple for in-laboratory study and especially for home sleep test (HST). What's more, the device's relative low cost can promote a more widespread application, improving the detection rate of potential OSA.[7] However, the traditional PPG based device is finger-worn pulse oximetry and the utility of this oximetry is limited due to the finger-worn probe.

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Other probes, such as wrist, forehead and ankle, has also been invested, but literature about these techniques in detection of OSA is limited.

In this study, we evaluated a wrist-worn oximetry (Dehaier wrist pulse oximeter DHR998 Plus) for the diagnosis of OSA in stroke patients undergoing standard PSG. We also compared this wrist-worn oximetry with the traditional finger-worn oximetry in the detection of OSA according to the 2007 AASM criteria.[8]

METHODS

Participations

A total of 151 ischemic stroke patients were recruited from Sleep Medicine Center of Qinhuangdao Harbor Hospital between March 2022 and November 2022. Individuals who were using home oxygen, medically unstable were not eligible to participate. Additionally, we excluded patients who had congestive heart failure, intrinsic pulmonary diseases, drug dependence, alcoholism, severe psychiatric disturbance, chronic kidney disease, pregnancy and those undergoing steroid or hormone-replacement therapy. Patients with sleep disorders other than OSA, such as narcolepsy, restless leg syndrome or upper airway resistance, were also excluded. All participants were asked to complete a uniform questionnaire containing questions regarding histories of current and previous illness and medical treatments. The Epworth Sleepiness Scale (ESS) questionnaire was completed before the subject underwent nocturnal polysomnography (PSG).

Data collection

All subjects completed a standard full overnight PSG by the Respironics Grael V2 Physiological Monitoring System (Grael V2, Compumedics, AUS). According to the American Academy of Sleep Medicine guidelines, the standard electroencephalogram derivations (EEG: from frontal, central, occipital regions: F4/M1, C4/M1, O2/M1 and back-up derivations: F3/M2, C3/M2 and O1/M2), chin electromyogram (EMG: located in the three chin electrodes and the middle of the right anterior tibialis), electro-oculogram (EOG: located in the cornea and retina) and electrocardiogram was recorded. The oral and nasal airflow, snoring, chest and abdominal breathing, oxygen saturation and body position were also recorded, along with total sleep time, sleep latency, sleep efficiency, arousal and respiratory events. According to the American Academy of Sleep Medicine manual, an obstructive apnea was defined as a reduction in airflow ≥ 90% lasting at least 10 seconds and associated with persistent respiratory effort; hypopnea was defined as a reduction in airflow ≥ 30% lasting at least 10 seconds and accompanied by a 4% or greater oxygen desaturation.[9] The AHI was calculated as the average of the total number of apnea and hypopnea events experienced per hour of sleep. The diagnosis of OSA was confirmed if the AHI was greater than 5 events/h and the severity of OSA was defined as mild, moderate and severe with an AHI greater than 5/h, 15/h and 30/h, respectively.

All subjects simultaneously wore a wrist-worn oximeter, the Dehaier wrist pulse oximeter DHR998 Plus (Beijing dehaier medical treatment technology co.,ltd) during the night. Dehaier wrist pulse oximeter DHR998 Plus utilizes a simple noninvasive wrist probe to obtain photo-plethysmography (PPG) signals. PPG can detect blood volume changes in the microvascular bed of the tissue. Proprietary software was used to analyze the PPG for baseline variations, envelope and rate.[10] Then a PPG derived respiration (PDR) waveform was generated. PDR amplitude changes are processed to produce an oxygen desaturation index, which are thought to be related with clinical AHI.[11] The oxygen desaturation index (ODI) includes three components, which are threshold, baseline and lasting time.[12] For threshold, the amount of oxygen desaturation decreased from the baseline was calculated. In this study, we used a 4% reduction in oxygen saturation to define the threshold in the analysis of Dehaier wrist pulse oximeter DHR998 Plus data(2007 AASM criteria). As for baseline, two different baselines, including the mean of all night oxygen and the mean of the top 20% of oxygen saturation over the 1 minute preceding the scanned oxygen saturation were adopted.[13,14] The lasting time was defined as an oxygen desaturation event lasting for at least 3 seconds. Finally, the ODI was computed by dividing the total oxygen desaturation counts with the total recording time (hours). We calculated the amount of oxygen desaturation events with a 4% decline from two kinds of baselines discussed above continuing more than 3 seconds per hour in the analysis of Dehaier wrist pulse oximeter DHR998 Plus data, which is presented as ODI4_C in the following.

We also used Pulsox-300i (KONICA MINOLTA, INC), which finger probe was used to obtain PPG based sleep oxygen saturation information. These data are also analyzed with

a computerized algorithm to generate clinically relevant respiratory wave-forms. Just as the analysis of Dehaier wrist pulse oximeter DHR998 Plus data, we also used a 4% oxygen desaturation index (presented as ODI4_P) to define respiratory events in the analysis of Pulsox-300i data.

Statistical analysis

The PSG was considered the gold standard for identifying and quantifying OSA. Descriptive statistics for continuous data are presented as means and standard deviations (normally distributed data) or median and 25-75 interquartile range (non-normally distributed data) as appropriate. Categorical data are presented as counts or percentage. The diagnosis and severity of OSA was defined by PSG derived AHI against thresholds of 5, 15 and 30 events/h. The utility of the Dehaier wrist pulse oximeter DHR998 Plus in detecting OSA was assessed in these ways, including evaluations for agreement with PSG and Pulsox-300i, receiver operator curve (ROC) analysis compared with Pulsox-300i. Sensitivity, specificity, positive and negative predictive value, area under the ROC and the cut-off values was computed for both Dehaier wrist pulse oximeter DHR998 Plus and Pulsox-300ito detect OSA based on different AHI thresholds. ROC statistical analysis and Pearson's coefficient was performed with R (http://www.R-project.org) and Empower-Stats software (www.empowerstats.com, X&Y solutions, Inc., Boston, MA, USA). The agreement and Bland-Altman diagram were plotted with MedCalc (MedCalc Software, Ostend, Belgium).

Table 1: Summary of patient characteristics

Patient characteristics	
Male/Female	113/38
Age (years)	51.7 (14.1)
BMI (kg/ m^2)	27.8 (4.7)
ESS	10 (6, 15)
AHI (events/h)	36 (14.9, 60.8)
cohort (n)	151
No OSA	14
Mild OSA	25
Moderate OSA	29
Severe OSA	83
High blood pressure (%)	52.3%
Diabetes (%)	17.7%

Data are presented as percentage or counts of cohort, mean (SD) for normally distributed data or median (interquartile range [25%-75%]) for non-normally distributed data. AHI, apnea-hypopnea index; BMI, body mass index; ESS, Epworth Sleepiness Scale; OSA, obstructive sleep apnea.

RESULTS

The clinical demographic of the patients are shown in Table 1. All the 151 patients successfully completed the nocturnal PSG, a real-time Dehaier wrist pulse oximeter DHR998 Plus and Pulsox-300i study (total recording time≥ 2 hours). Because 4 patients failed the Pulsox-300i study during the nocturnal PSG, the comparison of ODI4_C and ODI4_P was carried out in the other 147 patients in whom full-night PSG were available.

There was a significant correlation between AHI and ODI4_C (Pearson's coefficient= 0.74, P<0.01). Linear regression equation relating ODI4_C (X) and AHI (Y) was Y=0.85X+12.58 (R2=0.54, P<0.01, Figure 1A). There was also a significant correlation between AHI and ODI4_P (Pearson's coefficient=0.78, P<0.01). Linear regression equation relating ODI4_P (X) and AHI (Y) was Y=0.91X+18.75 (R2=0.61, P<0.01, Figure 1B). The concordance correlation coefficient between AHI and ODI4_C was 0.69 (95% CI, 0.61-0.77, P<0.01). The scatter diagram for AHI and ODI4_C in different stages of OSA was shown in Figure 2A. The concordance correlation coefficient between AHI and ODI4_P was 0.64 (95% CI, 0.56-0.71, P<0.01). The scatter diagram for AHI and ODI4_P in different stages of OSA was shown in Figure 2B. The agreement between ODI4_C and ODI4_P was moderately good, with interclass correlation coefficient (ICC) values of 0.83 (95% CI, 0.78-0.88, P<0.01). The Bland-Altman plot (Figure 3) showed good agreement between the C+ Wearable oximeter and Pulsox-300iestimated ODI in different stages of OSA, with most estimates falling within 2 standard deviations of the mean.

ROC analysis was used to assess the sensitivity and specificity of Dehaier wrist pulse oximeter DHR998 Plus in different thresholds of AHI (Figure 4). Sensitivity, specificity, positive and negative predictive value, area under the ROC and the cut-off values for both Dehaier wrist pulse oximeter DHR998 Plus and Pulsox-300iin different AHI thresholds were shown in Table 2.

DISCUSSION

In this study, we assessed the reliability of a wrist-worn device based on PPG to detect respiratory events during nocturnal sleep. We indicated that

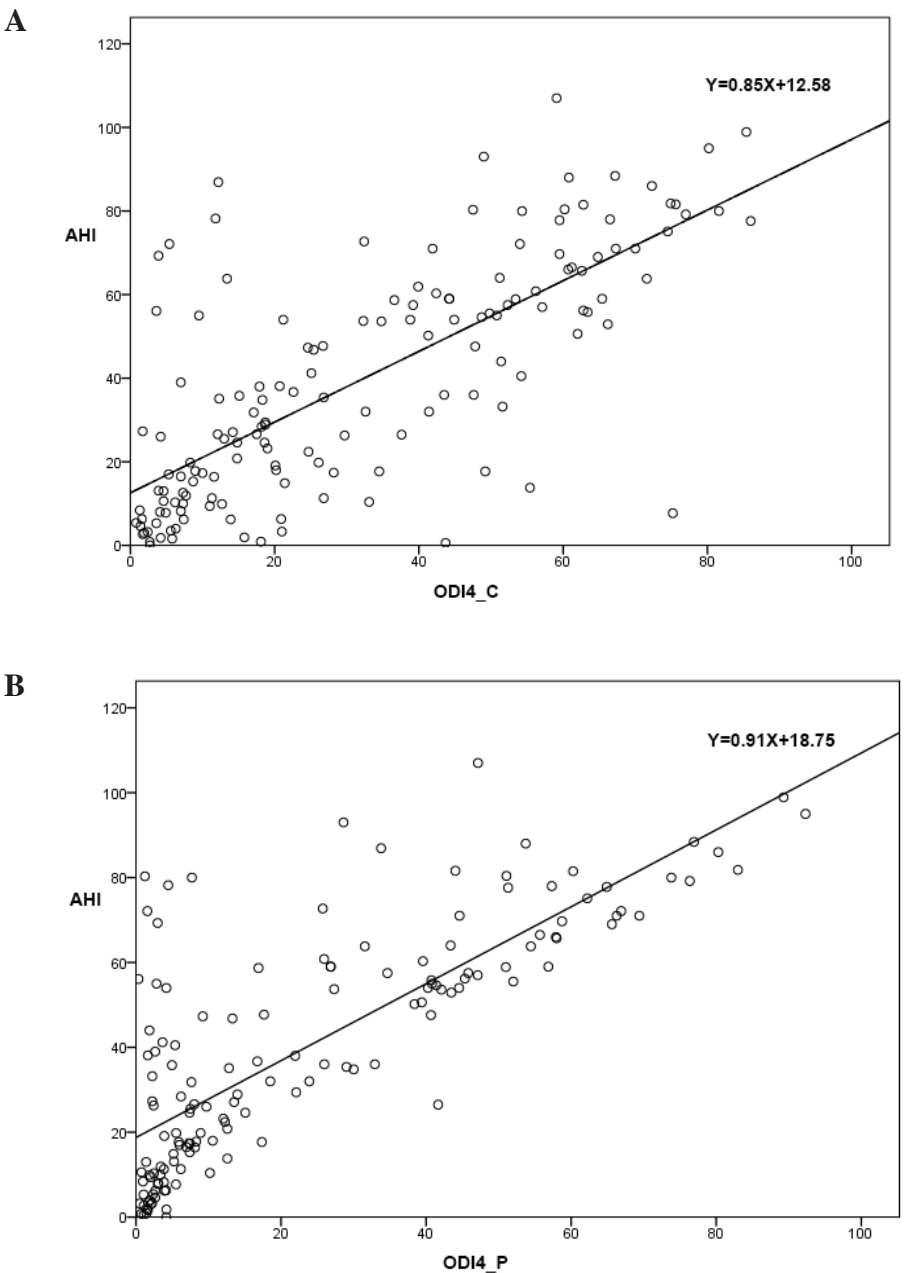

Figure 1. Linear regression result about association between ODI4_C and AHI (Figure 1A). Linear regression result about association between ODI4_P and AHI (Figure 1B).

the Dehaier wrist pulse oximeter DHR998 Plus derived ODI4_C is significantly correlated with the AHI measured by PSG. In addition, comparing with another pulse oximetry devicesPulsox-300i, we found the agreement between Dehaier wrist pulse oximeter DHR998 Plus and Pulsox-300i was moderately good. Sensitivity, specificity, positive and negative predictive value suggested that both the Dehaier wrist pulse oximeter DHR998 Plus and Pulsox-300i could be successful in detecting nocturnal sleep respiratory events, and the difference was not statistically significant.

Different probes were used in different pulse oximetry. In our study, a reflection probe was used in Dehaier wrist pulse oximeter DHR998 Plus and a transmission finger probe was used in Pulsox-300i. Although finger probes are reported more accurate[15], the reflection probe can be invested more widely in wrist, forehead or ankle, and it is more comfortable to wear the

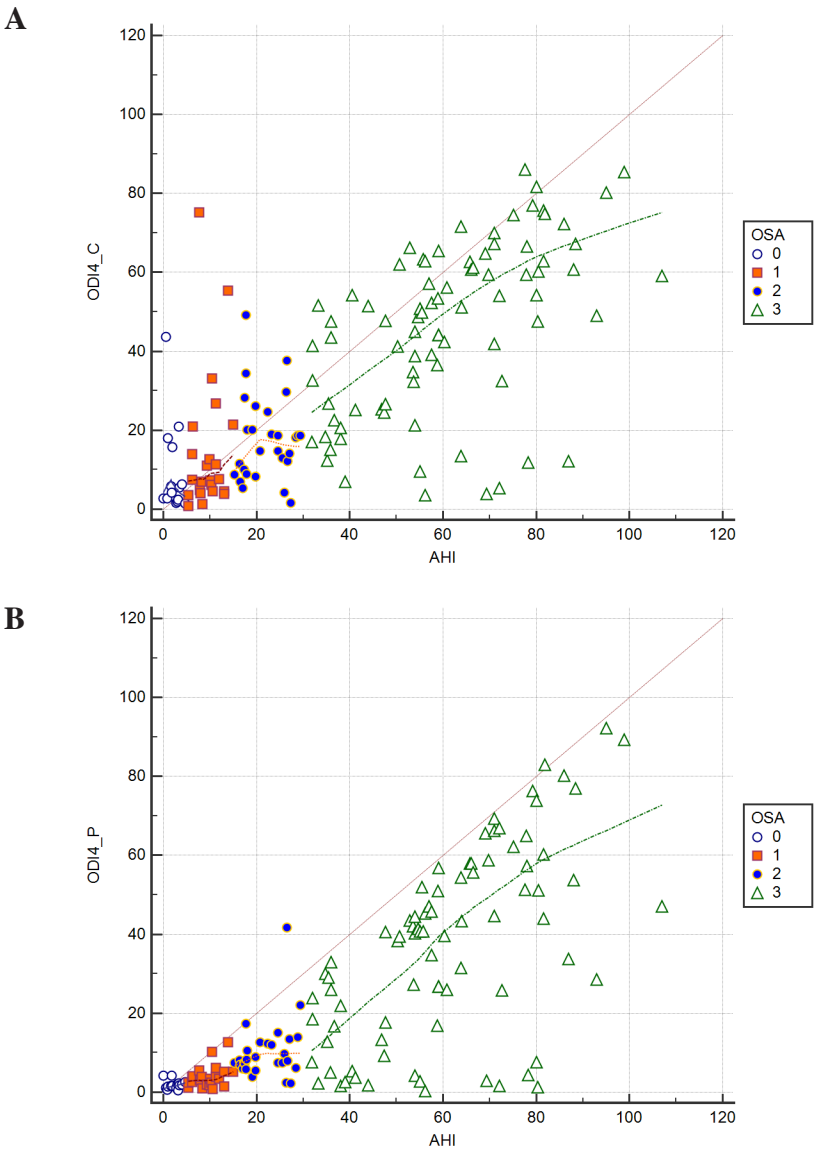

Figure 2. The scatter diagram for AHI and ODI4_C in different stages of OSA was shown in Figure 2A. The concordance correlation coefficient between AHI and ODI4_P was 0.64 (95% CI, 0.56-0.71, P<0.01). The scatter diagram for AHI and ODI4_P in different stages of OSA was shown in Figure 2B. The agreement between ODI4_C and ODI4_P was 0.83 (95% CI, 0.78-0.88, P<0.01).

wrist probe than the finger probe, especially for the HST patients. Considering the accuracy of the PPG signal obtained in wrist probe, we presented an adaptive filtering algorithm in the analysis of Dehaier wrist pulse oximeter DHR998 Plus data to improve the signal to noise ratio (SNR) and reduce the motion artifacts.[16] A calibration curve suitable for Dehaier wrist pulse oximeter DHR998 Plus was also constructed to ensure the accuracy and reliability of testing data.

The correlation between ODI4_C and AHI was 0.74, which is very similar to the correlation found in Romem *et al*.[11] Considering the relative weak concordance correlation coefficient between AHI and ODI4_C (0.69), it is speculated a low agreement between PSG-AHI and Dehaier wrist pulse oximeter DHR998 Plus -ODI4_C. What's more, the Dehaier wrist pulse oximeter DHR998 Plus tended to underestimate AHI according to the linear regression equation (AHI = 0.85ODI4_C + 12.58, Figure 1A). However, the same low agreement between AHI and Pulsox-300i-ODI4_P was found (concordance correlation coefficient = 0.64), and Pulsox-300i also underestimated AHI according to the linear regression equation (Figure 2A). Underestimation for AHI in the

Table 2: The efficiency for detecting OSA with C+ Wearable oximeter and Pulsox-300i (n=147)

AHI cut point	C+ Wearable oximeter	Pulsox-300i	P value
AHI=5			
AUC (95%CI)	0.84 (0.74, 0.94)	0.92 (0.87, 0.97)	0.21
Cut-off	6.65	4.32	
Sensitivity	0.88	0.77	
Specificity	0.71	1	
PPV	0.97	1	
NPV	0.38	0.31	
AHI=15			
AUC	0.85 (0.77, 0.92)	0.92 (0.87, 0.96)	0.05
Cut-off	11.45	5.53	
Sensitivity	0.88	0.85	
Specificity	0.69	0.92	
PPV	0.89	0.97	
NPV	0.68	0.67	
AHI=20			
AUC (95%CI)	0.85 (0.78, 0.91)	0.88 (0.83, 0.93)	0.24
Cut-off	11.7	11.3	
Sensitivity	0.93	0.75	
Specificity	0.65	0.96	
PPV	0.84	0.97	
NPV	0.83	0.67	
AHI=30			
AUC (95%CI)	0.88 (0.82, 0.93)	0.87 (0.87, 0.93)	0.76
Cut-off	31	15.9	
Sensitivity	0.74	0.77	
Specificity	0.9	0.95	
PPV	0.9	0.95	
NPV	0.74	0.77	

AHI, apnea-hypopnea index; AUC, area under the ROC curve; PPV, positive predictive value; NPV, negative predictive value.

utility of ODI has been reported in many previous studies.[11,12,17] The explanation for this underestimation is the sleep time and total recording time, in which sleep time is invested in the calculation of AHI and total recoding time is invested in the calculation of ODI. For patients with OSA, sleep time is less than total recoding time because of frequent apnea or hypopnea, especially for severe patients. In accordance with previous reports, in our results, the underestimation was more obvious in severe OSA patients than that in mild and moderate patients, and the underestimation seemed to be more obvious by detection of Pulsox-300i than Dehaier wrist pulse oximeter DHR998 Plus among severe OSA cases. There was a tendency of overestimation of AHI among mild and moderate patients by utility of Dehaier wrist pulse oximeter DHR998 Plus (Figure 2A), which was not detected in the results of Pulsox-300i (Figure 2B). This may contribute to the algorithm in the analysis of ODI or the sample size.

ROC was determined for 4 different AHI thresholds (AHI≥5 events/h, AHI≥15 events/h,AHI≥20 events/h and AHI≥30 events/h) between C+ Wearable oximeter and Pulsox-300i. There were no significant differences in both oximetry to detect OSA, as referred to the AUC (Table 2). Whether defining OSA as AHI ≥5 events/h and AHI≥15 events/h or using a

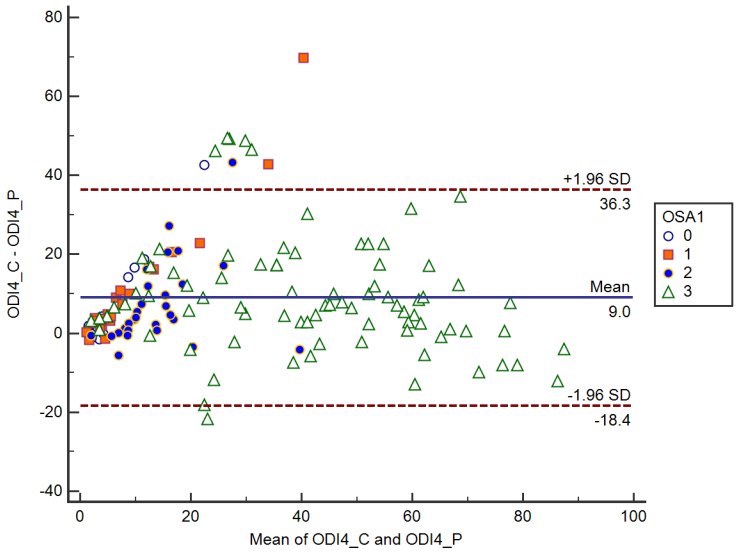

Figure 3. The Bland-Altman plot showed good agreement between the C+ Wearable oximeter and Pulsox-300i estimated ODI in different stages of OSA.

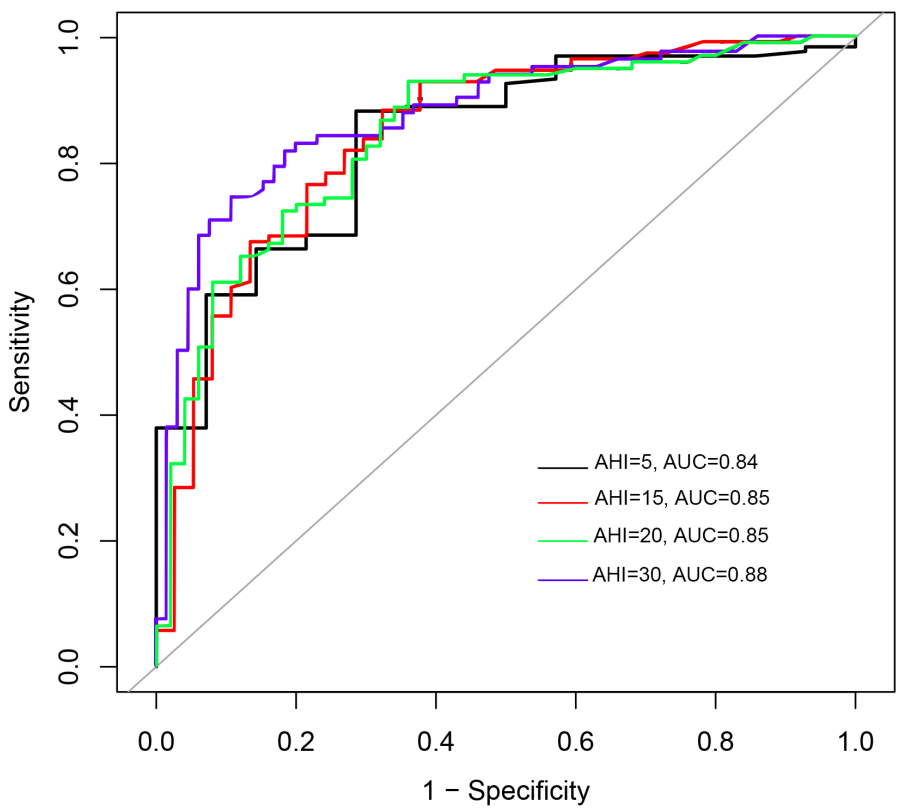

Figure 4. ROC analysis showed the sensitivity and specificity of Dehaier wrist pulse oximeter DHR998 Plusin different thresholds of AHI

higher threshold (AHI≥20 events/h and AHI≥30 events/h), we found a high degree of accuracy by Dehaier wrist pulse oximeter DHR998 Plus, as illustrated by the ROC AUC of 0.84, 0.85, 0.85 and 0.88, respectively. Furthermore, we found a high sensitivity (0.93) at the threshold of AHI≥20 events/h and a high specificity (0.9) at the threshold of AHI≥30 events/h by C+ Wearable oximeter in detecting OSA, which indicated the Dehaier wrist pulse oximeter DHR998 Plus could be more effective to the severe OSA patients.

The limitation of oximetry measurement is that it is unable to score sleep quality.18 Moreover, the device's monitoring effectiveness for sleep apnea and hypopnea is compromised by the absence of detection for oral and nasal airflow. Also, validation study for this device should be performed. The main advantage of using the oximetry is its great sensitivity or specificity in the diagnosis of severe OSA patients with cheaper price compared to PSG. The limitations of the study also include the limited number of subjects and lack of comparison PPG with PSG oxygen saturation measurement. Simultaneous PSG derived ODI 4% should be compared with PPG to address this issue in further research. This study focused on a cohort attending a sleep specialty clinic, thereby resulting in a selected cohort of patients with a higher predictive value for OSA. Investigation of oximetry among suspected subjects to screen OSA is suggested by the AASM guidelines for the utility of portable monitors. PPG based oximetry had similar performance compared with other portable monitoring devices.[19]

In conclusion, a wrist-worn single channel PPG based sleep monitoring device, compares favorably with simultaneous PSG and another finger-worn oximetry in the detection of OSA. This wrist-worn oximetry reveals favorable diagnostic reliability especially for severe OSA patients. Although the requirement for portable monitors in the diagnosis of OSA is at least three channels according to the AASM guidelines[19], our results indicate that single channel could also show a meaningful prediction in stroke patients. More studies are needed to certify its accuracy among OSA patients with complex comorbidities, including cardiovascular disorders, pulmonary diseases and so on. Future studies should focus on HST utility of the device and the improvement of diagnostic accuracy.

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