Diagnostic accuracy of level 3 portable sleep tests versus level 1 polysomnography for sleep-disordered breathing: a systematic review and meta-analysis

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Abstract

Background: Greater awareness of sleep-disordered breathing and rising obesity rates have fueled demand for sleep studies. Sleep testing using level 3 portable devices may expedite diagnosis and reduce the costs associated with level 1 in-laboratory polysomnography. We sought to assess the diagnostic accuracy of level 3 testing compared with level 1 testing and to identify the appropriate patient population for each test.

Methods: We conducted a systematic review and meta-analysis of comparative studies of level 3 versus level 1 sleep tests in adults with suspected sleep-disordered breathing. We searched 3 research databases and grey literature sources for studies that reported on diagnostic accuracy parameters or disease management after diagnosis. Two reviewers screened the search results, selected potentially relevant studies and extracted data. We used a bivariate mixed-effects binary regression model to estimate summary diagnostic accuracy parameters.

Results: We included 59 studies involving a total of 5026 evaluable patients (mostly patients suspected of having obstructive sleep apnea). Of these, 19 studies were included in the meta-analysis. The estimated area under the receiver operating characteristics curve was high, ranging between 0.85 and 0.99 across different levels of disease severity. Summary sensitivity ranged between 0.79 and 0.97, and summary specificity ranged between 0.60 and 0.93 across different apnea–hypopnea cut-offs. We saw no significant difference in the clinical management parameters between patients who underwent either test to receive their diagnosis.

Interpretation: Level 3 portable devices showed good diagnostic performance compared with level 1 sleep tests in adult patients with a high pretest probability of moderate to severe obstructive sleep apnea and no unstable comorbidities. For patients suspected of having other types of sleep-disordered breathing or sleep disorders not related to breathing, level 1 testing remains the reference standard.

Competing interests: None declared.

This article has been peer reviewed.

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CMAJ 2014. DOI:10.1503/cmaj.130952

Undiagnosed sleep-disordered breathing places a substantial burden on patients, families, health care systems and society.[1] Sleep fragmentation and recurrent hypoxemia cause daytime sleepiness and impaired concentration, which increase the risk of motor vehicle collisions and occupational accidents.[2–7] In addition, sleep-disordered breathing is associated with hypertension, stroke, cardiovascular disease, obesity and type 2 diabetes,[8–12] all of which involve greater use of health care resources.[13–17]

Obstructive sleep apnea is the most common type of sleep-disordered breathing. Narrowing of the upper airway during inspiration results in episodes of apnea (breathing cessation for at least 10 seconds), hypopnea (reduced airflow), oxygen desaturation and arousal from sleep due to respiratory effort.[18] Clinical signs and symptoms include snoring, reports of nocturnal apnea, gasping or choking witnessed by a partner, daytime sleepiness, morning headaches and inability to concentrate. Patients with obesity or cardiovascular disease are at increased risk.[19]

The severity of obstructive sleep apnea is usually graded using the apnea–hypopnea index (the mean number of apneas and hypopneas per hour of sleep) as follows: mild (5–14), moderate (15–29) and severe (≥ 30).[18,20]

Other, less common types of sleep-disordered breathing include upper airway resistance syndrome, obesity hyperventilation syndrome, central sleep apnea, and nocturnal hypoventilation/hypoxemia secondary to cardiopulmonary or neuromuscular disease. It is not uncommon for patients to have more than 1 type of sleep-disordered breathing.

Estimates of the prevalence of sleep-disordered breathing vary depending on the population (e.g., by sex, age and comorbidities).[21] According to the

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Wisconsin Sleep Cohort Study, values in American adults (aged 30–60 yr) are 24% for men and 9% for women.[1] A Canadian survey found a self-reported prevalence of sleep apnea of 3% among adults more than 18 years of age, and 5% among those more than 45 years of age.[22] As the population ages and rates of obesity increase, the prevalence of sleep-disordered breathing is climbing.[1,19,23,24] Given its clinical implications, accurate diagnosis and treatment of the condition are critical.

Level 1 sleep testing, or polysomnography, requires an overnight stay in a sleep laboratory with a technician in attendance. It captures a minimum of 7 channels of data (but typically ≥ 16), including respiratory, cardiovascular and neurologic parameters, to produce a comprehensive picture of sleep architecture. Level 1 is considered the reference standard for diagnosing all types of sleep-disordered breathing and sleep disorders.[19,25–27] However, limited facilities and the growing demand for sleep studies have resulted in long wait times.[28] Level 2 sleep testing uses level 1 equipment, but is performed without a technician in attendance.

Level 3 testing uses portable monitors that allow sleep studies to be done at the patient's home or elsewhere. This option was introduced as a more accessible and less expensive alternative to in-laboratory polysomnography. Level 3 devices record at least 3 channels of data (e.g., oximetry, airflow, respiratory effort). Unlike level 1, level 3 testing cannot measure the duration of sleep, the number of arousals or sleep stages, nor can it detect nonrespiratory sleep disorders.[27,29] Level 4 devices are also portable, but they capture less data — usually only 1 or 2 channels.[27,30]

We conducted a systematic review and meta-analysis to compare the diagnostic accuracy of the widely used level 3 portable monitors to in-laboratory polysomnography, and to determine the subpopulations of patients whose conditions might be most appropriately diagnosed with each test.

Methods

Literature search

We performed a comprehensive literature search of PubMed (MEDLINE and non-MEDLINE sources), the Cochrane Library and Embase for studies that compared level 3 to level 1 tests for the diagnosis of sleep-disordered breathing in adults (Appendix 1, available at www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.130952/-/DC1). We limited our search to English-language studies from 2007 to March 2012, with monthly updates from PubMed until March 2013. We also included studies from a previous systematic review prepared by our research unit, which covered the literature from 2004 to 2009. Consequently, this review covers the literature from 2004 to March 2013. We determined our date limit based on several previous Canadian and American assessments that examined the earlier literature.[31–40]

Study selection

Two reviewers independently screened titles and abstracts to identify possible studies for inclusion. All studies comparing level 3 with level 1 sleep tests involving adults were included if they reported on either diagnostic accuracy parameters or management after testing (Appendix 2, available at www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.130952/-/DC1). We followed PICOS (Patients, Intervention, Comparator, Outcomes and Study design) criteria to include or exclude studies. We assessed reviewer agreement using the κ statistic.

Data extraction

Two reviewers independently extracted data from included studies using a standard form. Our diagnostic accuracy parameters were sensitivity, specificity, area under the receiver operating characteristic (ROC) curve, and positive and negative likelihood ratios. We extracted safety data and technical failures from all of the studies that reported these parameters. Our clinical management parameters were acceptance of continuous positive airway pressure treatment, treatment adherence, mechanical estimates of residual apnea–hypopnea index, mean machine pressure difference between patients whose diagnoses were made with the 2 different tests, quality of life and functional status as measured by clinical sleepiness questionnaires (usually the Epworth Sleepiness Scale).

Disagreements were discussed and resolved between the reviewers. No third-party adjudication was needed.

Quality assessment

We used the Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) tool, which assesses bias (internal validity) and applicability (external validity) in multiple domains: flow and timing, reference-standard test, index test and patient selection.[41,42]

Statistical analysis

We pooled patient characteristics (age, body mass index [BMI] and score on the Epworth Sleepiness Scale) to obtain weighted averages. We extracted and grouped comorbidities. We presented technical failures and safety data as frequencies and proportions.

Because studies reported level 3 test performance at different apnea–hypopnea index severity levels, we examined diagnostic accuracy parameters in all studies to determine the overall ranges. We examined patterns at different severity levels in studies that reported multiple index cut-offs.

We performed a meta-analysis using a bivariate mixed-effects binary regression model. The model estimates the amount of between-study variation in sensitivity and specificity, as well as the degree of correlation between sensitivity and specificity through random effects, and uses the logit sensitivity and specificity to draw the summary ROC curves. This model requires the primary parameters of true-positive, false-positive, true-negative and false-negative. We included studies if they reported the parameters required for the model. If such parameters were not reported, we calculated them from the data provided, where possible. We estimated summary diagnostic accuracy parameters.[43–45] We assessed overall heterogeneity using the Q statistic. When heterogeneity was significant, we quantified it using the I^2 statistic. We estimated the summary ROC curves at different apnea–hypopnea severity levels. We performed all analyses using Stata SE version 12.

We conducted a subgroup sensitivity analysis to identify changes in diagnostic accuracy when studies that included only patients with comorbidities were removed from the analysis.

Results

We included 59 comparative studies (15 abstracts, 44 full-text articles) involving 5044 patients (5026 of whom were evaluable) in our analysis (Figure 1). The κ statistic showed reviewer agreement (0.86).

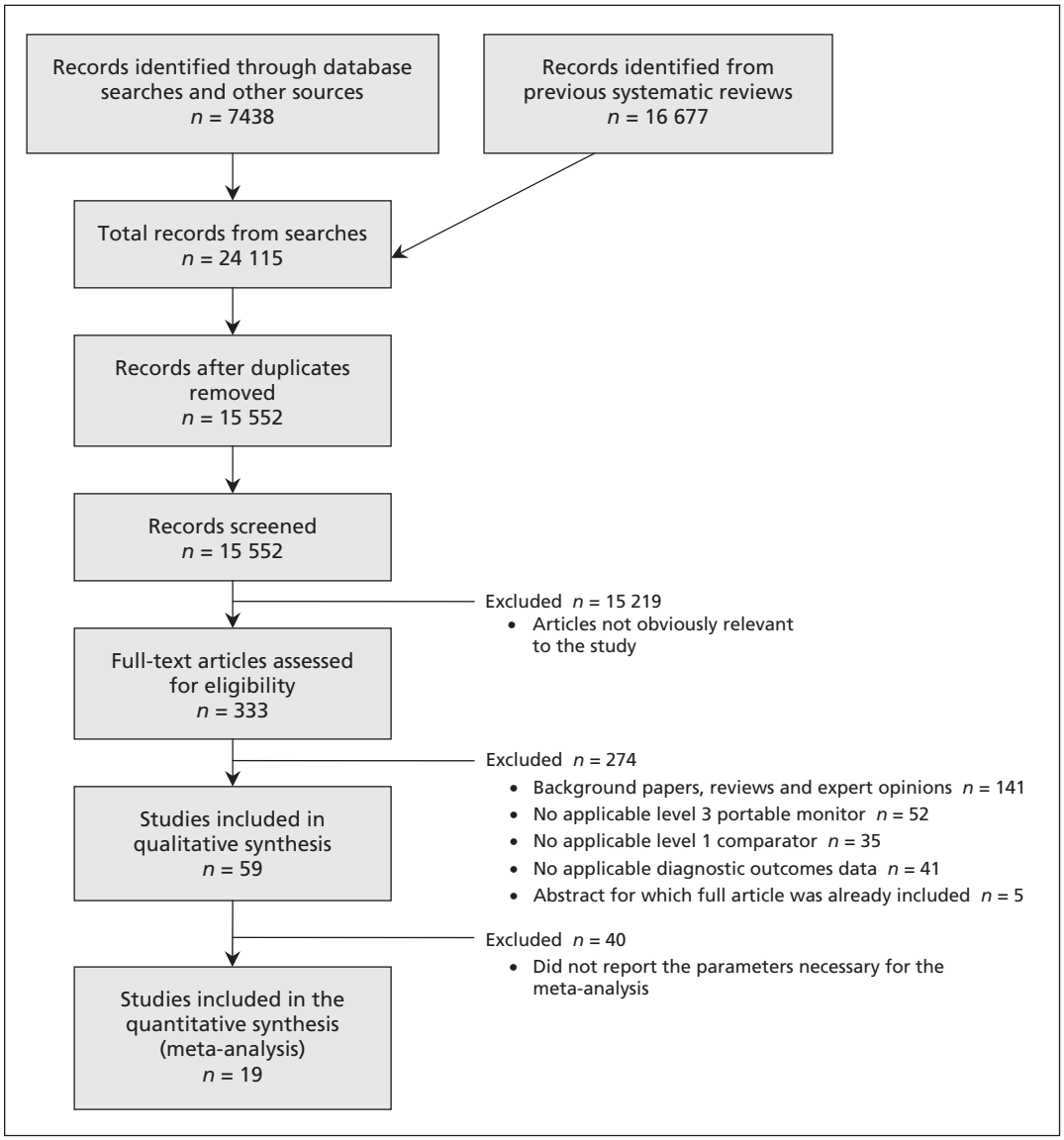

Figure 1: Selection of studies for inclusion in the review and meta-analysis.

We classified the included studies as "combination" studies (10 studies involving 572 evaluable patients, in which the patients underwent simultaneous in-laboratory level 3 and level 1 tests, followed by an at-home level 3 test), "simultaneous" studies (20 studies involving 1152 evaluable patients, in which the patients underwent simultaneous in-laboratory level 3 and level 1 tests) and "separate" studies (29 studies involving 3302 evaluable patients, in which an at-home level 3 test and an in-laboratory level 1 test were conducted, either with the same patients or on 2 different arms) (Table 1).[46–104]

Patient characteristics

The included studies recruited patients with suspected obstructive sleep apnea (Appendix 3, available at www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.130952/-/DC1). Patients were referred for sleep testing after a pretest assessment that included sleep questionnaires, history and clinical examination.

When we pooled participant characteristics from all studies, patients had a mean age of 50.8 years, a mean score of 11.6 on the Epworth Sleepiness Scale and a mean BMI of 30.4. The ratio of male to female patients was 2.9 to 1. A total of 1382 comorbidities were reported, with cardiovascular conditions the most common (1080 patients, 78.1% of total comorbidities). Hypertension was the most frequently reported cardiovascular condition (574 patients), followed by stable chronic heart disease (142 patients) and coronary artery disease (113 patients). Respiratory comorbidities were limited to a single patient with asthma and 9 patients with chronic obstructive pulmonary disease (0.7% of total comorbidities).

Study characteristics

The 4 channels measured in all of the studies were nasal airflow, thoracoabdominal movement, oxygen saturation and body position.

Two studies reported adverse events with in-laboratory level 3 tests (1 hypertensive crisis, 1 pacemaker interference).[46,52] One study reported sensor irritation in 27 patients.[46]

Technical failures affected 0.44% of patients who underwent level 1 tests, 1.30% of patients who underwent in-laboratory level 3 tests and 10.25% of patients who underwent level 3 tests at home (Appendix 4, available at www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.130952/-/DC1).

Diagnostic accuracy of sleep tests

Among all included studies, the area under the ROC curves for at-home (6 studies) and in-laboratory (7 studies) testing showed values of 0.90 or greater at all apnea–hypopnea index cut-offs, with the exception of 2 studies that reported values of 0.79 and 0.86 at an apnea–hypopnea index of moderate or severe (≥ 15 events/h) at home, and 2 studies that reported values ranging from 0.87 to 0.89 at moderate or severe cut-offs (≥ 15, ≥ 20 and ≥ 30 events/h) in laboratory (Appendix 5, available at www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.130952/-/DC1).

In studies reporting multiple cut-offs, with increasing disease severity, 7 of 10 at-home studies showed a decline in sensitivity and an increase in specificity, and 2 of the studies showed an increase in area under the ROC curve.[46–48,52,55,81,88,89,98,104] In addition, 7 of 14 in-laboratory studies showed a decline in sensitivity and an increase in specificity, and 2 studies showed an increase in area under the ROC curve.[47,48,51,52,58,61–63,65–67,69–71]

We found no significant difference in baseline characteristics between the 2 groups of patients in all 8 studies that reported disease management after the diagnosis by either test. None of the studies found significant differences in disease management parameters.[77–79,92,93,99,102,103]

In most of the studies, patients underwent both level 1 and level 3 tests to avoid the risk of internal bias due to differences between study groups. In all of the simultaneous studies, level 3 tests were scored manually by the same technician who scored the level 1 test, which may have resulted in observer bias. In contrast, most of the studies reported blinding the interpreters of level 3 tests to the level 1 test results, mitigating the risk of observer bias.

Most of the studies adequately described the tests, number of patients, recruitment methods and dropouts. Fifteen studies (only available as abstracts) had incomplete reporting of 1 or more elements (Table 2).

Most studies recruited patients suspected of having simple obstructive sleep apnea without comorbidities or with stable cardiovascular comorbidities. None of the studies included patients with other forms of sleep-disordered breathing (Table 2).

Results of the meta-analysis

We identified 19 studies reporting the parameters needed for our meta-analysis (Table 3). Among these studies, we found moderate to high heterogeneity at a mild apnea–hypopnea index cut-off in laboratory (≥ 5 events/h) and at home (≥ 10 events/h), and at a moderate cut-off for both settings (≥ 15 events/h) (I^2 53%–85%).[105] Overall, diagnostic accuracy improved as disease severity increased (Figures 2 and 3).

Table 1 (part 1 of 15): Characteristics of included studies

Study	Study design and level 3 device used	Patient population			Outcome measures
		Patient characteristics	Eligibility criteria		
			Inclusions	Exclusions	
Combination studies (simultaneous and separate)					
Abraham et al.[46]	Design: cohort Location: USA/UK No. of sites: 4 Device: ClearPath Nx-301 Channels: 3	No. of patients: 50 Sex: 34 M, 16 F Mean age: 55.5 ± 12.8 (range 23–78) yr Mean BMI: 32.6 ± 6.5 (range 19–48) Mean ESS: 10.6 ± 4.4 (1–23) Comorbidities: heart failure (LVEF ≤ 35%)	Stable New York Heart Association class III heart failure	Presence of cerebrovascular, neurovascular or terminal disease; severe COPD; known dermatologic condition or allergy to sensors or medical adhesives; documented MI within 6 wk of study	Diagnostic accuracy, adverse events, technical failures
Ayappa et al.[47]	Design: cohort Location: USA No. of sites: 1 Device: ARES Channels: 4	No. of patients: 102 (80 patients, 22 controls)* Sex: 69 M, 28 F Mean age: 44 (range 19–74) yr Comorbidities: NR Mean BMI: 28.7 (range 19–70) Mean ESS: 8.7	Suspected SDB, healthy volunteers for control	Inability to read English, inability to wear level 3 device on forehead	Diagnostic accuracy, diagnostic agreement, adverse events, technical failures
Garcia-Diaz et al.[48]	Design: cohort Location: Spain No. of sites: 1 Device: Apnoescreen II Channels: 4	No. of patients: 65* Sex: 54 M, 8 F Mean age: 54 ± 10.4 yr Comorbidities: hypertension (27), cardiovascular comorbidity (9) Mean BMI: 30.1 ± 3.9 Mean ESS: 12 ± 3.7	NR	Physical or mental impairment	Diagnostic accuracy, diagnostic agreement, adverse events, technical failures
Kuna et al.[49] (Abstract)	Design: cohort Location: USA No. of sites: 1 Device: Stardust II Channels: 4	No. of patients: 39 Sex: M Mean age: 54.0 ± 9.6 yr Comorbidities: NR Mean BMI: 35.8 ± 7.0 Mean ESS: NR	Suspected sleep apnea	NR	Diagnostic accuracy, diagnostic agreement
Kushida et al.[50] (Abstract)	Design: cohort Location: USA No. of sites: 1 Device: PMP-300E Channels: 4	No. of patients: 11 Sex: 7 M, 4 F Mean age: 42.1 yr Comorbidities: NR Mean BMI: 26.1 Mean ESS: 8.1	Age ≥ 18 yr, suspected OSA	NR	Diagnostic agreement

Continued.

Table 1 (part 2 of 15): Characteristics of included studies

Study	Study design and level 3 device used	Patient population			Outcome measures
		Patient characteristics	Eligibility criteria		
			Inclusions	Exclusions	
Combination studies (simultaneous and separate)					
Polese et al.[51] (Abstract)	Design: cohort Location: Brazil No. of sites: 1 Device: Stardust II Channels: 4	No. of patients: 43 Sex: 19 M, 24 F Mean age: mean: 70 ± 5 yr Comorbidities: NR Mean BMI: 30 ± 6 Mean ESS: 9 ± 7	Age ≥ 65 yr, suspected OSA	NR	Diagnostic accuracy, diagnostic agreement
Santos-Silva et al.[52]	Design: cohort Location: Brazil No. of sites: 1 Device: Stardust II Channels: 4	No. of patients: 82* Sex: 46 M, 34 F Mean age: 47 ± 14 yr Comorbidities: NR Mean BMI: 28 ± 5 Mean ESS: 10.4 ± 5.8	Age ≥ 21 yr, suspected OSA, ability to provide consent	Suspected other SDB, severe or unstable comorbid conditions, receiving oxygen or mechanical ventilation, neurologic disorders, sedative or hypnotic	Diagnostic accuracy, diagnostic agreement, adverse events, technical failures
Smith et al.[53]	Design: cohort Location: UK No. of sites: 1 Device: Embletta Channels: 4	No. of patients: 20 Sex: 14 M, 6 F Mean age: 61 ± 10 Comorbidities: congestive heart failure Mean BMI: 29 ± 6 Mean ESS: 8 ± 4	Informed consent, congestive heart failure, age 18–80 yr	None	Diagnostic accuracy, diagnostic agreement, technical failures
Tiihonen et al.[54]	Design: cohort Location: Finland No. of sites: 1 Device: "novel device" Channels: 8	No. of patients: 19 Sex: 11 M, 8 F Mean age: 46.8 ± 12.7 yr Mean BMI: 31.4 ± 10.3 Comorbidities: NR Mean ESS: NR	Suspected OSAS	NR	Diagnostic agreement
Tonelli de Oliveria et al.[55]	Design: cohort Location: Brazil No. of sites: 1 Device: Somnocheck Channels: 4	No. of patients: 157* Sex: 111 M, 38 F Mean age: 45 ± 12 yr Comorbidities: hypertension Mean BMI: 29.2 ± 5.5 Mean ESS: 11 ± 5	Age > 18 yr	Pregnancy, severe comorbidity (cancer, heart failure, etc.), difficulties that would interfere with examinations, residence outside hospital catchment area	Diagnostic accuracy, technical failures

Continued.

Table 1 (part 3 of 15): Characteristics of included studies

Study	Study design and level 3 device used	Patient population			Outcome measures
		Patient characteristics	Eligibility criteria		
			Inclusions	Exclusions	
Simultaneous studies					
Amir et al.[56]	Design: cohort Location: USA No. of sites: 1 Device: Morpheus Channels: 4	No. of patients: 55* Sex: 36 M, 17 F Mean age: 47.8 ± 11.3 yr Comorbidities: NR Mean BMI: 32.04 ± 7.9 (median 30.6) Mean ESS: NR	Age 21–80 yr	Pacemaker, COPD, and inability to undergo the test	Diagnostic accuracy
Bajwa et al.[57] (Abstract)	Design: cohort Location: USA No. of sites: 1 Device: Alice PDx Channels: 4	No. of patients: 7 Sex: NR Mean age: NR Comorbidities: NR Mean BMI: NR Mean ESS: NR	NR	NR	Diagnostic agreement
Candela et al.[58]	Design: cohort Location: Spain No. of sites: 1 Device: BITMED NGP140 Channels: 4	No. of patients: 103* Sex: 72 M, 20 F Mean age: 52.4 ± 11.8 yr Comorbidities: hypertension (37), COPD (8), observed apnea (78), excessive daytime sleepiness (70) Mean BMI: 31.8 ± 6.6 Mean ESS: 11.2 ± 4.8	Suspected SDB	NR	Diagnostic accuracy, diagnostic agreement, technical failures
Cheliout-Heraut et al.[59]	Design: cohort Location: France/Belgium No. of sites: NR Device: Somnolter Channels: 5	No. of patients: 104* Sex: 60 M, 30 F Mean age: 55.4 ± 8.7 (47–70) yr Comorbidities: NR Mean BMI: 26.7 ± 7.3 (mild OSA), 28.9 ± 5.3 (moderate OSA), 29.7 ± 4.1 (severe OSA) Mean ESS: NR	NR	Neurologic disorders, nocturnal parasomnias, restless leg syndrome and periodic limb movement	Diagnostic accuracy, technical failures

Continued.

Table 1 (part 4 of 15): Characteristics of included studies

Study	Study design and level 3 device used	Patient population			Outcome measures
		Patient characteristics	Eligibility criteria		
			Inclusions	Exclusions	
Simultaneous studies					
Divo et al.[60]	Design: cohort Location: Germany No. of sites: 1 Device: Apneagraph Channels: 4	No. of patients: 14 Sex: 12 M, 2 F Mean age: 52.7 ± 14.3 yr Comorbidities: NR Mean BMI: NR Mean ESS: NR	NR	NR	Sleep indices
Driver et al.[61]	Design: cohort Location: Canada No. of sites: 1 Device: MediByte Channels: 4	No. of patients: 80* Sex: 30 M, 43 F Mean age: mean: 53 ± 12 yr Comorbidities: NR Mean BMI: 32.2 ± 6.8 Mean ESS: NR	Patients with high care needs, known hypercapnia and known hypoventillation	None	Diagnostic accuracy, technical failures
Ferre et al.[62] (Abstract)	Design: cohort Location: Spain No. of sites: 1 Device: Somté Channels: 4	No. of patients: 37 Sex: 24 M, 13 F Mean age: 55.1 ± 11.5 yr Comorbidities: NR Mean BMI: 27.3 ± 3.9 Mean ESS: 10 ± 8.0	Suspected SDB	NR	Diagnostic accuracy, diagnostic agreement
Goodrich et al.[63]	Design: cohort Location: USA No. of sites:1 Device: LifeShirt Channels: 4	No. of patients: 50* Sex: 35 M, 13 F Mean age: 44 (22–69) yr Comorbidities: NR Mean BMI: NR Mean ESS: NR	Symptoms suggestive of OSA	COPD, neurologic and psychiatric disorders and significant medical conditions	Diagnostic accuracy, diagnostic agreement, technical failures
Grant et al.[64] (Abstract)	Design: cohort Location: USA No. of sites: 1 Device: Embletta Channels: 3	No. of patients: 95 Sex: NR Mean age: NR Comorbidities: NR Mean BMI: NR Mean ESS: NR	NR	NR	Diagnostic accuracy, diagnostic agreement

Continued.

Table 1 (part 5 of 15): Characteristics of included studies

Study	Study design and level 3 device used	Patient population			Outcome measures
		Patient characteristics	Eligibility criteria		
			Inclusions	Exclusions	
Simultaneous studies					
Ng et al.[65]	Design: cohort Location: Hong Kong No. of sites: 1 Device: Embletta Channels: 3	No. of patients: 90* Sex: 63 M, 17 F Mean age: 51.4 ±11.9 yr Comorbidities: NR Mean BMI: 27.1 ± 4.2 Mean ESS: 9.7 ± 5.3	Suspected OSAS, self-reported daytime sleepiness interfering with function, and 2 of the following: choking during sleep, gasping during sleep, recurrent awakenings from sleep, unrefreshed after sleep	None	Diagnostic accuracy, diagnostic agreement, technical failures
Ng et al.[66]	Design: cohort Location: Hong Kong No. of sites: 1 Device: ApneaLink Channels: 3	No. of patients: 50 Sex: 44 M, 6 F Mean age: 50 ± 11.8 yr Comorbidities: NR Mean BMI: 27.9 ± 4.8 Mean ESS: 10.1 ± 5.5	Daytime sleepiness, choking, unrestful sleep, fatigue, recurrent awakening from sleep and impaired concentration	None	Diagnostic accuracy, diagnostic agreement, technical failures
Nigro et al.[67]	Design: cohort Location: Argentina No. of sites: 1 Device: ApneaLink Channels: 3	No. of patients: 76* Sex: 47 M, 19 F Mean age: 51.5 ± 14.1 yr Comorbidities: NR Mean BMI: 29.3 ± 5.4 Mean ESS: NR	Suspicion of sleep apnea, signed informed consent, snoring with or without other symptoms, and age > 18 yr	Oxygen, CPAP	Diagnostic accuracy, diagnostic agreement, technical failures
Onder et al.[68]	Design: cross-sectional Location: Turkey No. of sites: 1 Device: WatchPAT 200 Channels: 4	No. of patients: 59* Sex: 36 M, 20 F Mean age (pooled): 42 yr Comorbidities: NR Mean BMI (pooled): 30.5 Mean ESS: NR	NR	Peripheral vasculopathy, pharyngeal deformity, diabetes mellitus, nephropathy, α-adrenergic receptor blockers or thoracic sympathectomy	Technical failures, sleep indices
Orr et al.[69] (Abstract)	Design: cohort Location: USA No. of sites: 1 Device: LifeShirt Channels: NR	No. of patients: 48 Sex: NR Mean age: NR Comorbidities: NR Mean BMI: NR Mean ESS: NR	NR	NR	Diagnostic accuracy, diagnostic agreement

Continued.

Table 1 (part 6 of 15): Characteristics of included studies

Study	Study design and level 3 device used	Patient population			Outcome measures
		Patient characteristics	Eligibility criteria		
			Inclusions	Exclusions	
Simultaneous studies					
Su et al.[70]	Design: cohort Location: USA No. of sites: 1 Device: SNAP Channels: 4	No. of patients: 60 Sex: 25 M, 35 F Mean age: 45.2 ± 12.3 yr Comorbidities: hypertension Mean BMI: 35.6 ± 10.1 Mean ESS: NR	Suspected OSAS, consecutive patient referrals	NR	Diagnostic accuracy, technical failure
Sullivan et al.[71] (Abstract)	Design: cohort Location: Canada No. of sites: 1 Device: Stardust Channels: 4	No. of patients: 34 Sex: NR Mean age: NR Comorbidities: NR Mean BMI: NR Mean ESS: NR	NR	NR	Diagnostic accuracy, diagnostic agreement
Takama et al.[72]	Design: cohort Location: Japan No. of sites: 1 Device: Morpheus Channels: 4	No. of patients: 99* Sex: 48 M, 35 F Mean age: 70 ± 10 yr Comorbidities: hypertension (75), dyslipidemia (66), diabetes mellitus (45), coronary artery disease (38), valvular disease (16), cardiomyopathy (16), other comorbid conditions (13) Mean BMI: NR Mean ESS: NR	Patients with coronary artery disease admitted to the hospital because of anterior chest pain or heart failure who had symptoms consistent with class II or III New York Heart Association classification	NR	Diagnostic accuracy
Tiihonen et al.[73]	Design: cohort Location: Finland No. of sites: 1 Device: APV2 remote analysis Channels: 4	No. of patients: 10 Sex: 5 M, 5 F Mean age: 46.7 ± 12.6 yr Comorbidities: NR Mean BMI: 37.3 ± 10.5 Mean ESS: NR	Suspicion of OSA	NR	Diagnostic agreement

Continued.

Table 1 (part 7 of 15): Characteristics of included studies

Study	Study design and level 3 device used	Patient population			Outcome measures
		Patient characteristics	Eligibility criteria		
			Inclusions	Exclusions	
Simultaneous studies					
To et al.[74]	Design: cohort Location: Hong Kong No. of sites: 1 Device: ARES Unicorder Channels: 4	No. of patients: 175 Sex: 132 M, 43 F Mean age: 47.8 ± 9.8 yr (M), 52.3 ± 12.2 yr (F) Comorbidities: hypertension (85), diabetes mellitus (27), hyperlipidemia (25), fatty liver (18), cerebrovascular accident (11) Mean BMI: 28.5 ± 4.9 (M), 29.2 ± 6.0 (F) Mean ESS: 9.8 ± 5.3 (M), 12.2 ± 5.0 (F)	Substantial sleepiness interfering with daily activities and 2 of the following symptoms: choking or gasping, recurrent awakenings, unrefreshed by sleep, daytime fatigue and impaired concentration	Pregnancy or patients who could not comply with the set-up of the device	Diagnostic agreement, technical failures
Yagi et al.[75]	Design: cohort Location: Japan No. of sites: 1 Device: Apnomonitor 5 Channels: 4	No. of patients: 22 Sex: 17 M, 5 F Mean age: 52.9 ± 13.3 (31–74) yr Comorbidities: NR Mean BMI: 25.7 ± 4.4 (18.8–39.3) Mean ESS: NR	Suspected SAS	NR	Diagnostic accuracy, diagnostic agreement
Separate studies					
Alonso et al.[76]	Design: cohort Location: Spain No. of sites: 1 Device: Edentrace II Channels: 4	No. of patients: 45 Sex: 39 M, 6 F Mean age: 52.3 ± 11 yr Comorbidities: hypertension (8), heart rhythm abnormalities (5), heart disease (3), cardiovascular accident (2), chronic obstructive pulmonary disorder (1), asthma (1) Mean BMI: 28.7 ± 4 Mean ESS: 8.9 ± 3 (0–19)	Suspected sleep apnea, residents of Burgos metropolitan area, and home suitable for study	Concomitant illness, symptoms of sleep disorders other than SAHS, occupation in which SAHS would increase occupational risk	Diagnostic accuracy, diagnostic agreement
Andreu et al.[77]	Design: RCT Location: Spain No. of sites: 1 Device: Stardust Channels: 4	No. of patients: 66* Sex: 54 M, 11 F Mean age: 52 ± 10 yr Comorbidities: hypertension (32) Mean BMI: 34 ± 7 Mean ESS: ≥ 12	ESS > 12	Impaired lung function, patients previously using CPAP, psychiatric diseases, neoplasm, restless leg syndrome, other dyssomnias and parasomnias	Adverse events, technical failures, clinical management

Continued.

Table 1 (part 8 of 15): Characteristics of included studies

Study	Study design and level 3 device used	Patient population			Outcome measures
		Patient characteristics	Eligibility criteria		
			Inclusions	Exclusions	
Separate studies					
Askenov et al.[78] (Abstract)	Design: cohort Location: USA No. of sites: 1 Device: NR Channels: NR	No. of patients: 452 (317 level 3, 135 level 1) Sex: NR Comorbidities: NR Level 3 Mean age: 59.1 ± 0.7 yr Mean BMI: 34.7 ± 0.5 Mean ESS: 13.9 ± 0.3 Level 1 Mean age: 59.2 ± 0.9 yr Mean BMI: 34.7 ± 0.6 Mean ESS: 14.5 ± 0.5	Apnea–hypopnea index ≥ 5	Patients using BPAP or PAP plus oxygen, or patients with no follow-up data	Clinical management outcomes, diagnostic agreement
Berry et al.[79]	Design: RCT Location: USA No. of sites: 1 Device: WatchPAT 100 Channels: 4	No. of patients: 106 (53 PM, 53 PSG) Comorbidities: NR PM arm Sex: 46 M, 7 F Mean age: 51.9 ± 1.7 yr Mean BMI: 34.0 ± 0.08 Mean ESS: 16.6 ± 0.47 PSG arm Sex: 47 M, 6 F Mean age: 55.1 ± 1.5 yr Mean BMI: 34.4 ± 0.9 Mean ESS: 16.2 ± 0.54	Excessive daytime sleepiness	Congestive heart failure, use of nocturnal oxygen, COPD, restless leg syndrome, use of narcotics, uncontrollable psychiatric disorders, night shift workers, previous treatment with CPAP, hypercapnia, neuromuscular diseases, cataplexy, use of α blockers	Clinical management outcomes
Bridevaux et al.[80]	Design: cross-sectional Location: Switzerland No. of sites: 1 Device: Embletta Channels: 4	No. of patients: 11 Sex: NR Mean age: 54 ± 14 yr Comorbidities: NR Mean BMI: NR Mean ESS: NR	Suspected OSA	NR	Diagnostic agreement

Continued.

Table 1 (part 9 of 15): Characteristics of included studies

Study	Study design and level 3 device used	Patient population			Outcome measures
		Patient characteristics	Eligibility criteria		
			Inclusions	Exclusions	
Separate studies					
Campbell et al.[81]	Design: cohort Location: New Zealand No. of sites: 1 Device: Siesta Sleep System Channels: NR	No. of patients: 31* Sex: 24 M, 6 F Mean age: 49.1 ± 13.8 (23–78) yr Comorbidities: NR Mean BMI: 31 ± 6.1 Mean ESS: 10.8 ± 4.9 (0–20)	Age > 18 yr, residence within the hospital's catchment area	Psychiatric disease, cardiovascular disease, limited mobility	Diagnostic accuracy, technical failures
Chung et al.[82]	Design: cohort Location: Canada No. of sites: 2 Device: Embletta Channels: 3	No. of patients: 24* Sex: 11 M, 10 F Mean age: 54 ± 11 yr Comorbidities: NR Mean BMI: 36 ± 9 Mean ESS: NR	Age > 18 yr	Unwilling or unable to give informed consent, other breathing disorder	Diagnostic agreement
Churchward et al.[83] (Abstract)	Design: cohort Location: Australia No. of sites: 1 Device: Somté Channels: NR	No. of patients: 20 Sex: 16 M, 4 F Mean age: 50 ± 13 yr Comorbidities: NR Mean BMI: 34 ± 8.3 Mean ESS: NR	Possible OSA	NR	Diagnostic accuracy
Cilli et al.[84] (Abstract)	Design: cohort Location: Turkey No. of sites: 1 Device: Embletta Channels: NR	No. of patients: 55 Sex: 49 M, 6 F Mean age: 46 yr Comorbidities: NR Mean BMI: NR Mean ESS: NR	NR	NR	Diagnostic accuracy
Danzi-Soares et al.[85]	Design: cohort Location: Brazil No. of sites: 1 Device: Stardust II Channels: 4	No. of patients: 79* Sex: 53 M, 17 F Mean age: 58 ± 7 yr Comorbidity: coronary artery disease Mean BMI: 27.6 Mean ESS: 7	Patients with coronary artery disease undergoing surgery	History of stroke and disability, clinical instability, use of supplemental oxygen	Diagnostic accuracy, diagnostic agreement

Continued.

Table 1 (part 10 of 15): Characteristics of included studies

Study	Study design and level 3 device used	Patient population			Outcome measures
		Patient characteristics	Eligibility criteria		
			Inclusions	Exclusions	
Separate studies					
Finkel et al.[86]	Design: cohort Location: USA No. of sites: 1 Device: ARES Channels: 4	No. of patients: 26 Sex: NR Mean age: NR Comorbidities: NR Mean BMI: NR Mean ESS: NR	Age > 18 yr, undergoing elective surgery	Previous diagnoses of OSA, use of home oxygen, allergy to synthetic material, inability to use sleep apnea detection device	Diagnostic accuracy
Fordyce et al.[87] (Abstract)	Design: cohort Location: Canada No. of sites: 1 Device: NR Channels: NR	No. of patients: 9 Sex: 6 M, 3 F Mean age: 40.3 yr Comorbidities: NR Mean BMI: 25.4 Mean ESS: NR	History of snoring	BMI ≥ 30, adjusted neck circumference ≥ 42 cm, ESS < 10	Diagnostic accuracy
Furokawa et al.[88]	Design: cohort Location: Japan No. of sites: 1 Device: FM-500 Channels: 4	No. of patients: 81 Sex: 51 M, 30 F Mean age: 64.9 ± 9.6 yr Comorbidity: hypertension Mean BMI: 25.9 ± 4.3 Mean ESS: 6.5 ± 4.1 (PSG)	Primary hypertension	NR	Diagnostic accuracy, diagnostic agreement, technical failures
Gjevre et al.[89]	Design: cohort Location: Canada No. of sites: 1 Device: Embletta Channels: 4	No. of patients: 47 Sex: F Mean age: 52 ± 11 yr Comorbidities: NR Mean BMI: 34.9 ± 9.0 Mean ESS: 9.6 ± 4.4 (0–19)	Age > 21 yr	Neuromuscular disease, renal failure, suspicion of SDB other than OSA, cardiovascular diseases, cerebrovascular accidents	Diagnostic accuracy, diagnostic agreement. technical failures
Grover et al.[90] (Abstract)	Design: cohort Location: USA No. of sites: 1 Device: Alice Channels: 4	No. of patients: 5 Sex: NR Mean age: NR (range 29–59 yr) Comorbidities: NR Mean BMI: NR Mean ESS: NR	Polysomnography naive	NR	Diagnostic agreement, technical failures

Continued.

Table 1 (part 11 of 15): Characteristics of included studies

Study	Study design and level 3 device used	Patient population			Outcome measures
		Patient characteristics	Eligibility criteria		
			Inclusions	Exclusions	
Separate studies					
Hernandez et al.[91]	Design: cohort Location: Spain No. of sites: 2 Device: respiratory polygraph Channels: 4	No. of patients: 88 Sex: 71 M, 17 F Mean age: 50.3 ± 11.6 yr Comorbidities: NR Mean BMI: 29.6 ± 4.2 Mean ESS: NR	SAHS	NR	Diagnostic accuracy, diagnostic agreement
Kuna et al.[92]	Design: RCT Location: USA No. of sites: 2 Device: Embletta Channels: NR	No. of patients: 296* Comorbidities: NR Mean ESS: NR Level 3 Sex: 108 M, 5 F Mean age: 55.1± 10.3 yr Mean BMI: 35.0 ± 7.5 Level 1 Sex: 104 M, 6 F Mean age: 51.8 ± 10.4 yr Mean BMI: 34.2 ± 5.2	Suspected OSA	People with normal results on PSG or level 3 test with apnea–hypopnea index < 5, SDB other than OSA (such as central sleep apnea)	Clinical management outcomes
Lettieri et al.[93]	Design: cohort Location: USA No. of sites: 1 Device: Stardust Channels: 5	No. of patients: 210 Comorbidities: NR Group 1 Sex: 45 M, 25 F Mean age: 50.4 ± 9.2 yr Mean BMI: 32.2 ± 4.8 Mean ESS: 14.8 ± 4.8 Group 2 Sex: 50 M, 20 F Mean age: 47.1 ± 8.0 yr Mean BMI: 30.0 ± 3.5 Mean ESS: 14.1 ± 4.2 Group 3 Sex: 48 M, 22 F Mean age: 45.5 ± 5.4 yr Mean BMI: 28.5 ± 3.0 Mean ESS: 13.9 ± 4.4	Meet criteria for OSA with no comorbidity	Ineligibility for home sleep testing, cardiopulmonary disorder, hypertension, heart failure, coronary artery disease, poorly controlled asthma, moderate to severe COPD or supplementary oxygen requirement	Clinical management outcomes

Continued.

Table 1 (part 12 of 15): Characteristics of included studies

Study	Study design and level 3 device used	Patient population			Outcome measures
			Eligibility criteria		
		Patient characteristics	Inclusions	Exclusions	
Separate studies					
Levendowski et al.[94]	Design: cohort Location: USA No. of sites: 3 Device: ARES Channels: 4	No. of patients: 37 Sex: NR Mean age: NR Comorbidities: NR Mean BMI: NR Mean ESS: NR	Apnea–hypopnea index < 10 or > 40 based on in-home baseline study; BMI > 32; nonretropalatal airway obstruction; previous airway surgery other than nasal, adenoid or tonsil; and SDB other than OSA	None	Diagnostic agreement
Masa et al.[95]	Design: RCT Location: Spain No. of sites: 8 Device: BreastSC20 Channels: 4	No. of patients: 377* Sex: 263 M, 85 F Mean age: 48.7 ± 11.8 yr Comorbidities: smoking (23.9%), heart disease (37%), cerebrovascular disease (1.9%), hypertension (30.7%), depression or anxiety (23.3%) Mean BMI: 31 ± 6.6 Mean ESS: 11.6 ± 5.5	Age 18–70 yr, referral to sleep centre with snoring, witnessed apneas, and ESS > 10 or morning tiredness	Severe or unstable heart disease, suspected SDB other than SAHS, inability to set up portable monitor	Diagnostic accuracy, technical failures
Masdeu et al.[96]	Design: cohort Location: Spain No. of sites: 1 Device: ARES Channels: 4	No. of patients: 85 (66 patients, 19 controls) Sex: 61 M, 24 F Mean age: 42.4 yr Comorbidities: NR Mean BMI: 29 Mean ESS: 7.8	High likelihood of OSA	Congestive heart failure, central sleep apnea	Diagnostic accuracy Diagnostic agreement
Nakayama et al.[97]	Design: cross-sectional Location: Japan No. of sites: 1 Device: Morpheo Channels: 7	No. of patients: 322 Sex: M Mean age: 43.8 ± 8.4 yr Comorbidity: hypertension Mean BMI: 23.7 ± 3.1 Mean ESS: 8.1 ± 4.3	NR	NR	Diagnostic agreement, technical failures

Continued.

Table 1 (part 13 of 15): Characteristics of included studies

Study	Study design and level 3 device used	Patient population			Outcome measures
		Patient characteristics	Eligibility criteria		
			Inclusions	Exclusions	
Separate studies					
Quintana-Gallego et al.[98]	Design: cohort Location: Spain No. of sites: 1 Device: Apneoscreen II Channels: 4	No. of patients: 90* Sex: 65 M, 10 F Mean age: 56.1 ± 11.7 yr Comorbidities: CHF (stable heart failure due to systolic dysfunction [LVEF ≤ 45%], ischemic [42.3%], idiopathic [39.4%], other [18.3%]) Mean BMI: 28.6 ± 4.4 Mean ESS: NR	LVEF ≤ 45% and no change in drug doses for 4 wk before the study	Instability of heart failure, acute MI in the previous 3 mo, unstable angina, or congenital heart disease	Diagnostic accuracy, diagnostic agreement, technical failure
Rosen et al.[99]	Design: RCT, Location: USA No. of sites: 7 Device: Embletta Channels: 4	No. of patients: 373 (197 completed) Comorbidities: NR Level 3 No. of patients: 187 No. completed: 105 Sex: 107 M, 80 F Mean age: 45.6 ± 11.6 yr Mean BMI: 37 ± 8.7 Mean ESS: 14 ± 3.9 Level 1 No. of patients: 186 No. completed: 92 Sex: 118M, 68 F Mean age: 46.3 ± 12.3 yr Mean BMI: 37.5 ± 8.7 Mean ESS: 14.1 ± 3.6	High suspicion of OSA, ESS > 12	Treatment with CPAP, substantial pulmonary disease, use of supplemental oxygen, awake hypercapnia or hypoventilation syndrome, respiratory or heart failure, neuromuscular disease, concerns about unsafe driving, chronic narcotic use, > 5 alcoholic drinks/d, uncontrolled psychiatric disturbance, or SDB other than OSA	Technical failures, clinical management outcomes
Shrivastava et al.[100] (Abstract)	Design: cohort Location: USA No. of sites: 1 Device: Edentrace Channels: NR	No. of patients: 99 Sex: NR Mean age: NR Comorbidities: NR Mean BMI: NR Mean ESS: NR	Community-based primary care clinic population	NR	Diagnostic accuracy

Continued.

Table 1 (part 14 of 15): Characteristics of included studies

Study	Study design and level 3 device used	Patient population			Outcome measures
		Patient characteristics	Eligibility criteria		
			Inclusions	Exclusions	
Separate studies					
Skomro et al.[101] (Abstract)	Design: cohort Location: Canada No. of sites: 1 Device: Embletta Channels: 4	No. of patients: 33 Sex: 27 M, 6 F Mean age: 48.3 ± 13.1 yr Comorbidities: NR Mean BMI: NR Mean ESS: 11.7 ± 4.2	Referral for suspected OSA, age > 18 yr	Respiratory/heart failure, presence of other sleep disorders, safety-sensitive occupation, use of hypnotics, upper airway surgery, CPAP, pregnancy	Diagnostic accuracy, diagnostic agreement, technical failures
Skomro et al.[102]	Design: prospective RCT prospective Location: Canada No. of sites: 1 Device: Embletta Channels: 4	No. of patients: 102 (51 in each arm)* Level 3 Sex: 30 M, 14 F Mean age: 47.8 ± 11.3 yr Comorbidities: NR Mean BMI: 31.4 ± 5.9 Mean ESS: 12.5 ± 3.6 Level 1 Sex: 30 M, 15 F Mean age: 49.8 ± 11.3 yr Comorbidities: NR Mean BMI: 34.6 ± 6.7 Mean ESS: 12.8 ± 4.8	Suspicion of OSA, age > 18 yr, residence within a 1-h drive, ESS > 10	Respiratory/heart failure, clinical features of another sleep disorder, CPAP or oxygen therapy, pregnancy and inability to provide informed consent	Clinical management outcomes
To et al.[103]	Design: prospective RCT Location: China No. of sites: 1 Device: ARES Channels: 4	No. of patients: 371 Comorbidities: NR Algorithm I No. of patients: 187 Sex: 138 M, 49 F Mean age: 50.87 ± 0.80 yr Mean BMI: 29.05 ± 0.32 Mean ESS: 14.5 Algorithm II (at home) No. of patients: 184 Sex: 136 M, 48 F Mean age: 49.76 ± 0.78 yr Mean BMI: 28.90 ± 0.30 Mean ESS: 13.9	Self-reported daytime sleepiness	Pregnancy, unwillingness to participate	Diagnostic accuracy, clinical management outcomes

Continued.

Table 1 (part 15 of 15): Characteristics of included studies

Study	Study design and level 3 device used	Patient population			Outcome measures
		Patient characteristics	Eligibility criteria		
			Inclusions	Exclusions	
Separate studies					
Yin et al.[104]	Design: cohort Location: Japan No. of sites: 1 Device: Stardust II Channels: 4	No. of patients: 90 (44 PSG) PSG Sex: 40 M, 4 F Mean age: 52.3 ± 13.5 yr Comorbidities: NR Mean BMI: 26.7 ± 5.3 Mean ESS: NR	Suspected OSA	NR	Diagnostic accuracy, diagnostic agreement

Note: APAP = automatic positive airway pressure, BMI = body mass index, BPAP = bilevel positive airway pressure, COPD = chronic obstructive pulmonary disease, CPAP = continuous positive airway pressure, ESS = Epworth Sleepiness Scale, F = female, LVEF = left ventricular ejection fraction, M = male, MI = myocardial infarction, NR = not reported, OSA = obstructive sleep apnea, OSAS = obstructive sleep apnea syndrome, PAP = positive airway pressure, PAT = peripheral arterial tonometry, PM = portable monitoring, PSG = polysomnography, RCT = randomized controlled trial, SAH = sleep apnea–hypopnea, SAHS = sleep apnea–hypopnea syndrome, SAS = sleep apnea syndrome, SDB = sleep-disordered breathing.
*Not all patients completed the study. Results reported only for evaluable patients (i.e., those who completed the tests, had their records analyzed or who started CPAP treatment).

Table 2 (part 1 of 2): Quality appraisal of the included studies using the QUADAS-2 tool

	Bias (internal validity)				Applicability concerns (external validity)		
Study	Selection of patients	Index test	Reference standard	Flow and timing	Selection of patients	Index test	Reference standard
Abraham et al.[46]	Low risk	Unclear	Unclear	Low risk	Low risk	Unclear	Low risk
Alonso Alvarez et al.[76]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Amir et al.[56]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Andreu et al.[77]	Low risk	Low risk	Low risk	Low risk	Low risk	Unclear	Low risk
Askenov et al.[78]	Low risk	Unclear	Low risk	Unclear	Low risk	Low risk	Low risk
Ayappa et al.[47]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Bajwa et al.[57]	High risk	High risk	Unclear	Low risk	Unclear	High risk	Low risk
Berry et al.[79]	Low risk	Low risk	Low risk	High risk	Low risk	Low risk	Low risk
Bridevaux et al.[80]	High risk	Low risk	Low risk	Unclear	Unclear	Low risk	Low risk
Campbell et al.[81]	Low risk	Unclear	Low risk	Low risk	Low risk	Low risk	Low risk
Candela et al.[58]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Cheliout et al.[59]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Chung et al.[82]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Churchward et al.[83]	Unclear	High risk	Unclear	Unclear	Unclear	Unclear	Low risk
Cilli et al.[84]	High risk	High risk	Unclear	Unclear	Unclear	Unclear	Low risk
Danzi-Soares et al.[85]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Divo et al.[60]	High risk	Low risk	Low risk	Low risk	Unclear	Low risk	Low risk
Driver et al.[61]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Ferre et al.[62]	High risk	High risk	Unclear	Low risk	Unclear	High risk	Low risk
Finkel et al.[86]	Low risk	Unclear	Unclear	High risk	Low risk	Low risk	Low risk
Fordyce et al.[87]	Low risk	Unclear	Unclear	Unclear	Low risk	Low risk	Low risk
Furokawa et al.[88]	High risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Garcia-Diaz et al.[48]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Gjevre et al.[89]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Goodrich et al.[63]	Low risk	Low risk	Low risk	Low risk	Unclear	Low risk	Low risk
Grant et al.[64]	High risk	Unclear	Low risk	Unclear	Unclear	Low risk	Low risk
Grover et al.[90]	High risk	Low risk	Low risk	Low risk	Unclear	Low risk	Unclear
Hernandez et al.[91]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Kuna et al.[49]	High risk	Low risk	Unclear	Low risk	Unclear	Low risk	Unclear
Kuna et al.[92]	High risk	Low risk	Unclear	Unclear	Unclear	Low risk	Unclear

Continued.

Table 2 (part 2 of 2): Quality appraisal of the included studies using the QUADAS-2 tool

	Bias (internal validity)				Applicability concerns (external validity)		
Study	Selection of patients	Index test	Reference standard	Flow and timing	Selection of patients	Index test	Reference standard
Kushida et al.[50]	High risk	Low risk	Low risk	Unclear	Unclear	Low risk	Unclear
Lettieri et al.[93]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Levendowski et al.[94]	Low risk	Low risk	Unclear	Unclear	Low risk	Low risk	Unclear
Masa JF et al.[95]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Masdue et al.[96]	Low risk	Low risk	Low risk	Unclear	Low risk	Low risk	Unclear
Nakayama et al.[97]	High risk	Low risk	Unclear	Low risk	Unclear	Low risk	Unclear
Ng et al.[65]	High risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Ng et al.[66]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Nigro et al.[67]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Onder et al.[68]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Unclear
Orr et al.[69]	High risk	Unclear	Unclear	Unclear	High risk	Unclear	Unclear
Polese et al.[51]	Low risk	Low risk	Low risk	Unclear	Low risk	Low risk	Low risk
Quintana-Gallego et al.[98]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Rosen et al.[99]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Santos-silva et al.[52]	Low risk	Low risk	Low risk	Low risk	Low risk	High risk	Low risk
Shrivastava et al.[100]	Unclear	Unclear	Unclear	Unclear	Unclear	Low risk	Unclear
Skomro et al.[102]	Low risk	Low risk	Unclear	Low risk	Low risk	High risk	Unclear
Skomro et al.[101]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Smith et al.[53]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Unclear
Su et al.[70]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Sullivan et al.[71]	High risk	Unclear	Unclear	Unclear	Unclear	Low risk	Unclear
Takama et al.[72]	Low risk	Unclear	Unclear	Low risk	Low risk	Low risk	Unclear
Tiihonen et al.[54]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Tiihonen et al.[73]	High risk	Low risk	Low risk	Low risk	Unclear	Low risk	Low risk
To et al.[74]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
To et al.[103]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Tonelli de Oliveira et al.[55]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Yagi et al.[75]	High risk	Low risk	Low risk	Low risk	Unclear	Low risk	Low risk
Yin et al.[104]	Unclear	Low risk	Low risk	Unclear	Unclear	Low risk	Low risk

Note: QUADAS-2 = Quality Assessment of Diagnostic Accuracy Studies-2.

Table 3: Results of the meta-analysis of studies including the primary parameters of true-positive, false-positive, true-negative and false-negative

Location, apnea–hypopnea cut-off	No. of studies	Overall heterogeneity		Sensitivity (95% CI)	Specificity (95% CI)	Area under the ROC curve (95% CI)	Positive LR (95% CI)	Negative LR (95% CI)
		I^2 (95% CI)	p value for Q statistic					
Home, ≥ 5 events/h	8[46,47,52,55,84,85,89,102]	0	0.5	0.93 (0.90–0.95)	0.60 (0.51–0.68)	0.89 (0.86–0.92)	2.3 (1.9–2.9)	0.11 (0.07–0.16)
Laboratory, ≥ 5 events/h	7[47,52,61,65,67,70,118]	85 (68–100)	0.001	0.96 (0.90–0.98)	0.76 (0.63–0.85)	0.92 (0.90–0.94)	3.9 (2.6–6.1)	0.05 (0.02–0.13)
Home, ≥ 10 events/h	6[46,47,55,76,89,91]	53 (0–100)	0.06	0.83 (0.73–0.89)	0.81 (0.70–0.89)	0.89 (0.86–0.91)	4.3 (2.7–7.0)	0.22 (0.14–0.33)
Laboratory, ≥ 10 events/h	6[47,48,58,61,65,70]	0	0.3	0.92 (0.87–0.95)	0.85 (0.77–0.90)	0.93 (0.91–0.95)	6.0 (4.0–8.9)	0.09 (0.05–0.15)
Home, ≥ 15 events/h	8[46–48,52,55,85,89,104]	82 (62–100)	0.002	0.79 (0.71–0.86)	0.79 (0.63–0.89)	0.85 (0.82–0.88)	3.7 (2.1–6.7)	0.26 (0.19–0.37)
Laborator, ≥15 events/h	9[47,48,52,56,58,61,65,67,70]	66 (23–100)	0.03	0.92 (0.86–0.96)	0.91 (0.85–0.95)	0.97 (0.95–0.98)	10.6 (6.1–18.2)	0.08 (0.04–0.15)
Home, ≥ 30 events/h	5[48,52,55,88,104]	0	0.4	0.79 (0.72–0.85)	0.90 (0.84–0.95)	0.86 (0.83–0.89)	8.2 (4.7–14.6)	0.23 (0.16–0.32)
Laboratory, ≥ 30 events/h	4[48,52,58,67]	0	0.5	0.97 (0.92–0.99)	0.93 (0.89–0.96)	0.99 (0.98–1.00)	14.9 (8.6–25.8)	0.03 (0.01–0.08)

Note: CI = confidence interval, LR = likelihood ratio, ROC = receiver operator characteristic.

Sensitivity analysis

When we removed the 3 studies that recruited only patients with comorbidities from the meta-analysis, the results of in-laboratory sleep testing remained unchanged, because the excluded studies had only been done at the patients' homes. Sensitivity in the at-home setting showed a slight improvement, ranging from 1% to 3% at all apnea–hypopnea index cut-offs, with the exception of 10 or more events per hour (where sensitivity decreased from 83% to 81%). Specificity improved by 2% and 3% at cut-offs of 5 or more and 10 or more events per hour, respectively, but remained unchanged at cut-offs of 15 or more and 30 or more events per hour. The area under the ROC curve improved slightly (1%) at all cut-offs other than 10 or more events per hour.

Interpretation

Level 3 portable devices scored well for sensitivity (the ability of a test to correctly identify those who have the disease), and specificity (the ability of a test to correctly identify those who do not have the disease), with a trade-off of increasing specificity and decreasing sensitivity as disease severity increased. The areas under the ROC curves (a measure that combines sensitivity and specificity to show the overall discriminatory power of the test, with a value of 1 indicating perfect discrimi-

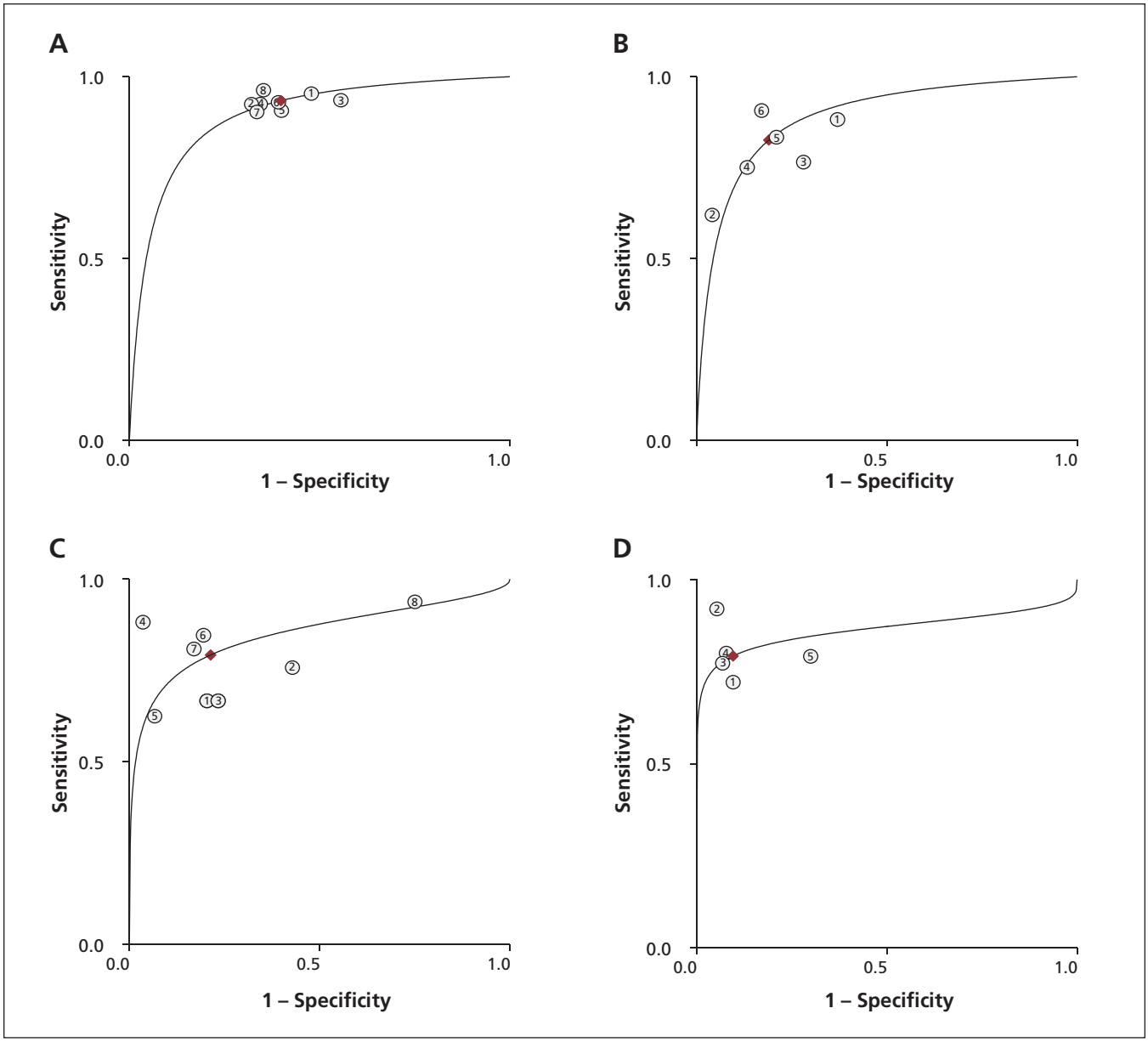

Figure 2: Summary receiver operating characteristic (ROC) curves comparing level 3 at-home sleep studies with level 1 in-laboratory studies. (A) ROC for apnea–hypopnea index ≥ 5 events/h. (B) ROC for apnea–hypopnea index ≥ 10 events/h. (C) ROC for apnea–hypopnea index ≥ 15 events/h. (D) ROC for apnea–hypopnea index ≥ 30 events/h.

nation) confirmed the performance of level 3 devices. The performance of level 3 devices was better in the laboratory than at home — the devices had a high technical failure rate when testing was done at home. Bruyneel and colleagues reported similar rates in their study comparing level 1 in-laboratory to unattended level 1 at-home sleep studies (the latter is considered level 2 testing). The unattended level 1 studies had similar rates of technical failures, despite using full polysomnography equipment, suggesting the failures were because a sleep technician was not in attendance.[106]

Despite the heterogeneity we saw at some apnea–hypopnea index cut-offs in our meta-analysis, the pooled estimates of diagnostic accuracy parameters appear reliable. We used a model that accounts for this heterogeneity[107–110] despite the use of different level 3 devices, which each measured the same core parameters.

The studies included in this review were designed to evaluate diagnostic accuracy rather than identify subpopulations of patients who might benefit from each test. Most patients in these studies had uncomplicated obstructive sleep apnea without unstable comorbidities. The patients were typically referred from sleep or respiratory clinics where a comprehensive pretest evaluation had been completed, suggesting a high pretest probability of obstructive sleep apnea (e.g., symptoms such as snoring and day-

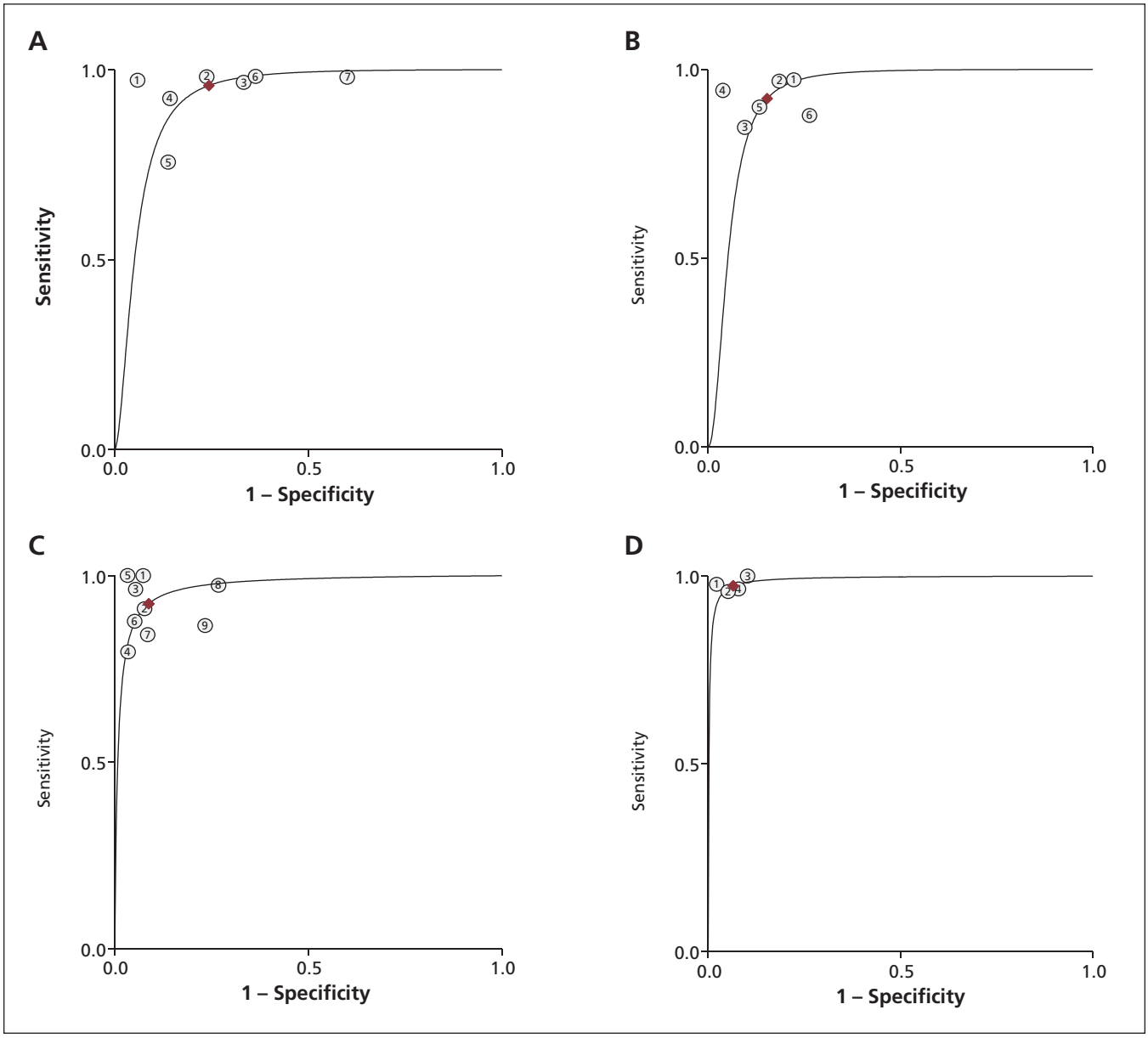

Figure 3: Summary receiver operating characteristic (ROC) curves comparing level 3 and level 1 in-laboratory sleep studies. (A) ROC for apnea–hypopnea index ≥ 5 events/h. (B) ROC for apnea–hypopnea index ≥ 10 events/h. (C) ROC for apnea–hypopnea index ≥ 15 events/h. (D) ROC for apnea–hypopnea index ≥ 30 events/h.

time sleepiness). Family physicians play a key role in the diagnosis of sleep-disordered breathing. Reuveni and colleagues discussed the need for educational programs to increase awareness among family physicians of the signs of obstructive sleep apnea.[111] Such programs will likely increase testing, optimize the use of diagnostic resources and expedite treatment.[112–114]

Our findings confirm those of previous reviews, health technology assessments and clinical practice guidelines based on earlier evidence of portable monitor use in the diagnosis of sleep-disordered breathing.[25–27,31–39,115] These reviews concluded that level 3 devices are useful in the diagnosis of obstructive sleep apnea in patients with a high pretest likelihood of having moderate to severe forms of the condition. The American Academy of Sleep Medicine and Canadian Sleep Society/Canadian Thoracic Society guidelines recommend that portable sleep studies be provided under the direction of health professionals with accreditation in sleep medicine and as part of a comprehensive assessment.[25–27] The US Centers for Medicare & Medicaid Services has determined that portable devices (with a minimum of 3 channels) are acceptable for diagnosing obstructive sleep apnea in patients with clinical signs or symptoms suggestive of the condition.[116]

Limitations

We included only English-language studies in this review, therefore it is possible that relevant studies in other languages were excluded. In addition, none of the studies included patients with forms of sleep-disordered breathing other than obstructive sleep apnea, limiting the generalizability of the results to patients with other forms of sleep-disordered breathing.

Conclusion

Level 3 sleep studies are safe and convenient for diagnosing obstructive sleep apnea in patients with a high pretest probability of moderate to severe forms of the condition without substantial comorbidities. Level 1 polysomnography remains the cornerstone for the diagnosis in patients suspected of having comorbid sleep disorders, unstable medical conditions or complex sleep-disordered breathing. Further studies assessing the use of portable sleep studies in patients with conditions other than obstructive sleep apnea, and in patients with obstructive sleep apnea and comorbidities, are needed.

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Funding: Production of this work has been made possible by a financial contribution from Alberta Health and under the auspices of the Alberta Health Technologies Decision Process: the Alberta Model for Health Technology Assessment and Policy Analysis. The views expressed herein do not necessarily represent the official policy of Alberta Health. The study sponsor had no role in the design of the study, the collection, analysis or interpretation of data, the writing of the report, or the decision to submit the article for publication.

Acknowledgments: The authors thank Dr. Babak Bohlouli, University of Alberta, Department of Medicine, for his help with screening, reviewing and abstracting the data; Ms. Sarah Ndegwa for her help with reviewing and abstracting data; and Dr. Dominic Carney for his clinical advice throughout the project.