European Archives of Oto-Rhino-Laryngology (2021) 278:873–881
https://doi.org/10.1007/s00405-020-06008-5

MISCELLANEOUS

Application of automatic detection based on overnight airflow and blood oxygen in patients with sleep disordered breathing

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Received: 24 February 2020 / Accepted: 24 April 2020 / Published online: 14 May 2020

Abstract

Purpose To explore the feasibility of automatic detection based on air flow and blood oxygen in patients with sleep disordered breathing.

Methods This study proposes a new automated detection method for sleep disordered breathing based on overnight airflow and blood oxygen saturation (SaO_2). In this regard, local range (LR) of the airflow was adopted to detect apnea events and the SaO_2 sudden drops were used to help determine hypopnea events. Pearson correlation index was used to evaluate the relationship between the two automated methods (this study vs. Remlogic software) and the manual reports. Error and mean absolute error (MAE) were used to assess the two automated methods.

Results For all patients, the apnea–hypopnea index (AHI), apnea index (AI) and hypopnea index (HI) for our automated scoring and manual reports were highly correlated (the Pearson correlation index were 0.996, 0.995 and 0.928, respectively, $P < 0.001$). However, HI for Remlogic automated scoring and clinical manual reports was poorly correlated ($r = 0.316$, $P < 0.001$). Compared with the manual reports, mean absolute error of AHI, AI and HI between the two automated methods (this study vs. Remlogic software) were statistically significant ($P < 0.0001$). Furthermore, among the three subgroups (group 1, AHI < 15/h, group 2, 15/h ≤ AHI < 30/h and group 3, AHI ≥ 30/h), the mean error and MAE of AHI between the two automated methods were also statistically significant ($P < 0.01$).

Conclusions Generally, good agreements were shown between our automated detection and clinical reports. This procedure is robust and effective, which would significantly shorten the analysis time.

Keywords Sleep apnea–hypopnea syndrome · Airflow record · Automated detection · Blood oxygen

Introduction

Sleep apnea hypopnea syndrome (SAHS) is a common sleep disordered breathing disease. It's characterized by repetitive episodes of complete obstruction (sleep apnea events) or partial obstruction (hypopnea events) of the upper airway. According to the contemporary global investigation [1], prevalence of obstructive sleep apnea in China is 23.3%, and the prevalence of moderate and severe sleep apnea in China is 8.8%. Among the 16 countries, the number of affecting individuals was highest in China. It is one of the most common health disorders. OSA is commonly seen in patients with hypertension, atrial fibrillation, diabetes, coronary artery disease, and stroke [2]. Hence, it is important to detection apnea events and hypopnea events accurately.

Currently, polysomnography (PSG) is used to diagnose sleep disordered breathing diseases, which is still considered the "gold standard" method to date [3]. Generally speaking, PSG was an overnight recording in a sleep laboratory. Depending on the American Academy of Sleep Medicine (AASM) guidelines, all electrodes are connected to the scalp and the skin surface to get physiological signals. Because of wires hanging from one's head and body, patients may

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This article is part of the Topical Collection on sleep apnea syndrome. Guest Editors: Manuele Casale, Rinaldi Vittorio.

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be unable to sleep well. Sleep technologists are required to spend a lot of time monitoring and manually reviewing the overnight recording for designating sleep stages, apnea and hypopnea types, events duration on the basis of AASM guidelines.

Respiratory signals including nasal airflow/pressure and respiratory efforts generated by respiratory muscles and oxygen saturation (SaO_2) were elementary signals to detect sleep apnea and hypopnea events. So by means of using physiological signals, many researchers had employed different methods to identify apnea and hypopnea events. The frequently used signals included SaO_2 [4, 5], airflow [6, 7], snore sounds [8], ECG [9, 10], or a combination of these signals [11, 12]. This process was time-consuming and costly, and required skillful personnel [13–15]. Park et al. [16] had compared automated method using the Embletta X100 (which is an unattended 11-channel portable PSG Device with an automated scoring system called Remlogic system.) with manual result of 116 suspected obstructive sleep apnea patients; they found that an overall agreement between automated scoring and manual scoring was around 60.5%, and the automated method tended to excessively underestimate the apnea–hypopnea index. To improve the automated detection effectiveness, Marcin Ciolek et al. [17] used a robust airflow envelope to detect 30 patients' airflow, accuracy, sensitivity, specificity, and Cohen's coefficient of agreement was 95%, 90%, 96%, and 0.82, respectively. The shortfall of this article was they only used one single channel to detect and the sample number was small. Then, Tian et al. [18] detected respiratory nasal airflow signal and the oximetry signal of 30 patients; sensitivity and specificity were 83.7% and 82.9%, respectively. Alvarez et al. [19] enlarged the number of patients to 148, but they had similar findings. The two studies showed that both the sensitivity and specificity were under 90%. To improve the detection effectiveness and decrease the cost of the artifact work, our study will use the local range and "SaO_2 drop" to detect both the airflow and oximetry signal based on AASM 2012 guidelines [20].

Methods

Study population

Subjects who complained of snoring or other symptoms (such as daytime sleepiness) of OSA, and who were referred to our sleep center between July 2019 and October 2019 were consecutively enrolled.

Sleep evaluation

Object total sleep was evaluated by standard PSG (Embla systems N7000 or S4500, Natus Medical Incorporated, Pleasanton, CA, USA). According to AASM guidelines, three pairs of electroencephalograms, bi-lateral electrooculograms, modified lead II electrocardiograms, bipolar chin electromyograms, oral–nasal airflow, thoracic and abdominal respiratory effort, pulse oximetry, a posture and snoring sensor were recorded and obtained. The flow data were stored as a time series with 0.005-s interval (i.e., sampling rate 200 Hz), and the SaO_2 data were stored as a time series of 10-Hz or 2-Hz sampling rate. Sleep recordings were automatically diagnosed and then compared to the manually checked results by two skilled technicians.

Apnea was defined as an absence of oronasal airflow by at least 90% relative to baseline and lasting ≥ 10 s. Hypopnea was defined as any upper airflow reduction of 50% for at least 10 s, accompanied by either a decrease in oxyhemoglobin saturation at least 3% or terminated by awakening [20]. The apnea–hypopnea index (AHI) was indicated by the number of apnea and hypopnea events per hour of sleep. SAHS was diagnosed as the AHI ≥ 5 times per hour. SAHS was classified as mild (5–15), moderate (15–30), or severe (≥ 30), respectively [20].

Local range (LR), LR thresholds and apnea events

The airflow waveform was directly involved in the occurrence of respiratory events [21]. Clear oscillations were observed for normal breathing periods; whereas, apnea and hypopnea cause obvious amplitude reduction. Therefore, an intensive analysis of the information from the two channels was suggested to help in SAHS diagnosis. In this study, the local range (LR) was adopted to evaluate the airflow situation.

LR was defined as the difference between the local maximum and the local minimum of a segment of airflow data P.

$$\mathrm{LR}\,(t) = \max(P(t \rightarrow t + \Delta t)) - \min(P(t \rightarrow t + \Delta t)).$$

Here, LR (t) was the local range at time t and P $(t \rightarrow t + \Delta t)$ was the airflow slice from time t to $t + \Delta t$. The slice length Δt was chosen to be 10 s according to the clinical minimum duration of detecting breathing events.

To determine an apnea event using LR (or more precisely 1/LR), two thresholds, Ta and Tc ($0 < \mathrm{Ta} < \mathrm{Tc}$), were introduced. Ta was the threshold to distinguish two apnea events. If 1/ LR between two events were larger than Ta, the two events were considered as a single event. Tc was the threshold to distinguish apnea events. Thus, if 1/

LR > Tc, it was considered as an apnea event. In our study, the best Ta and Tc were 10 and 25, respectively.

"SaO_2 drops" and hypopnea events

According to the definition, one hypopnea must have one SaO_2 drop. In this study, a "SaO_2 drop" event was marked when two simple rules were satisfied: (1) the SaO_2 data drops at least 3%; and (2) the drop slope should be larger than a certain value, here 0.001 is adopted.

Event number and AHI calculation

The number of SAH events can be achieved by the automated detection procedure, as described previously. The total sleep time should be obtained. An alternative way was to obtain the total sleep time from the EEG data. According to reports by the American Academy of Sleep Medicine (AASM), the sleeping period of adults was divided into periods of Wakefulness (W), Non-Rapid Eye Movement (including NREM 1 (N1), NREM 2 (N2), NREM 3 (N3) and REM (R)) [22]. Therefore, the total sleep time was automatically calculated as a summation of N1, N2, N3 and R.

During the whole study, firstly, we detected apnea events from airflow data using local range. Then, we detected SaO_2 desaturation events utilizing SaO_2 data and merged the apnea and SaO_2 desaturation events to get sleep apnea and hypopnea events. Finally, statistical analysis of event number AHI, AI and HI was performed.

Statistical methodology

All the analysis was conducted in a personal laptop (Intel i7-8650U, 16 GB RAM), Protocol code was written and run in MATLAB (R2019a). The average cost time for analyzing the overnight data per patient was less than 3 s (including reading raw ASCII data of about 90–100 MB).

Statistical analysis was performed with SPSS 20.0 (IBM, Armonk, NY, USA). Descriptive statistics were calculated for all variables. Continuous variables were summarized through means and standard deviations. The Pearson correlation analysis was utilized. Besides, statistical results have also been compared, e.g., the AHI, AI, HI, etc. Ideally, the automated diagnosed results should be identical to the clinical manually marked results and also the automated diagnosed results by our study and the Remlogic software (self-contained by Embla) should be distinguished. Therefore, the commonly used mean absolute error (MAE) is adopted:

$$MAE = \frac{1}{n}\sum_{i=1}^{n}|X_{i,predicted} - X_{i,standard}|$$

A cutoff of $P < 0.05$ was used to determine statistical significance.

Results

All 143 patients were enrolled in the experiment, aged 16–74, with an average age of 40.6 years, including 122 men and 21 women. Apnea–hypopnea index (AHI), apnea index (AI) and hypopnea index (HI) of manual reports were 44.2 ± 26.74 events/h, 37.0 ± 27.85 events/h and 6.8 ± 6.84 events/h, respectively (Table 1). All of the manual reports were analyzed by two experienced technicians. We divided the patients into three subgroups. In detail, group 1 was snoring and mild SAHS (AHI < 15/h, $n = 26$), group 2 was moderate SAHS (15/h ≤ AHI < 30/h, $n = 24$) and group 3 was severe SAHS (AHI ≥ 30/h, $n = 93$).

For all patients, AHI, AI and HI for our automated scoring were 43.4 ± 26.35 events/h, 35.7 ± 26.92 events/h and 7.6 ± 7.73 events/h, respectively. They were highly correlated with the results of manual reports (the Pearson correlation index was 0.996, 0.995 and 0.928, respectively, $P < 0.001$). Similar findings were got by Remlogic software (AHI, $r = 0.971$, AI, $r = 0.918$, $P < 0.001$). However, HI for Remlogic automated scoring and clinical manual reports was poorly correlated ($r = 0.316$, $P < 0.001$) (Figs. 1, 2 and 3d). Detailly, three subgroups were analyzed. Firstly, AHI for our automated scoring of all the three groups was highly correlated with the results of manual reports ($r = 0.893$, 0.847 and 0.993, respectively, $P < 0.001$) (Fig. 1a–c). Similar finding of group 3 was got by Remlogic software ($r = 0.925$, $P < 0.001$) (Fig. 1c). But AHI and HI for Remlogic software for group 1 and group 2 were moderately correlated with the results of manual reports ($r < 0.80$, $P < 0.001$) (Fig. 1, 3a, b). Then, AI for two automated scoring was both highly correlated with the results of manual reports (this study vs. Remlogic software, the Pearson correlation index were 0.941 vs. 0.828, 0.956 vs. 0.842 and 0.990 vs. 0.811, respectively, $P < 0.001$) (Fig. 2a–c). Finally, HI for our automated scoring of group 2 and group 3 was highly correlated with the results of manual reports ($r = 0.910$, 0.936, respectively, $P < 0.001$) (Fig. 3b, c).Otherwise, HI for Remlogic

Table 1 Characteristics of subjects

Characteristics	All patients ($n = 143$)
Age (years) (mean ± SD, range)	40.6 ± 11.44 (16–74)
Male/Female (%)	122/21 (85.3/14.7)
Body mass index (kg/m^2) (mean ± SD, range)	27.2 ± 3.72 (19.3–38.1)
AHI (/h) (mean ± SD, range)	44.2 ± 26.74 (1.2–98.7)
AI (/h) (mean ± SD, range)	37.0 ± 27.85 (0.2–96.0)
HI (/h) (mean ± SD, middle, range)	6.8 ± 6.84 (4.90–35.0)

AHI apnea–hypopnea index, *AI* apnea index, *HI* hypopnea index

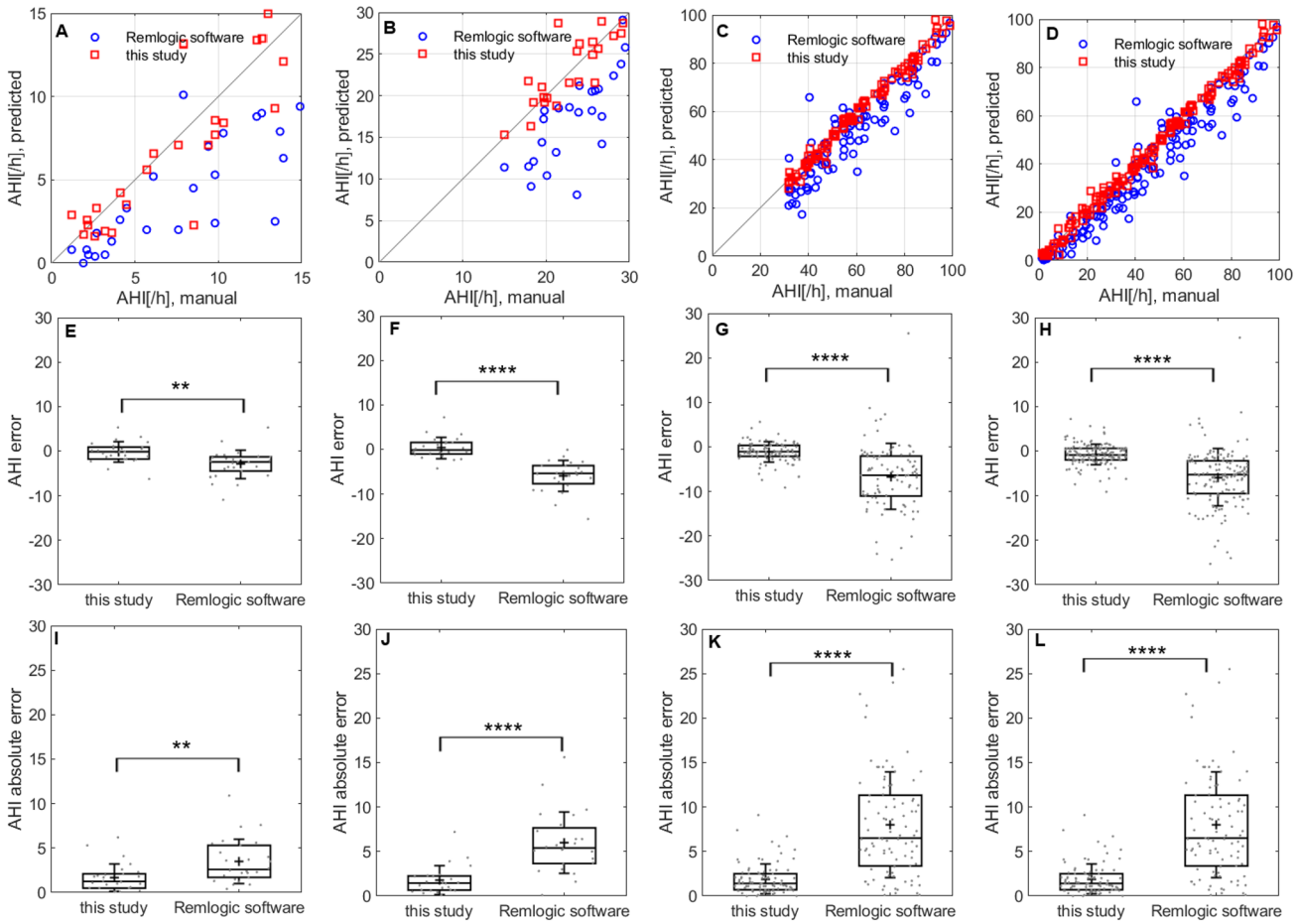

Fig.1 The AHI distribution, error and absolute error between all the patients and three groups *AHI* apnea and hypopnea index. **a**, **e**, **i** Snoring and mild SAHS. **b**, **f**, **j** Moderate SAHS. **c**, **g**, **k** Severe SAHS. **d**, **h**, **l** All the 143 patients. **a**–**d** Comparison of the AI distribution between predicting results and clinical manually marked results. **e**–**h** Comparison of AI error between predicting results and clinical manually marked results. **i**–**l** Comparison of AI absolute error between predicting results and clinical manually marked results. $^{*}P<0.05$, $^{**}P<0.01$, $^{****}P<0.0001$

software for group 3 was poorly correlated with the results of manual reports ($r=0.270$, $P<0.001$) (Fig. 3c).

Furthermore, we compared our automated method with the Remlogic software. For all patients, it was found that the range of the middle error between two methods was − 1.10 to 0.70 and − 6.40 to 1.50, respectively (Table 2). Meanwhile, in this study, the middle MAE between our automate diagnosis method and manual analysis was from 0.60 to 1.90; whereas, the middle MAE between Remlogic software and manual analysis was from 1.10 to 6.90 (Table 2). It was shown that both AHI error and AHI absolute error of two methods were statistically significant ($P<0.0001$) (Fig. 1e–l). We also found that almost AI error and AI absolute error of two methods were statistically significant except AI error of group 1 (mean ± SD, − 0.18 ± 1.260 vs. − 0.65 ± 2.181) and AI absolute error of group 2 (middle MAE, 1.65 vs. 2.25) (Fig. 2e–l). It was also shown that almost HI error and HI absolute error of two methods were statistically significant except HI error of all patients (mean ± SD, 0.84 ± 2.902 vs. 1.08 ± 8.422) and HI absolute error of group 1 (middle MAE, 1.15 vs.1.30) (Fig. 3e–l).

Finally, the sensitivity and positive predictive value (PPV) of our study were 93.0% and 95.7%, respectively.

Discussions

To the best of our knowledge, there are plenty of commercial products which currently present on the market and offer a system for automatic sleep scoring analysis. Software tools include Embla Remlogic, Noxturnal, Somnolyzer System, Michele Sleep Soring and so on. In the work conducted by Punjabi et al. [23], it was important to note the average correlation between the manual and Somnolyzer-scored AHI value was 0.93. In the work carried out by Park et al. [16], it was shown that the average correlation between the

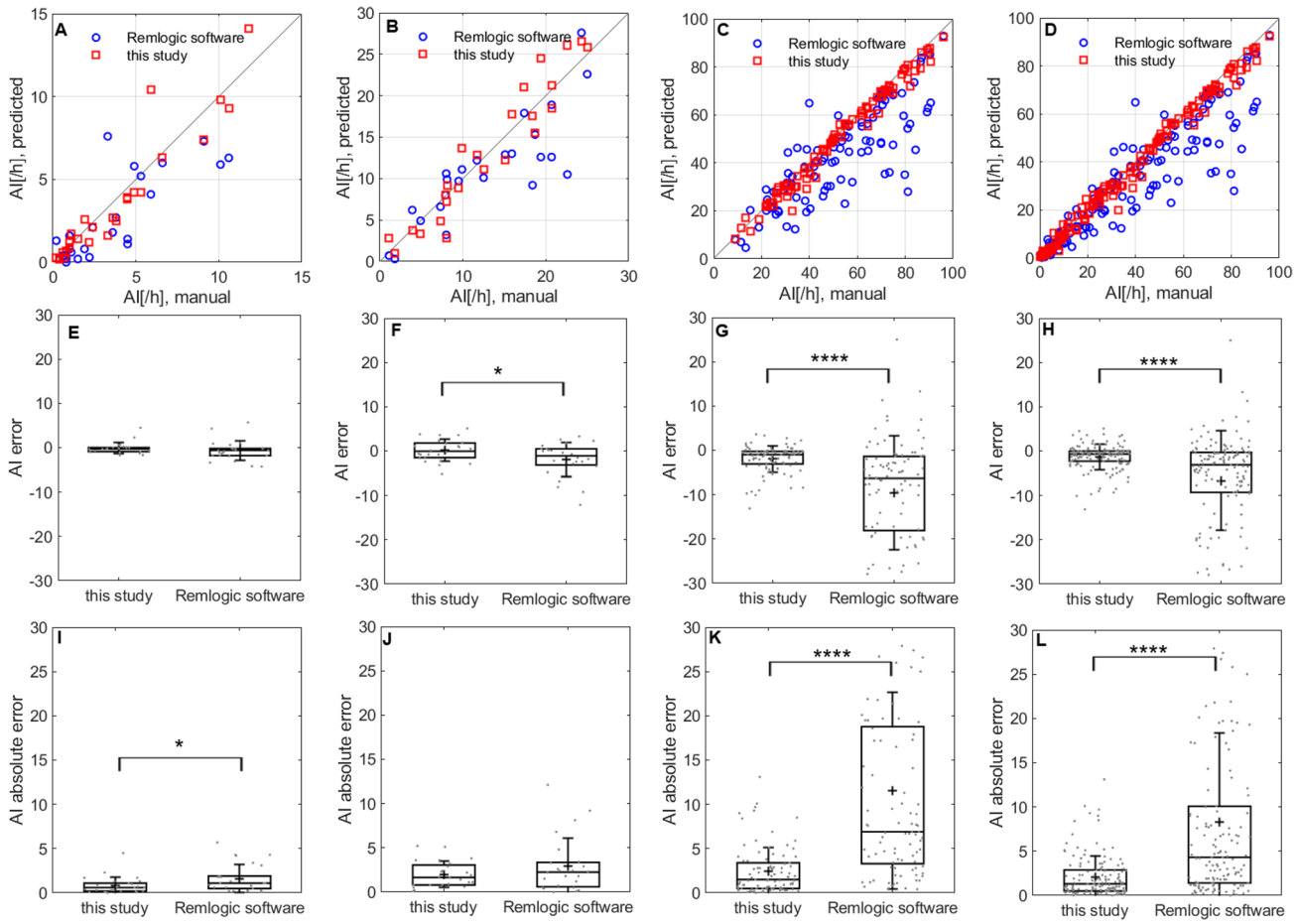

Fig. 2 The apnea index distribution, error and absolute error between all the patients and three groups *AI* apnea index. **a**, **e**, **i** Snoring and mild SAHS. **b**, **f**, **j** Moderate SAHS. **c**, **g**, **k** Severe SAHS. **d**, **h**, **l** All the 143 patients. **a**–**d** Comparison of the AI distribution between predicting results and clinical manually marked results. **e–h** Comparison of AI error between predicting results and clinical manually marked results. **i-l** Comparison of AI absolute error between predicting results and clinical manually marked results. *$P<0.05$, **$P<0.01$, ****$P<0.0001$

manual and Remlogic-scored AHI, obstructive AI and HI value was 0.761, 0.791 and 0.451, respectively. There was different from those between two methods. One reason was that Embla Remlogic and Somnolyzer System were two separate algorithms that belong to different companies. The other important factor was that Somnolyzer System used the AASM (2007) criteria but Embla Remlogic used the newest AASM (2012) criteria to date. In our study, the AHI, AI and HI between the manual and Remlogic scored were highly correlated. Both our study and Park's work [16] showed that Remlogic-scored HI had poor agreement with manual scoring. From this study, we found that our automated detection reports and clinical manual reports generally demonstrated good agreement. Statically, the AHI, AI and HI were very similar, higher than Remlogic software did. Specially, the similar result could be achieved among our three groups. In detail, this study showed the best correlation between our automated detection reports and manual reports. According to our result, scatter diagram and error analysis both showed that our method was central tendency, but Remlogic software may underestimate the AHI (Fig. 1e–h), AI (Fig. 2f–h) and HI (Fig. 3e–g), which was similar to Park's finding [16]. Furthermore, in point of MAE, we found that our automated detection method had better agreement with manual analysis than the Remlogic software among all three groups and all test patients.

It is more practical and accurate to detect sleep apnea and hypopnea events using the main signals of respiratory and blood oxygen. Firstly, the two signals are recorded by data segments or epochs. Then, manual scoring is found in the way of the combination of these two signals and the additional signals of EEG, EMG, ECG, snore sound and position. Finally, it was found that there were lots of detecting findings based on different combination methods.

During the past two decades, about 14 articles studied the single airflow signal and 27 articles studied the single blood

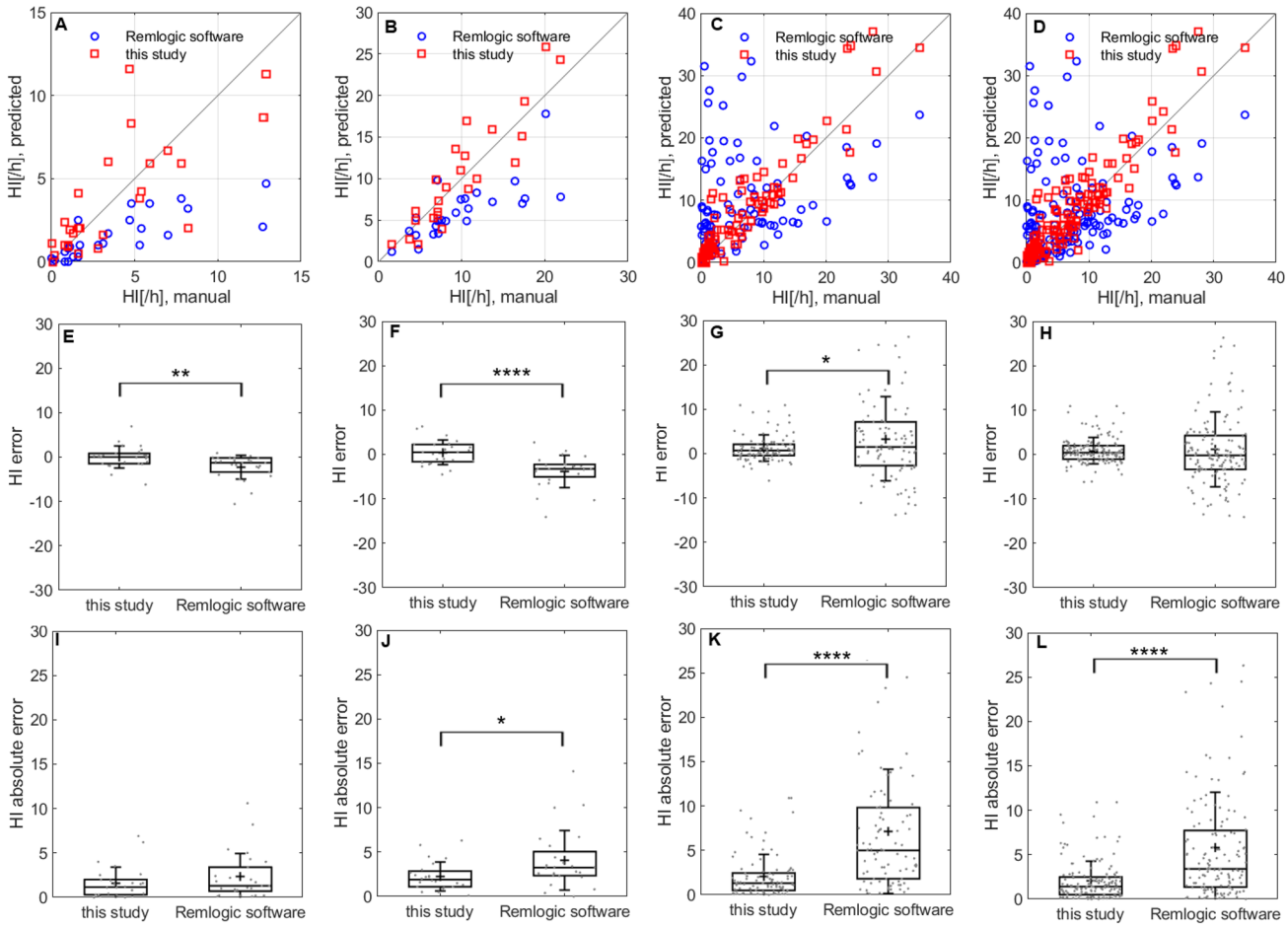

Fig.3 The HI distribution, error and absolute error between all the patients and three groups *HI* hypopnea index. **a**, **e**, **i** Snoring and mild SAHS. **b**, **f**, **j** Moderate SAHS. **c**, **g**, **k** severe SAHS. **d**, **h**, **l** All the 143 patients. **a**–**d** Comparison of the AI distribution between predicting results and clinical manually marked results. **e**–**h** Comparison of AI error between predicting results and clinical manually marked results. **i**–**l** Comparison of AI absolute error between predicting results and clinical manually marked results. $^{*}P<0.05$, $^{**}P<0.01$, $^{****}P<0.0001$

oxygen signal, but only 4 articles studied the combination airflow and blood oxygen signals.

On account of the influence of airway obstruction, airflow signal was the most important respiratory signal used for detecting sleep apnea. Two studies published by Gutiérrez-Tobal et al. [24, 25] used the same large dataset (148 patients) to make a distinction between OSA positive and OSA negative. In the first study, a logistic regression analysis (LRA) model was used, which was performance improved using multilayer perceptron (MLP) model in the second study. The accuracy, sensitivity and specificity of the two articles were 82.4%, 88.0%, 70.8% vs. 91.5%, 92.5%, 89.5%, respectively. Then Gutiérrez-Tobal et al. [26] reported an AdaBoost algorithm– classification and regression trees (CART) which was utilized to separate normal and apneic patients got good accuracy. The accuracy, sensitivity and specificity were 86.5%, 89.0%, 80.0%, respectively. Selvaraj and Narasimhan [27] used a per-second basis logical algorithm to distinguish apneic and normal patients; sensitivity and PPV were 83.6% and 72.3%. So, it is important to improve classification approach to get a more acceptable performance.

Like the airflow signal, SaO_2 was another important physiological signal using for detecting sleep apnea events. Marcos et al. [28–30] reported a lot of methods such as a threshold-based technique, neural networks including radial basis function and multi-layer perception (MLP), and support vector machine had distinguished OSA-positive and OSA-negative patient. The accuracy, sensitivity, specificity was 81.3–3%, 81.3–97%, 79.3–100%, respectively. Rolón et al. [31] used an MLP neural network method to distinguish mild, moderate and severe patients. The accuracy, sensitivity and specificity were 85.8%, 85.6%, 85.9%, respectively.

To improve the detection effectiveness, a combination of airflow and SaO_2 signals had been applied. Tian et al.

Table2 Total and three groups of patients' error and MAE

Parameter	Group	Error			MAE		
		A (mean ± SD, middle)	B (mean ± SD, middle)	*P* value	A (mean ± SD, middle)	B (mean ± SD, middle)	*P* value
AHI	1	0.26 ± 2.311 (− 0.15)	− 2.94 ± 3.179 (− 2.45)	0.0011**	1.70 ± 1.556 (1.25)	3.52 ± 2.496 (2.60)	0.0027**
	2	0.35 ± 2.404 (0.15)	− 5.98 ± 3.472 (− 5.40)	< 0.0001****	1.78 ± 1.610 (1.45)	5.98 ± 3.472 (5.40)	< 0.0001****
	3	− 1.19 ± 2.246 (− 1.10)	− 6.69 ± 7.392 (− 6.40)	< 0.0001****	1.89 ± 1.688 (1.40)	7.99 ± 5.944 (6.50)	< 0.0001****
Total AHI		− 0.76 ± 2.348 (− 0.90)	− 5.89 ± 6.414 (− 5.30)	< 0.0001****	1.84 ± 1.642 (1.40)	6.84 ± 5.381 (5.60)	< 0.0001****
AI	1	− 0.18 ± 1.260 (0.30)	− 0.65 ± 2.181 (− 0.60)	0.339	0.82 ± 0.957 (0.60)	1.62 ± 1.569 (1.10)	0.031*
	2	0.15 ± 2.504(− 0.05)	− 1.92 ± 3.888 (− 1.10)	0.033*	1.99 ± 1.468 (1.65)	2.97 ± 3.130 (2.25)	0.174
	3	− 1.99 ± 3.033 (− 1.00)	−9.57 ± 12.851 (− 6.30)	< 0.0001****	2.46 ± 2.662 (1.50)	11.52 ± 11.114 (6.90)	< 0.0001****
Total AI		− 1.30 ± 2.856 (− 0.70)	− 6.66 ± 11.235 (− 3.10)	< 0.0001****	2.09 ± 2.343 (1.30)	8.29 ± 10.091 (4.30)	< 0.0001****
HI	1	− 0.04 ± 2.446 (0)	− 2.23 ± 2.686 (− 1.30)	0.0034**	1.62 ± 1.809 (1.15)	2.31 ± 2.610 (1.30)	0.269
	2	0.45 ± 2.791 (0.50)	− 3.80 ± 3.694 (− 3.25)	< 0.0001****	2.27 ± 1.620 (1.90)	4.10 ± 3.350 (3.25)	0.020*
	3	1.19 ± 3.006 (0.70)	3.27 ± 9.484 (1.50)	0.045*	2.10 ± 2.449 (1.30)	7.15 ± 7.007 (5.00)	< 0.0001****
Total HI		0.84 ± 2.902 (0.40)	1.08 ± 8.422 (− 0.20)	0.748	2.04 ± 2.221 (1.40)	5.76 ± 6.224 (3.40)	< 0.0001****

A automated diagnosis method in this study, *B* automated diagnosis by Remlogic software, *AHI* apnea–hypopnea index, *AI* apnea index, *HI* hypopnea index, *group* 1 snoring and mild SAHS ($n = 26$), *group* 2 moderate SAHS ($n = 24$), *group* 3 severe SAHS ($n = 93$), *MAE* mean absolute error

*$P < 0.05$, **$P < 0.01$, ****$P < 0.0001$

[18] used time-delay neural network applied to airflow and SaO_2 signals to detect apnea and hypopnea events; the sensitivity and specificity were 83.7% and 82.9%. Similarly, Álvarez et al. [19] used a nonparametric threshold-based method for airflow and SaO_2 signals to distinguish OSA-positive and OSA-negative patients. The accuracy, sensitivity and specificity were 84.5%, 84.0%, 85.4%, respectively. Apnea and normal events were distinguished by multivariable fuzzy temporal profile model, which accuracy is 90.0% [32]. Huang et al. [15] found it had good accuracy to detect apnea and hypopnea events using the respiratory event detection algorithm. The sensitivity and PPV were 97.6% and 95.7%. In our study, we use the local range and "SaO_2 drop" to detect apnea and hypopnea events. According to the AASM definition, we clarify that SaO_2 drop events can be triggered by both apnea and hypopnea events. Since apnea events have previously been detected by the airflow data, the rest drop events should be caused by hypopnea events. Among the five articles, our specificity and was higher than the previous two articles, which were similar to Huang's report, but their patients' sample was smaller.

We should account into some drawbacks that restrict the generalization of our result. The population under study could be larger that we can distinguish simple snoring and mild SAHS. An important limitation should be pointed out. Our procedure could noot differentiate obstructive, mixed and central events because of the imperfect used signals. These detailed diagnoses could be obtained by adding and combining more channels such as ECG or snoring.

Conclusion

This procedure is accurate, robust and effective, which would shorten the clinical diagnosis time and improve the diagnosis effectiveness compared with the traditional clinical automated method.

Author contributions All authors contributed to the study conception and design. JH and LR contribute equally to this paper. Material preparation, data collection and analysis were performed by JH, LR, LC, ZJ, TZ and HW. The first draft of the manuscript was written by JH and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript. Conceptualization: JH, LR and LC; Methodology: LR and LC; Formal analysis and investigation: JH and ZJ; Writing-original draft preparation: JH and LR; Writing-review and editing: HW; Funding acquisition: HW; Resources: HW; Supervision: TZ.

Funding This work was funded by the Science and Technology Commission of Shanghai Municipality of China (Grant no 17411962000) and also supported by the Health and Family Planning Commission of Shanghai Municipality of China (Grant no 2019SY059).

Compliance with ethical standards

Conflict of interest None of the above-mentioned authors has a conflict of interest regarding this publication.

Ethics approval Our study was performed in accordance with Declaration of Helsinki and its amendments. The Ethics Committee of Shanghai Fudan University Affiliated Eye and ENT Hospital has confirmed that no ethical approval is required. All the procedures being performed were part of the routine care.

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