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SLEEP BREATHING PHYSIOLOGY AND DISORDERS • REVIEW

New diagnostic tools to screen and assess a still too underestimated disease: the role of the wrist-worn peripheral arterial tonometry device—a systematic review

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Abstract

Purpose Home sleep apnea testing devices aim to overcome the drawbacks of polysomnography (PSG). Among these, the WatchPAT (WP) (Itamar Medical Ltd., Caesarea, Israel) has recently been introduced on the market for diagnosis of Obstructive Sleep Apnea (OSA). The aim of this review was to provide a comprehensive overview of the studies validating the WP for the diagnosis of sleep-disordered breathing through comparison with PSG.

Methods A systematic review was performed to identify all clinical studies concerning WP validation compared with PSG as diagnostic tools. A qualitative analysis of the data was conducted.

Results In this review, 18 studies were included for a total of 1049 patients, aged 8 to 70 years old, with 74 of these being pediatric patients. In most studies, patients completed an overnight PSG and simultaneously wore WatchPAT in a sleep laboratory, while others compared the results obtained on two different nights. Both protocols showed good results in terms of AHI, ODI, RDI, and SO2. Moreover, some studies calculated the sensitivity and specificity of the WP ranging from 87 to 96% and from 66 to 80%, respectively. Excellent results were found also in pediatric patients.

Conclusion The WP represents an effective and convenient tool for OSA diagnosis compared to standard reference systems.

Keywords Obstructive sleep apnea syndrome · Diagnosis · Polysomnography · WatchPAT · Peripheral arterial tone

Introduction

Approximately one billion of the adult population aged from 30 to 69 years old worldwide suffer from Obstructive Sleep Apnea (OSA) [1]. The main cause of this condition is partial or complete upper airway (UA) collapse during sleep, leading to reduced (hypopnea) or absent (apnea) airflow. OSA is a main cause of excessive daytime sleepiness and is associated with a high risk of developing hypertension, atrial fibrillation, heart failure, coronary heart disease, type 2 diabetes mellitus, cerebrovascular accident, and death.

According to a recent epidemiological study in Italy, there are 12,329,614 patients affected by moderate to severe OSA (27% of the population), and an overall prevalence of more than 24 million people aged from 15 to 74 years old (54% of the population). However, only 460,000 patients with moderate to severe OSA are diagnosed (4% of the estimated prevalence) and 230,000 treated (2% of the estimated prevalence) suggesting a substantial gap in the diagnostic and treatment workflow [2].

Currently, OSA can be diagnosed with several methods from laboratory-based to home sleep testing [3, 4]. To date, the gold standard method is full-night polysomnography (PSG), which requires the following measurements: electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG) or heart rate, chin electromyography (EMG),

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airflow, arterial oxygen saturation, and respiratory effort [5]. However, PSG is an expensive exam (equipment, maintenance costs, staff costs, and full-night time occupation of the laboratory). PSG can also be annoying due to the attached sensors and having the exam in an unfamiliar place [6–8]. For these reasons, cheaper and portable devices have been developed to detect OSA outside the hospital setting. Since 2008, when the Centers for Medicare and Medicaid Services (CMS) declared the use of home testing reimbursable, many insurance companies have accepted the use of Home Sleep Apnea Testing (HSAT) for OSA diagnosis [9, 10].

HSAT is not as expensive as PSG and it avoids the need for patients to face long wait times for an attended in-hospital PSG [11].

Among several HSAT devices, the WatchPAT (WP) device (Itamar Medical Ltd., Caesarea, Israel) is attached to the patient's wrist, like a watch and derives data based on a change of peripheral arterial tone (PAT) [12]. The PAT signal is a non-invasive measure of the arterial pulsatile volume changes at the fingertip: the signal reduction and the consequent accelerated pulse rate reflect sympathetic activation suggesting autonomic arousals and micro-arousals usually found in sleep apnea. The PAT algorithm is founded on PAT signal reduction combined with oximetry desaturations. In this way, it provides the following data: Apnea Hypopnea Index (AHI), Respiratory Disturbance Index (RDI), Oxygen Desaturation Index (ODI), total sleep time, and sleep stage percentages [13, 14]. In addition, the PAT-HSAT device allows information about snoring and body position [15].

This review aimed to provide a comprehensive overview of the evidence validating the PAT-HSAT device as a diagnostic tool for sleep-disordered breathing through a comparison with the gold standard.

General study design

The study was performed according to the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement [16].

Data source and study searching

An electronic search was performed on PubMed/MEDLINE, Google Scholar, and Ovid databases. An example of a search strategy is the one used for PubMed/MEDLINE: "Watch PAT" and "Obstructive Sleep Apnea," "Diagnostic techniques," "Peripheral arterial tonometry," "Polysomnography," "home polysomnography recording," "Home monitoring," and "Home Sleep Apnea Test." All searches were adjusted to fit the specific requirements for each database. A cross-reference search minimized the risk of missing relevant data. The last research was run in December 2021.

Inclusion/exclusion criteria

Only WP validation studies compared with standard PSG were chosen. Exclusion criteria for the study were (1) studies not in English; (2) case reports, reviews, conference abstracts, letters, and pediatric studies; (3) studies with unclear and/or missing data; (4) studies evaluating only the WP use in clinical practice without a comparison study; and (5) studies not using WP for OSA diagnosis. No publication date restriction was imposed.

Data extraction and data analysis

All articles were initially screened by title and abstract. Full-text versions of each publication were assessed and articles were excluded if the content was judged not to be strictly related to the subject of this review. Data from the included studies were systematically extracted using a structured form. A qualitative synthesis analysis was performed.

Statistical analysis and summary of findings

It was impossible to perform the intended statistical analysis and summary of findings as described in our protocol because of the heterogeneous reporting style and a lack of data in the individual studies included in this review. Thus, the effects on the individual outcomes and the overall quality assessments were described only in narrative fashion. In addition, available data in the retrospective studies were used. The authors of the included studies were not contacted for further information.

Results

The search criteria returned 34 articles: Eight papers were removed as they were considered irrelevant or duplicates and another eight were excluded after further screening, resulting in 18 articles fulfilling the criteria for inclusion in this review. The flow diagram of the selection process is shown in Fig. 1 (PRISMA flow diagram). The population in the included studies consisted of 1049 patients, aged 8 to 70 years old, with 74 of these being pediatric patients. All the included studies were prospective clinical studies. The baseline characteristics of these studies are reported in Table 1. A further description of the studies conducted in the reports can be found in Table 2. In addition, in Table 3 the limitations and strengths of each of the included studies are reported.

Two models of WP were used in the included studies, the WatchPAT 100 (WP100) and the WatchPAT 200 (WP200). A new version of WP is currently available on the market,

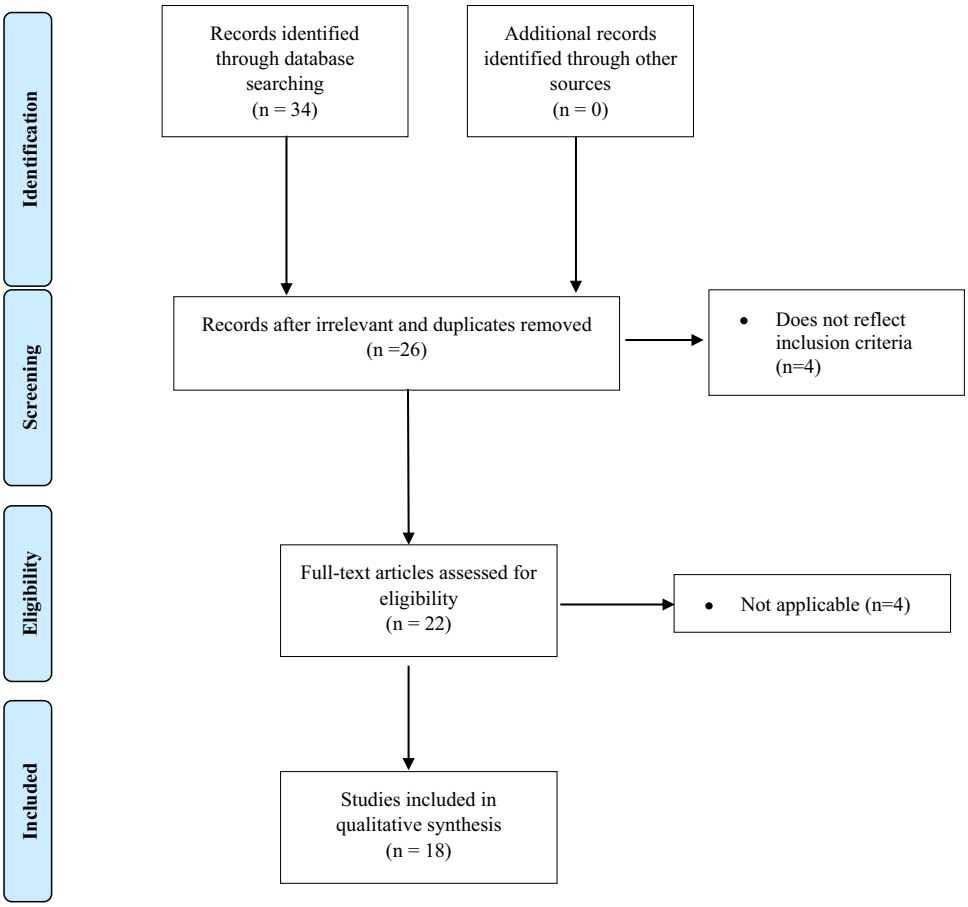

Fig. 1 Flowchart outlining the paper selection process of the systematic review (based on PRISMA guidelines). PRISMA indicates preferred reporting items for systematic review and meta-analysis

Table 1 General characteristics of included studies

Author (year)	Country	Study design	N. patients	Mean age (years)	Sex (M/F)	BMI (kg/m2)
Ayas (2003)	USA	Prospective	30	47.0 ± 14.8	19/11	31.0 ± 7.6
Bar (2003)	Israel	Prospective	102	41.4 ± 15.2	78/24	26.8 ± 5.5
Boyd (2016)	USA	Prospective	28	51.4 ± 10.8	21/7	-
Ceylan (2012)	Turkey	Prospective	51	45.3 ± 10.5	-	29.4 ± 4.0
Choi (2010)	Korea	Prospective	27	40.9 ± 11.2	21/4	26.2 ± 2.6
Choi (2018)	Republic of Korea	Prospective	38	15.1 ± 1.4	28/10	23.5 ± 5.5
Hedner (2011)	Sweden USA Israel	Multi-center Study cohort	227	49 ± 14	-	29 ± 6
Korkuyu (2014)	Turkey	Prospective	30	49.2 ± 9.6	25/5	29.6 ± 4.4
O'Brien (2012)	USA	Prospective	31	30.2 ± 7.1	21 F	31.9 ± 8.1
Onder (2012)	Turkey	Prospective	56	Group 1: 30.43 ± 2.84 Group 2: 54.97 ± 4.74	Group 1 (10/10) Group 2 (19/17)	Group 1: 30.27 ± 5.58 Group 2: 30.81 ± 3.22
Pang (2007)	Singapore	Prospective	37	50.1 ± 12.2	12/25	34.6 ± 5.2
Penzel (2004)	Germany	Prospective	17	-	-	-
Pillar (2002)	Germany	Prospective	94	46.2 ± 14.4	-	28.5 ± 5.4
Pittman (2004)	USA	Prospective	29	43.2 ± 10.8	21/8	33.9 ± 7.1
Tanphaichitr (2018)	Thailand	Prospective	36	10.2 ± 1.8	22/14	-
Weimin (2013)	China	Prospective	28	47.5 ± 13.5	20/8	30.0 ± 5.7
Yuceege (2014)	Turkey	Prospective	90	-	90	-
Zou (2006)	Sweden	Prospective	98	60 ± 6.7	55/43	28 ± 4.2

the WP300. Like the WP200, the WP300 calculates the RDI, the AHI, and PAT sleep staging identification. In addition to these parameters, WP300 allows measurement of PAT central Apnea–Hypopnea Index (pAHIc), percentage of total sleep time with Cheyne-Stokes Respiration pattern (%CSR), and optionally an acoustic decibel detector used for snoring level and body position from an external integrated snoring and body position (SBP/RESBP) sensor. However, no studies were found on this latest version of WP.

PSG and WP simultaneously

Most of the included studies followed the same protocol: the patients completed an overnight PSG and simultaneously wore WP. Two different settings were considered in the trials: sleep laboratory and at home.

When performed in sleep laboratory, a high correlation between the two systems was found for most of the parameters (AHI [7, 13, 17–21], RDI [13, 19, 22, 23], ODI [13, 17], and SO_2 [17, 18, 21]). Moreover, some studies calculated the sensitivity (87–96%) and specificity (66–80%) of the WP when compared to PSG as the gold standard [7, 13, 18].

Of these in-laboratory studies, two used WP100 [7, 19], five used WP200 [13, 17, 20–22], and one did not specify the model of WP [18].

Following the same protocol, WP accuracy to monitor a new measure of positive airway pressure (PAP) effectiveness, the "Effective AHI," was assessed on patients who had been prescribed PAP therapy for ≥ 2 months. A high correlation between the PSG and WP for the effective AHI was found [24].

Good results were also found when PSG was performed at home (WP100 [25] and WP200 [14, 26]), showing a good correlation for AHI [14, 25], RDI [14, 25, 26], ODI [25, 26], and mean and minimum oxygen saturation [14, 26]. For AHI and RDI, the WP seemed to overestimate severity at higher ranges [14].

PSG and WP used separately

Three studies used the PSG and the WP in different sessions. First, in Bar et al. [12], WP100 and PSG data were recorded simultaneously in the sleep laboratory and a subgroup of 14 patients from the study cohort underwent two additional unattended home sleep studies with the WP device only. The authors compared the RDI obtained with PSG and with WP in three different analyses: laboratory PSG vs. laboratory WP, laboratory PSG vs. home WP, and two home sleep studies. They found a high correlation for the RDI in all three cases. One year later in Pittman et al. [27], all the participants completed two overnight diagnostic studies: one night in the sleep laboratory where subjects performed the PSG wearing the WP100, and 1 night at home with only the WP. Data were compared using Chicago and Medicare criteria. For the first one, PAT RDI was compared to the PSG RDI.C, while using Medicare criteria, PAT ODI was compared to the PSG RDI.M. High concordance in both comparisons was found when performed in the sleep laboratory and with the data derived from the at-home test. Lastly, Choi et al. [6] included 25 adult subjects with suspected OSA who underwent laboratory-based PSG evaluation and, after 1 month, hospital-based portable monitoring using WP100. They found a high correlation and good agreement for AHI and the lowest oxygen saturation between WP PSG.

Pediatric studies

To date, WP is indicated for use in patients 12 years and above; However, in the reported studies, it was also used for children younger than 12 years old.

Two studies were performed to assess the accuracy and clinical reliability of WP for OSA diagnosis in pediatric patients. Tanphaichitr et al. [28] recruited 36 patients aged 8 to 15 years old with clinically suspected OSA. All participants underwent PSG wearing WP (WP200) in the sleep laboratory. They found excellent agreement between the two methods for the AHI (intraclass correlation coefficient (ICC) = 0.89) and ODI (ICC = 0.87). Moreover, the correlation between methods was very good for the ODI (correlation coefficient (r) = 0.83) and moderate for the AHI (r = 0.64). The same protocol was followed by Choi et al. [8] using the same model of WP, showing no significant differences between the mean AHI measured with the WP200 and the mean AHI according to the respiratory rules for children (RRC) and adults (RRA). They also observed no significant differences in average minimum arterial oxygen saturation between the WP200 and PSG. Lastly, they reported the sensitivity and specificity of WP, both considering RRC and RRA.

Discussion

The main purpose of this systematic review was to report the evidence on the PAT-HSAT device efficacy in OSA diagnosis compared to conventional PSG. This new diagnostic tool was designed to overcome drawbacks of the PSG [6–8] as it is more portable and cheaper, allowing more comfortable diagnosis of OSA at home. Of the included studies, some of them performed PSG wearing PAT-HSAT device simultaneously [7, 8, 13, 14, 17–25, 28] while others performed diagnostic studies on two different nights [6, 12, 27]. Both protocols showed good results in terms of AHI, ODI, RDI, and SO_2. PAT-HSAT sensitivity and specificity ranged from 87 to 96% and from 66 to 80%,

Table 2 Summary of the studies on the comparison between WP and PSG

Author (year)	Device	AHI	sO2 (%)	RDI	ODI	Sleep time	Other outcomes
Ayas (2003)	WP100	PSG: 23 ± 23.9 WP: 23 ± 15.9	-	-	-	-	AHI < 10: sensitivity = 82.6% specificity = 71.4% AHI < 15: sensitivity = 93.3% specificity = 73.3% AHI < 20: sensitivity = 90.9% and specificity = 84.2% AHI < 30: sensitivity = 83.3% specificity = 91.7%
Bar (2003)	WP100	-	-	Correlation between the PSG-RDI scores and the WP-RDI scores (r = 0.88, p < 0.0001, n = 99)	-	-	-
Boyd (2016)	WP200	PSG: 18.3 ± 16.1 WP: 20.0 ± 16.1	-	-	-	-	-
Ceylan (2012)	WP200	PSG: 27 ± 23.4 WP: 29.6 ± 20.9	-	PSG: 28.1 ± 23.2 WP: 32.1 ± 19.5	PSG: 19.6 ± 20.0 WP: 20.4 ± 19.5	-	AHI < 15: Sensitivity = 93.1% Specificity = 66.1% Positive predictive value = 79.4% Negative predictive value = 84.6% Diagnostic accuracy = 80.8% AHI < 30: Sensitivity = 88.2% Specificity = 80.0% Positive predictive value = 71.4% Negative predictive value = 92.3% Diagnostic accuracy = 83.0%
Choi (2010)	WP100	PSG: 31.5 ± 28.9 WP: 27.5 ± 23.5	-	-	-	-	-

Table 2 (continued)

Author (year)	Device	AHI	sO2 (%)	RDI	ODI	Sleep time	Other outcomes
Choi (2018)	WP200	WP: 8.0 ± 14.0 PSG (RRC): 8.6 ± 15.5 PSG (RRA): 8.0 ± 15.4	WP: 91.2 ± 5.4 PSG: 91.4 ± 5.2	-	-	-	AHI-RRC as gold standard: Cutoff of ≥ 1: sensitivity = 100%, specificity = 73%, accuracy = 90% Cutoff of ≥ 5: sensitivity = 100%, specificity = 96%, accuracy = 97% Cutoff of ≥ 10: sensitivity = 75%, specificity = 93%, accuracy = 89% AHI-RRA as gold standard: Cutoff of ≥ 5: sensitivity = 100%, specificity = 96%, accuracy = 97% Cutoff of ≥ 15: sensitivity = 80%, specificity = 100%, accuracy = 97% Cutoff of ≥ 30: sensitivity = 100%, specificity = 100%, accuracy = 100%
Hedner (2011)	WP100	-	-	ICC determined by the PSG and WP was 0.87	-	-	Agreement in detecting light/deep 88.6% ± 5.9% Agreement in detecting REM sleep: 88.7% ± 5.5% Agreement in quantifying: sleep efficiency (78.4% ± 9.9% vs. 78.8% ± 13.4%), REM latency (237 ± 148 vs. 225 ± 159 epochs), and REM percentage (14.4% ± 6.5% vs. 19.3% ± 8.7%)
Korkuyu (2014)	WP200	PSG: 33.5 ± 24.6 WP: 35.5 ± 26.8	PSG: 93.1 WP: 92.6	-	-	PSG: 437.3 ± 54.6 WP: 400.9 ± 76.5	-
O'Brien (2012)	WP200	WP: 7.7 ± 13.4 PSG: 5.4 ± 8.5	WP: 95.5 ± 1.1 PSG: 95.8 ± 1.1	WP: 11.7 ± 3.4 PSG: 6.1 ± 8.6	-	WP: 396.5 ± 65.7 PSG: 376.2 ± 74.4	-
Onder (2012)	WP200	Group 1 PSG: 18.72 ± 27 WP: 23.44 ± 25.41 Group 2 PSG: 19.84 ± 20.10 WP: 23.50 ± 22.95	Group 1 PSG: 95.22 ± 2.22 WP: 94.34 ± 2.58 Group 2 PSG: 93.70 ± 4.83 WP: 93.15 ± 4.61	-	Group 1 PSG: 18.57 ± 27.41 WP:16.16 ± 21.34 Group 2 PSG: 18.24 ± 22.56 WP: 15.49 ± 20.93	Group 1 PSG: 358.45 ± 45.50 WP:371.66 ± 33.33 Group 2 PSG: 304.35 ± 79.39 WP: 370.07 ± 32.05	-

Table 2 (continued)

Author (year)	Device	AHI	sO2 (%)	RDI	ODI	Sleep time	Other outcomes
Pang (2007)	Not specified	PSG: 34.87 WP: 35.1	PSG: 82.03 WP: 81.46	-	-	PSG: 5.65 h WP: 5.33 h	Sensitivity: AHI > 5: 0.94 AHI > 15: 0.96 AHI > 35: 0.83 Specificity: AHI > 5: 0.80 AHI > 15: 0.79 AHI > 35: 0.72
Penzel 2004	WP100	PSG: 15 ± 20	-	WP: 23 ± 16	PSG: 20 ± 19 WP: 15 ± 19	PSG: 375 ± 66 (su 14 pz) WP: 394 ± 46 (su 14 pz)	-
Pillar (2002)	WP200	-	-	PSG: 27 ± 24 (ASDA-ARI) WP: 29 ± 19 (PAT-AAI)	-	-	-
Pittman (2004)	WP100	-	-	Lab PSG: 31.6 WP: 34.2 Home WP: 30.2	Lab PSG: - WP: 16.9 Home WP:16.7	Lab PSG: 347.4 WP: 340.3 Home WP: 344.1	-
Tanphaichitr (2018)	WP200	PSG: 8.0 (5.5, 12) WP: 2.9 (0.5, 7.5)	PSG: 87.1 ± 8.1 WP: 89.4 6 7.1	-	PSG: 2.5 (1.4; 8.3) WP: 1.3 (0.2; 3.8)	-	-
Weimin (2013)	WP200	PSG: 23.00 ± 21.55 WP: 25.99 ± 19.09	-	-	-	-	-
Yuceege (2013)	WP200	-	-	-	-	PSG: 226.9 ± 46.3 WP: 227.6 ± 39.2	-
Zou (2006)	WP100	PSG: 25.5 ± 22.9 WP: 27.0 ± 18.7	-	PSG: 31.6 ± 22.7 WP: 30.4 ± 18.7	PSG: 13.3 ± 15.3 WP: 17.7 ± 16.7	-	-

Table 3 Strengths and limitations of the included studies

Author (year)	Country	Strengths	Limitations
Ayas (2003)	USA	1. WatchPAT and the PSG on the same night simultaneously	1. Accuracy of the device may be affected if another disorder yields substantial sleep disruption 2. The device does not measure airflow and thus cannot differentiate hypopneas from apneas 3. Recordings were performed in laboratory setting 4. Small study population at only one sleep center 5. No event-by-event analysis of WatchPAT versus PSG data
Bar (2003)	Israel	1. WatchPAT and the PSG on the same night simultaneously 2. Recordings were performed at home	1. The study population consisted of patients with snoring/sleep apnea syndrome and healthy volunteers 2. PAT was evaluated for apneas and hypopneas but not for increased upper airway resistance syndrome
Boyd (2016)	USA	1. WatchPAT and the PSG on the same night simultaneously	1. Only patients with severe OSA who varied widely in their adherence to PAP therapy were included; thus, the study group may not be representative of the population of patients with severe OSA who are treated with PAP therapy 2. Recordings were performed in laboratory setting 3. This was a single-night study; however, it is known that patterns of sleep-disordered breathing may vary from night to night 4. Since the study group was composed only of patients with severe OSA, the results of the study cannot be applied to patients with milder levels of disease
Ceylan (2012)	Turkey	1. WatchPAT and the PSG on the same night simultaneously	1. The device does not measure airflow and thus cannot differentiate hypopneas from apneas 2. Recordings were performed in laboratory setting 3. Some patients may have difficulty in placing the the device accurately on their wrist and fingers
Choi (2010)	Korea	-	1. There is a possibility of night-to-night variation because the PSG and Watch-PAT were not conducted simultaneously on the same night 2. Recordings were performed in laboratory setting 3. Small study population
Choi (2018)	Republic of Korea	1. WatchPAT and the PSG on the same night simultaneously	1. Small study population 2. The WP200 does not provide sleep apnea results that distinguish it as central, obstructive, or mixed type 3. There is a possibility of failure during the WP200 testing 4. Overnight PSG did not include monitoring of CO2 in this study 5. Recordings were performed in laboratory setting
Hedner (2011)	Sweden USA Israel	1. WatchPAT and the PSG on the same night simultaneously	1. The study population did not include children or patients with specific movement or neurological disorders, 2. The current study was conducted before implementation of the new AASM scoring manual 3. Scoring accuracy between labs was not validated, which can introduce variability 4. Recordings were performed in laboratory setting
Korkuyu (2014)	Turkey	1. WatchPAT and the PSG on the same night simultaneously	1. Recordings were performed in laboratory setting

Table 3 (continued)

Author (year)	Country	Strengths	Limitations
O'Brien (2012)	USA	1. Women were recruited whether they reported habitual snoring or not, so the results are likely representative of third trimester pregnant women more generally 2. WatchPAT and the PSG on the same night simultaneously 3. Recordings in the present study were performed at home	1. Watch-PAT against attended PSG was not validated 2. Only women in the third trimester were studied, so the results may not apply to the first and second trimesters
Onder (2012)	Turkey	1. WatchPAT and the PSG on the same night simultaneously	1. Recordings were performed in laboratory setting
Pang (2007)	Singapore	1. WatchPAT and the PSG were conducted on the same night simultaneously, thereby eliminating the possibility of night-to-night variation	1. The total sleep time for the portable home device may not reflect the true sleep time 2. The apnea and hyponea events on the Watch PAT could not be counted simultaneously and correlated with that of the level I PSG 3. Recordings were performed in laboratory setting
Penzel (2004)	Germany	1. WatchPAT and the PSG on the same night simultaneously	1. Patients with absolute arrhythmias, autonomic neuropathy, diabetes, and/or multiple system atrophy were excluded because the tonometry signal as well as the pulse oximetry signal depends on regular pulses
Pillar (2002)	Germany	1.WatchPAT and the PSG on the same night simultaneously	1. Population consisted of healthy volunteers and patients with snoring 2. Recordings were performed in laboratory setting
Pittman (2004)	USA	1. WatchPAT and the PSG on the same night simultaneously 2. Recordings were performed at home	1. Small study population with suspected OSA at only 1 sleep center 2. There is a possibility of night-to-night variation because the PSG and Watch-PAT were not conducted simultaneously on the same night 3. No event-by-event analysis of WatchPAT versus PSG data
Tanphaichitr (2018)	Thailand	1. WatchPAT and the PSG on the same night simultaneously	1. Not able to identify and include patients with a P-AHI less than 1 2. The PAT probe used in this study was designed for adult fingers. Although patients aged 8 to 15 years were selected and the probe was sealed to the finger using adhesive tape, it is possible that the probe may have loosened during testing 3. Recordings were performed in laboratory setting
Weimin (2013)	China	1. WatchPAT and the PSG on the same night simultaneously	1. Recordings were performed in laboratory setting 2. Small study population 3. No event-by-event analysis of WatchPAT versus PSG data
Yuceege (2014)	Turkey	1. WatchPAT and the PSG on the same night simultaneously	1. No event-by-event analysis of WatchPAT versus PSG data 2. Recordings were performed in laboratory setting

Table 3 (continued)

Author (year)	Country	Strengths	Limitations
Zou (2006)	Sweden	1. The study included a general-population sample enriched by a cardiovascular-disease risk group. The study subjects therefore have a broad spectrum and are likely to represent the true target population for simplified OSA diagnostic tools 2. Recordings in the present study were performed at home 3. WatchPAT and the PSG were conducted on the same night simultaneously	1. In terms of the study design, it should be noted that, if a device is primarily intended for OSA diagnostics in a sleep-lab population, it needs to be tested in this population first. This has been the case with the WP_100 device. The present study did not run a validation test with attended in-lab PSG 2. The ODI validation was hampered by oximetry failures among the ambulatory PSG recordings, and the two devices used different oximetry data collection algorithms 3. Population cohort was enriched of hypertensive subjects 4. Female participants were almost exclusively postmenopausal 5. Age span of the included population was proportionally narrow, in the region of 60 years 6. The body mass index of the included population was slightly higher than the population mean 7. With regard to the recording technique, the high prevalence of sleep-disordered breathing was not entirely unexpected, considering the use of a nasal cannula/pressure together with a thermistor

respectively [7, 13, 18]. In 2017, AASM Clinical Practice guidelines defined PAT signal as technically adequate [29]. PAT finger plethysmograph and SO_2 probe represent the cornerstones of the PAT-HSAT device. In this way, it can identify the respiratory events by digital vasoconstriction mediated by α-adrenergic receptors that are exquisitely sensitive to the surges in a sympathetic activity that accompany respiratory events [13, 14]. This device does not require a sleep technician to be set because scoring is automated, and the physician can make adjustments displaying the entire tracing.

PAT-HSAT has been frequently used not only to make a primary diagnosis but also to evaluate the postoperative outcomes after OSA intrapharyngeal surgery [30].

The PAT-HSAT showed excellent results also in pediatric population, suggesting that it can be a valid alternative to standard PSG [8, 28].

Recently, a new model of disposable PAT-HSAT device has been proposed with the name of "WatchPAT One," allowing a telemedicine HSAT. The patient can receive this tool directly at home and, thanks to its disposable feature, does not need to be returned to the laboratory. This new approach reduced the test cost and the risk of infection by limiting the number of presentations by patients to the laboratory by using disposable devices [11].

This device can also be used in older people without any problems because aging does not influence diagnostic accuracy as shown by the study which investigated the consequences of aging and associated peripheral vascular tone impairment in respiratory disturbance [17].

PAT-HSAT device could tend to overestimate apnea events when AHI was in the lower range. A possible explanation could be that the PAT-HSAT device might record events that were missed by standard scoring criteria or related to sleep fragmentation (arousals) other than those induced by apneas [7]. Yuceege et al. [26] suggested that PAT-HSAT had high sensitivity and specificity in drivers with RDI > 15 and older than 45 years old, while diagnostic accuracy was limited in subjects with RDI < 15 and younger than 45 years old.

On the contrary, O'Brien et al. [14] found that evaluating RDI, the PAT-HSAT device appeared to overestimate severity at higher ranges probably because PAT-HSAT device uses changes probably due to more sensitivity to subcortical activation that would not be scored on traditional PSG.

Among pediatric subjects, Tanphaichitr et al. [28] suggested that AHI and ODI obtained from PAT signal tended to underestimate the degree of sleep apnea compared to PSG.

The PAT-HSAT device should not be used in the following cases: (1) use one of the following drugs: alpha-blockers, short-acting nitrates (less than 3 h before the study); (2) permanent pacemaker: atrial pacing or VVI without sinus rhythm; (3) sustained non-sinus cardiac arrhythmias; and (4)

children weighing less than 29.5 kg. For pediatric patients also, the following cautions could be applied: (1) pediatric patients with severe comorbidities (Down syndrome, neuromuscular disease, underlying lung disease, or obesity hypoventilation) should perform a full PSG; (2) it is recommended that the physician makes sure that the patient and his/her guardian are aware that the use of specific medications and other substances used might interfere with sleep and interfere with the study.

In the literature, there is another study on the same topic. In 2013, Yalamanchali S. et al. [31] showed a positive correlation between PAT-based device and traditional PSG on the main respiratory indexes. However, this meta-analysis is currently old because new studies have emerged in these years.

Recently, Iftikhar IH et al. [32] performed a strict meta-analysis analyzing the agreement in AHI determination between PAT and PSG studies suggesting surprisingly clinically significant discordance in AHI values between WP and PSG, misclassification on sleep apnea severity, and poor diagnostic test performance. This review analyzed 2 PAT devices currently approved by the US Food & Drug Administration: WP and NightOwl (Ectosense, Belgium). The authors showed a WP AHI percentage error of 230%. The meta-analysis of Cohen's kappa for agreement between PSG and WP studies for classifying patients with no sleep apnea, mild, moderate, or severe sleep apnea severity was 0.45 (SE, 0.06), 0.29 (SE, 0.05), 0.25 (SE, 0.07), and 0.64 (SE, 0.05), respectively. However, this review had stringent selection criteria, included only six studies, and evaluated two different PAT devices; instead, our review is more extensive (eighteen articles included) and analyzes only the sensitivity and specificity of WP. However, it is crucial to underline that the PAT-HSAT device is not indicated in patients with comorbid conditions for which the accuracy of an HSAT has not yet been investigated or the presence of other sleep breathing disorders. Sleep physicians should follow a strong algorithm in order to select the ideal patient, interpret the studies, manage technical failures and "negative" studies, and provide treatment recommendations.

A recent study [33] supported the PAT-HSAT device's ability to differentiate central sleep apnea and total sleep apnea events during sleep. Although central sleep-disordered conditions are much less common than obstructive events, it is crucial to perform this discrimination because central events are associated with increased morbidity and mortality in heart failure patients, and it gives us information on which treatment to choose. This review had some limitations. Firstly, there are few studies in the literature on this topic. Moreover, the population included in this review was very heterogeneous, and the studies followed different protocols, limiting the comparison of the results. Lastly, no clinical studies used the most updated models of WP, the WP300 and WP One, but all the studies included older versions of the WP.

Conclusion

The PAT-HSAT device is an effective, comfortable, practical, inexpensive device with excellent concordance with to the standard reference systems. Many patients are hesitant, infirm, or not near a sleep laboratory to obtain a PSG. The PAT-HSAT also allows the diagnosis to be made via telemedicine, reducing costs and waiting time for the examination. However, the PAT-HST device is not appropriate for all patients at risk for OSA due either to comorbid conditions for which the accuracy of an HSAT is unknown or the presence of other sleep disorders that cannot be adequately addressed with an HSAT. Patient selection is important, but even the most cautious and meticulous provider will still have both technical failures and "negative" studies. These studies should either be repeated or the patient should be referred for PSG. Further studies are necessary to confirm these promising results.

Data availability The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical approval No institutional review board approval was necessary because of the nature of this project.

Consent to participate This article does not contain any studies with human participants or live animal performed by any of the authors.

Conflict of interest The authors declare no competing interests.

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