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REVIEW

Diagnostic accuracy of level IV portable sleep monitors versus polysomnography for obstructive sleep apnea: a systematic review and meta-analysis

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Abstract

Purpose Obstructive sleep apnea (OSA) is the most common sleep-related breathing disorder. In-laboratory, overnight type I polysomnography (PSG) is the current "gold standard" for diagnosing OSA. Home sleep apnea testing (HSAT) using portable monitors (PMs) is an alternative testing method offering better comfort and lower costs. We aimed to systematically review the evidence on diagnostic ability of type IV PMs compared to PSG in diagnosing OSA.

Methods *Participants*: patients ≥16 years old with symptoms suggestive of OSA;*intervention*: type IV PMs (devices with < 2 respiratory channels); *comparator*: in-laboratory PSG; *outcomes*: diagnostic accuracy measures;*studies*: cross-sectional, prospective observational/experimental/quasi-experimental studies; *information sources*: MEDLINE and Cochrane Library from January 1, 2010 to May 10, 2016. All stages of review were conducted independently by two investigators.

Results We screened 6054 abstracts and 117 full-text articles to select 24 full-text articles for final review. These 24 studies enrolled a total of 2068 patients with suspected OSA and evaluated 10 different PMs with one to six channels. Only seven (29%) studies tested PMs in the home setting. The mean difference (bias) between PSG-measured and PM-measured apnea-hypopnea index (AHI) ranged from − 14.8 to 10.6 events/h. At AHI ≥ 5 events/h, the sensitivity of type IV PMs ranged from 67.5–100% and specificity ranged from 25 to 100%.

Conclusion While current evidence is not very strong for the stand-alone use of level IV PMs in clinical practice, they can potentially widen access to diagnosis and treatment of OSA. Policy recommendations regarding HSAT use should also consider the health and broader social implications of false positive and false negative diagnoses.

Keywords Obstructive sleep apnea · Home sleep apnea testing · Polysomnography · Systematic review

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s11325-017-1615-1) contains supplementary material, which is available to authorized users.

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Introduction

Obstructive sleep apnea (OSA) is a sleep-related, chronic breathing disorder characterized by recurrent, transient apneas, or hypopneas during sleep caused by intermittent narrowing or collapse of the upper airway. Patients with OSA have frequent sleep disruption resulting in unrefreshing sleep, daytime sleepiness, fatigue, and impaired concentration and memory [1]. OSA increases the risk of motor vehicle accidents [2], hypertension, ischemic heart disease, heart failure, arrhythmias, and stroke [3]. OSA has been associated with a two- to sixfold increase in the risk of all-cause mortality [4, 5]. The prevalence of OSA is increasing, currently affecting 13% of the men and 6% of the women between ages 30 and 70 years [6]. OSA remains a highly underdiagnosed because of lack of awareness and limited access to testing [7].

Patients with symptoms suggestive of OSA are usually referredfor a diagnostic sleep study anda clinical assessment by a qualified sleep specialist [8]. The reference standard test used to diagnose OSA is overnight polysomnography (PSG) conducted in a sleep laboratory, supervised by a qualified sleep technician [9, 10]. The PSG reports on several physiologic parameters captured through seven or more recording channels [11]. The main diagnostic parameter calculated based on PSG is the apnea-hypopnea index (AHI), i.e., the average number of apneas and hypopneas per hour of sleep [10]. The diagnosis of OSA is made if the AHI is ≥ 5 events/h for patients reporting symptoms (e.g., daytime sleepiness, snoring) or ≥15 events/h, regardless of symptoms [8, 9].

Diagnostic sleep studies can be performed at home as well. The sleep monitors are classified as type I–IV where PSG is a type I device for in-laboratory testing, and type II–IV are portable sleep monitors for home sleep apnea testing (HSAT) [11]. According to the American Academy of Sleep Medicine (AASM) criteria, a type II portable monitor (PM) is a full unattended portable PSG (≥ 7 channels), type III monitors have four to seven channels, and type IV monitors have one to two channels with one of them being oximetry [11]. A major limitation of most PMs is their inability to distinguish between the sleep and the wake periods, and reporting of the number of apneas and hypopneas per hour of recording time rather than sleep time, a parameter also known as the respiratory event index (REI) [12]. Since REI tends to underestimate the "true" AHI, the current AASM guideline recommends performing a confirmatory PSG in patients withnegative HSAT [12]. The guideline supports the use PSG or HSAT with a "technically adequate device" in uncomplicated patents with moderate to high risk of OSA and only PSG for those with significant comorbidities [12].

HSAT generally offers a more patient-centered approach by permitting a simplified home sleep testing in a more familiar and comfortable setting, at lower costs and shorter wait times than PSG [13]. These factors may support broader testing for OSA, as a means of expanding the diagnosis of subclinical disease and addressing the population health burden of OSA. Evidence on diagnostic accuracy of HSAT continues to accumulate. Commissioned by the Agency for Healthcare Research and Quality (AHRQ), the Tufts Evidence-based Practice Center conducted the most comprehensive comparative effectiveness review of existing diagnostic and treatment modalities for OSA covering the period up to September 2010 [14]. The aim of this project was to update this systematic review with a specific focus on evaluating the diagnostic ability of type IV PMs compared to PSG in patients with suspected OSA.

Methods

The protocol of this systematic review has been registered in the International Prospective Register of Systematic Reviews (PROSPERO) database on April 20, 2016 (registration number: CRD42016037470). The study reporting followed the Preferred Reporting Items in Systematic Reviews and Meta-Analyses (PRISMA) guideline [15].

Study selection criteria

Population Our systematic review targeted studies that included patients who were at least 16 years old with symptoms suggestive of OSA. Studies where more than 20% of the study population had any of the following were excluded: a neuromuscular disease (e.g., multiple sclerosis, muscular dystrophy), Down syndrome, Prader-Willi syndrome, major congenital skeletal abnormalities, narcolepsy, narcotic addiction, Alzheimer's disease, epilepsy, or had experienced a disabling stroke. Studies that included only general population or those with established sleep apnea or other sleep disorders were excluded.

Intervention and comparator The interventions reviewed included type IV PMs applied at home or in a sleep laboratory for diagnosing OSA. The comparator of interest was overnight PSG conducted in a sleep laboratory. For consistency, we classified types of sleep monitors following the rules applied in the previous systematic review [14]. Based on the classification used in the latter publication, type III monitors have ≥ 4 channels, including at least two respiratory channels (two airflow or one airflow and one effort channel), but cannot differentiate between sleep and wake or measure arousals. Type IV PMs include devices that do not meet criteria for type III monitors. Studies with single-channel PMs that used heart rate, heart rate variability, or actigraphy, and those that used clinical features (e.g., neck circumference, body mass index) as additional predictive factors for diagnosis of OSA were excluded. Studies with type II or III monitors were also excluded.

Outcomes We included studies that reported at least one of the following measures for diagnostic performance: sensitivity, specificity, area under the receiver operating characteristic (ROC) curve, and Bland-Altman analysis of concordance (mean of the differences (i.e., bias) and levels of agreement) [16] when comparing clinical diagnosis based on the sleep test, AHI, REI, or respiratory disturbance index (RDI). Since these parameters are not defined consistently in literature [14], for each evaluated study, we extracted and reported the definitions used by the authors.

Studies We included cross-sectional and prospective studies that used experimental, quasi-experimental, or observational designs of any follow-up duration and excluded all other study types (e.g., case reports, case series, reviews, editorials or commentaries, clinical guidelines). We also excluded (1) animal studies, (2) non-English articles, (3) studies that had less

than 10 study participants for each test, and 4) studies based on retrospective analysis of existing clinical databases.

Information sources

All eligible studies were identified through a systematic comprehensive search of the Ovid MEDLINE(R), Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, and Cochrane Library databases for the period from January 1, 2010 to May 10, 2016. The selection of this timeframe was justified by the availability of a prior systematic review that covered the time period up to September 2010 [14].

Search strategy

The search strategy was designed by an information specialist (JB), using an existing past review[14] as a guide. The search strategy included Medical Subject Headings terms and textwords in the following concept areas: sleep apnea, polysomnography and other diagnostic tests, general diagnostic accuracy terms, randomized controlled trials, and other specified designs (see Online Resource 1 for deatiled search strategy). Duplicates were removed at the database level and at the citation manager level. In addition, we hand-searched the reference lists of full-text articles under review.

Selection of studies and data extraction

All stages of the review (review of titles and abstracts, review of full texts, data abstraction, and assessment of quality) were conducted independently by groups of two reviewers (LA, PP, SC, SMC, VR, YS) and compared. Disagreements were resolved by consensus. Reasons for exclusions of full-text articles were recorded. For the full-text articles included in the final review, we extracted the following information into an Excel database: study characteristics (e.g., country, design), participant characteristics (e.g., inclusion and exclusion criteria, age, gender, OSA severity), details on compared sleep monitors (e.g., name, number, and type of channels), and estimates of their diagnostic accuracy. When available, we extracted study specific criteria set by authors to qualify a sleep study (PM and/or PSG) as valid and appropriate for analysis.

Assessment of quality of studies

The quality of studies was assessed using the Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) tool [17]. The tool assesses study quality in four domains including patient selection, index and reference tests, and flow and timing for the risk of bias (ROB) and applicability.

Data synthesis

For the studies included in the final review, we descriptively presented the study, patient, and device characteristics as well as the results from the diagnostic accuracy testing. In cases where the authors published the Bland-Altman plots but did not provide the corresponding numerical values (mean of differences, limits of agreement), we used the free Plot Digitizer software program to extract them from the plot. In addition, studies that calculated the bias and 95% limits of agreement estimates as "PSG AHI/RDI minus PM AHI/RDI," we reversed the values to standardize reporting of all these estimates as "PM AHI/RDI minus PSG AHI/RDI".

We did not apply indirect comparisons between different PMs considering variability in their structures (i.e., channels) and population studied. Instead, we conducted separate meta-analysis for each PM versus PSG comparison to obtain summary estimates on sensitivity and specificity. For this purpose, we used bivariate random-effects models that consider both the within-study variability in sensitivity and specificity and the correlation between these two measures [18]. PMs were selected for meta-analysis if they have been tested in at least four studies [18] conducted in the same setting (in laboratory or at home) using similar AHI/RDI cutoffs and if the authors provided sufficient details to extract or calculate the number of patients with true positive, false positive, true negative, and false negative test results.

Results

Our search resulted in 6647 MEDLINE and 780 Cochrane records or 6054 total records after removing duplicates (Fig. 1). After screening titles and abstracts, 5939 records were excluded. The full texts of the remaining 115 abstracts were retrieved for more detailed evaluation. Two more potential full-text articles were identified at this stage, one through a review of reference lists and another after contacting an author for a study-related question. After review of full texts, we excluded 93 articles with the most common reasons being not containing an analysis of interest ($n = 30$), investigating a type III device ($n = 26$), or not having the population of interest ($n = 16$). The final review included 24 prospective studies.

Characteristics of included studies

The studies were conducted in 12 different countries including six in the USA; three in Argentina and Australia; two in Canada, China, and Japan; and one in France, Germany, Ireland, Republic of Korea, Saudi Arabia, and Turkey (Table 1). All studies used a cross-sectional design to test PMs against PSG with three studies applying a random order when testing in-laboratory PSG against home PM [26, 36, 39]. Among the 24 studies, the mean age of participants varied

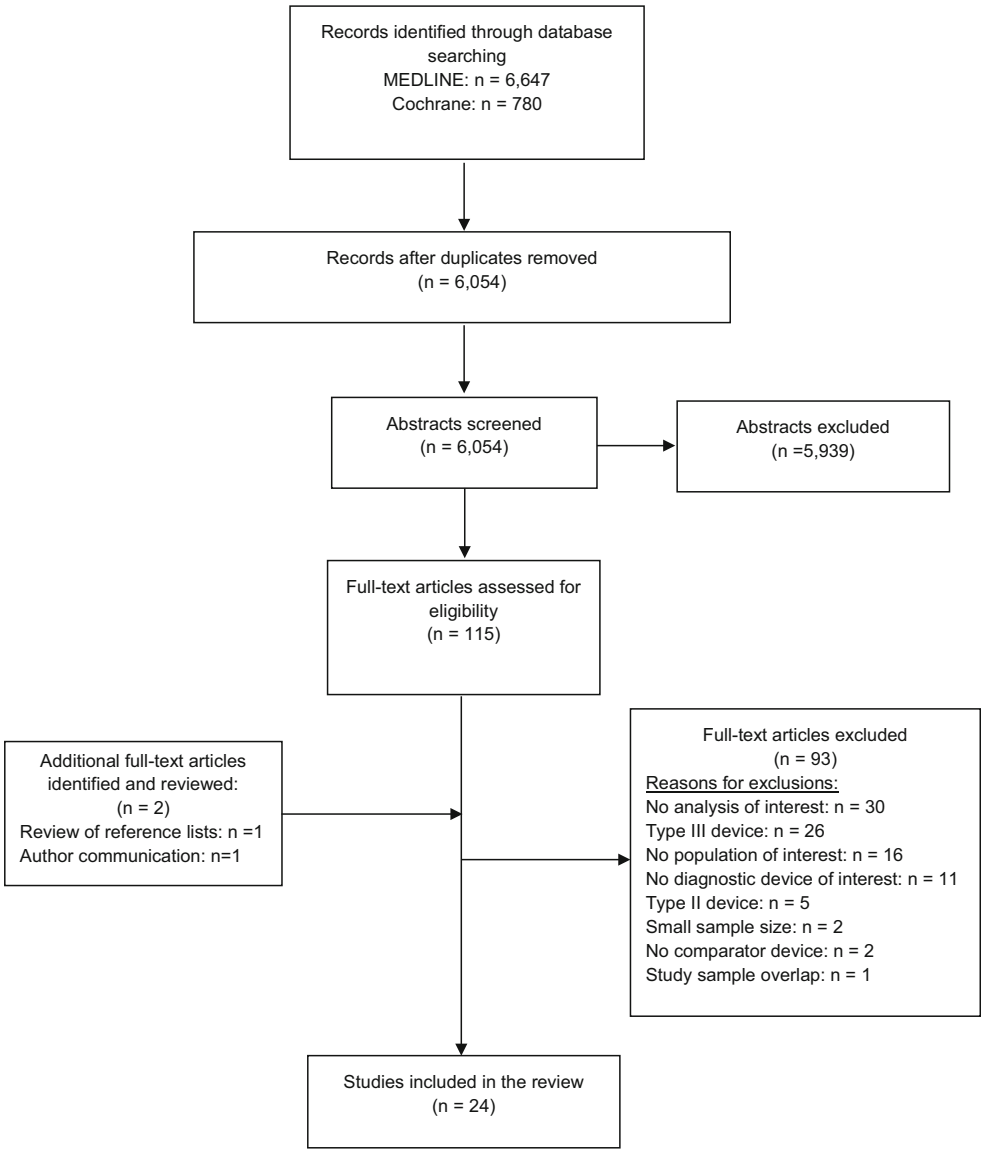

Fig. 1 Flow diagram of selection of studies

from 40.9 to 64.6 years, the proportion of males from 24.0 to 88.4%, and the mean BMI from 25.5 to 36.3 kg/m^2. The type and number of patients with comorbidities were not reported in 12 studies, although five of them excluded patients with serious comorbidities. The remaining 12 studies reported several comorbidities in the patient population including hypertension (20.3 to 55% of the patient population), ischemic heart disease (7–50%), diabetes (5–30%), and asthma (6–16%). Patients had a high pre-test probability of OSA; the mean AHI ranged from 8 to 42.7 events per hour of sleep.

Overall, the 24 studies evaluated 10 different type IV PMs including (i) single-channel devices such as BresoDx [19, 20], ApneaLink [22, 25, 29, 30, 32, 34], SD-101 [27, 38], Flow Wizard [35, 36], SleepMinder [41], and oximetry [21, 23, 33, 37]; (ii) two-channel devices such as ApneaLink Ox [31, 39] and SleepView [42]; and (iii) four-channel devices such as WatchPAT 100 [24] and WatchPAT 200 [26, 28, 40] (Table 1).

Quality of included studies

The results of the quality assessment of these studies using QUADAS-2 are presented in Fig. 2. In all four domains, the proportion of studies with unclear ROB was quite large (38 to 50%), reflecting poor reporting practices. About 17% of the studies were evaluated as high ROB for the "index test" domain that jointly evaluates if the test interpretation was done without knowing the results of the reference test (PSG) and if the thresholds for analyses were pre-specified. In terms of applicability, 17 studies (71%) were scored as high risk because they tested PMs only in a sleep laboratory setting.

Overall, blinding of PSG results when interpreting PM results (and vice versa) was applied only in 13 studies (54.2%) and not reported in the remainder (see Online Resource 2). Criteria for a good quality sleep study were defined in 14 studies (58.3%), and the proportion of patients excluded from the

Table 1 Characteristics of included studies

Author, year	Country	Sampling population and enrollment	Demographics: Age (years), mean (SD); %Male	OSA risk factors: BMI (kg/m^2), mean (SD); ESS, mean (SD); PSG AHI (events/h), mean (SD), % with AHI ≥ 5, 15 events/h	Comorbidities	Portable monitor device, number and type of channels
Alshaer 2013 [19]	Canada	Sampling population:referred for a sleep study for SDB with at least two of the following symptoms: a history of loud habitual snoring, restless sleep, morning headaches or excessive daytime sleepiness. Enrollment: consecutive patients	Age: 53.5 (13.5) %Male: 72.0	BMI: 30.1 (6.4) ESS: nr AHI: 14.9 events/h AHI ≥ 5: nr AHI ≥ 15:nr	nr	Device: not named [later named BresoDx, see below] No. of channels: 1 Type of channels: breath sounds recorder
Alshaer 2016 [20]	Canada	Sampling population:referred for PSG due to a history suggestive of OSA including at least two of the following symptoms: a history of loud habitual snoring, restless sleep, morning headaches, or excessive daytime sleepiness. Enrollment: consecutive patients	Age: 53.4 (15.6) %Male: 59.3	BMI: 30.9 (7.7) ESS: nr AHI: 20.9 (21.0) events/h AHI ≥ 5: nr AHI ≥ 15: nr	nr	Device: BresoDx No. of channels: 1 Type of channels: breath sounds recorder
Amir 2012 [21]	USA	Sampling population:admitted to eithercardiology department ($n = 60$) or ambulatory sleep lab for clinically suspected sleep disordered breathing ($n = 14$) Enrollment: unclear	Age: 64.6 (14.3) %Male: 73.0	BMI: 30.9 (8.7) ESS: nr AHI: median = 29 (range: 0 to 88) events/h AHI ≥ 5: nr AHI ≥ 15: 62.5%	IHD (50%), DM (30%), renal insufficiency (19%), hypertension (55%)	Device: Morpheus Ox (oximetry) No. of channels: 1 Type of channels: oximetry (using photoplethysmography and saturation data)
BaHammam 2011 [22]	Saudi Arabia	Sampling population:referred to a sleep clinic with a history of snoring and clinical suspicion of sleep-disordered breathing Enrollment: consecutive patients	Age: 46.3 (12.6) %Male: 61.1	BMI: 34.1 (7.9) ESS: nd AHI: 34.1 (32.4) events/h AHI ≥ 5: 85.3% AHI ≥ 15: 62.1%	Hypertension (35%), IHD without HF (7%), DM (29%), hypothyroidism on treatment (13%), hyperlipidemia (37%)	Device: ApneaLink No.of channels: 1 Type of channels: nasal airflow
Barak-Shinar 2013 [23]	USA	Sampling population:referred to a sleep clinic for the diagnosis of SDB Enrollment: consecutive patients	Age: 52.5 (14.3) %Male: 56.4	BMI: 31.3 (6.4) ESS: 10.2 AHI: 15.5 (17.4) events/h AHI ≥ 5: 72.1% AHI ≥ 15: 38.6%	Hypertension (34%)	Device: Morpheus Ox (oximetry) No.of channels: 1 Type of channels: oximetry (using photoplethysmography and saturation data)
Choi 2010 [24]	Republic of Korea	Sampling population:subjects with suspected OSA Enrollment: unclear	Age: 40.9 (11.2) %Male: 84.0	BMI: 26.2 (2.6) ESS: nd AHI: 31.5 (28.9) events/h AHI ≥ 5: 76.0% AHI ≥ 15: 68.0%	nr (patients with major comorbidities were excluded)	Device: WatchPAT 100 No. of channels: 4 Type of channels: PAT signal, heart rate, pulse oximetry, actigraphy
Crowley 2013 [25]	USA	Sampling population:a selected sample of police officers with and without symptoms ofsleep disorders Enrollment: unclear	Age: 45.4 (10.8) %Male: 88.4%	BMI: 30.4 (5.3) ESS: 8.8 (3.9) AHI: 9.4 (17.1) events/h AHI ≥ 5: 41.9% AHI ≥ 15: 16.3%	nr	Device: ApneaLink No. of channels: 1 Type of channels: nasal airflow
Garg 2014 [26]	USA	Sampling population:high risk African Americans selected based on Berlin questionnaire	Age: 44.7 (10.6) %Male: 24.0	BMI:nr ESS: 12.0 (5.5) AHI: 30.3 (35.0) events/h	Average number of comorbidities was two; hypertension (54%),	Device: WatchPAT 200 No. of channels: 4 (+ 2 optional)

Table 1 (continued)

Author, year	Country	Sampling population and enrollment	Demographics: Age (years), mean (SD); %Male	OSA risk factors: BMI (kg/m^2), mean (SD); ESS, mean (SD); PSG AHI (events/h), mean (SD), % with AHI ≥ 5, 15 events/h	Comorbidities	Portable monitor device, number and type of channels
		Enrollment: consecutive		AHI ≥ 5: 41.9% AHI ≥ 15: 16.0%	diabetes (24%), peripheral neuropathy (8%)	Type of channels: PAT signal, heart rate, pulse oximetry, actigraphy, snore microphone (optional), body positioning (optional)
Kobayashi 2013 [27]	Japan	Sampling population:suspected OSA syndrome based on information about habitual snoring or episodes of apnea witnessed by family members Enrollment: consecutive	Age: 50.0 (13.5) %Male: 83.3	BMI: 25.5 (3.3) ESS: 9.9 (3.4) AHI: 24.5 (21.2) events/h AHI ≥ 5: 70.7% AHI ≥ 15: 54.7%	nr	Device: SD-101; SD-101 and oximetry No. of channels: 1; 2 Type of channels: sheet-like device with an array of pressure sensorswith and without pulse oximetry
Körkuyu 2015 [28]	Turkey	Sampling population:subjects referred for PSG with the preliminary diagnosis of OSA Enrollment: unclear	Age: 49.2 (9.6) %Male: 83.3	BMI: 29.6 (4.4) ESS: nr AHI: 33.5 (24.6) events/h AHI ≥ 5: 93.3% AHI ≥ 15: 83.3%	nd (patients with major comorbidities were excluded)	Device: WatchPAT 200 No. of channels: 4 (+2 optional) Type of channels: PAT signal, heart rate, pulse oximetry, actigraphy, snore microphone (optional), body positioning (optional)
Nigro 2010 [29]	Argentina	Sampling population:referred to a sleep lab for suspected OSA Enrollment: consecutive	Age: 51.5 (14.1) %Male: 71.2	BMI: 29.3 (5.4) ESS: nr AHI: 9.5 (IQR: 4.1–34.1) events/h AHI ≥ 5: nr AHI ≥ 15: nr	nr	Device: ApneaLink No. of channels: 1 Type of channels: nasal airflow
Nigro 2011 [30]	Argentina	Sampling population:referred to a sleep lab for possible OSA Enrollment: consecutive	Age: 49.6 (15.1) %Male: 77.0	BMI: 29.3 (IQR: 25.2–32.5) ESS: nr AHI: 11.8 (IQR: 5.8–32.3) events/h AHI ≥ 5: nr AHI ≥ 15: nr	Hypertension (50%), IHD (11%), cerebrovascular ischemia (5.5%), arrhythmia (3.3%), asthma (10%), chronic obstructive pulmonary disease (5.5%); allergic rhinitis (24.4%)	Device: ApneaLink No. of channels: 1 Type of channels: nasal airflow
Nigro 2013 [31]	Argentina	Sampling population:referred to a sleep lab for possible OSA Enrollment: consecutive	Age: 48.2 (14.5) %Male: 69.1	BMI: 30 (7.2) ESS: AHI: nr PSG RDI: 15.1 (IQR: 6.3–34.6) events/h AHI ≥ 5: nr AHI ≥ 15: nr	Hypertension (44%), IHD (9%), cerebrovascular ischemia (3.6%), arrhythmia (11%), asthma (3.6%), allergic rhinitis (27.3%)	Device: ApneaLink Ox No. of channels: 2 Type of channels: nasal airflow, pulse oximeter
Oktay 2011 [32]	USA	Sampling population:referred for suspected OSA Enrollment: consecutive	Age: 45.1 (11.3) %Male: 45.3	BMI: 35.9 (9.1) ESS: 10 (4.9) AHI: nr AHI ≥ 5: 75.5%	Hypertension (43%), impaired cognition (32%), mood disorders (40%), insomnia (32%), arrhthmias 11%;	Device: ApneaLink No. of channels: 1 Type of channels: nasal airflow

Table 1 (continued)

Author, year	Country	Sampling population and enrollment	Demographics: Age (years), mean (SD); %Male	OSA risk factors: BMI (kg/m^2), mean (SD); ESS, mean (SD); PSG AHI (events/h), mean (SD), % with AHI ≥ 5, 15 events/h	Comorbidities	Portable monitor device, number and type of channels
				AHI ≥ 15:35.8%	asthma (26%), bronchitis (9%), DM type 1 (6%), DM type 2 (11%)	
Poupard 2012 [33]	France	Sampling population:referred to a sleep lab for suspected OSA Enrollment: consecutive	Age: 57 (14) %Male: 65.1	BMI: 29 (5) ESS: nr AHI: nr AHI ≥ 5: 78.3% AHI ≥ 15: 50.0%	Chronic obstructive pulmonary disease (0.9%), heart failure (4.7%)	Device: analytical software[not named] No. of channels: 1 Type of channels: oximetry
Ragette 2010 [34]	Germany	Sampling population:patientswith high pre-test probability for sleep apnea referred to sleep lab Enrollment: consecutive	Part I Age: 54.7 (13.3) %Male: 76.5 Part II Age: 59.1 (4.6) %Male: 72.5	Part I BMI: 29.5 (5.1) ESS: nr AHI: nr AHI ≥ 5: 80.4% AHI ≥ 15: 49.0% Part II BMI: 28.0 (4.4) ESS: nr AHI: nr AHI ≥ 5: 72.4% AHI ≥ 15: 38.2%	Part I Hypertension (45%), IHD (9%), heart failure (3%), chronic bronchitis (15%), asthma (6%), DM (7%) Part II Hypertension (44%), IHD (7%), heart failure (8%), chronic bronchitis (31%), asthma (16%), DM (5%)	Device: ApneaLink No. of channels: 1 Type of channels: nasal airflow
Rofail 2010 [35]	Australia	Sampling population:referred to a sleep lab for suspected OSA Enrollment: consecutive	Age: 49.4 (14.5) %Male: 68.0	BMI: 30.5 (6.7) ESS: 9.9 (5) AHI: 21.4 (25.0) events/h AHI ≥ 5: nr AHI ≥ 15: nr	Hypertension (42%)	Device: Flow Wizard No. of channels: 1 Type of channels: nasal airflow
Rofail 2010 [36]	Australia	Sampling population:referred to a sleep lab for suspected OSA Enrollment: random (when device available)	Age: 46 (11.7) %Male: 77.1	BMI: 29.7 (5.1) ESS: 9.7 (5.0) AHI: 18.7 (21.2) events/h AHI ≥ 5: nr AHI ≥ 15: nr	nr (patients with major comorbidities were excluded)	Device: Flow Wizard and oximetry (separately) No. of channels: 1 Type of channels: nasal airflow and pulse oximetry (separately)
Romem 2014 [37]	USA	Sampling population:referred for suspected OSA based on symptoms (snoring, witnessed apnea, daytime sleepiness), comorbidities (hypertension, heart failure), and physical examination (BMI, Mallampati score, neck circumference) Enrollment: consecutive	Age: 52.1 (14.2) %Male: 52.0	BMI: 36.3 (9.7) ESS: nr AHI: 8 (IQR: 3.2–19.6) events/h AHI ≥ 5: 67.7% AHI ≥ 15: 32.3%	Significant cardiopulmonary comorbidities (29.3%), pulmonary disease (18.5%), cardiac disease (15.4%), on chronic narcotic pain medication (10.8%), β-blocker/calcium channel blocker therapy (32.3%)	Device: Morpheus Ox (oximetry) No. of channels: 1 Type of channels: oximetry (using photoplethysmography and saturation data)
Tsukahara 2014 [38]	Japan	Sampling population:suspected OSA patients with complaints of habitual snoring, excessive daytime sleepiness, or episodes of apnea confirmed by family members who were referred for clinical sleep evaluation	Age: 55.3 (18) %Male: 75.2	BMI: 27.7 (7.8) ESS: 9.1 (7.7) AHI: 42.7 (38.3) events/h AHI ≥ 5: nr AHI ≥ 15: nr	nr	Device: SD-101 No. of channels: 1 Type of channels: sheet-like device with an array of pressure sensors

Table 1 (continued)

Author, year	Country	Sampling population and enrollment	Demographics: Age (years), mean (SD); %Male	OSA risk factors: BMI (kg/m^2), mean (SD); ESS, mean (SD); PSG AHI (events/h), mean (SD), % with AHI ≥ 5, 15 events/h	Comorbidities	Portable monitor device, number and type of channels
Ward 2015 [39]	Australia	Enrollment: unclear Sampling population: referred to a sleep lab for suspected OSA Enrollment: consecutive	Age: 50.7 (13.5) %Male: 62.0	BMI: 31.3 (6.3) ESS: 9.3 (5.6) AHI: 28.5 events/h AHI ≥ 5: 94.2% AHI ≥ 15: 72.1%	nr (patients with major comorbidities were excluded)	Device: ApneaLink Ox No. of channels: 2 Type of channels: nasal airflow, pulse oximeter
Weimin 2013 [40]	China	Sampling population:referred to a sleep lab for suspected OSA Enrollment: unclear	Age: 47.5 (13.5) %Male: 71.4	BMI: 30.0 (5.7) ESS: 7.57 (5.3) AHI: 23.0 (21.6) events/h AHI ≥ 5: 85.7% AHI ≥ 15: 57.1%	nr (patients with major comorbidities were excluded)	Device: WatchPAT 200 No. of channels: 4 (+ 2 optional) Type of channels: PAT signal, heart rate, pulse oximetry, actigraphy, snore microphone (optional), body positioning (optional)
Zaffaroni 2013 [41]	Ireland	Sampling population:referred to a sleep lab for suspected OSA Enrollment: consecutive	Age: 49.9 (12.3) %Male: 79.7	BMI: 31.3 (6.2) ESS: nr AHI: 26.1 (28.5) events/h AHI ≥ 5: 81.1% AHI ≥ 15: 52.7%	Hypertension (20.3%), DM (10.8%), statintherapy (17.6%)	Device: SleepMinder No. of channels: 1 Type of channels: non-contact bedside bio-motion sensor
Zou 2015 [42]	China	Sampling population:subjects with possible OSA and volunteers with no reported snoring Enrollment: consecutive	Age: 43.4 (13.2) %Male: 75.3	BMI: 26.6 (3.6) ESS: 8.0 (median) AHI: 19.2 (median) events/h AHI ≥ 5: 76.3% AHI ≥ 15: 58.1%	nr	Device: SleepView No. of channels: 2 Type of channels: oronasal airflow, pulse oximetry

AHI apnea hyponea index, *BMI* body mass index, *DM* diabetes mellitus, *ESS* Epworth Sleepiness Scale, *HF* heart failure, *IHD* ischemic heart disease, *IQR* interquartile range, *nr* not reported, *OSA* obstructive sleep apnea, *PAT* peripheral arterial tone, *PSG* polysomnography, *RDI* respiratory disturbance index, *SDB* sleep-disordered breathing, *SD* standard deviation

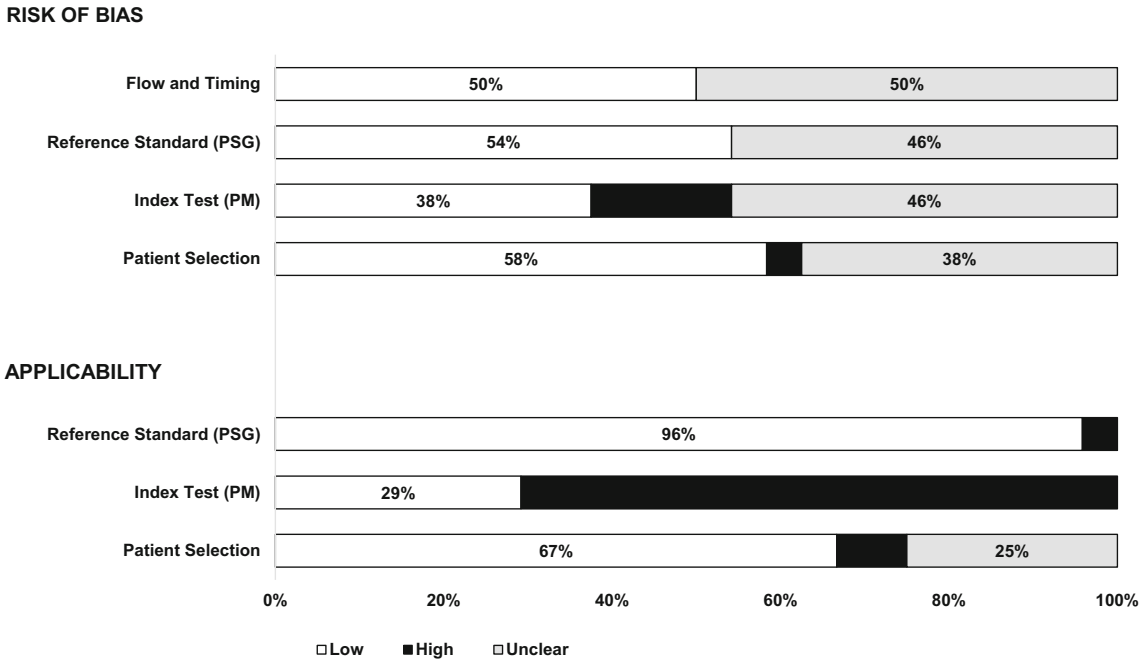

Fig. 2 Quality of included studies based on QUADAS-2

final analysis due to technical failure or other errors varied from zero to 25%.

Diagnostic accuracy of type IV monitors

Table 2 presents the results of the diagnostic accuracy assessments in the included studies. Out of 24 studies, six compared the performance of PM both in laboratory (simultaneously with PSG) and in home settings [20, 25, 26, 32, 34, 39]. One compared in-lab PSG with in-home PM [36], and the remaining 17 studies compared in-lab PM and PSG (simultaneously) [19, 21–24, 27–31, 33, 35, 37, 38, 40–42]. The sample size in these studies varied from 25 to 198 patients.

One study did not report concordance analysis [38] and the other did not report AHI/RDI values from the PM [33]. From the remaining 22 studies, 14 calculated the mean of differences as PM AHI/RDI minus PSG AHI/RDI and 8 as PSG AHI/RDI minus PM AHI/RDI (Table 2). After reversing the values from the latter 8 studies, the mean of the differences (bias) between the PM-measured AHI/RDI and PSG-measured AHI/RDI varied from − 14.8 to 10.6 events/h with the lower and upper limits of agreement ranging from − 66.0 to 78.8 events/h (Table 2). Among the five studies that tested the PM both at home and in the laboratory setting and reported bias estimates [25, 26, 32, 34, 39], the estimates were not largely different and limits of agreement estimates overlapped (Fig. 3).

None of the studies compared clinical diagnosis of OSA informed by the PM or PSG. Most studies compared AHI/RDI measured as number of events during the total sleep time from PSG against the AHI/RDI measured as number of events over the total recording time from PM (Table 2). One study measured other indices [33], and another did not report a threshold analysis [28]. Most frequently, studies used AHI/RDI cutoffs of 5 and 15 events/h to report on diagnostic performance.

In studies that tested the performance of PMs in both settings (home and laboratory) [25, 26, 32, 34, 39], the sensitivity and specificity values were better from tests conducted in the sleep laboratory (simultaneously with PSG) than when conducted at home. Table 3 reports the sensitivity and specificity ranges for AHI/RDI cutoffs of 5 and 15 events/h for single-, two-, and four-channel PMs. The sensitivity at AHI/RDI cutoff value at 5 events/h ranged between 0.68–1.0 for single-channel PMs, 0.77–0.93 for two-channel, and 0.96–1.00 for four-channel PMs. The sensitivity values somewhat decreased and specificity values increased when moving the threshold from 5 to 15 events/h. For comparison purposes, Table 3 shows the results from the past systematic review [14].

Meta-analysis of PMs

Only the ApneaLink device was tested in ≥ 4 studies and qualified for the quantitative meta-analysis for summary diagnostic accuracy measures (Table 4). The mean estimates for sensitivity and specificity based on six studies of ApneaLink [22, 25, 29, 30, 32, 34] (all conducted in sleep laboratories) were 0.88 (95% confidence interval (CI) 0.82 to 0.92) and 0.64 (95% CI 0.52 to 0.75) for the AHI/RDI cutoff of 5 events/h and 0.82 (95% CI 0.69 to 0.90) and 0.88 (95% CI 0.83 to 0.91) for the AHI/RDI cutoff of 15 events/h. No heterogeneity was observed between the studies for both cutoffs ($I^2 = 0$ and p value for Q statistics > 0.05).

Table 2 Diagnostic accuracy of type IV PMs against PSG: evidence summary

Author	Index test (vs PSG)	Number (total)	Setting (for PM)	Bias (LOI) from Bland-Altman plots*(events/h)	ROC analysis				
					Threshold (events/h)		Sensitivity (95% CI, if available)	Specificity (95% CI, if available)	AUC
					Index (PM)	PSG			
Alshaer 2013 [19]	[Not named]	50	Lab	AASM criteria: 3.1 (− 7.6, 13.8)	AHI ≥ 10 (TRT)	AHI ≥ 10 (TRT)	96	64	nr
				TV50 criteria: 1.4 (− 8.9, 11.7)	AHI ≥ 10 (TRT)	AHI ≥ 10 (TRT)	95	69	nr
					AHI ≥ 10 (TRT)	AHI ≥ 10 (TST)	93	72	nr
Alshaer 2016 [20]	BresoDx	135	Lab	10.6 (− 9.9 to 11.3)	AHI ≥ 5 (TRT)	AHI ≥ 5 (TRT)	97.9	79.5	0.92
					AHI ≥ 10 (TRT)	AHI ≥ 10 (TRT)	87.3	90.6	0.93
					AHI ≥ 15 (TRT)	AHI ≥ 15 (TRT)	88.7	96.3	0.94
					AHI ≥ 30 (TRT)	AHI ≥ 30 (TRT)	83.3	99.1	0.99
					AHI ≥ 5 (TRT)	AHI ≥ 5 (TST)	98.1	82.8	0.91
					AHI ≥ 10 (TRT)	AHI ≥ 10 (TST)	87.5	96.4	0.94
					AHI ≥ 15 (TRT)	AHI ≥ 15 (TST)	77.4	97.3	0.92
					AHI ≥ 30 (TRT)	AHI ≥ 30 (TST)	65.6	100	0.97
		100	Home	nr	AHI ≥ 12 (TRT)	AHI ≥ 10 (TRT)	73.5	88.2	0.84
Amir 2012 [21]	Morpheus Ox	64	Lab	1.3 (− 17.6, 20.1)†	AHI ≥ 15 (TST)	AHI ≥ 15 (TST)	98 (87.1, 99.6)	96 (79.8, 99.3)	nr
BaHammam 2011 [22]	ApneaLink	95	Lab	Automated scoring:− 5.8 (− 30.7, 19.1)	AHI ≥ 5 (TRT)	AHI ≥ 5 (TST)	0.79	0.68	0.854
					AHI ≥ 10 (TRT)	AHI ≥ 10 (TST)	0.70	0.89	0.856
					AHI ≥ 15 (TRT)	AHI ≥ 15 (TST)	0.65	0.94	0.805
					AHI ≥ 30 (TRT)	AHI ≥ 30 (TST)	0.63	0.98	0.878
				Manual scoring: 5.4 (− 11.2, 22.0)	AHI ≥ 5 (TRT)	AHI ≥ 5 (TST)	1.00	0.43	0.971
					AHI ≥ 10 (TRT)	AHI ≥ 10 (TST)	1.00	0.56	0.976
					AHI ≥ 15 (TRT)	AHI ≥ 15 (TST)	0.98	0.58	0.924
					AHI ≥ 30 (TRT)	AHI ≥ 30 (TST)	1.00	0.80	0.997
Barak-Shinar 2013 [23]	Morpheus Ox	140	Lab	0.4 (− 8.6, 9.1)†	AHI ≥ 5 (TST)	AHI ≥ 5 (TST)	97.0 (91.6, 99.4)	97.4 (86.5, 99.9)	nr
					AHI ≥ 15 (TST)	AHI ≥ 15 (TST)	94.4 (84.6, 98.8)	96.5 (90.1, 99.3)	nr
Choi 2010 [24]	Watch-PAT 100	25	Lab	− 4.1 (− 24.7, 16.7)†	AHI ≥ 5 (TST)	AHI ≥ 5 (TST)	1.00	0.83	nr
					AHI ≥ 15 (TST)	AHI ≥ 15 (TST)	0.81	0.77	nr
					AHI ≥ 30 (TST)	AHI ≥ 30 (TST)	0.92	0.92	nr
Crowley 2013 [25]	ApneaLink	44	Lab	3.9 (− 9.6, 17.5)†	AHI ≥ 5 (TRT)	AHI ≥ 5 (TST)	88.9	56.0	0.883
							80.0	75.8	0.918

Table 2 (continued)

Author	Index test (vs PSG)	Number (total)	Setting (for PM)	Bias (LOI) from Bland-Altman plots*(events/h)	ROC analysis				
					Threshold (events/h)		Sensitivity (95% CI, if available)	Specificity (95% CI, if available)	AUC
					Index (PM)	PSG			
					AHI ≥ 10 (TRT)	AHI ≥ 10 (TST)			
					AHI ≥ 15 (TRT)	AHI ≥ 15 (TST)	100.0	91.7	0.994
		38	Home: 1 night	− 0.4 (− 15.8, 15.1)†	AHI ≥ 5 (TRT)	AHI ≥ 5 (TST)	81.3	77.3	0.921
					AHI ≥ 10 (TRT)	AHI ≥ 10 (TST)	77.8	82.8	0.889
					AHI ≥ 15 (TRT)	AHI ≥ 15 (TST)	66.7	90.6	0.953
		36	Home: 2 nights average	0 (− 15.0, 15.0)†	AHI ≥ 5 (TRT)	AHI ≥ 5 (TST)	87.5	85.0	0.944
					AHI ≥ 10 (TRT)	AHI ≥ 10 (TST)	77.8	88.9	0.903
					AHI ≥ 15 (TRT)	AHI ≥ 15 (TST)	66.7	93.3	0.958
Garg 2014 [26]	WatchPAT 200	74	Lab	1.28 (− 44.72, 47.26)	AHI ≥ 5 (TST)	AHI ≥ 5 (TST)	nr	nr	0.94
					AHI ≥ 10 (TST)	AHI ≥ 10 (TST)	nr	nr	0.96
					AHI ≥ 15 (TST)	AHI ≥ 15 (TST)	nr	nr	0.96
		73	Home	0.64 (− 45.86, 47.14)	AHI ≥ 5 (TST)	AHI ≥ 5 (TST)	96 (85, 99)	43 (22, 66)	0.9093
					AHI ≥ 10 (TST)	AHI ≥ 10 (TST)	90 (77, 97)	69 (48, 86)	0.9464
					AHI ≥ 15 (TST)	AHI ≥ 15 (TST)	92 (79, 98)	77 (58, 90)	0.9224
Kobayashi 2013 [27]	SD-101	53	Lab	− 4.1 (− 24.6, 13.7)†	RDI[a] ≥ 5 (TRT)	AHI ≥ 5 (TST)	94.7	60.0	nr
					RDI ≥ 15 (TRT)	AHI ≥ 15 (TST)	87.5	85.7	0.964
	SD-101 with oxymetry	53	Lab	− 1.9 (− 14.1, 9.9)†	RDI ≥ 5 (TRT)	AHI ≥ 5 (TST)	100	66.7	nr
					RDI ≥ 15 (TRT)	AHI ≥ 15 (TST)	96.9	90.5	0.985
Körkuyu 2015 [28]	WatchPAT 200	30	Lab	1.7 (− 24.3, 27.8)†	Nr	Nr	nr	nr	nr
Nigro 2010 [29]	ApneaLink	66	Lab	0.5 (− 17.3, 18.3)	AHI ≥ 5 (TRT)	RDI[b] ≥ 5 (TST)	88.2 (76.1,95.5)	86.7 (59.5,98.0)	0.88
					AHI ≥ 10 (TRT)	RDI ≥ 10 (TST)	88.9 (73.9,96.8)	90.0 (73.4,97.8)	0.89
					AHI ≥ 15 (TRT)	RDI ≥ 15 (TST)	93.5 (78.5,99.0)	91.4 (76.9,98.1)	0.93
Nigro 2011 [30]	ApneaLink	90	Lab	Automated scoring:− 1.2 (− 22.1, 19.6)	AHI ≥ 5 (TRT)	RDI[b] ≥ 5 (TST)	89.3 (80.1,95.3)	60.0 (32.3,83.7)	0.747
					AHI ≥ 10 (TRT)	RDI ≥ 10 (TST)	80.4 (67.6,89.8)	82.3 (65.5,93.2)	0.814
					AHI ≥ 15 (TRT)	RDI ≥ 15 (TST)	76.7 (61.4,88.2)	83.0 (69.2,92.4)	0.80
					AHI ≥ 20 (TRT)	RDI ≥ 20 (TST)	87.9 (71.8,96.6)	94.7 (85.4,98.9)	0.913
					AHI ≥ 30 (TRT)	RDI ≥ 30 (TST)	88.5 (69.8,97.6)	95.3 (86.9,99.0)	0.92
							89.3 (80.1, 95.3)	86.7 (59.5, 98.3)	0.88

Table 2 (continued)

Author	Index test (vs PSG)	Number (total)	Setting (for PM)	Bias (LOI) from Bland-Altman plots*(events/h)	ROC analysis				
					Threshold (events/h)		Sensitivity (95% CI, if available)	Specificity (95% CI, if available)	AUC
					Index (PM)	PSG			
				Manual scoring:− 4.3 (− 20.9, 12.2)	AHI ≥ 5 (TRT)	RDI ≥ 5 (TST)			
					AHI ≥ 10 (TRT)	RDI ≥ 10 (TST)	73.2 (59.7, 84.2)	91.2 (76.3, 98.1)	0.822
					AHI ≥ 15 (TRT)	RDI ≥ 15 (TST)	72.1 (56.3,84.7)	97.9 (88.7,99.9)	0.85
					AHI ≥ 20 (TRT)	RDI ≥ 20 (TST)	87.9 (71.8,96.6)	98.2 (90.6,100)	0.931
					AHI ≥ 30 (TRT)	RDI ≥ 30 (TST)	84.6 (65.1,95.6)	98.4 (91.6,100)	0.915
Nigro 2013 [31]	ApneaLink Ox	55	Lab	Automated scoring, oxygen desaturation ≥ 4% for hypopnea: − 6.5 (− 27.8, 14.8)	AHI ≥ 5 (TRT)	RDI[b] ≥ 5 (TST)	76.7 (61.4,88.2)	91.7 (61.5,99.8)	0.84
				Automated scoring, oxygen desaturation ≥ 3% for hypopnea: − 3.7 (− 23.5, 16.2)	AHI ≥ 5 (TRT)	RDI ≥ 5 (TST)	90.7 (77.9,97.4)	83.3 (51.6,97.9)	0.87
				Manual scoring, oxygen desaturation ≥ 3% for hypopnea: − 2.7 (− 20.1, 14.7)	AHI ≥ 5 (TRT)	RDI ≥ 5 (TST)	93.0 (80.9,98.5)	91.7 (61.5,99.8)	0.92
Oktay 2011 [32]	ApneaLink	53	Lab	− 0.98 (− 19.6, 18.0)†	RDI[a] ≥ 5 (TRT)	AHI ≥ 5 (TST)	90.0	76.9	0.899
					RDI ≥ 10 (TRT)	AHI ≥ 10 (TST)	82.1	80.0	0.913
					RDI ≥ 15 (TRT)	AHI ≥ 15 (TST)	79.0	88.2	0.922
					RDI ≥ 20 (TRT)	AHI ≥ 20 (TST)	100	92.5	0.988
					RDI ≥ 30 (TRT)	AHI ≥ 30 (TST)	66.7	95.5	0.961
			Home	− 3.1 (− 25.3, 18.7)†	RDI ≥ 5 (TRT)	AHI ≥ 5 (TST)	67.5	76.9	0.815
					RDI ≥ 10 (TRT)	AHI ≥ 10 (TST)	75.0	92.0	0.859
					RDI ≥ 15 (TRT)	AHI ≥ 15 (TST)	73.7	85.3	0.924
					RDI ≥ 20 (TRT)	AHI ≥ 20 (TST)	76.9	92.5	0.956
					RDI ≥ 30 (TRT)	AHI ≥ 30 (TST)	55.6	95.5	0.924
Poupard 2012 [33]	Oximetry	106	Lab	−5.7 (−28.0, 18.3)	VHI ≥ 5 (TRT)	AHI ≥ 5 (TST)	91	88	nr
					VHI ≥ 15 (TRT)	AHI ≥ 15 (TST)	81	98	nr
					VHI ≥ 30 (TRT)	AHI ≥ 30 (TST)	67	99	nr
				− 13.5 (− 40.0, 13.7)	ODI ≥ 5 (TST)	AHI ≥ 5 (TST)	65	100	nr
					ODI ≥ 15 (TST)	AHI ≥ 15 (TST)	58	100	nr
					ODI ≥ 30 (TST)	AHI ≥ 30 (TST)	59	100	nr
Ragette 2010 [34]	ApneaLink	102	Lab	0.7 (− 11.7, 13.9)†			93.9	50.0	nr

Table 2 (continued)

Author	Index test (vs PSG)	Number (total)	Setting (for PM)	Bias (LOI) from Bland-Altman plots*(events/h)	ROC analysis				
					Threshold (events/h)		Sensitivity (95% CI, if available)	Specificity (95% CI, if available)	AUC
					Index (PM)	PSG			
					RDI[a] ≥ 5 (TRT)	AHI ≥ 5 (TST)			
					RDI ≥ 10 (TRT)	AHI ≥ 10 (TST)	91.9	87.5	nr
					RDI ≥ 15 (TRT)	AHI ≥ 15 (TST)	92.0	88.5	nr
		131	Home	− 1.2 (− 19.0, 18.4)†	RDI ≥ 5 (TRT)	AHI ≥ 5 (TST)	91.8	76.5	nr
					RDI ≥ 10 (TRT)	AHI ≥ 10 (TST)	80.0	85.5	nr
					RDI ≥ 15 (TRT)	AHI ≥ 15 (TST)	73.1	84.7	nr
Rofail 2010 [35]	Flow Wizard	198	Lab	6.2 (− 11.0, 23.2)	RDI[a] ≥ 10 (TRT)	AHI ≥ 5 (TST)	0.94 (0.92,0.98)	0.62 (0.47,0.77)	0.84
					RDI ≥ 20 (TRT)	AHI ≥ 5 (TST)	0.79 (0.72,0.85)	0.79 (0.66,0.91)	nr
					RDI ≥ 30 (TRT)	AHI ≥ 5 (TST)	0.47 (0.41,0.53)	0.94 (0.88,1.00)	nr
					RDI ≥ 20 (TRT)	AHI ≥ 30 (TST)	0.98 (0.91,1.00)	0.60 (0.49,0.74)	0.96
					RDI ≥ 30 (TRT)	AHI ≥ 30 (TST)	0.98 (0.92,1.00)	0.81 (0.76,0.88)	nr
Rofail 2010 [36]	Flow Wizard and Oximetry (separate)	92	Home (first night)	Flow Wizard: 6.1 (− 21.9, 34.1)	RDI[a] ≥ 20 (TRT)	AHI ≥ 5 (TST)	0.75 (0.63,0.85)	0.79 (0.61,0.97)	0.80
					RDI ≥ 30 (TRT)	AHI ≥ 30 (TST)	0.90 (0.84,0.98)	0.83 (0.76,0.87)	0.94
				Oximetry: − 6.8 (− 36.2, 22.6)	ODI ≥ 7 (TRT)	AHI ≥ 5 (TST)	0.63 (0.66,0.86)	0.83 (0.74,0.80)	0.80
					ODI ≥ 10 (TRT)	AHI ≥ 30 (TST)	0.90 (0.86,0.96)	0.88 (0.75,0.94)	0.91
		72	Home (3 nights)	Flow Wizard: 5.7 (−20.9, 32.4)	RDI ≥ 20 (TRT)	AHI ≥ 5 (TST)	0.80 (0.67,0.93)	0.87 (0.77,0.97)	0.85
					RDI ≥ 30 (TRT)	AHI ≥ 30 (TST)	0.90 (0.83,0.98)	0.85 (0.78,0.89)	0.95
				Oximetry: − 6.5 (− 34.5, 21.5)	ODI ≥ 7 (TRT)	AHI ≥ 5 (TST)	0.77 (0.63,0.91)	0.89 (0.80,0.98)	0.81
					ODI ≥ 10 (TRT)	AHI ≥ 30 (TST)	0.90 (0.87,0.97)	0.85 (0.73,0.92)	0.91
Romem 2014 [37]	Morpheus Ox	65	Lab	6.3 (− 66.0, 78.8)†	AHI ≥ 5 (TST)	AHI ≥ 5 (TST)	80	86	0.909
					AHI ≥ 15 (TST)	AHI ≥ 15 (TST)	70	91	0.903
Tsukahara 2014 [38]	SD-101	101	Lab	nr	RDI[a] ≥ 5 (TRT)	AHI ≥ 5 (TST)	96.6	69.2	nr
					RDI ≥ 20 (TRT)	AHI ≥ 20 (TST)	70.5	97.5	nr
					RDI ≥ 14 (TRT)	AHI ≥ 20 (TST)	90.2	90	0.949
					RDI ≥ 20 (TRT)	AHI ≥ 20 (TRT)	84.8	90.9	nr
					RDI ≥ 23 (TRT)	AHI ≥ 20 (TRT)	84.8	92.7	0.954
Ward 2015 [39]	ApneaLink Ox	104	Lab	− 13.5 (− 37.2, 10.4)†	AHI ≥ 5 (TRT)	AHI ≥ 5 (TST)	0.80 (0.71,0.88)	1.0	nr
							0.74 (0.63,0.84)	1.0	nr

Table 2 (continued)

Author	Index test (vs PSG)	Number (total)	Setting (for PM)	Bias (LOI) from Bland-Altman plots*(events/h)	ROC analysis				
					Threshold (events/h)		Sensitivity (95% CI, if available)	Specificity (95% CI, if available)	AUC
					Index (PM)	PSG			
					AHI ≥ 15 (TRT)	AHI ≥ 15 (TST)			
					AHI ≥ 30 (TRT)	AHI ≥ 30 (TST)	0.50 (0.36,0.64)	1.0	nr
		104	Home	− 14.8 (− 44.5, 14.2)†	AHI ≥ 5 (TRT)	AHI ≥ 5 (TST)	0.80 (0.72,0.89)	0.83 (0.76, 0.91)	nr
					AHI ≥ 15 (TRT)	AHI ≥ 15 (TST)	0.66 (0.55,0.77)	1.0	nr
					AHI ≥ 30 (TRT)	AHI ≥ 30 (TST)	0.43 (0.28, 0.57)	0.98 (0.94,1.02)	nr
Weimin[c]2013 [40]	WatchPAT 200	28	Lab	− 3.0 (− 19.5, 13.6)	AHI ≥ 5 (TST)	AHI ≥ 5 (TST)	0.96 (0.79,1.00)	0.25 (0.01, 0.81)	0.969
					AHI ≥ 15 (TST)	AHI ≥ 15 (TST)	0.94 (0.70,1.00)	0.67 (0.35,0.90)	0.930
					AHI ≥ 30 (TST)	AHI ≥ 30 (TST)	0.86 (0.42,1.00)	0.95 (0.76,1.00)	0.973
Zaffaroni 2013 [41]	SleepMinder	74	Lab	0.05 (− 24.84, 24.94)	AHI ≥ 5 (TST)	AHI ≥ 5 (TST)	98	47	0.90
					AHI ≥ 15 (TST)	AHI ≥ 15 (TST)	90	92	0.97
					AHI ≥ 30 (TST)	AHI ≥ 30 (TST)	84	89	0.96
Zou 2015 [42]	SleepView	93	Lab	− 3.1 (− 19.8, 26.1)	AHI ≥ 16.8 (TRT)	AHI ≥ 5 (TST)	80.28 (69.13, 88.78)	95.45 (77.16, 99.88)	0.923
					AHI ≥ 22.3 (TRT)	AHI ≥ 15 (TST)	87.04 (75.10, 94.63)	84.62 (69.47, 94.14)	0.924
					AHI ≥ 37.8 (TRT)	AHI ≥ 30 (TST)	94.87 (82.68, 99.37)	92.59 (82.11, 97.94)	0.979

AASM American Academy of Sleep Medicine, *AHI* apnea hypopnea index, *AUC* area under the curve, *nr* not reported, *CI* confidence interval, *ODI* oxygen desaturation index, *RDI* respiratory disturbance index, *PM* portable monitor, *PSG* polysomnography, *ROC* receiver operating characteristic, *TRT* total recording time (same as "time in bed"; excludes artifacts and poor quality data in most studies), *TST* total sleep time, *VHI* ventilatory hypoxemic index

*Bland-Altman plots calculate the mean of differences ($\bar{d}$) between PM AHI/RDI and PSG AHI/RDI (bias) and its 95% limits of agreement (LOA) using $\bar{d} \pm 1.96\ s$ or $\bar{d} \pm 2\ s$ formula where s is the standard deviation of the difference

†Estimated from study published plots using the Plot Digitizer software program (i.e., estimates may slightly differ from actual results)

[a] In the studies by Kobayashi et al.[27], Oktay et al.[32], Ragette et al.[34], Rofail et al.[35, 36], and Tsukahara et al.[38], RDI is the total number ofapneas and hyponeas divided by time in bed from the PM

[b] In the studies by Nigro et al.[29–31], RDI is the total number of apneas, hyponeas, and respiratory effort-related arousals divided by total sleep time from the PSG

[c] For AHI ≥ 5, 15, and 30 cutoffs, sensitivity and specificity were calculated using the actual dataset provided in the article (please note that the article presented "optimal cut-off" results but did not specify what were these cutoffs)

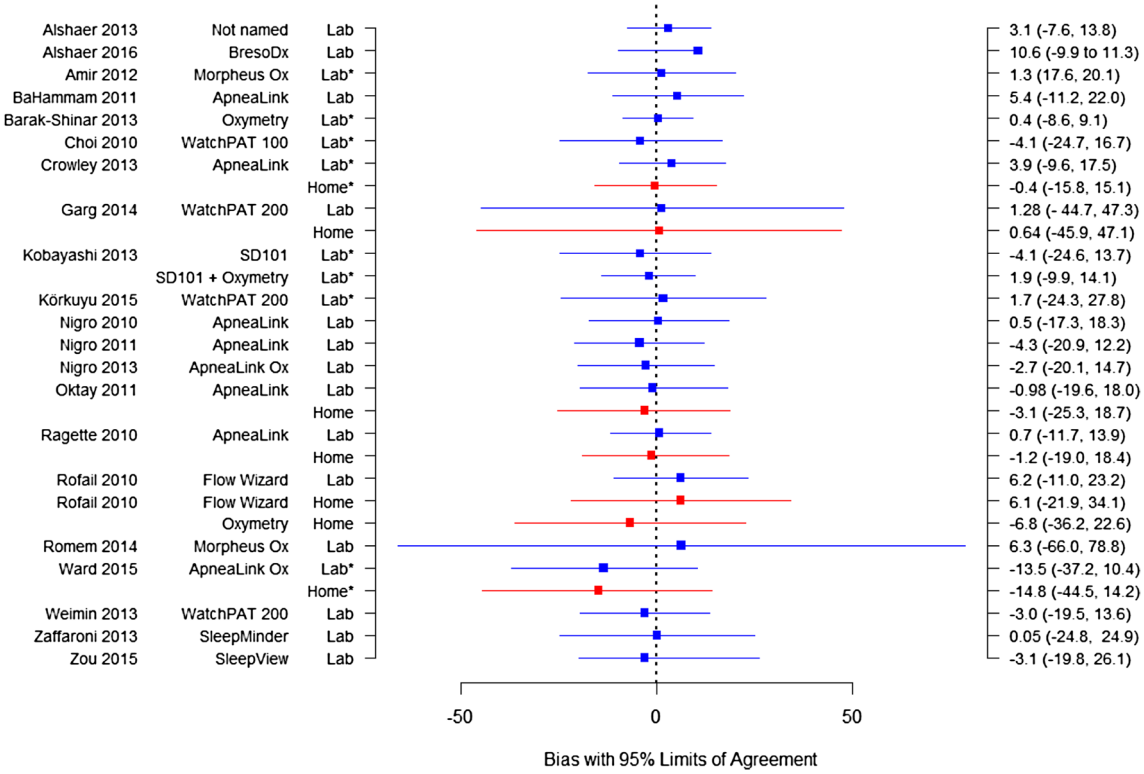

Fig. 3 Mean difference between PM and PSG AHI/RDI (forest plot of Bland-Altman analysis). The plot shows the mean difference between PM AHI/RDI and PSG AHI/RDI (bias) and their 95% limits of agreement for each study. Asterisks (*) indicate the studies for which a digitizer program was used to extract values from published plots. Whenever studies reported AHI values both from manual and automatic scoring, only manual scoring results are shown here. *AHI* apnea hypopnea index, *CI* confidence interval, *RDI* respiratory disturbance index, *PM* portable monitor, *PSG* polysomnography

Discussion

The systematic review summarized evidence on diagnostic accuracy of type IV PMs for HSAT from English studies published from January 2010 to May 2016. In total, we found 24 studies evaluating 10 different types of portable devices against the current standard testing, PSG. The prior systematic review that covered the time period up to September 2010, reported that in total 23 unique type IV PMs have been evaluated against PSG. Only one study was repeatedly included both in the

Table 3 Sensitivity and specificity ranges of type IV PMs: current and past systematic review

AHI/RDI cutoff values from PSG and PM (events/h)	Single-channel PMs $n = 13$ [20–23, 25, 27, 29, 30, 32, 34, 37, 38, 41]		Two-channel PMs $n = 2$ [31, 39]		Three or more channel PMs $n = 3$ [24, 26, 40]	
	Sensitivity range	Specificity range	Sensitivity range	Specificity range	Sensitivity range	Specificity range
Current review (January 1, 2010 to May 10, 2016)						
≥ 5	0.68–1.00	0.43–0.97	0.77–0.93	0.83–0.92	0.96–1.00	0.25–0.83
≥ 15	0.65–1.00	0.58–0.98	0.66–0.74	1.00	0.81–0.94	0.67–0.77
Past review (up to September 2010) [14]						
	$n = 12$		$n = 6$		$n = 6$	
≥ 5	0.85–0.96	0.50–1.00	0.92–0.98	0.50–1.00	0.85–1.00	0.67–1.00
≥ 15	0.43–1.00	0.42–1.00	0.67–0.91	0.78–0.96	0.75–0.92	0.50–1.00

Studies excluded ($n = 6$) from this table included: three studies testing single-channel PMs [19, 35, 36] and one study testing a two-channel PM[42] that used other thresholds; one study testing a single-channel PM thatreported measures other than AHI/RDI[33]; and one study ofa four-channel PM that did not report data on sensitivity andspecificity [28]

AHI apnea hypopnea index, *PM* portable monitor, *PSG* polysomnography, *RDI* respiratory disturbance index

Table 4 Meta-analysis of diagnostic accuracy of type IV PM ApneaLink (laboratory setting)

PPSG and PM AHI/RDI cutoff	No. of studies	Sensitivity (95% CI)	Specificity (95% CI)	Area under ROC curve	Positive LR (95% CI)	Negative LR (95% CI)
≥ 5 events/h	6 [22, 25, 29, 30, 32, 34]	0.88 (0.82, 0.92)	0.64 (0.52, 0.75)	0.842	2.53 (1.86, 3.46)	0.19 (0.12, 0.27)
≥ 15 events/h	6 [22, 25, 29, 30, 32, 34]	0.82 (0.69, 0.90)	0.88 (0.83, 0.91)	0.888	6.61 (4.58, 9.42)	0.21 (0.11, 0.35)

AHI apnea hypopnea index, *CI* confidence interval, *LR* likelihood ratio, *PM* portable monitor, *PSG* polysomnography, *RDI* respiratory disturbance index, *ROC* receiver operating characteristic

current and in the past systematic review (because of the time overlap of the literature search) [34]. After completing our review, we can report that 28 unique type IV PMs have been compared against PSG so far.

The portable devices in the current review had one, two, or four channels, and their diagnostic accuracy varied by the type, number of channels, test setting, and AHI/RDI thresholds used for diagnosis. Only one third of studies tested PMs in home setting. The mean difference between PSG AHI/RDI and PM AHI/RDI ranged from − 14.8 to 10.6 events/h. At AHI ≥ 5 events/h, the sensitivity of type IV PMs ranged from 0.68 to 1 for single-, from 0.77 to 0.93 for two-, and from 0.96 to 1 for four-channel PMs indicating some improvement of sensitivity with the increase of number of channels. For the same threshold, the specificity of type IV PMs ranged from 0.43 to 0.97 for single-, from 0.83 to 0.92 for two-, and from 0.25 to 0.83 for four-channel PMs.

As expected, the prevalence of OSA was much higher in patients referred to sleep clinics for sleep studies than what has been reported in the general population [6]. Using an AHI cutoff of 5 events/h, the prevalence of OSA in the included studies ranged from 41.9 to 94.2% and from 16.0 to 83.3% when using a cutoff of 15 events/h. The studies were conducted in 12 different countries and included patient populations that varied in several characteristics such as age, gender, BMI, and comorbidity profiles. These variabilities could partially explain the wide ranges of diagnostic accuracy parameters in this systematic review, similar to what was observed in past reviews [14, 43]. The current AASM guideline does not recommend the use of PMs in patients with significant comorbid conditions because of lack of data supporting their diagnostic accuracy in these patients [12]. Half of the studies in this review included patients with comorbid conditions, in part addressing this evidence gap.

Following current recommendations for quality assessment of studies, we used the QUADAS-2 tool which assesses both the risk of bias and applicability in four major domains [17]. The percent of studies with uncertain ROB varied from 38% to 50% across four ROB domains. Poor reporting quality may indicate poor methodological quality, limiting the strength of inferences that are possible from these data. The prior systematic review used a different tool to evaluate ROB [14]. From 24 studies in the review, 29% were graded as level A (good quality), 46% as B (fair/moderate quality), and 25% as level C (poor quality) [14]. Using this assessment tool, we graded 25% of the studies in our review as level A, 63% as level B, and 13% as level C (data not shown).

We assessed the concordance between PMs and PSG by reviewing the results from Bland-Altman plots. In most studies, the denominator for AHI/RDI calculations was based on total sleep time for PSG and total recording time for PMs. Since the total sleep time is usually shorter than the total recording time, it is more likely for PMs to underestimate than overestimate the risk of OSA. The analyses of concordance, however, showed that this was not always the case; the bias estimates had a wide range varying from − 14.8 to 10.6 events/h with accompanying 95% LOA ranging from − 66 to 78.8 events/h. This was similar to the previous systematic review that also reported a high level of discordance with bias estimates ranging from − 17 to 12 events/h and 95% LOA estimates ranging from − 49 to 61 events/h [14]. In practice, this means that some type IV PMs overestimate and some underestimate AHI/RDI values potentially leading to misdiagnosis of OSA. For PMs tested at home and compared with sleep laboratory PSG, this could relate to either spontaneous night to night variability in sleep apnea severity or to changes in sleep apnea severity that relate to body position, alcohol and other substance use, sleep quality, or other variables. In particular, a significant night to night variability has been reported in studies in this review that tested the PM in the sleep laboratory and then at home [25, 26, 32, 34, 39] or tested the same PM at home over consecutive nights [36]. Considering the significant risk of OSA over- or underestimation with type IV PMs in our review, we further support the current AASM guideline recommending to perform HSAT for at least one night and to perform PSG for those with negative HSAT [12].

A set of AHI/RDI thresholds have been used by the authors to grade OSA severity, most commonly including thresholds of ≥ 5, 10, 15, and 30 events/h of sleep. Expectedly, the estimates of sensitivity, specificity, and area under the ROC curve varied (in some cases, substantially) by the threshold level. Furthermore, due to differences in populations studied, type and number of channels, as well as sleep study setting, we observed wide variations in these estimates under fixed thresholds as well. The results of the current review are similar to those from the past systematic review. For example, for single-channel PMs when using an AHI/RDI cutoff ≥ 15

events/h, the sensitivity ranged from 0.65 to 1 in the current and from 0.43 to 1 in the past review, and the specificity varied from 0.58 to 0.98 in the current and from 0.42 to 1.00 in the past review [14]. The clinical implications of such variations could be quite significant, especially when translating these results to proportions of patients with false positive and false negative results. Another important issue is the setting where the PM testing is done. In our systematic review, only seven out of 24 studies tested PMs at home. The reported sensitivity and specificity estimates of PMs were generally better if they were done in a laboratory setting than at home; a finding that was in agreement with a prior systematic review and meta-analysis of type III devices [43].

One major limitation in current studies was that most of them tested PMs only in a laboratory setting where the issues of technical failure are more easily identified and corrected. Past studies reported that the diagnostic accuracy of PMs is better in the sleep laboratory setting than at home [43]. Policy recommendations regarding specific PMs for HSAT should be supported by evidence gathered in the setting in which the test will be used. Another limitation was that integration with clinician judgment was not explored. OSA is a clinical diagnosis, informed by history, physical examination, and diagnostic test results [8]. The key question about diagnostic devices is whether and how they improve the overall accuracy of the diagnosis of sleep apnea, taking all relevant data into account. This requires understanding of how test results support and improve clinical judgment. None of the studies we evaluated addressed this question. Integration of test results with clinical judgment remains an important evidence gap.

Due to observed heterogeneity in patient populations and differences in the type and number of PM channels, we decided to meta-analyze each specific PM separately (i.e., refrain from indirect comparisons). In addition, we decided to separate studies by setting because a past systematic review of type III monitors showed that testing conducted in sleep laboratories (simultaneously with PSG) resulted in better diagnostic accuracy than sleep testing conducted at home (at different night from PSG) [43]. Furthermore, bivariate random-effects models required having at least four studies of similar type to allow valid conclusions [18]. With all these considerations, we were only able to do meta-analysis for the ApneaLink monitor tested in six studies conducted in sleep laboratories. We concluded that ApneaLink had a higher sensitivity and lower specificity under an AHI threshold of ≥ 5 events/h (lower disease severity) compared to the threshold of ≥ 15 events/h or higher disease severity, similar to what was reported in a past meta-analysis of type III PMs [43].

The limitations of this review warrant discussion. Due to logistical reasons, our search was limited to English language articles. Next, in defining what constitutes a type IV PM, we followed the prior AHRQ systematic review to generate a consistent body of evidence [14]. Both the AHRQ review and the recent AASM guideline defined type III studies as devices that include two respiratory parameters (breathing effort and airflow), oxygen saturation and an electrocardiography or heart rate recording [12, 14]. Following the prior AHRQ review, we considered PMs not meeting type III criteria as type IV, excluding single-channel PMs that use heart rate, heart rate variability, or actigraphy [14]. The AASM guideline defined type IV as devices with one to two parameters that record oxygen saturation, heart rate, and/or airflow [12]. The final AASM recommendation was supportive of HSAT for uncomplicated patients with technically adequate devices that, at minimum, record "nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or else PAT with oximetry and actigraphy" [12]. Therefore, the guideline supports HSAT only with type III devices and the WatchPAT device (as per current review). We, however, were not able to calculate summary estimates for the diagnostic accuracy of WatchPAT due to the small number of identified studies testing this device in this review.

In conclusion, we found that the diagnostic accuracy of type IV PMs for HSAT varies depending on the number of channels, setting, and disease severity. While evidence is not very strong for their stand-alone use in routine clinical practice, in settings and populations where there is a high demand and a limited capacity in performing PSG or where OSA is highly underdiagnosed (e.g., patients with significant comorbidities), these monitors can help to expand access to early OSA identification and timely management. Future studies should consider testing the diagnostic accuracy of these devices in making a clinical diagnosis of OSA and test their performance both in sleep laboratories and at home. Policy recommendations regarding PM use should consider the health and societal implications of false positive and false negative diagnoses and its cost-effectiveness.

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Compliance with ethical standards The manuscript does not contain clinical studies or patient data.

Conflict of interest The authors declare that they have no conflict of interest.

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