GUIDELINE SYNTHESIS

Screening and Diagnosis of Obstructive Sleep Apnea

Guidelines Being Compared:

1 American Academy of Sleep Medicine (AASM)

Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline.

2017 Mar 15

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2 American College of Physicians (ACP)

Diagnosis of obstructive sleep apnea in adults: a clinical practice guideline from the American College of Physicians

2014 Aug 05

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Areas of Agreement and Difference

A direct comparison of recommendations presented in the above guidelines for the screening and diagnosis of obstructive sleep apnea (OSA) in adults is provided.

Areas of Agreement

Diagnosis of OSA in Adults with Comorbid Conditions

use of HSAT in adults with significant cardiorespiratory disease, potential respiratory muscle weakness due to neuromuscular condition, awake hypoventilation or suspicion of sleep-related hypoventilation, chronic opioid medication use, history of stroke or severe insomnia in order to diagnose OSA. The ACP makes a weak recommendation based on moderate-quality evidence for the first-line use of polysomnography for diagnostic testing in patients with suspected OSA, and if polysomnography is not available, portable sleep monitors are an appropriate alternative in patients without serious comorbidities. The ACP also notes that the utility of portable monitors for patients with serious comorbid conditions, including chronic lung disease, congestive heart failure, or neurologic disorders, has not been verified because most available studies excluded these patients.

Questionnaires and Clinical Prediction Rules/Algorithms

The AASM makes a **strong** recommendation against the use of these tools in the absence of polysomnography or HSAT. The ACP does not make a recommendation for or against the use of these tools and notes that while sleepiness questionnaires, such as the Epworth Sleepiness Scale (ESS), help in assessing the symptom severity of OSA they cannot assess the AHI (a necessary but not sufficient component of OSA) and lack sufficient sensitivity and specificity to replace a sleep study in diagnosing OSA. While there is low-quality evidence suggesting that some clinical prediction rules can be used to effectively predict OSA diagnosis, the applicability of these rules to the general population cannot be determined from the existing literature, adds the ACP.

Areas of Difference

Screening

The ACP recommends that clinicians target their assessment of OSA to individuals with unexplained daytime sleepiness, the clinically relevant OSA symptom most responsive to treatment. Additional common presenting symptoms cited by the developer include unintentional sleep episodes during wakefulness, unrefreshing sleep, fatigue, insomnia, and snoring; the best documented risk factor for OSA is obesity. If other causes have been ruled out, further evaluation may be warranted in patients with daytime sleepiness, states the ACP.

OSA, defined as the presence of excessive daytime sleepiness and at least two of the following three criteria: habitual loud snoring, witnessed apnea or gasping or choking, or diagnosed hypertension. The developer defines an uncomplicated patient as the absence of the following: conditions that place the patient at increased risk of non-obstructive sleep-disordered breathing; concern for significant non-respiratory sleep disorder(s) that require evaluation; and environmental or personal factors that preclude the adequate acquisition and interpretation of data from HSAT.

Diagnostic Testing in Uncomplicated Adults

The AASM and the ACP agree that polysomnography is considered the reference standard for diagnostic testing in uncomplicated adult patients with suspected OSA. Both guideline developers also address the use of home sleep apnea testing (HSAT) with portable sleep monitors. With regard to which of the two methods is preferred, the ACP makes a **weak** recommendation based on moderate-quality evidence for the first-line use of polysomnography for diagnostic testing in patients with suspected OSA. If polysomnography is not available, portable sleep monitors are an appropriate alternative in patients without serious comorbidities, states the ACP.

The AASM makes a **strong** recommendation for the use of either polysomnography or HSAT with a technically adequate device in patients for whom diagnostic testing is planned. If HSAT is selected for initial testing and the test is negative, inconclusive or technically inadequate, polysomnography should be performed to establish a diagnosis of OSA, recommends the AASM.

The AASM defines a technically adequate portable sleep monitoring device as one that incorporates a minimum of the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or peripheral arterial tonometry (PAT) with oximetry and actigraphy. The test should include a minimum of 4 hours of technically adequate oximetry and flow data, obtained during a recording attempt that encompasses the habitual sleep period, adds the AASM. According to the ACP, direct evidence from studies comparing one monitor with another is lacking. Monitors with more channels perform better

Comparison of Recommendations

AASM (2017)	The following are good practice statements, the implementation of which is deemed necessary for appropriate and effective diagnosis and management of OSA. • Diagnostic testing for OSA should be performed in conjunction with a comprehensive sleep evaluation and adequate follow-up. • Polysomnography is the standard diagnostic test for the diagnosis of OSA in adult patients in whom there is a concern for OSA based on a comprehensive sleep evaluation. **Diagnosis of OSA in Adults Using Clinical Tools, Questionnaires and Prediction Algorithms** **Recommendation 1**: The Task Force (TF) recommends that clinical tools, questionnaires and prediction algorithms not be used to diagnose OSA in adults, in the absence of polysomnography or home sleep apnea testing. (**Strong**) **HSAT for the Diagnosis of OSA in Adults** **Recommendation 2**: The TF recommends that polysomnography, or home sleep apnea testing (HSAT) with a technically adequate device, be used for the diagnosis of OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA. (**Strong**) **Recommendation 3**: The TF recommends that if a single home sleep apnea test is negative, inconclusive or technically inadequate, polysomnography be performed for the diagnosis of OSA. (**Strong**) *Remarks*: The following remarks are based on specifications used by studies that support these recommendation statements: An uncomplicated patient is defined by the absence of:

and sleep related hypoxemia). Examples of these conditions include significant cardiopulmonary disease, potential respiratory muscle weakness due to neuromuscular conditions, history of stroke and chronic opiate medication use.

2. Concern for significant non-respiratory sleep disorder(s) that require evaluation (e.g., disorders of central hypersomnolence, parasomnias, sleep related movement disorders) or interfere with accuracy of HSAT (e.g., severe insomnia).
3. Environmental or personal factors that preclude the adequate acquisition and interpretation of data from HSAT.

An increased risk of moderate to severe OSA is indicated by the presence of excessive daytime sleepiness and at least two of the following three criteria: habitual loud snoring, witnessed apnea or gasping or choking, or diagnosed hypertension.

HSAT is to be administered by an accredited sleep center under the supervision of a board-certified sleep medicine provider.

A single HSAT recording is conducted over at least one night.

A technically adequate HSAT device incorporates a minimum of the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or else peripheral arterial tonometry (PAT) with oximetry and actigraphy. For additional information regarding HSAT sensor requirements, refer to *The American Academy of Sleep Medicine (AASM) Manual for the Scoring of Sleep and Associated Events*.

A technically adequate diagnostic test includes a minimum of 4 hours of technically adequate oximetry and flow data, obtained during a recording attempt that encompasses the habitual sleep period.

Diagnosis of OSA in Adults with Comorbid Conditions

	significant cardiorespiratory disease, potential respiratory muscle weakness due to neuromuscular condition, awake hypoventilation or suspicion of sleep-related hypoventilation, chronic opioid medication use, history of stroke or severe insomnia. (**Strong**) **Diagnosis of OSA in Adults Using a Split-Night versus a Full-Night Polysomnography Protocol** **Recommendation 5**: The TF suggests that, if clinically appropriate, a split-night diagnostic protocol, rather than a full-night diagnostic protocol for polysomnography be used in the diagnosis of OSA. (**Weak**) *Remarks*: Clinically appropriate is defined as the absence of conditions identified by the clinician that are likely to interfere with successful diagnosis and treatment using a split-night protocol. This recommendation is based on a split-night protocol that initiates CPAP titration only when the following criteria are met: (1) a moderate to severe degree of OSA is observed during a minimum of 2 hours of recording time on the diagnostic polysomnography, AND (2) at least 3 hours are available for CPAP titration. **Repeat Polysomnography for the Diagnosis of OSA in Adults** **Recommendation 6**: The TF suggests that when the initial polysomnogram is negative and there is still clinical suspicion for OSA, a second polysomnogram be considered for the diagnosis of OSA. (**Weak**)
ACP (2014)	**Recommendation 1**: *ACP recommends a sleep study for patients with unexplained daytime sleepiness*. (**Grade: weak recommendation, low-quality evidence**) Clinicians should target their assessment of OSA to individuals with unexplained daytime sleepiness. This assessment should include evaluation of the risk

episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, and snoring. If other causes have been ruled out (for example, thyroid disease, gastroesophageal reflux disease, or other respiratory diseases), further evaluation for OSA may be warranted in patients with daytime sleepiness, which is the clinically relevant OSA symptom most responsive to treatment. Evidence is lacking on the effect of CPAP on improving other outcomes, including hypertension, diabetes, coronary heart disease events, and mortality, especially among individuals without daytime sleepiness. For guidance on treatment, clinicians should refer to the ACP guideline on management of OSA. Sleepiness questionnaires, such as the Epworth Sleepiness Scale (ESS), help in assessing the symptom severity of OSA but cannot assess the AHI (a necessary but not sufficient component of OSA) and lack sufficient sensitivity and specificity to replace a sleep study in diagnosing OSA.

Recommendation 2: *ACP recommends polysomnography for diagnostic testing in patients suspected of OSA. ACP recommends portable sleep monitors in patients without serious comorbidities as an alternative to polysomnography when polysomnography is not available for diagnostic testing*. (**Grade: weak recommendation, moderate-quality evidence**)

Full-night, attended, in-laboratory polysomnography is considered the reference standard diagnostic test and is recommended in patients with suspected OSA. However, in the absence of polysomnography, portable monitors may be used as an alternative diagnostic test in such patients. Both the AASM and the Centers for Medicare & Medicaid Services consider an AHI score of at least 15 events per hour or at least 5 events per hour with symptoms (such as daytime somnolence and fatigue) as criteria for OSA diagnosis. Evidence shows that compared with polysomnography, type II, III, and IV monitors have a wide range of difference in AHI estimates. These monitors have a high positive likelihood ratio and low negative likelihood ratio for various AHI cutoff levels to predict OSA. Monitors with more channels perform better than those with fewer channels, and type IV

	head comparisons of type III and IV monitors, but indirect evidence from studies comparing each monitor with polysomnography suggested that type III monitors performed better than type IV monitors in predicting AHI scores suggestive of OSA. Although portable monitors may be useful, data loss of 3% to 20% has been reported for type III and IV monitors. Furthermore, inadequate data resulting in limited interpretation of results from the use of type III monitors has been reported for 13% to 20% of the evaluations. The utility of portable monitors for patients with serious comorbid conditions, including chronic lung disease, congestive heart failure, or neurologic disorders, has not been verified. Evidence from studies comparing one monitor with another is lacking. The Figure in the original guideline document summarizes the recommendations and clinical considerations.

Strength of Evidence and Recommendation Grading Schemes

AASM (2017)	**Quality of a Body of Evidence** **High**: Corresponds to a high level of certainty that the true effect lies close to that of the estimate of the effect. **Moderate**: Corresponds to a moderate level of certainty in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. **Low**: Corresponds to a low level of certainty in the effect estimate; the true effect may be substantially different from the estimate of the effect. **Very low**: Corresponds to very little certainty in the effect estimate; the true effect is likely to be substantially different from the estimate of effect. **Strength of Recommendations**

Measure).

Weak: A WEAK recommendation reflects a lower degree of certainty in the appropriateness of the patient-care strategy and requires that the clinician use his/her clinical knowledge and experience, and refer to the individual patient's values and preferences to determine the best course of action.

Example Characteristics of AASM Strengths of Recommendations

AASM Strength of Recommendation		Example Characteristics Guiding Recommendation
FOR	STRONG	• There is a high degree of clinical certainty that the balance between benefits vs. harms (i.e., net benefits) favors benefits for this patient-care strategy. • The vast majority of well-informed patients would most likely choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.
	WEAK	• There is a lower degree of clinical

			benefits vs. harms (i.e., net benefits) favors benefit for this patient-care strategy. • The majority of well-informed patients would most likely choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.
	AGAINST	WEAK	• There is a lower degree of clinical certainty in the balance between benefits vs. harms (i.e., net harms) of this patient-care strategy. • The majority of well-informed patients would most likely not choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.

			the balance between benefits vs. harms (i.e., net harms) of this patient-care strategy. • The vast majority of well-informed patients would most likely not choose this patient-care strategy, compared to alternative patient-care strategies or no treatment.
ACP (2014)	**Grading of Quality of Evidence** **High-Quality Evidence**: Evidence is considered high quality when it is obtained from 1 or more well-designed and well-executed randomized, controlled trials (RCTs) that yield consistent and directly applicable results. This also means that further research is very unlikely to change confidence in the estimate of effect. **Moderate-Quality Evidence**: Evidence is considered moderate quality when it is obtained from RCTs with important limitations—for example, biased assessment of the treatment effect, large loss to follow-up, lack of blinding, unexplained heterogeneity (even if it is generated from rigorous RCTs), indirect evidence originating from similar (but not identical) populations of interest, and RCTs with a very small number of participants or observed events. In addition, evidence from well-designed controlled trials without randomization, well-designed cohort or case-control analytic studies, and multiple time series with or without intervention are in this category. Moderate-quality evidence also means that further research will probably have an important effect on confidence in the estimate of effect and may change the estimate.		

evidence means that further research is very likely to have an important effect on confidence in the estimate of effect and will probably change the estimate. However, the quality of evidence may be rated as moderate or even high, depending on circumstances under which evidence is obtained from observational studies. Factors that may contribute to upgrading the quality of evidence include a large magnitude of the observed effect, a dose-response association, or the presence of an observed effect when all plausible confounders would decrease the observed effect.

Insufficient Evidence to Determine Net Benefits or Risks: When the evidence is insufficient to determine for or against routinely providing a service, the recommendation was graded as "insufficient evidence to determine net benefits or risks." Evidence may be conflicting, of poor quality, or lacking, and hence the balance of benefits and harms cannot be determined. Any estimate of effect that is very uncertain as evidence is either unavailable or does not permit a conclusion.

The American College of Physicians' Guideline Grading System*		
Quality of Evidence	**Strength of Recommendation**	
	Benefits Clearly Outweigh Risks and Burden or Risks and Burden Clearly Outweigh Benefits	**Benefits Finely Balanced with Risks and Burden**
High	Strong	Weak
Moderate	Strong	Weak
Low	Strong	Weak
Insufficient evidence to determine net benefits or risks		

*Adopted from the classification developed by the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) workgroup.

Click on the links below for details of guideline development methodology

AASM (2017)	ACP (2014)
The AASM and ACP clinical practice guidelines were developed from systematic reviews of the evidence. As part of the systematic review supporting the AASM guideline, original meta-analysis was performed on both diagnostic and clinical outcomes for each PICO (Population/Problem, Intervention, Comparison, Outcome) question, when possible. The ACP guideline is based on a comparative effectiveness review sponsored by the Agency for Healthcare Research and Quality (AHRQ), the 2007 Technology Assessment of Home Diagnosis of Obstructive Sleep Apnea-Hypopnea Syndrome, and an updated literature review through May 2013. Both systematic reviews provide relevant details of the literature search and selection process, including the electronic databases that were searched, time period of the search, search terms used, and the inclusion and exclusion criteria applied. To assess the quality and strength of the selected evidence, the guideline developers weighted it according to a rating scheme and provide the scheme. Both the AASM and the ACP formulated the guideline recommendations using an expert consensus process based on evaluation of the evidence, and rate the strength of the individual recommendations according to a scheme. To validate the guidelines, the ACP sought internal peer review and an independent peer review process via journal publication; the AASM sought both internal and external review.	

Benefits and Harms

Benefits

AASM (2017)	• Use of HSAT may provide potential benefits to patients with suspected OSA. Such benefits could include convenience, comfort, increased access to testing, and decreased cost. HSAT can be performed in the home environment with

	the patient is unable to leave the home or healthcare setting for testing. In addition, HSAT may be less costly when used appropriately. • The split-night protocol, in comparison to a full-night baseline assessment followed by a separate positive airway pressure (PAP) titration, has the potential to provide the needed diagnostic information and effective CPAP settings within the same recording. • A second night of polysomnography in symptomatic patients allows for the diagnosis of OSA in 8% to 25% of patients with initial false negative studies. Establishing a diagnosis of OSA in these patients allows for treatment that leads to improved symptom control (e.g., less daytime sleepiness), better QOL, and potentially decreased cardiovascular morbidity over time. Refer to the "Benefits versus Harms" sections in the original guideline document for benefits/harms assessment of specific recommendations.
ACP (2014)	Appropriate screening and diagnosis for OSA. Evidence was mixed to correlate OSA with predictors of long-term clinical outcomes, and no causal relationships have been established.

Harms

AASM (2017)	• Harms of HSAT could result from the need for additional diagnostic testing among patients with technically inadequate or inconclusive HSAT findings, or from false-positive and false-negative results leading either to unnecessary testing and treatment or to misdiagnosis and subsequent inappropriate therapy or lack of therapy. • Potential disadvantages of the split-night study include insufficient diagnostic sampling (e.g., limited rapid eye movement [REM] sleep time and limited supine time in those with difficulty initiating sleep), and insufficient time to ascertain appropriate CPAP treatment settings. • Routinely repeating a polysomnography in patients with an initial negative polysomnography has potential downsides. There is a risk that repeat testing

	to the patient, increased utilization of resources and healthcare costs, and perhaps even delays in the care of other patients awaiting polysomnography. Refer to the "Benefits versus Harms" sections in the original guideline document for benefits/harms assessment of specific recommendations.
ACP (2014)	Evidence was mixed to correlate OSA with predictors of long-term clinical outcomes, and no causal relationships have been established.

Abbreviations

AASM, American Academy of Sleep Medicine

ACP, American College of Physicians

AHI, apnea–hypopnea index

AHRQ, Agency for Healthcare Research and Quality

CPAP, continuous positive airway pressure

ESS, Epworth Sleepiness Scale

GRADE, Grading of Recommendations, Assessment, Development and Evaluation

HSAT, home sleep apnea testing

OSA, obstructive sleep apnea

PAP, positive airway pressure

PAT, peripheral arterial tonometry

PICO, Population/Problem, Intervention, Comparison, Outcome

QOL, quality of life

RCT, randomized-controlled trial

Status

This synthesis was prepared by ECRI Institute on May 25, 2017. The information was verified by ACP on June 5, 2017 and by AASM on June 12, 2017.