

# A Single-Center Validation of the Accuracy of a Photoplethysmography-Based Smartwatch for Screening Obstructive Sleep Apnea

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**Background:** Obstructive sleep apnea (OSA), the most common upper-airway disease, is closely associated with the risk of cardiovascular diseases. However, the early screening of OSA is a main challenge, relying on polysomnography (PSG) or home sleep apnea test (HSAT) in hospitals. Photoplethysmography (PPG) has been developed as a novel technology for screening of OSA, while the validation of PPG-based smart devices is limited compared to that for PSG or HSAT devices.

**Objective:** This study aimed to investigate the feasibility and validity of a PPG-based smartwatch in the screening of OSA.

**Methods:** A total of 119 patients were recruited from the Chinese People's Liberty Army General Hospital (Beijing, China). Among them, 20 patients were assessed for a whole-night sleep study by a smartwatch and PSG simultaneously, as well as 82 cases by a smartwatch and HSAT simultaneously. Using PSG or HSAT as the "gold standard", we compared the accuracy, sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV), and positive likelihood ratio (+LR) or negative likelihood ratio (-LR) at three apnea hypopnea index (AHI) levels: AHI $\geq$ 5, AHI $\geq$ 15, and AHI $\geq$ 30.

**Results:** A total of 17/119 patients were excluded from the study due to the poor quality of PPG signals. Among the remaining cases, 83 patients were diagnosed with OSA. Compared to HSAT device, the accuracy, sensitivity, and specificity of the PPG-based smartwatch in predicting moderate-to-severe OSA patients (AHI $\geq$ 15) were 87.9%, 89.7%, and 86.0%, respectively. Compared to PSG device, the accuracy, sensitivity, and specificity of the PPG-based smartwatch in predicting OSA in patients (AHI $\geq$ 5) were 81.1%, 76.5%, and 100%, respectively.

**Conclusion:** The PPG-based smartwatch outperformed in terms of detecting OSA; nevertheless, validation in a large-scale population is imperative.

**Trial Registration:** Chinese Clinical Trial Registry of the International Clinical Trials Registry Platform of the World Health Organization ChiCTR-OOC-17014138; <http://www.chictr.org.cn/showproj.aspx?proj=24191>.

**Keywords:** obstructive sleep apnea, photoplethysmography, polysomnography, home sleep apnea test, pulse oximeter, sleep

## Introduction

Sleep apnea-hypopnea syndrome (SAS) is one of the most common sleep-disordered breathing (SDB). Among different types of SAS, obstructive sleep apnea (OSA) is highly prevalent among all age-based groups of adults. Based on the literature,<sup>1</sup> China has the largest number of OSA patients, approximately 175 million, accounting for 23.6% of the investigated individuals (range of age,

30–69 years old). As the population of overweight or obese people, as well as aging individuals, is increasing, the prevalence of OSA is expected to increase accordingly. The main clinical features of OSA are snoring, morning headache, excessive daytime sleepiness, and memory loss. OSA may also lead to several commodities, such as cardiovascular diseases (CVDs) and diabetes mellitus.<sup>2</sup> Epidemiological studies have shown that OSA is an independent risk factor of CVDs, including hypertension, coronary artery disease, arrhythmias, heart failure, and stroke.<sup>3</sup> Considering the prevalence and negative influences of CVDs on the Chinese population,<sup>4</sup> it could be speculated that OSA imposes a heavy national socioeconomic burden.

However, due to the lack of awareness, the majority of patients in China do not refer to hospitals until the appearance of severe complications of OSA. Moreover, the standard diagnosis requires clinical examinations, such as polysomnography (PSG) or home sleep apnea test (HSAT).<sup>5</sup> Nevertheless, these methods are time-consuming, expensive, and labor-intensive, requiring to be performed in hospitals overnight by certified technicians. Therefore, nearly 90% of patients must wait for a prolonged period for the tests, leading to a delayed diagnosis in a large population.

Recently, smart wearable devices have facilitated the monitoring of wearers' health status optimally. Among them, the accurate detection of pulse rate variability (PRV) and blood oxygen saturation by photoplethysmography (PPG) provides a novel tool for the ambulatory screening of OSA.<sup>6,7</sup> The PPG measures the attenuated light reflected or absorbed by human blood vessels and tissues. Thus, the pulsating state of blood vessels and pulse wave can be recorded. Furthermore, conventional pulse oximeters use two LEDs at different wavelengths and a photodiode to estimate blood oxygen saturation noninvasively, based on the difference in absorption coefficients between hemoglobin and deoxyhemoglobin. At present, PPG is an uncomplicated and inexpensive optical measurement method that is used in numerous devices (eg, smartwatches and phones). Several studies have reported promising results in the diagnosing of sleep-related respiratory disorders as follows: 1) Using the respiratory signals, major records that can reflect sleep duration and wakefulness, such as electrocardiogram (ECG) data,<sup>8</sup> are extracted to provide a comprehensive sleep respiratory status. 2) Medical devices based on PPG technology are extensively utilized. According to the respiration or PRV

signals (oral/nasal airflow or respiratory inductive plethysmography), the respiratory events could be assessed.<sup>9–12</sup>

The smartwatch GT2 (HUAWEI Device Co., Ltd., Shenzhen, China)<sup>13</sup> is a wearable device composed of seven sensors, including an accelerometer, a gyroscope, a geomagnetic sensor, an optical pulse rate sensor, an ambient light sensor, an air pressure sensor, and a capacitive sensor. PPG signals, based on the data of optical heart rate sensor and wrist pulse oximeter, are transmitted via the Bluetooth technology to a smartphone serving as a temporary data storage device, and then, are sent to a cloud data center for analysis. The data are imported into a proprietary algorithm to generate clinically relevant respiratory waveforms and PRV, and to detect the sleep-wake states, thereby evaluating the OSA. Thus, sleep time, apnea-hypopnea index (AHI), and oxygen saturation could be estimated. Although the mentioned device is broadly utilized, its accuracy in screening of OSA, especially compared to other portable devices, is limited.

Therefore, the present study aimed to investigate the feasibility and validity of a PPG-based smartwatch in the screening of OSA. This study is a part of the heart healthcare investigation launched by the Chinese People's Liberty Army (PLA) General Hospital (Beijing, China).

## Methods

### Study Population

The participants for this pilot study were recruited from the Outpatient Department of the Chinese PLA General Hospital from September 29, 2019 to November 10, 2019. This study was conducted in accordance with the Declaration of Helsinki. The Ethics Committee of the Chinese PLA General Hospital and the China Food and Drug Administration approved the study protocol (Approval No. S2017-105-02). Adults who aged  $\geq 18$  years old, who were able to provide informed consent and willing to wear the smartwatch, were enrolled in this study. Individuals with a pacemaker or implantable defibrillator, hemodynamic instability (eg, congestive heart failure, severe pulmonary disease, neuromuscular disease, central sleep apnea, periodic limb movement disorder (PLMD), insomnia, parasomnias, or narcolepsy), and those who were ineligible for HSAT were excluded from this study.

### A PPG-Based Smartwatch

We used a smartwatch GT2 (HUAWEI Device Co., Ltd.) to capture PPG signals. This device utilizes a simple,

noninvasive technique based on optically obtained volumetric measurements of an organ, that is, the wrist. The OSA screening algorithm was embedded into the smartwatch. PPG signals are frequently recorded using a pulse oximeter to detect blood volume changes in the microvascular bed of the tissue. Compared to end-tidal carbon dioxide ( $\text{EtCO}_2$ ), the PPG-derived respiratory rate is more stable and less affected by the motion-induced artifact and patient talk.<sup>14</sup> Thus, combined with pulse oximetry, PPG is a robust tool for screening early respiratory compromise.<sup>15</sup> A smartwatch detects a user's motions. Using the spectra of PPG and acceleration signals, a rare while continuous activity in the patient was defined as "asleep," and when a noticeable movement was detected, the patient was identified as "awake." In the present study, data from sleep for >7 h were deemed reliable and were included in the final analysis.

Using the machine learning algorithm and the overnight PPG signals, including green light, infrared light, and red-light sources, the initial screening model of sleep apnea was established. The PRV characteristics were extracted from green light signals, blood oxygen saturation data were estimated and extracted from infrared and red-light signals, and the risk of sleep apnea was evaluated by constructing a classification model based on the characteristics of PRV and blood oxygen saturation. In addition, the acceleration signal from the wrist was used for an effective signal screening and an abnormal scene discrimination. Subsequently, respiratory waveforms were derived from PPG signals, sleep time was recorded, and AHI was calculated. Besides, 30% and 90% reduction<sup>16</sup> in the respiratory waveforms for defining hypopnea and apnea could be applied by the software, respectively.

## Study Procedure

During the test, under the professional guidance of medical staff and experimenters, each subject was asked to use an HSAT or PSG device for sleep monitoring and wear a smartwatch as well.<sup>13</sup>

The patient was asked to wear a smartwatch on the wrist properly before going to bed; the watch band should be moderately tight (it should not slip to the back when gently shaking the hand). The smartwatch could automatically detect the sleep onset of the patient and collect the physiological signals via the wrist.

After being expert in the use of the above-mentioned devices, the HSAT device and the smartwatch (Figures 1, 2 and 3) were used by participants at their

accommodation places, set up before sleep, and their performance was confirmed by a technician through video chat. Physiological signals, such as blood oxygen level, body movement, and nasal airflow, were collected during sleep. The HSAT device was ResMed ApneaLink™ Air (ResMed Corp., San Diego, CA, USA), and the analysis software was ApneaLink Air (ResMed Corp.) (Figure 4).

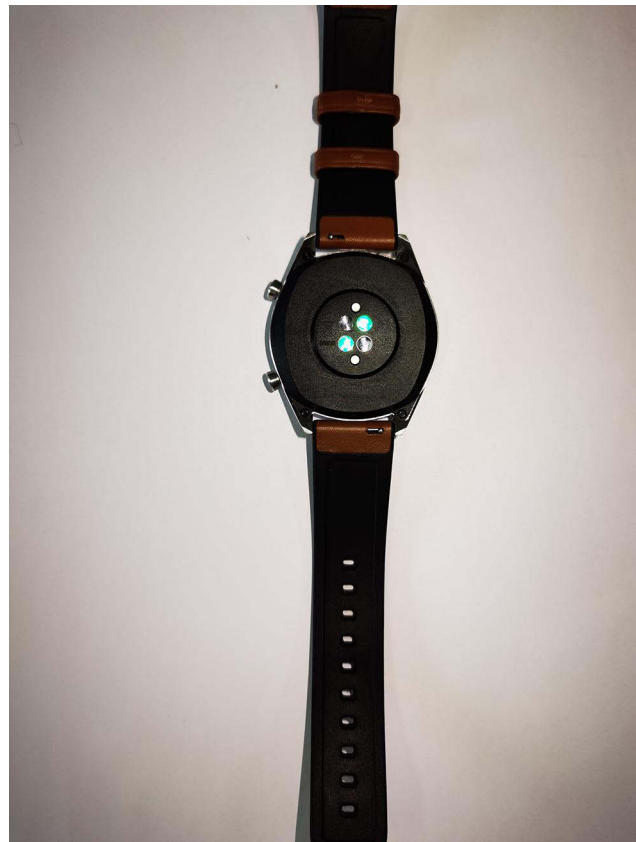
PSG tests were conducted in the Sleep Laboratory of the Respiratory Department at the Chinese PLA General Hospital, according to the commonly accepted clinical standards.<sup>16</sup> The EEG montage included encephalogram leads, O1M2, O2M1, C3M2, C4M1, F3M2, and F2M1, and electromyogram leads for the left eye, right eye, chin, and legs (left and right sides, separately). The EEG and respiratory status were measured by nasal airflow (nasal pressure) and oronasal airflow (thermistor), thoracic and abdominal respiratory efforts (respiratory inductance plethysmography), and pulse oximetry. The PSG devices were Embla N7000 (NeuroLite AG, Belp, Switzerland) and Philips Alice PDX (Philips Healthcare, Inc., Amsterdam, the Netherlands), and the REMLOGIC™ and Sleepware



**Figure 1** Front photo of the smartwatch.



**Figure 2** Back photo of the smartwatch.



**Figure 3** Smartwatch's green light.

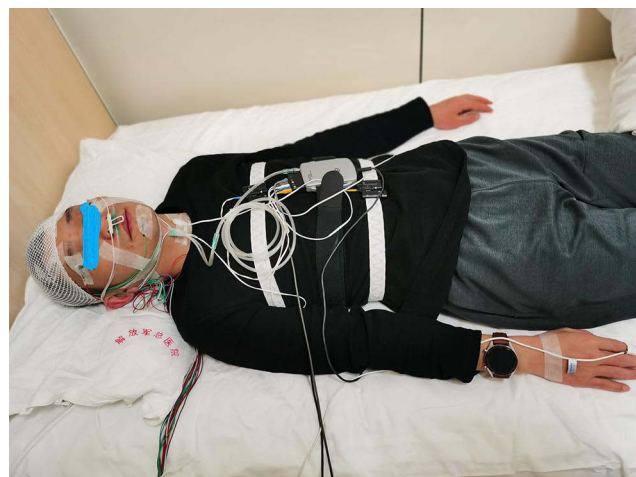


**Figure 4** Patient wears a portable monitor (ApneaLink Air) and a smartwatch.

G3 (Philips Healthcare, Inc.) software were utilized (Figure 5).

The smartwatch also collected the PPG signals and transdermal oxygen saturation signals when that was worn on the wrist by the subjects. After data collection, technicians scored the data following the 2018 American

Academy of Sleep Medicine (AASM) scoring manual;<sup>16</sup> OSA was diagnosed by physicians in the report (as the gold standard). For primary clinical purposes, the severity of OSA was defined as follows: “normal” =  $AHI < 5$ , “mild” =  $AHI$  equal to 5–14.9, “moderate” =  $AHI$  equal to 15–29.9, and “severe” =  $AHI \geq 30$ . In addition, if the estimated sleep



**Figure 5** Wearing of a smartwatch and a PSG device.

time was <3 h, the data were regarded as poor quality and were excluded from the study.

This single-center pilot study of OSA screening was a part of the pre-mobile atrial fibrillation app (mAFA) II registry. The pre-mAFA studies were developed for the examination of patients' cardiovascular status using mobile health technologies. Strict steps were enforced for data security. All the data were managed on a platform under privacy protections, and analyzed by researchers at the Chinese PLA General Hospital. The study was also registered in the Chinese Clinical Trial Registry (ChiCTR-OOC-17014138).

## Diagnosis and Confirmation of OSA

Before testing, physicians conducted a full examination on patients who needed to sleep monitoring. Since OSA coexisted with other diseases, a detailed sleep assessment with respect to sleep habits, physical examination, symptoms, and complications was carried out by physicians before diagnosis to select the PSG or HSAT method. Patients were asked about the typical symptoms of OSA (e.g., unrefreshing sleep, excessive daytime sleepiness, fatigue or insomnia, awakening with a gasping or choking sensation, loud snoring, or witnessed apneas). The data related to clinical features and physical examinations were collected. HSAT or PSG test was conducted by a registered polysomnographic technologist (RPSGT) independently. After PSG or HSAT, the diagnosis of OSA was confirmed using the AASM guidelines<sup>6</sup> by two different physicians independently based on the medical history, data of physical examinations, and results of the tests (Figure 6).

## Statistical Analysis

Continuous variables were tested for normality using the Kolmogorov–Smirnov test. Data with normal distribution were presented as mean  $\pm$  standard deviation (SD). Data with abnormal distribution were analyzed using the Mann–Whitney *U*-test and presented as median (interquartile range (IQR)). Categorical variables were analyzed using the Pearson's chi-square test or the Fisher's exact test, as appropriate.

In this test, the detection algorithm was applied to distinguish the following four categories: true positive (TP), true negative (TN), false positive (FP), and false negative (FN). Using  $AHI \geq 5$  as an example, the confusion matrix of the test is presented in (Appendix 1). The sensitivity was defined as  $TP/(TP+FN)$  (Appendix 2) and specificity as  $1-FP/(TN+FP)$  (Appendix 2). The sensitivity and specificity were calculated based on the interpretation of data obtained from the smartwatch and the physician's

diagnosis. In addition, the kappa coefficient and intraclass correlation coefficient (ICC) were calculated. Besides, 95% confidence intervals (CIs) and likelihood ratio were calculated using the MedCalc 18.9.1 software (MedCalc Software BVBA, Ostend, Belgium).

Accuracy (with a comprehensive investigation of sensitivity and specificity) was defined as the mean value of sensitivity and specificity (Appendix 3). For screening  $AHI \geq 15$  and  $AHI \geq 30$ , the confusion matrix and statistical indicators were calculated similarly to those for  $AHI \geq 5$ ; the difference was noted only in the threshold of dichotomies.

A two-sided *P*-value <0.05 was considered statistically significant. The statistical analysis was performed using the SPSS 25.0 software (IBM Corp., Armonk, NY, USA). An excellent agreement was defined as kappa coefficient >0.80.

## Results

### Patients' Demographic and Clinical Characteristics at Baseline

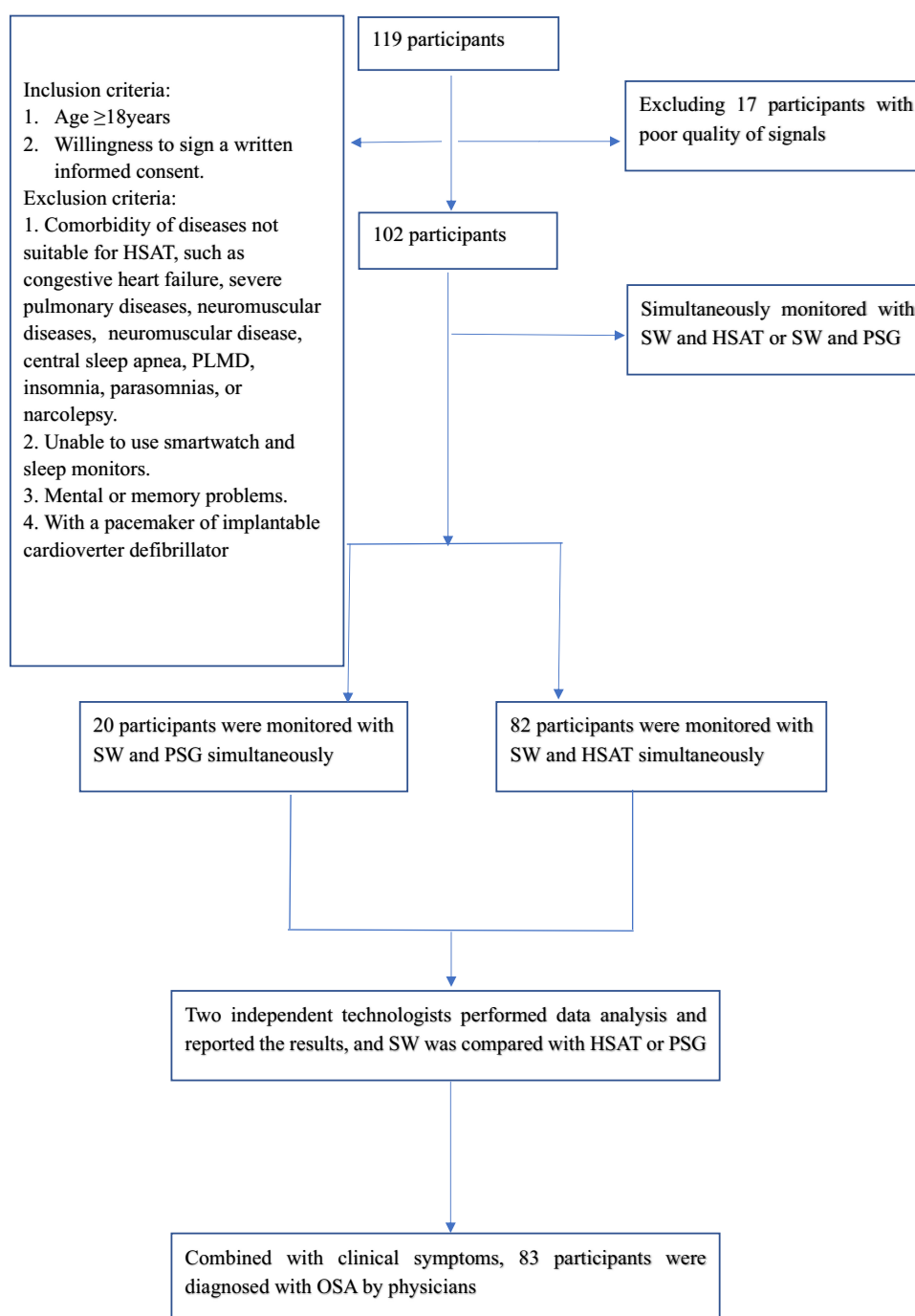
Patients' demographic and clinical characteristics at baseline are presented in Table 1. The cohort consisted of 102 subjects (median age, 49 years old; IQR=38–57 years old), in which 17 subjects with poor PPG signals were excluded; besides, there were 24 (23.5%) female cases, and the mean body mass index (BMI) of all subjects was 26.6 kg/m<sup>2</sup>. Subsequently, 83/102 (81.3%) patients were diagnosed with OSA, as confirmed by physicians based on patients' medical history, data of physical examinations, and the results of HSAT or PSG test upon patients' enrollment. Combined with clinical evaluation, 30/102 (36.1%) patients were diagnosed with mild OSA, 18 (21.7%) with moderate OSA, and 35 (42.2%) with severe OSA. In addition, 19 patients were excluded from the process of diagnosing OSA.

### Results of Using Both Devices (PSG and HSAT) as the Gold Standard

The overall sensitivity and specificity of the smartwatch compared to HSAT and PSG are as follows (Figure 7):

Screening of patients with severe OSA ( $AHI \geq 30$ ): accuracy of 88.4%, sensitivity of 85.7%, and specificity of 91.0% (Figure 7A).

Screening of patients with moderate-to-severe OSA ( $AHI \geq 15$ ): accuracy of 88.2%, sensitivity of 88.7%, and specificity of 87.8% (Figure 7B).



**Figure 6** Flowchart of the study.

Screening of patients with OSA ( $AHI \geq 5$ ): accuracy of 81.1%, sensitivity of 67.5%, and specificity of 94.7% (Figure 7C).

Figure 7 shows the receiver operating characteristic (ROC) curves for the three thresholds used to screen the severity of OSA.

## Results of Using PSG Device as the Gold Standard

In this study, polysomnography was used as the gold standard compared to the smartwatch for 20 patients (male (19) vs female (1) cases). The participants' median age was 46 years old, and the cohort included 3

**Table 1** Patients' Demographic and Clinical Characteristics at Baseline (n=102)

Characteristic	Value
<b>Demographics</b>	
Age (years old); mean (SD)	48.5±13.7
Female, n(%)	24(23.5)
BMI (kg/m <sup>2</sup> ); mean (SD)	26.6±3.8
AHI (hospital); mean (SD)	24.2±21.4
<b>OSA severity (Assessed by PSG or HAST test +clinical evaluation)</b>	
Mild, n (%)	30 (36.1)
Moderate, n (%)	18 (21.7)
Severe, n (%)	35 (42.2)
Patients without OSA	19(18.6)
<b>Medical History</b>	
Hypertension, n (%)	33(32.4)
Coronary heart disease, n (%)	10(9.8)
Atherosclerosis, n (%)	7 (6.9)
Paroxysmal atrial fibrillation, n (%)	7 (6.9)
Arrhythmia, n (%)	9 (8.7)
Hyperlipidemia, n (%)	15 (14.7)
Hyperuricemia, n (%)	4(3.9)
Diabetes, n (%)	10 (9.8)
Gastroesophageal reflux, n (%)	4 (3.9)
NAION <sup>a</sup> , n (%)	9 (8.8)
Xerophthalmia, n (%)	4(4.0)
Chronic obstructive pulmonary disease, n (%)	3 (2.9)
Asthma, n (%)	1 (1.0)
Rhinitis, n (%)	7 (6.9)
Pharyngitis, n (%)	8 (7.8)
Cerebrovascular disease, n (%)	2 (2.0)
Anxiety disorder, n (%)	4 (3.9)
Depressive disorder, n (%)	3 (2.9)
Nephropathy, n (%)	6 (5.9)
Dermatosis, n (%)	6(5.9)
<b>Medications, n (%)</b>	
Anticoagulants	4 (3.9)
Antiplatelet	6 (5.9)
Antiarrhythmic	4 (3.9)
Antihypertensive	34 (33.3)
Antiallergic	8 (7.8)
Steroid hormone	4 (3.9)
Hypnotics	6 (5.9)

**Note:** <sup>a</sup>Non-arteritic anterior ischemic optic neuropathy.

normal individuals, 3 cases with mild OSA, 4 cases with moderate OSA, and 10 cases with severe OSA (Figure 8).

Screening of patients with severe OSA (AHI≥30): accuracy of 80.0%, sensitivity of 80.0%, and specificity of 80.0% (Figure 8D).

Screening of patients with moderate-to-severe OSA (AHI≥15): accuracy of 92.9%, sensitivity of 85.7%, and specificity of 100% (Figure 8E).

Screening of patients with OSA (AHI≥5): accuracy of 88.2%, sensitivity of 76.5%, specificity of 100% (Figure 8F), and overall accuracy of 87.0%.

Figure 8 shows the ROC curves for the three thresholds used to screen the severity of OSA.

## Data Acquired from HSAT Devices (As the Gold Standard)

HSAT devices were used as the gold standard in 82 cases (male (59) vs female (23) cases). The participants' median age was 49 years old. Among them, there were 16 normal individuals, 27 cases with mild OSA, 14 cases with moderate OSA, and 25 cases with severe OSA (Figure 9).

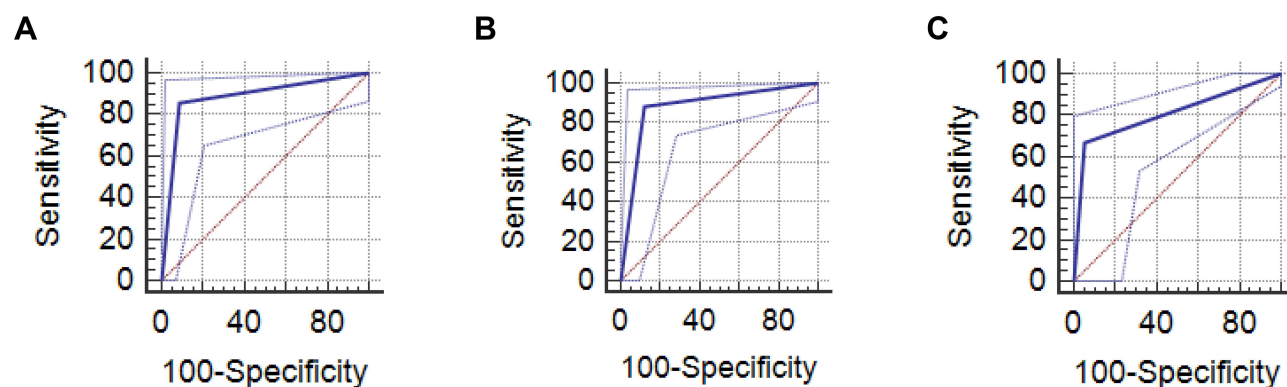
Screening of patients with severe OSA (AHI≥30): The values of accuracy, sensitivity, and specificity were 90.5%, 88.0%, and 93.0%, respectively (Figure 9G).

Screening of patients with moderate-to-severe OSA (AHI≥15): The values of accuracy, sensitivity, and specificity were 87.9%, 89.7%, and 86.0%, respectively (Figure 9H).

Screening of patients with OSA (AHI≥5): The values of accuracy, sensitivity, and specificity were 79.5%, 65.2%, and 93.8%, respectively (Figure 9I).

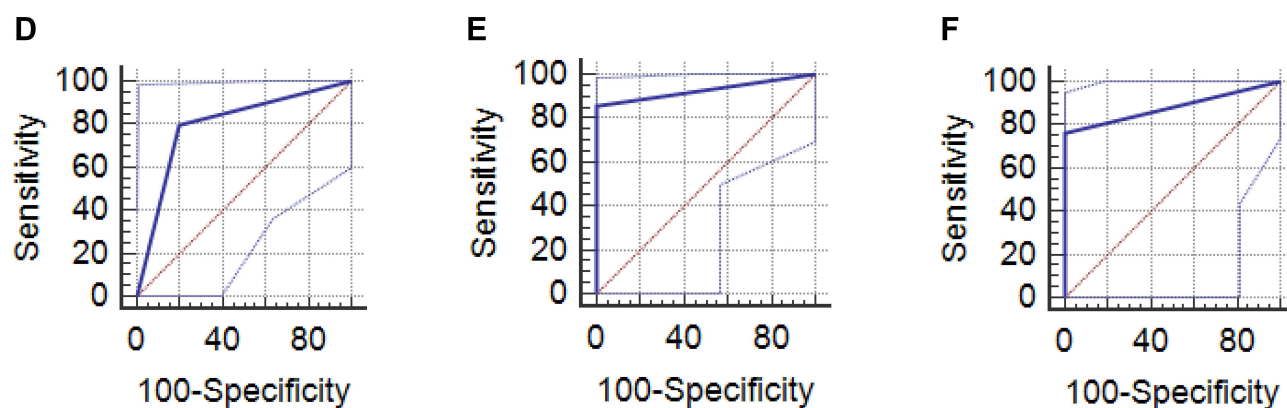
Figure 9 shows the ROC curves for the three thresholds used to screen the severity of the OSA.

The results of HSAT or PSG test are summarized in Table 2. The results of screening algorithm used in the smartwatch were consistent with those results obtained from the testing of medical device used to diagnose sleep apnea. In addition, we concluded that the diagnostic efficiency of smartwatch for moderate-to-severe apnea was higher than that of the mild condition. Moreover, for moderate-to-severe OSA patients (AHI≥15), the predictive ability of the smartwatch did not significantly differ compared to that of HSAT ( $P=0.75$ ) or PSG ( $P=0.52$ ). The Cohen's kappa coefficient of the PPG-based smartwatch and PSG/HAST for diagnosing OSA was 0.507, and the asymptotic 95% CI was (0.396, 0.619). The Cohen's kappa coefficient of the PPG-based smartwatch and HAST for diagnosing OSA was 0.493, and the asymptotic 95% CI was (0.370, 0.613). The Cohen's kappa coefficient of the PPG-based smartwatch and PSG for diagnosing OSA was 0.552, and the asymptotic 95% CI was (0.259, 0.837) (Table 2). Using the AHI tested by HSAT/PSG and



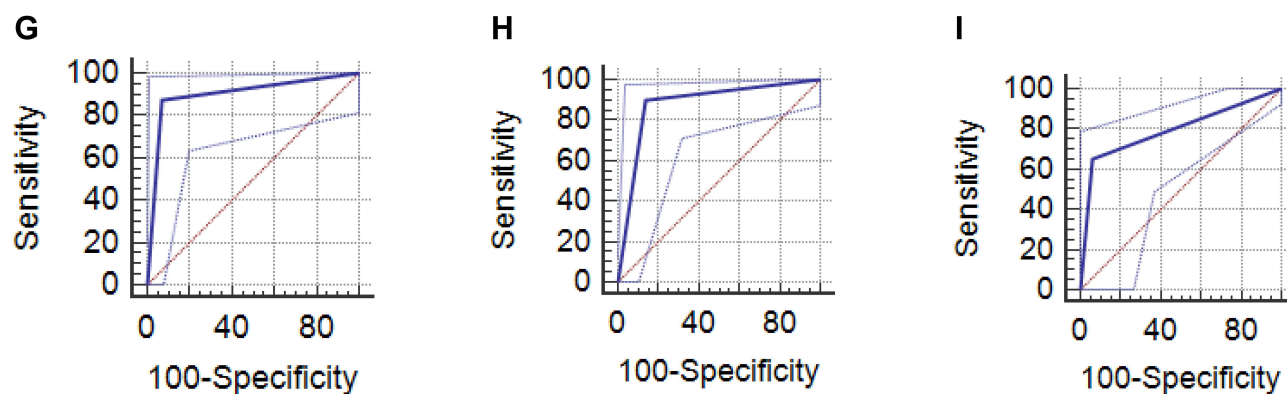
**Figure 7** ROC curve of the smartwatch compared to both HSAT and PSG devices.

**Notes:** (A) Severe OSA ( $AHI \geq 30$ ); (B) moderate-to-severe OSA ( $AHI \geq 15$ ); (C) OSA ( $AHI \geq 5$ ). The blue line is the ROC curve, and the light-blue line indicates the 95% confidence interval.



**Figure 8** ROC curve of the smartwatch compared to the PSG device.

**Notes:** (D) Severe OSA ( $AHI \geq 30$ ); (E) moderate-to-severe OSA ( $AHI \geq 15$ ); (F) OSA ( $AHI \geq 5$ ). The blue line is the ROC curve, and the light-blue line represents the 95% confidence interval.



**Figure 9** ROC curve of the smartwatch compared to the HSAT device.

**Notes:** (G) Severe OSA ( $AHI \geq 30$ ); (H) moderate-to-severe OSA ( $AHI \geq 15$ ); (I) OSA ( $AHI \geq 5$ ). The blue line is the ROC curve, and the light-blue line represents the 95% confidence interval.

**Table 2** Detailed Diagnostic Performance of the PPG-Based Smartwatch Compared to HSAT or PSG

Index	Smartwatch vs HSAT (n=82)			Smartwatch vs PSG (n=20)			Smartwatch vs Both (n=102)		
	AHI $\geq$ 5	AHI $\geq$ 15	AHI $\geq$ 30	AHI $\geq$ 5	AHI $\geq$ 15	AHI $\geq$ 30	AHI $\geq$ 5	AHI $\geq$ 15	AHI $\geq$ 30
Sensitivity, %	65.2	89.7	88.0	76.5	85.7	80.0	67.5	88.7	85.7
Specificity, %	93.8	86.0	93.0	100	100	80.0	94.7	87.8	91.0
Accuracy, %	79.5	87.9	90.5	88.3	92.9	80.0	81.1	88.3	88.4
95% CI (SEN <sup>b</sup> )	52.4–76.5	75.8–97.1	68.8–97.5	50.1–93.2	57.2–98.2	44.4–97.5	56.3–77.4	77.0–95.7	69.7–95.2
95% CI (SPE <sup>c</sup> )	69.8–99.8	72.1–94.7	83.0–98.1	29.2–100	54.1–100	44.4–97.5	75.0–99.9	75.2–95.4	81.5–96.6
PPV <sup>d</sup> , %	65.2	89.7	88.0	100	85.7	80.0	98.2	88.7	76.9
NPV <sup>e</sup> , %	39.5	86.0	94.6	42.9	100	80.0	40.0	87.8	90.4
AUC <sup>f</sup>	0.795	0.879	0.905	0.811	0.929	0.800	0.811	0.882	0.837
p-LHR <sup>g</sup>	10.42	6.43	12.54	12.82	-	4.0	12.82	7.24	9.57
n-LHR <sup>h</sup>	0.37	0.12	0.13	0.34	0.14	0.25	0.34	0.13	0.16
Kappa(95% CI)	0.493(0.370,0.613)			0.552(0.259, 0.837)			0.507(0.396,0.619)		
ICC <sup>i</sup>	0.833			0.724			0.814		

**Notes:** <sup>b</sup>Sensitivity; <sup>c</sup>specificity; <sup>d</sup>positive predictive value; <sup>e</sup>negative predictive value; <sup>f</sup>area under the curve; <sup>g</sup>positive likelihood ratio; <sup>h</sup>negative likelihood ratio; <sup>i</sup>intraclass correlation coefficient.

smartwatch respectively, the ICC between smartwatch and PSG/HSAT was 0.817, the ICC between smartwatch and PSG was 0.724, and the ICC between smartwatch and HSAT was 0.833, which represented a strong correlation of PPG-based smartwatch with HSAT/PSG.

## Discussion

In the present study, we demonstrated a promising diagnostic performance of OSA screening using a PPG-based smartwatch. To the best of our knowledge, this is the first study on OSA screening in China using a PPG-based smartwatch. The main findings were as follows: (1) smartwatch demonstrated a promising potential for the screening of OSA compared to HSAT or PSG test, especially in moderate-to-severe OSA patients; (2) no significant difference was detected in the results of PPG-based smartwatch compared to HSAT or PSG in screening of moderate-to-severe OSA patients.

A smart device, such as a PPG-based smartwatch, was used to monitor the health status during sleep time. Firstly, its feasibility makes it extremely convenient to test at home. Secondly, the low load reduces disturbance during sleep monitoring. Finally, the repeatability and low cost

can be conducive to screen OSA in a large population, considering the high prevalence of the condition in China.

Some studies have established a correlation between OSA and HRV,<sup>17</sup> as well as blood oxygen saturation. Owing to the agreement between PRV and HRV,<sup>18</sup> as well as the portability and continuity of PRV monitoring, we used PRV as a surrogate for HRV. The local changes in blood oxygen saturation were related to OSA, while the respiratory event-associated awakening could result in the maturation of heart rate and respiratory rate. These phenomena were captured by pulse wave signal. As well as monitoring of PRV, the smartwatch also uses three types of light simultaneously to monitor the blood oxygen saturation, including green light, red light, and infrared light. Thus, respiratory events can be measured more accurately than those assessed only by green light.

In order to mimic a sleep environment, the majority of the patients (82/102, 80.4%) used HSAT for sleep monitoring. Although this might sacrifice the accuracy for mild OSA patients, it is an acceptable approach for the majority of the patients. In addition, patients using HSAT also undergo a strict evaluation of the indications, according to the AASM guidelines.<sup>19</sup>

Due to the limitation in the detection, HSAT is only appropriate to identify moderate and severe OSA patients

according to the AASM guidelines and suggestions,<sup>6,19</sup> wherein  $AHI \geq 15$ . Since both were home-based tests, we firstly compared smartwatch and HSAT to identify the test that mimicked the real-world scenario of sleep status. As expected, the sensitivity was 89.7%, specificity was 86%, and accuracy was 89.7% in moderate patients, which is in good agreement with other studies,<sup>7,12,20–24</sup> while that for severe OSA patients was high (Table 3).

We searched the literature concerning PPG-based technologies for screening of OSA (Table 3) and retrieved several studies, wherein Morpheus Ox (WideMed Ltd, Herzliya, Israel) was compared with in-lab PSG among different populations. Specifically, the sensitivity and specificity were mostly between 80–95%, which are adequate for screening of OSA.

Nevertheless, the current study has three major limitations. First, a limited number of patients were recruited in this study. In previous studies,<sup>7,20,21</sup> the sample size was relatively small, and bias to the results was inevitable. Secondly, our research subjects were snoring individuals with a high probability of OSA-positive, thereby deeming it as a high-risk population of OSA. In fact, it is reflected in the high prevalence (83/102, 81.3%) of OSA in our study population. Therefore, the effectiveness of smartwatch in the general population needs to be confirmed, which is also our

further step of the study. Thirdly, as we concentrated only on AHI, the sleep/wake parameters and PPG-derived oxygen desaturation index were neglected, which need to be validated in the subsequent study, considering the poor performance in similar researches reported previously.<sup>25,26</sup>

Intriguingly, a previous study<sup>27</sup> demonstrated that changes in skin color, tattoos, temperature, blood perfusion, erratic movement, and variations in skin pressure or even hairy wrists, as well as fluctuations, in oxygen levels affect the readings via PPG. The artifacts of PPG might be attributed to motion, vasomotor drugs, fluid administration, deep gasp, and heart rate changes.<sup>28</sup> In the current study, we did not concentrate on the control of the external environment factors, and hence, the variable conditions among individuals might influence the accuracy of recognition of PPG signals. For instance, the optical signal would be affected when the smartwatch was not appropriately worn, in which loose wearing would leak the light, and very tight wearing would compress the blood vessels, reducing the blood flow. In such cases, the validity of the heartbeat cycle and signal-to-noise ratio (SNR) are weighed by the algorithm to determine validity of the optical signal.

The subjects in our study exhibited several complications, such as hypertension, hyperlipidemia, arrhythmia, and

**Table 3** Data from the Literature on OSA Screening Using PPG Technology

Studies	Tools	Population	Sensitivity %			Specificity %		
			AHI $\geq 5$	AHI $\geq 15$	AHI $\geq 30$	AHI $\geq 5$	AHI $\geq 15$	AHI $\geq 30$
Ayal Romem et al. <sup>7</sup>	Morpheus Ox vs PSG	High pre-test suspicion for OSA	80	70	-	86	91	-
Papini GB et al. <sup>12</sup>	rPPG <sup>g</sup> vs PSG	Sleep-disordered population	77	62	46	72	91	98
Offer Amir et al. <sup>20</sup>	Morpheus Ox vs PSG	Patients with severe cardiovascular disease	-	98	-	-	96	-
Deganit Barak-Shinar et al. <sup>21</sup>	Morpheus Ox vs PSG	General population	97.03	94.44	-	97.44	96.51	-
Pan Hong et al. <sup>22</sup>	Morpheus Ox vs PSG	High pre-test suspicion for OSA	93	88	92	79	93	95
Yan Li et al. <sup>23</sup>	Morpheus Ox vs PSG	Suspected OSA outpatients	95.3 <sup>h</sup>	89.7 <sup>i</sup>	68.8	50.0	90.0	97.0
Philipp Faßbende et al. <sup>24</sup>	SomnoCheck micro <sup>®</sup> vs PSG	Preoperative patients: STOP <sup>j</sup> score $\geq 2$	100	92	-	44	77	-

**Notes:** <sup>g</sup>Reflective photoplethysmography; <sup>h</sup>5 $\leq$ AHI $<15$ , mild OSA patients; <sup>h</sup>15 $\leq$ AHI $<30$ , moderate OSA patients; <sup>i</sup>snoring, tiredness, observed apnea.

coronary heart disease. Only 13/102 (12.7%) patients had no other complications except for snoring. The most common complication was hypertension, which accounted for 32.4% of all patients. This reflects an urgent need for the screening of OSA among high-risk populations. Thus, we concluded that PPG could be beneficial for such populations.

## Conclusions

In summary, the PPG-based smartwatch was found more effective in comparison to simultaneous in-lab PSG or HSAT devices in screening of suspected OSA cases, especially in screening of moderate-to-severe OSA patients. However, further development using a larger sample size study (ie, a general population or concentration on the home use of the devices and improved algorithm in the diagnostic veracity with multiple assessments at night) is required for a more reliable assessment.

## Data Sharing Statement

The data that supporting the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

## Ethical Statement

This study was performed according to the Declaration of Helsinki. The study protocol was approved by the Ethics Committee of the Chinese PLA General Hospital (Approval No. S2017-105-02). All participants provided written informed consent.

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## Author Contributions

YB Chen collected and analyzed the data, and drafted the manuscript as well. WF Wang and HZ recruited the patients, gave the examination, and made the diagnosis. YT Guo revised the manuscript. LX Xie and YD Chen supervised this study. All the authors read and approved the final version of the manuscript. All authors contributed to data analysis, drafting or revising the article, have agreed on the journal to which the article will be submitted, gave

final approval of the version to be published, and agree to be accountable for all aspects of the work.

## Disclosure

The abstract of this paper was presented at the ESC CONGRESS 2020 as a e-poster presentation with interim findings in the session entitled e-Cardiology/Digital Health on August 28, 2020. The authors declare that there is no conflict of interest.

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