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.14 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...
Wisconsin Sleep Cohort Study, values in American adults (aged 30–60 yr) are 24% for men and 9% for women. 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. As the population ages and rates of obesity increase, the prevalence of sleep-disordered breathing is climbing. 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. However, limited facilities and the growing demand for sleep studies have resulted in long wait times. 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. Level 4 devices are also portable, but they capture less data — usually only 1 or 2 channels.

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.

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.

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 I² 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).46,103 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.46–48,52,55,81,89,98,104 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.47,48,51,52,56,61–63,65–67,69–71

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.71–79,81,89,102,103

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

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

| Study          | Patient population                                                                 | Eligibility criteria                                                  | Outcome measures                  |
|----------------|-------------------------------------------------------------------------------------|------------------------------------------------------------------------|-----------------------------------|
| **Simultaneous studies** |                                                                                      |                                                                        |                                   |
| Divo et al.60  | Study design and level 3 device used: 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 | Study design and level 3 device used: 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 hypoventilation | None | Diagnostic accuracy, technical failures |
| Ferre et al.62 (Abstract) | Study design and level 3 device used: 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 | Study design and level 3 device used: 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) | Study design and level 3 device used: 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.
| Study | Study design and level 3 device used | Patient population | Eligibility criteria | Outcome measures |
|-------|-------------------------------------|--------------------|---------------------|------------------|
| **Simultaneous studies** |
| Ng et al.65 | Design: cohort Location: Hong Kong No. of sites: 1 Device: Emblettta 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.
| Study                  | Study design and level 3 device used | Patient characteristics | Eligibility criteria         | Outcome measures          |
|-----------------------|-------------------------------------|-------------------------|-----------------------------|--------------------------|
| **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: 35.6 | Suspected OSAS, consecutive patient referrals |      |
| 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 |
| Tiilhonen 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.
| Study          | Study design and level 3 device used | Patient population characteristics | Eligibility criteria                      | Outcome measures               |
|---------------|-------------------------------------|----------------------------------|-------------------------------------------|-------------------------------|
| **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 | 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 | Eligibility criteria | Outcome measures                  |
|------------------------------|-------------------------------------|--------------------|----------------------|-----------------------------------|
| **Askenov et al.**<sup>78</sup> (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.**<sup>79</sup> | 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.**<sup>80</sup> | Design: cross-sectional Location: Switzerland No. of sites: 1 Device: Embletta Channels: 4 | No. of patients: 11 Sex: NR Comorbidities: NR Mean age: 54 ± 14 yr 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 | Eligibility criteria                                                                 |
|------------------------|--------------------------------------|--------------------|---------------------------------------------------------------------------------------|
| **Separate studies**   |                                      |                    |                                                                                       |
| Campbell et al.81      | Design: cohort                        | No. of patients: 31* Sex: 24 M, 6 F | Age > 18 yr, residence within the hospital’s catchment area | Psychiatric disease, cardiovascular disease, limited mobility | Diagnostic accuracy, technical failures |
|                        | Location: New Zealand                | Mean age: 49.1 ± 13.8 (23–78) yr Comorbidities: NR Mean BMI: 31 ± 6.1 Mean ESS: 10.8 ± 4.9 (0–20) | | | |
|                        | No. of sites: 1                      |                    |                                                                                       |
|                        | Device: Siesta Sleep System          |                    |                                                                                       |
|                        | Channels: NR                         |                    |                                                                                       |
|                        |                                      | No. of patients: 31* Sex: 24 M, 6 F | Age > 18 yr, residence within the hospital’s catchment area | Psychiatric disease, cardiovascular disease, limited mobility | Diagnostic accuracy, technical failures |
|                        | Location: Canada                     | Mean age: 49.1 ± 13.8 (23–78) yr Comorbidities: NR Mean BMI: 31 ± 6.1 Mean ESS: 10.8 ± 4.9 (0–20) | | | |
|                        | No. of sites: 2                      |                    |                                                                                       |
|                        | Device: Embletta                      |                    |                                                                                       |
|                        | Channels: 3                          |                    |                                                                                       |
| Chung et al.82         | Design: cohort                        | No. of patients: 24* Sex: 11 M, 10 F | Age > 18 yr | Unwilling or unable to give informed consent, other breathing disorder | Diagnostic agreement |
|                        | Location: Canada                     | Mean age: 54 ± 11 yr Comorbidities: NR Mean BMI: 36 ± 9 Mean ESS: NR | | | |
|                        | No. of sites: 2                      |                    |                                                                                       |
|                        | Device: Embletta                      |                    |                                                                                       |
|                        | Channels: 3                          |                    |                                                                                       |
| Churchward et al.83    | Design: cohort                        | No. of patients: 20 Sex: 16 M, 4 F | Possible OSA | NR | Diagnostic accuracy |
| (Abstract)             | Location: Australia                  | Mean age: 50 ± 13 yr Comorbidities: NR Mean BMI: 34 ± 8.3 Mean ESS: NR | | | |
|                        | No. of sites: 1                      |                    |                                                                                       |
|                        | Device: Somté                         |                    |                                                                                       |
|                        | Channels: NR                         |                    |                                                                                       |
| Cilli et al.84         | Design: cohort                        | No. of patients: 55 Sex: 49 M, 6 F | NR | NR | Diagnostic accuracy |
| (Abstract)             | Location: Turkey                     | Mean age: 46 yr Comorbidities: NR Mean BMI: NR Mean ESS: NR | | | |
|                        | No. of sites: 1                      |                    |                                                                                       |
|                        | Device: Embletta                      |                    |                                                                                       |
|                        | Channels: NR                         |                    |                                                                                       |
| Danzi-Soares et al.85  | Design: cohort                        | No. of patients: 79* Sex: 53 M, 17 F | Patients with coronary artery disease undergoing surgery | History of stroke and disability, clinical instability, use of supplemental oxygen | Diagnostic accuracy, diagnostic agreement |
|                        | Location: Brazil                     | Mean age: 58 ± 7 yr Comorbidities: coronary artery disease Mean BMI: 27.6 Mean ESS: 7 | | | |
|                        | No. of sites: 1                      |                    |                                                                                       |
|                        | Device: Stardust II                  |                    |                                                                                       |
|                        | Channels: 4                          |                    |                                                                                       |

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

| Study | Study design and level 3 device used | Patient population | Eligibility criteria |
|-------|-------------------------------------|--------------------|----------------------|
| **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 | Eligibility criteria | Outcome measures               |
|----------------|-------------------------------------------------------------------------|--------------------|----------------------|---------------------------------|
|                |                                                                         |                    |                      |                                 |
| **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.
| Study                  | Design and level 3 device used | Patient population | Eligibility criteria                                                                 | Outcome measures                        |
|-----------------------|--------------------------------|--------------------|--------------------------------------------------------------------------------------|-----------------------------------------|
| **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                                      |
| 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 |
| 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 |
| 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 |

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

| Study                        | Study design and level 3 device used | Patient population | Eligibility criteria | Outcome measures |
|------------------------------|-------------------------------------|--------------------|----------------------|-----------------|
| 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 | | Diagnostic accuracy |

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

| Study      | Study design and level 3 device used | Patient characteristics | Eligibility criteria | Outcome measures                          |
|------------|--------------------------------------|-------------------------|----------------------|------------------------------------------|
|            |                                      |                         | 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 | Eligibility criteria | Outcome measures |
|---|---|---|---|---|
| | | | 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

| Study                        | Bias (internal validity) | Applicability concerns (external validity) |
|------------------------------|--------------------------|--------------------------------------------|
|                              | 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.57              | Low risk                | Low risk  | Low risk           | Low risk        | Low risk              | Low risk  | 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           | Low 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           |
| Cheliouit et al.59           | Low risk                | Low risk  | Low risk           | Low risk        | Low risk              | Low risk  | Low risk           |
| Chung et al.92               | 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   | Unclear           | Unclear         | Low risk              | 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.
| Study                    | Bias (internal validity) | Applicability concerns (external validity) |
|-------------------------|--------------------------|-------------------------------------------|
|                         | 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   | Low risk           | Unclear       |
| Lettieri et al.93        | Low risk                 | 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   | Low risk           | Unclear       |
| Masa JF et al.95         | Low risk                 | 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   | Low risk           | Low risk       |
| Nakayama et al.97        | High risk                | Low risk   | Unclear            | Low risk         | Unclear               | Low risk   | Low risk           | Unclear       |
| Ng et al.65              | Low risk                 | Low 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           | Low risk       |
| Nigro et al.67           | Low risk                 | 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   | Low risk           | Unclear       |
| Orr et al.69             | High risk                | Unclear   | Unclear            | Unclear         | High risk              | Unclear   | Unclear            | Unclear       |
| Polese et al.51          | Low risk                 | Low risk   | Low risk           | Unclear         | Low risk               | 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           | Low risk       |
| Rosen et al.99           | Low risk                 | Low risk   | Low risk           | Low risk         | Low risk               | Low risk   | Low risk           | Low risk       |
| Santos-silva et al.62    | Low risk                 | 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   | Low risk           | Unclear       |
| Skomro et al.102         | Low risk                 | Low risk   | Unclear            | 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           | Low risk       |
| Smith et al.53           | Low risk                 | 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           | Low risk       |
| Sullivan et al.71        | High risk                | Unclear   | Unclear            | Unclear         | Unclear               | Low risk   | Low risk           | Unclear       |
| Takama et al.72          | Low risk                 | Unclear   | Unclear            | Unclear         | Low risk               | Low risk   | Low risk           | Unclear       |
| Tiilhonen et al.54       | Low risk                 | Low risk   | Low risk           | Low risk         | Low risk               | Low risk   | Low risk           | Low risk       |
| Tiilhonen et al.73       | High risk                | Low risk   | Low risk           | Low risk         | Unclear               | Low risk   | Low risk           | Low risk       |
| To et al.74              | Low risk                 | 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           | Low risk       |
| Tonelli de Oliveira et al.55 | Low risk      | 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           | Low risk       |
| Yin et al.104            | Unclear                  | Low risk   | Unclear            | Unclear         | Low risk               | Low risk   | 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) |
|----------------------------------|----------------|----------------------|---------------------|---------------------|---------------------------------|---------------------|---------------------|
| **Home, ≥ 5 events/h**          | 646–47,52,55,84,88,102 | 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        | 647,52,61,65,67,70,118 | 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**         | 646,47,55,76,89,91   | 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       | 647,48,58,61,65,70   | 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**         | 646–48,52,55,84,88,104 | 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)    |
| Laboratory, ≥15 events/h        | 647,48,52,56,58,61,65,67,70 | 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**         | 648,52,55,84,104     | 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       | 648,52,58,67         | 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-
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 heterogeneity107–110 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.11 Such programs will likely increase testing, optimize the use of diagnostic resources and expedite treatment.12-14

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 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.28-29 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.106

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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Affiliations: Health Technology and Policy Unit, School of Public Health (El Shayeib, Topfer, Stafinski, Menon), Sleep Medicine Program (Pawluk), Department of Psychiatry, University of Alberta, Edmonton, Alta.

Contributors: Mohamed El Shayeib selected the studies, extracted the data, conducted the meta-analysis, analyzed the results and drafted the manuscript. Leigh-Ann Topfer conducted the literature search, and edited and revised the manuscript. Tania Stafinski helped conceive the design of the review, extracted the data, and edited and revised the manuscript. Lawrence Pawluk edited and revised the manuscript. Devidas Menon helped conceive the design of the review, extracted the data, and edited and reviewed the manuscript. All of the authors approved the final version submitted for publication.

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