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SPECIAL ARTICLES

A transition to the American Academy of Sleep Medicine–recommended hypopnea definition in adults: initiatives of the Hypopnea Scoring Rule Task Force

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The American Academy of Sleep Medicine (AASM) recommends that hypopneas be identified using a definition that is based on a ≥ 30% decrease in airflow associated with a ≥ 3% reduction in the oxygen saturation or an arousal (H3A) for diagnosis of obstructive sleep apnea (OSA) in adults. This conflicts with the Centers for Medicare & Medicaid Services definition, which requires a ≥ 4% decrease in the oxygen saturation to identify a hypopnea (H4) and does not acknowledge arousals. In 2018, the AASM Board of Directors constituted a Hypopnea Scoring Rule Task Force with a mandate to "create a strategy for adoption and implementation of the AASM recommended adult hypopnea scoring criteria among members, payers and device manufacturers." The task force initiated several activities including a survey of AASM-accredited sleep facilities and discussions with polysomnography software vendors. Survey results indicated that most sleep facilities scored polysomnograms using only the Centers for Medicare & Medicaid Services definition. Vendors indicated that they could easily support dual scoring. Informal testing among task force members' sleep facilities confirmed there would be little additional work if dual scoring was performed. The task force convened several meetings of a working group of OSA content experts and interested parties, with the purpose of creating research recommendations to study the impact on relevant clinical outcomes using the different definitions of hypopnea. Several possible prospective and retrospective approaches were discussed with emphasis on the group of patients diagnosed with OSA based on an apnea-hypopnea index using H3A but not H4. Based on the deliberations of the working group, the Hypopnea Scoring Rule Task Force submitted recommendations to the AASM Foundation concerning research project strategies for potential grant funding. Further discussions within the Hypopnea Scoring Rule Task Force focused on developing advocacy initiatives among patient stakeholder groups to change payer policy.

Keywords: sleep scoring, hypopnea, apnea-hypopnea index

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INTRODUCTION

The purpose of this article is to inform the American Academy of Sleep Medicine (AASM) membership and medical providers taking care of patients with obstructive sleep apnea (OSA) of the rationale for creation of a Hypopnea Scoring Rule Task Force (HSRTF), the activities and findings of the task force, and recommendations for future research concerning the recommended adult hypopnea definition (H3A; see **Table 1**) and its impact on patient care.

RATIONALE FOR CREATION OF THE HSRTF

In 2018, the AASM Board of Directors released a position statement with the recommendation that respiratory events associated with arousal be used in the evaluation of suspected OSA.[1] The AASM Board of Directors felt that many sleep facilities and providers were solely counting respiratory events associated with a ≥ 4% oxygen desaturation based on the current AASM Scoring Manual "acceptable" hypopnea definition for adults (H4; **Table 1**).[2] This approach may result in missing a diagnosis of OSA in symptomatic patients who otherwise would be diagnosed based on the recommended hypopnea definition (H3A; **Table 1**) and would potentially benefit from treatment. The "recommended" hypopnea definition (H3A) in the current version of the AASM Scoring Manual defines a hypopnea in adults based on a ≥ 30% drop in airflow for ≥ 10 seconds associated with an arousal or a ≥ 3% oxygen desaturation.[2] Such a definition allows a wider spectrum of symptomatic patients with OSA to qualify for positive airway pressure (PAP) and other treatments compared with one based solely on a ≥ 4% desaturation. The goal is not to diagnose more patients with OSA but to allow the option for treatment of symptomatic patients not diagnosed under the H4 definition. The Centers for Medicare & Medicaid Services (CMS) and many insurance providers require use of a hypopnea rule based on 4% desaturations (H4). The existence of these 2 hypopnea

Table 1—Definitions of abbreviations used.

Abbreviation	Definitions
H3A	Recommended hypopnea definition based on a ≥ 30% reduction in airflow for ≥ 10 seconds associated with a ≥ 3% decrease in the oxygen saturation or an arousal
AHI3A*	AHI based on H3A
H4†	Acceptable hypopnea definition based on a ≥ 30% reduction in airflow for ≥ 10 seconds associated with a ≥ 4% decrease in the oxygen saturation
AHI4*	AHI based on H4
H4nOSA	Individuals meeting AHI criteria for diagnosis of OSA using H3A but not H4

*Apnea (as defined by AASM Scoring Manual[2]): ≥ 90% reduction in airflow for ≥ 10 seconds. †Definition utilized by Centers for Medicare & Medicaid Services. AHI = apnea-hypopnea index, OSA = obstructive sleep apnea.

definitions causes confusion in the field and may lead to the missed diagnosis of OSA even when the patient undergoes polysomnography. The AASM Board of Directors voted to support only 1 hypopnea rule (H3A) in the upcoming Scoring Manual 3 and will designate the hypopnea rule based on a 4% desaturation as "optional" instead of "acceptable." For many sleep facilities that are not using the current AASM-recommended scoring criteria, it may require more education and effort to make this change. Certain payers will require scoring respiratory events using 2 hypopnea definitions and reporting an apnea-hypopnea index (AHI) based on the 2 hypopnea definitions. The AASM Board of Directors created the HSRTF with the mandate to create a strategy for adoption and implementation of the AASM-recommended adult hypopnea scoring criteria (H3A) among members, payers, and device manufacturers in advance of this change that is expected with the next version of the AASM Scoring Manual.

HISTORY OF THE HYPOPNEA RULE

In 2001, the CMS accepted the use of an AHI based on a hypopnea defined by ≥ 30% drop in airflow associated with a ≥ 4% drop in the oxygen saturation (H4, AHI4) (**Table 1**). In 2007, the AASM Scoring Manual listed a recommended hypopnea definition consistent with H4 and an alternative definition based on a ≥ 50% drop in airflow for ≥ 10 seconds associated with a ≥ 3% desaturation or an arousal.[3] In 2012, based on consensus, the Sleep Apnea Definition Task Force recommended a hypopnea definition based on a ≥ 30% drop in airflow for ≥ 10 seconds associated with a ≥ 3% drop in the oxygen saturation or an arousal (H3A), with the rationale that this would allow a wider spectrum of symptomatic patients to qualify for treatment.[4] The AASM Scoring Manual subsequently included a recommended hypopnea definition (H3A, AHI3A) and an acceptable definition (H4, AHI4).[2] However, a major obstacle to implementation of the H3A definition is that CMS continues to require the use of the H4 definition. AASM representatives met with CMS in both June 2013 and June 2018 to discuss the AASM's recommendation to use the more inclusive H3A definition, rather than the H4 hypopnea definition, in the national coverage determination for PAP therapy for OSA.[5] Through the discussion, it was clear that CMS would require more published data concerning the long-term health consequences of hypopneas scored using the H3A definition before considering adopting this change. The need for additional data concerning use of the H3A vs H4 definition is one reason the AASM Board of Directors formed the HSRTF with a goal of making recommendations for future research evaluating the impact of the H3A definition.

THE HSRTF

The HSRTF, consisting of 5 sleep medicine physicians, met for the first time in 2018 and initiated several projects. First, the HSRTF created a survey for AASM-accredited sleep facilities to determine which hypopnea scoring rule was currently being used in AASM-accredited sleep facilities. The survey found that most sleep facilities used the H4 rule. A mandate to use the H3A hypopnea definition, with reporting of H4 as optional, would likely necessitate scoring and reporting an AHI based on both hypopnea definitions in many sleep facilities.

To address concerns that reporting 2 hypopnea definitions would be difficult or require significant additional effort, the HSRTF met with representatives from most of the software vendors to address this issue. The polysomnography software vendors reported that changes in software to allow scoring and reporting of hypopneas based on 2 definitions could easily be accomplished and would require little extra scoring effort for most patients. Several task force members implemented dual scoring and reporting in their sleep facilities and confirmed that minimal additional work was required.

The HSRTF then invited a panel of key stakeholders involved with diagnosis and management of OSA (Hypopnea Scoring Rule Working Group) for a series of discussions regarding the best approaches to study the impact of the hypopnea definition on clinically meaningful outcomes and to assist in developing recommendations to the AASM Board of Directors concerning research goals. The Working Group consisted of HSRTF members and other content experts in the field of sleep apnea research, patient representatives, members of the AASM Board of Directors, and physicians representing large medical associations, including the American College of Chest Physicians, American Thoracic Society, Sleep Research Society, American Academy of Neurology, as well as sleep providers from the Veterans Administration Health Care System and sleep-related journal editors.

HSRTF AND WORKING GROUP FINDINGS

The Working Group of the HSRTF held a series of 4 teleconferences to discuss the following: introduction to the goals of the Working Group, review of existing data concerning the impact of using the H3A definition of hypopnea (recommended

hypopnea rule), general research approaches, and developing recommendations to submit to the AASM Foundation for consideration of funding for potential research to determine the impact of use of the H3A definition on relevant clinical outcomes. A summary of the findings of the Working Group is presented in the subsequent sections.

EFFECT OF THE RECOMMENDED HYPOPNEA DEFINITION ON PREVALENCE

The prevalence of OSA varies substantially based on the definition of hypopnea applied, with the AHI4 definition resulting in the lowest prevalence of OSA.[6] Regardless of the hypopnea definition, the increase in the prevalence of obesity has resulted in a large percentage of the population with an AHI ≥ 5 events/h. For example, a recent population study found a large percentage of individuals with an AHI ≥ 5 events/h using either the H4 (47%) or H3A (72%) hypopnea definitions. The study also found that there was a higher AHI3A threshold (compared with AHI4A) with respect to the link with metabolic syndrome, diabetes, and hypertension.[7] This study did not address patient-related treatment outcomes, such as improved quality of life or symptom relief. The very large percentage identified as having OSA based on AHI alone, using either hypopnea definition, illustrates the importance of requiring **both** an AHI ≥ 5 events/h and symptoms or comorbidity for a diagnosis of OSA in milder patients.

Using data from the Sleep Heart Health Study, the prevalence of OSA (AHI > 5 events/h) in the study population was 52.10% with the AHI4 definition, and 83.17% when using the AHI3A definition. The Sleep Heart Health Study cohort was oversampled for snorers, which at least partially explains the high prevalence rates.[6] Another analysis of the Sleep Heart Health Study data indicates 39% (476 of 1,219) participants with normotension at baseline but hypertension at a later time point were found to have OSA by the AHI3A definition but not by the AHI4 definition at baseline.[8]

Application of the AHI4 definition, rather than the AHI3A definition, results in fewer younger people (< 65 years old) and fewer women being diagnosed with OSA and being eligible for treatment.[9] The odds of the AHI4 definition not identifying OSA (AHI4 < 5 events/h and AHI3A ≥ 5 events/h, H4nOSA) in women were twice the odds in men, and this association persisted after controlling for age and body mass index.[10] Adopting the H3A definition of hypopnea would reduce the health disparities associated with OSA treatment by age and sex. The differential impact of the hypopnea definitions on race has not yet been adequately explored.

For patients with milder OSA, qualification for continuous PAP (CPAP) reimbursement by CMS criteria requires both an AHI ≥ 5 events/h and symptoms or cardiovascular comorbidities. Korotinsky et al[9] analyzed 112 consecutive patients undergoing sleep studies. Using both the AHI and clinical history, 80.5% were eligible for CPAP using the H3A definition and 63% using the H4 definition. When considering only patients aged ≥ 65 years, the same percentage (92.6%) were eligible for CPAP using either hypopnea definition. The H4 definition appears to exclude younger patients from qualifying for CPAP who would otherwise qualify using the H3A definition. The presumptive increase in CPAP eligibility if using the H3A definition in the Medicare population may be smaller than predicted from population-based studies. A larger study in a clinical population using both the AHI and clinical history is needed to assess the impact of the use of the H3A compared with H4 definitions in patients being evaluated for OSA.

IMPORTANCE OF OXYGEN DESATURATION AND AROUSAL

The severity of oxygen desaturation associated with hypopneas is a critical pathophysiologic factor in determining the impact of hypopnea events on the occurrence of cardiovascular sequelae of OSA. Indices of oxygen desaturation have been linked to increased prevalence of coronary heart disease and congestive heart failure.[11] It has been suggested that a ≥ 4% oxygen desaturation, rather than ≥ 3%, is associated with increased cardiovascular morbidity,[12] while other studies have noted that use of an H3A hypopnea definition is associated with the presence of arrhythmias[13] and hypertension.[14] Population studies have identified that patients with severe OSA are most at risk for cardiovascular morbidity and death; however, randomized controlled trials (RCTs) have not documented a benefit of CPAP treatment on cardiovascular outcomes. Findings related to cardiovascular outcomes may be less relevant to patients with mild OSA, in whom benefits in daytime sleepiness, mood, and quality of life are more relevant treatment targets. As discussed below, use of the H3A metric does identify sleepy patients who may benefit from treatment.

It is believed that frequent arousal from sleep impairs the restorative nature of sleep and that respiratory events associated with arousal have physiological significance independent of any associated arterial oxygen desaturation. Review of the literature is complicated by the fact that many studies of outcomes did not separate the effects of hypopneas scored based only on arousal. An observational cohort study by Won et al[13] defined a group of participants meeting diagnostic criteria for OSA using the H3A but not the H4 definition (H4nOSA; **Table 1**). This group was found to be sleepier than a no-OSA group (average Epworth Sleepiness Scale [ESS] score of 11.9 vs 9.5), and 63.4% of those in the H4nOSA group depended on inclusion of arousal in the hypopnea definition. Of interest, the ESS score in the H4nOSA group was similar to that in the group of patients with OSA with a diagnosis based on the H4 definition. This suggests that, in milder patients, inclusion of arousal criteria in a hypopnea definition will identify a group of sleepy individuals who may benefit from treatment.

OSA DIAGNOSIS USING AHI3A VS AHI4

After the second Working Group virtual meeting, which addressed the above published information relevant to the H3A definition, the consensus was to concentrate efforts on the group of patients diagnosed with OSA based on AHI3A but not on AHI4 (H4nOSA). This group is denied CPAP treatment in many locales, even though a significant number of these patients could benefit.

Evidence that treatment of H4nOSA with CPAP or any other therapeutic modality improves sleepiness or quality of life or reduces the incidence of cardiovascular disease is limited. To our knowledge, the only study that specifically addresses this issue is the RCT by Wimms et al[15] (MERGE trial) of auto-adjusting PAP (APAP) vs standard care for 3 months in patients with mild OSA (diagnosed by either AHI3A or AHI4) that showed improvement in daytime sleepiness and quality of life (Short Form-36 [SF-36] vitality) in the APAP group. A home sleep apnea test (measuring airflow, effort, saturation) was used to diagnose mild OSA, and arousals were scored based on an artificial intelligence algorithm. Those randomized to APAP treatment were required to pass a 1-hour PAP tolerance test before starting treatment. A subgroup of those with mild OSA (H4nOSA) (**Table 2**) was analyzed (n = 50 on PAP and n = 45 standard care). There was a significant improvement in quality of life, as measured by the SF-36 vitality scale (the major endpoint of the study), in the PAP group (8.4 vs −0.8). The median PAP adherence was 4 hours, and 81% of patients wished to continue APAP after the study. This study supports the contention that H4nOSA patients benefit from treatment. This study also demonstrates that a significant number of patients with mild OSA diagnosed by either H3A or H4 are in the H4nOSA group (95/300, approximately 1/3). In some (but not all) studies of patients with mild OSA, although not specifically H4nOSA, a favorable impact of treatment on sleepiness has been observed.[16]

Given the limited data evaluating treatment in the H4nOSA group, the Working Group concluded that research efforts should be focused on determining the characteristics of the H4nOSA group with respect to associations with daytime sleepiness or impaired quality of life. If benefit of treatment could be supported in this group, this would provide evidence to support use of the H3A. Two general approaches were discussed. One was prospective RCTs of PAP in H4nOSA patients. The other was additional analyses of existing trial datasets to show this group had similar morbidity and/or outcomes compared with patients diagnosed based on AHI4. The Working Group then discussed the challenges of PAP outcomes research in general and the best approach relevant to the impact of the H3A definition, especially regarding the H4nOSA group. Before attempting to reach a consensus regarding research recommendations, the Working Group considered the results from previous RCTs, methodologic challenges in their conduct, alternative trial designs, and the potential availability of data to perform retrospective analyses. A summary of these considerations appears in the Appendix. The opinions of the Working Group were then considered by the HSRTF in recommendations made for potential research initiatives to be funded by the AASM Foundation.

PRESENTATION OF RESEARCH CONSIDERATIONS TO THE AASM FOUNDATION

Based on the Working Group discussion of potential retrospective and prospective research opportunities, the HSRTF drafted research recommendations for the AASM Foundation to consider. Members of the HSRTF met with the AASM Foundation Board of Directors to discuss the relative merits of different research approaches. Given the difficulties and duration of prospective studies, an analysis of existing data was deemed preferable as a first approach. In September 2021, the AASM Foundation issued a request for applications for retrospective analysis of existing datasets to explore the effect of PAP treatment on symptoms/morbidity in untreated patients with H4nOSA.

IMPORTANCE OF ADVOCACY GROUPS, CONVERSATIONS WITH INSURERS

In their deliberations, the HSRTF felt that the AASM and other professional and patient advocacy sleep organizations are best situated to advocate for the treatment of OSA in patients. Using a restrictive definition of hypopneas limits the number of patients eligible for treatment through insurance coverage. In addition to reducing health disparities in OSA management, using the AASM-recommended definition of hypopnea (AHI3A) would allow for identification of more patients who may benefit from treatment. Forty percent of patients diagnosed with H4nOSA had incident hypertension within 5 years of observation and may benefit from insurance policies covering more targeted therapy.[8] The HSRTF is currently working with the AASM Board of Directors to develop an advocacy strategy aimed at adoption of the H3A definition of hypopneas by CMS and third-party payers.

SUMMARY AND RECOMMENDATIONS

Use of the H3A hypopnea definition in adults results in a greater likelihood of diagnosing OSA in symptomatic younger individuals (< 65 years) and women who may benefit from treatment but would be excluded using the H4 definition

Table 2—Change from baseline on CPAP versus standard care in H4nOSA.

	CPAP (n = 50)	Standard Care (n = 45)	Treatment Difference	*P*
ESS	−3.6 (−4.5 to −2.6)	0.3 (−0.7 to −1.3)	−3.9 (−5.3 to −2.5)	< .0001
Vitality scale	8.4 (6.0 to 10.8)	−0.8 (−3.3 to −1.8)	9.2 (5.6 to 12.7)	< .0001

Data from Wimms et al (supplementary data Table S6).[15] CPAP = continuous positive airway pressure, ESS = Epworth Sleepiness Scale, H4nOSA, individuals meeting apnea-hypopnea index criteria for diagnosis of obstructive sleep apnea using recommended hypopnea definition based on a ≥ 30% reduction in airflow for ≥ 10 seconds associated with a ≥ 3% decrease in the oxygen saturation or an arousal but not a ≥ 4% decrease in oxygen saturation. An increase in the vitality scale (a component of the SF-36) represents improvement.

(H4nOSA). A RCT of CPAP in milder patients (the MERGE trial[15]) supports a benefit of CPAP treatment on sleepiness and quality of life in the H4nOSA population. Additional research is needed to confirm the results. While the AHI threshold for association with cardiovascular and metabolic disorders is higher for AHI3A than AHI4, no randomized trial supports the use of CPAP treatment to improve cardiovascular outcomes using either AHI4 or AHI3A. However, there is evidence for improvement in sleepiness and quality of life with CPAP in milder patients, suggesting that symptom management is the major goal of treatment in this population. Therefore, the clinical validity of the H3A definition should be judged on the ability to identify symptomatic milder patients who would benefit from treatment. Analysis of existing OSA datasets using H4nOSA and novel prospective studies (eg, clinical registries, propensity matching and adaptive trials, and CPAP withdrawal trials) will potentially be useful in supporting the utility of PAP prescription for H4nOSA to improve quality of life/sleepiness, as well as in establishing association with cardiovascular/metabolic disorders.

APPENDIX

The Working Group considered the results from previous RCTs, methodologic challenges in their conduct, alternative trial designs, and the potential availability of data to perform retrospective analyses. The subsequent sections of the Appendix provide a summary of these considerations.

Challenges of performing randomized clinical trials of PAP therapy

The "gold standard" for demonstrating effectiveness of PAP therapy in treating cardiometabolic outcomes has been hampered by a concern of withholding treatment of "sleepy" individuals with sleep apnea or individuals with moderate to severe sleep apnea. This has led to research designs that excluded participants who potentially would have had the most improvement in cardiometabolic outcomes with PAP in comparison to sham/best medical care controls.[17] Thus, the RCTs to date targeting cardiometabolic outcomes have not been positive except for a study of the effect of CPAP on blood pressure in patients with a obstructive sleep apnea and resistant hypertension: (the HIPARCO randomized clinical trial).[18] This has resulted in the conclusion that the populations studied were different from clinic populations in that (1) "sleepy" individuals with sleep apnea and individuals with moderate to severe OSA were excluded, (2) compliance with PAP was insufficient, or (3) PAP was ineffective in mitigating disease progression.[19] Based on prior studies of CPAP treatment for mild OSA, outcomes such as improvement in daytime sleepiness and quality of life, rather than cardiovascular outcomes, would be more likely to demonstrate a benefit of CPAP in H4nOSA.

Pack et al[19] recently suggested that alternative study designs using propensity matching would be a suitable alternative to traditional RCTs. This strategy has been successfully utilized for U.S. Food & Drug Administration approval of orthopedic devices.[20] The challenge is to ensure that the matching, weighting, and adjustment of the covariates in each of the groups that are analyzed is balanced and that the effects of healthy user and healthy adherer biases, as well as hidden confounders, are minimized.[19] This approach is most useful when two presumably equivalent therapies are tested.

An alternative, more novel strategy would be to utilize an adaptive RCT. As opposed to a traditional RCT, the adaptive RCT allows the research team to review and adapt the trial during the conduct of the study.[21] This allows for (1) refining the sample size, (2) abandoning treatments or doses that are ineffective, (3) changing the allocation ratio of participants to trial arms, (4) identifying participants (ie, unique endophenotypes) most likely to benefit from a treatment and focusing recruitment efforts on those participants, and (5) stopping the trial at an early stage for success or lack of efficacy. This approach has proven to be successful during the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic with the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) initiative[22] and the Randomized Embedded Multifactorial Adaptive Platform (REMAP) trial group.[23]

Potential retrospective studies by data mining completed studies or registries

It is possible that data may be available from completed clinical trials that can address whether treatment of H4nOSA can improve clinical outcomes. For example, the Apnea Positive Pressure Long-term Efficacy Study (APPLES) randomized participants with OSA to active or sham CPAP with a 6-month follow-up for several clinical outcomes. It is possible that re-analysis of a subset of participants with H4nOSA would be informative. Recent analyses from APPLES demonstrated that 74% of the cohort with mild OSA based on the AHI3A definition had self-reported sleepiness and most would likely be H4nOSA. Other clinical trials also may have relevant data.[24]

Potential prospective studies

Several prospective study designs to document benefits of CPAP treatment in patients with H4nOSA were proposed. The first would be a prospective study of untreated H4nOSA who were symptomatic. The group would be randomized to APAP treatment or standard care with a study duration of 6 weeks to 3 months. Endpoints would include parameters that have improved with PAP treatment in previous studies of patients with mild OSA, such as the SF-36 vitality scale and the ESS. The prospective randomized trial of APAP vs standard care by Wimms et al[15] used a 3-month study duration and found treatment was associated with improvement in the ESS score and SF-36 vitality score. Issues with this approach included the difficulty recruiting a sufficient number of patients (11 centers in the study by Wimms et al took over 2 years to complete recruitment), the cost of sleep studies and PAP equipment, and concerns about adequate adherence.

The second approach would use a CPAP withdrawal design evaluating current PAP users with adequate adherence. To be included, a prior diagnosis of H4nOSA would be required, and patients would be randomized to continued CPAP vs CPAP withdrawal for 2 weeks to 1 month. Endpoints would be a comparison of change in parameters such as the ESS score and SF-36 vitality

score from pre-CPAP withdrawal values. The CPAP withdrawal design demonstrated a robust effect of CPAP treatment on blood pressure in patients with moderate to severe OSA in a 2-week study.[25] The magnitude of blood pressure change was greater than seen in conventional randomized trials. Young et al[26] documented a return of subjective/and objective measures of sleepiness to pretreatment levels after only two nights of PAP withdrawal in patients with both severe and mild OSA.

Potential advantages of the CPAP withdrawal approach include a shorter study duration, assurance of adequate PAP adherence, the potential for a greater magnitude of effect (based on previous withdrawal trials), and no need to pay for sleep studies or to purchase PAP devices. Disadvantages of this approach include the challenges in establishing the nature of the previous diagnosis (time since diagnosis, type of study accepted) and the need to perform the study in locales where an H3A rule is acceptable for PAP reimbursement (where patients with H4nOSA are using CPAP). Another concern is that CPAP withdrawal might not result in a return of sufficient sleep apnea to be detrimental ("carryover effect of prior CPAP treatment"). This potential problem could be mitigated by testing to demonstrate that CPAP withdrawal is associated with a return of mild sleep apnea. There is also the possibility that such a design might be less convincing to stakeholders. Finally, a hybrid prospective approach including diagnosis and treatment of untreated patients with subsequent CPAP withdrawal (or no withdrawal) in adherent patients was discussed.

ABBREVIATIONS

AASM, American Academy of Sleep Medicine
AHI, apnea-hypopnea index
APAP, auto-adjusting positive airway pressure
CMS, Centers for Medicare & Medicaid Services
CPAP, continuous positive airway pressure
ESS, Epworth Sleepiness Scale
HSRTF, Hypopnea Scoring Rule Task Force
OSA, obstructive sleep apnea
PAP, positive airway pressure
RCT, randomized controlled trial
SF-36, Short Form-36

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