

**Agreement between Results of Home Sleep Testing for
Obstructive Sleep Apnea with and without a Sleep Specialist**

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ABSTRACT

Background: Obstructive sleep apnea is a prevalent yet underdiagnosed condition associated with cardiovascular morbidity and mortality. Home sleep testing offers an efficient means for diagnosing obstructive sleep apnea but has primarily been deployed in clinical samples with a high pretest probability. The current study sought to assess if obstructive sleep apnea can be diagnosed with home sleep testing in a non-referred sample without involvement of a sleep medicine specialist.

Methods: A study of community-based adults with untreated obstructive sleep apnea was undertaken. Misclassification of disease severity based on home sleep testing with and without involvement of a sleep medicine specialist was assessed, and agreement was characterized using scatter plots, Pearson's correlation coefficient, Bland-Altman analysis, and the kappa statistic. Analyses were also conducted to assess whether any observed differences varied as a function of pretest probability of obstructive sleep apnea or subjective sleepiness.

Results: The sample consisted of 191 subjects with over half (56.5%) having obstructive sleep apnea. Without involvement of a sleep medicine specialist, obstructive sleep apnea was not identified in only 5.8% of the sample. Analyses comparing the categorical assessment of disease severity with and without a sleep medicine specialist showed that in total, 32 subjects (16.8%) were misclassified. Agreement in the disease severity with and without a sleep medicine specialist was not influenced by the pretest probability or daytime sleep tendency.

Conclusion: Obstructive sleep apnea can be reliably identified with home sleep testing in a non-referred sample irrespective of the pretest probability of the disease.

INTRODUCTION

It is well established that identifying modifiable risk factors for chronic diseases and intervening early can help slow disease progression and possibly even reduce associated morbidity and mortality.¹ Obstructive sleep apnea, which affects approximately 24% of adult men and 9% of adult women in the general population², is an independent risk factor for incident hypertension and cardiovascular disease.^{3;4} Yet, over 80% of those with obstructive sleep apnea remain undiagnosed.^{5;6} Given the available evidence that treatment of obstructive sleep apnea can decrease blood pressure and possibly mitigate adverse cardiovascular endpoints,^{7;8} early case-identification has clinical and public health merit. The advent of home sleep testing has been a useful addition to the diagnostic armamentarium for obstructive sleep apnea as it offers a simple, objective, and economical means for assessing those that may be affected. However, current guidelines recommend that home sleep testing be restricted to only those patients with a high pretest probability for obstructive sleep apnea and a sleep trained provider be involved in the review and interpretation of the recording. While self- or interview-administered questionnaires such as the Berlin⁹ and the STOP-BANG¹⁰ questionnaires are useful in identifying those with a high pretest probability for obstructive sleep apnea, these instruments have varying levels of sensitivity, specificity, and predictive value depending on the specific population in which they are used, the underlying prevalence of disease in study sample, and disease severity.^{11;12} More importantly, self-reported data are inherently limited because many of those affected with obstructive sleep apnea underreport symptoms of snoring and cessation of breathing during sleep, or they not have a bedpartner to aid in identifying signs or symptoms. Clinical prediction models and morphometric measures, which represent the next layer of techniques to assess risk, are simple to implement but have limited sensitivity and specificity.^{11;12} Thus, many patients with remain undiagnosed and are at risk for the associated cardio-metabolic sequelae. The current study sought to evaluate if assessment

of obstructive sleep apnea can be performed with home sleep testing independent of a sleep medicine specialist in a non-referred sample that may have an admixture of low and high pretest probability for obstructive sleep apnea. It was hypothesized that there would be a high degree of agreement between the results derived from home sleep testing for obstructive sleep apnea with and without involvement of a sleep medicine specialist.

METHODS

Study Sample and Screening Assessments

Case-identification of undiagnosed obstructive sleep apnea was undertaken for the current study in a general community sample from the local Baltimore-Washington area. Recruitment was based on newspaper advertisements and mailed invitations using a commercially available electronic mailing list. A total of 827 respondents expressed interest in participating in the study and were screened by a telephone interview which was conducted by trained research assistants using a structured questionnaire. Eligibility criteria included age between of 21 and 80 years and no prior treatment for obstructive sleep apnea. Those with a history of prior upper airway surgery for obstructive sleep apnea (N=45) or treatment with an oral appliance (N=22) or positive pressure therapy (N=557) were not eligible. Shiftwork, a preference of an early or delayed sleep schedule suggestive of a circadian rhythm disorder, or restless legs syndrome were also considered exclusionary (N=12). Thus, 636 people responding to the study advertisements were considered as screen failures. A total of 191 eligible subjects completed a telephone questionnaire which included demographic information such as age, sex, and race, as well as the self-reported medical history on prevalent hypertension, high cholesterol, asthma, chronic obstructive lung disease, coronary artery disease, and hypothyroidism. The Epworth Sleepiness Scale assesses average sleep propensity with eight questions on the likelihood of dozing in various situations on a 4-point scale (0-3) was all administered to all those that enrolled in the study. An ESS score of ≥ 11 out of a maximum 24 is considered subjectively sleepy.¹³ Finally, all those consented to the study completed the Berlin Questionnaire, a validated three part questionnaire used to assess obstructive sleep apnea risk (low versus high).⁹ The research protocol was approved by the Johns Hopkins University Institutional Review Board on human research (IRB Approval Number: NA_00036672).

Assessment of Obstructive Sleep Apnea

To examine differences in detection of obstructive sleep apnea and severity classification with and without involvement of a sleep medicine specialist, the ApneaLink Plus®, a type III portable monitoring device, was used for home sleep testing in volunteers that qualified for the study. Apnealink Plus® (type III), which has been previously validated,¹⁴ was given to study subjects by research assistants who were not registered polysomnologists. Nasal airflow was recorded with a nasal cannula connected to a pressure transducer. Pulse oximetry was used to assess oxyhemoglobin saturation, and respiratory effort was measured with a pneumatic sensor attached to an effort belt. At least four hours of interpretable recording time was required for inclusion in the study. The scoring software for ApneaLink Plus® was configured to identify disordered breathing events according to standard criteria as follows. Apneas were identified if there was a 90% or greater reduction in airflow for at least 10 seconds, and hypopneas were identified if there was a $\geq 30\%$ reduction in airflow for at least 10 seconds which was associated with either an oxyhemoglobin desaturation of at least 4%. The apnea-hypopnea index, the disease defining metric for obstructive sleep apnea, was the number of apneas and hypopneas per hour of recording time. Disease severity was categorized employing commonly used clinical cut-points as follows: < 5.0 events/h (normal), 5.0–14.9 events/h (mild), 15.0–29.9 events/h (moderate), and ≥ 30 events/h (severe). To compare diagnostic classification with and without sleep specialist involvement, the apnea-hypopnea index was derived in two ways. First, the apnea-hypopnea index was determined without a sleep medicine specialist by subjecting each sleep recording to the Apnealink Plus® software to determine the presence and severity of obstructive sleep apnea. The sleep recording was also independently scored by a board certified sleep physician (RNA) who was blinded to any of the other results but used the aforementioned criteria for scoring apneas and hypopneas. Specifically,

the sleep physician did not have access to results of the automated ApneaLink Plus® assessments. Thus, two independent measures of disease severity were derived.

Statistical Analysis

Agreement in disease severity with and without involvement by a sleep medicine specialist was characterized as follows. Using the apnea-hypopnea index as a continuous measure, initial assessments of agreement used bivariate scatter plots and Pearson's correlation coefficient. In addition, Bland-Altman analysis¹⁵ and the average difference in the apnea-hypopnea index with and without involvement of a sleep specialist were used to characterize the bias between the two assessments. The kappa statistic was also used to examine whether classification of disease severity (normal, mild, moderate, and severe) differed when comparing the apnea-hypopnea index obtained with and without a sleep specialist. Additional analyses were conducted to assess whether the agreement varied as a function of pre-test probability of obstructive sleep apnea risk or daytime sleepiness. All analyses were performed by using SAS 9.1 statistical software system.

RESULTS

The study sample consisted of 191 eligible subjects with a median age of 53.2 years (25th–75th percentile: 47.3–59.9). The mean BMI was 28.4 kg/m² (SD: 4.9 kg/m²) and men constituted 63.4% of the sample. Self-reported prevalent medical conditions in the sample were as follows: hypertension (24.6%), high cholesterol (9.2%), asthma (4.7%), coronary artery disease (0.5%), and. The overall failure rate with home sleep testing was 2.2% which represents the sample proportion that required retesting due to less than four hours of interpretable recording of oxygen saturation and airflow signal. Loss of the oximetry signal was the most common reason for failure. A majority of the subjects (73.8%) did not report subjective sleepiness (Epworth sleepiness score < 11). Based on the responses on the Berlin Questionnaire, 93 (48.7%) and 98 (51.3%) subjects were categorized as having a low and high pretest probability of obstructive sleep apnea, respectively, Using the sleep medicine specialist as the reference, obstructive sleep apnea was present is 56.5% of the sample, and the median apnea-hypopnea index was 6.2 events/hr (25th–75th percentile: 2.3–15.6). Of those with obstructive sleep apnea, 51.9% had mild, 34.2 % had moderate, and 13.9% had severe disease. Figure 1 shows the apnea-hypopnea index values derived with and without involvement of a sleep medicine specialist and the associated Bland-Altman plot. Overall, the correlation between the two derived apnea-hypopnea indices was high ($r = 0.96$, 95% CI: 0.95–0.97) and the average bias was low (Δ apnea-hypopnea index: 1.8 events/hr, 95% CI: 1.1–2.4).

Based on the apnea-hypopnea index derived without a sleep medicine specialist, obstructive sleep apnea was not identified in only 5.8% of the sample. Analyses comparing the categorical assessment of disease severity with and without involvement of a sleep medicine specialist showed that, in total, 32 subjects (16.8%) were misclassified (Figure 2). Of these, 10 subjects (5.2%) were classified as having less severe disease and 22 subjects (11.5%) were classified as having greater

disease severity using the sleep specialist as the reference, yielding a kappa statistic of 0.75 (95% CI: 0.69–0.79) indicating substantial agreement between the two assessments.

To examine whether the level of agreement between the two diagnostic approaches varied as function of subjective sleepiness or the pretest probability of obstructive sleep apnea, subgroup analyses were conducted. Stratified analyses that examined misclassification in disease severity as a function of subjective sleep tendency showed that of the 50 subjects characterized as subjectively sleepy with an Epworth sleepiness score ≥ 11 , seven (14.0%) were misclassified (Figure 3). Disease severity class was underestimated in 10.0% of sleepy subjects when a sleep medicine specialist was not involved. Similarly, in those without subjective sleepiness (Epworth sleepiness score < 11), 12.1% of the 141 subjects were classified in a less severe obstructive sleep apnea category when there was no sleep medicine specialist involved. The difference in disease severity misclassification by subjective sleepiness was not statistically significant (10.0% versus 12.1%, $p = 0.43$). Analyses were also conducted to examine whether there was heterogeneity in misclassification as a function of pretest probability as assessed by the Berlin Questionnaire. As with self-reported sleepiness, misclassification in disease severity did not differ between high-risk and low-risk Berlin categories ($p = 0.83$). In the high risk group (N=98), 16 subjects overall (16.3%) were misclassified, whereas in the low risk group (N=93), 16 subjects (17.2%) were misclassified (Figure 3).

DISCUSSION

The current study suggests that case-identification of obstructive sleep apnea using home sleep testing in a non-referred sample can be effectively accomplished irrespective of the pre-test probability. While overall misclassification in identification and disease classification with and without a sleep specialist was 16.8%, the diagnosis was missed in less than 6% of our community-based sample when a sleep specialist was not involved in any capacity. Moreover, home sleep testing without a sleep specialist appropriately identified obstructive sleep apnea irrespective of whether subjects were categorized as low-risk or high-risk for obstructive sleep apnea, as determined by the Berlin Questionnaire, or whether there was subjectively sleepiness. Thus, risk stratification prior to portable sleep testing does not alter the diagnostic accuracy of home sleep testing that does not include a sleep specialist.

The results reported herein extend the available evidence on home sleep testing for obstructive sleep apnea. Currently, there is a dearth of information on the use of home sleep testing in a non-referred sample that includes subjects with high and low pretest probability for obstructive sleep apnea. Based on current recommendations, the preponderance of the available literature has assessed the use of home sleep testing primarily in clinic-based populations with a high pretest probability of the disease. In the only available study exploring the use of home sleep testing in subjects with a low pretest probability,¹⁶ it was demonstrated that three nights of home sleep testing can effectively and economically diagnose obstructive sleep apnea. However, given that a sleep clinic sample was assessed and the enrolled patients were not subjected to a standardized pretest assessment of risk, the results of that study are not generalizable to other patient samples. In contrast, the results of our study are more applicable to a larger pool of patients that may benefit from diagnostic sleep testing because of the non-referred nature of our sample of which approximately half was at low risk. While the role of health care providers not trained in sleep

medicine has also been previously examined, the primary focus of the published data has been on streamlining management in patients that are referred for clinical care.¹⁷ Thus, the results of the current study are distinct and expand the limited empirical evidence base by demonstrating that obstructive sleep apnea can be reliably diagnosed without a sleep-trained provider even in those with a low pretest probability, the group most likely to have false negatives and consequently remain undiagnosed.

The use of automated diagnostic tools to improve screening and diagnostic efficiency in clinical practice is not novel. An example that has leveraged such tools is screening for breast cancer screening with mammography. Previous large scale prospective studies and clinical trials have demonstrated that computer-aided analysis can reduce the need for specialized expertise for screening mammograms and help improve breast cancer detection.¹⁸⁻²⁰ A similar conceptual framework might also be considered in the early identification of other chronic diseases, such as obstructive sleep apnea. Given that cardiovascular disease remains the leading cause of morbidity and mortality,²¹ it is reasonable to identify key potential risk factors and address them preemptively. The prevalence of obstructive sleep apnea in those affected by hypertension, heart failure, coronary artery disease, stroke, and atrial fibrillation is alarmingly high, with estimates ranging from 12% to 83% depending on the underlying disorder.^{22,23} Furthermore, the prevalence of obstructive sleep apnea in type 2 diabetes, another established risk factor for cardiovascular disease, is estimated to be 50-80%.²⁴ Thus, it is reasonable to consider testing for those with a low clinical suspicion but with associated comorbidities such as type 2 diabetes and heart disease, given that treatment of obstructive sleep apnea with positive airway pressure therapy has been shown to improve cardiovascular outcomes.^{25,26} Moreover, the noted association between motor vehicle accidents and obstructive sleep apnea²⁷ is a major public safety concern further highlighting the need to screen those at risk. Thus, the ability to economically and expeditiously identify obstructive sleep apnea in

various patient population subsets by home sleep testing has important implications on healthcare costs, public safety, and medical outcomes. These implications are potentially even more substantial if simple tools for case identification can be deployed by healthcare providers of any specialty.

The current study has several strengths and limitations that merit discussion. First, the fairly large sample size from a community-based setting spanning the full spectrum of disease severity increases the generalizability of the reported findings. Second, the inclusion of subjects with both high and low pretest probability of obstructive sleep apnea as well sleepy and non-sleepy subjects, substantiates the utility of home sleep testing as a diagnostic tool with broad clinical utility. Third, there is a dearth of information regarding the use of home sleep testing in asymptomatic or low risk individuals. The current investigation helps fill this knowledge gap in that particular subgroup. Limitations of our study include the use of one expert that reviewed the raw recordings. Variability amongst sleep experts in their visual assessment of the recordings is well documented²⁸⁻³⁰ and can affect the observed misclassification. Moreover, there are a large number and types of home sleep testing devices, each having a distinct approach for identifying disordered breathing events. Thus, results from one device, as used in the current study, cannot be extrapolated to other devices, and the heterogeneity of performance across devices cannot be determined. Moreover, the current study did not examine treatment prescription which may require participation of physician experienced in sleep medicine. Nonetheless, it has been previously demonstrated that treatment-related outcomes for obstructive sleep apnea are similar when comparing a model that has a sleep specialist to one that does not.¹⁷ Finally, it is important to recognize that home sleep testing with portable monitoring can yield false negative results compared to a full-montage in lab sleep study because the severity assessment is based on total recording time and not total sleep time. These limitations notwithstanding, the findings of the current study demonstrate that testing for obstructive sleep apnea with portable sleep monitoring may be effectively conducted irrespective of the pretest

probability. There is little doubt that early treatment for symptomatic obstructive sleep apnea is warranted,³¹⁻³³ and home monitoring by those without specialty training in sleep medicine is feasible and can increase access to diagnosis and early case-identification. The use of an objective test that is simple to attain, even in those at low risk represents a paradigm shift in testing for obstructive sleep apnea.

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ACCEPTED MANUSCRIPT

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Figure 1: Scatterplot (left) and Bland-Altman plot (right) of the apnea-hypopnea index (AHI) with and without sleep specialist involvement.

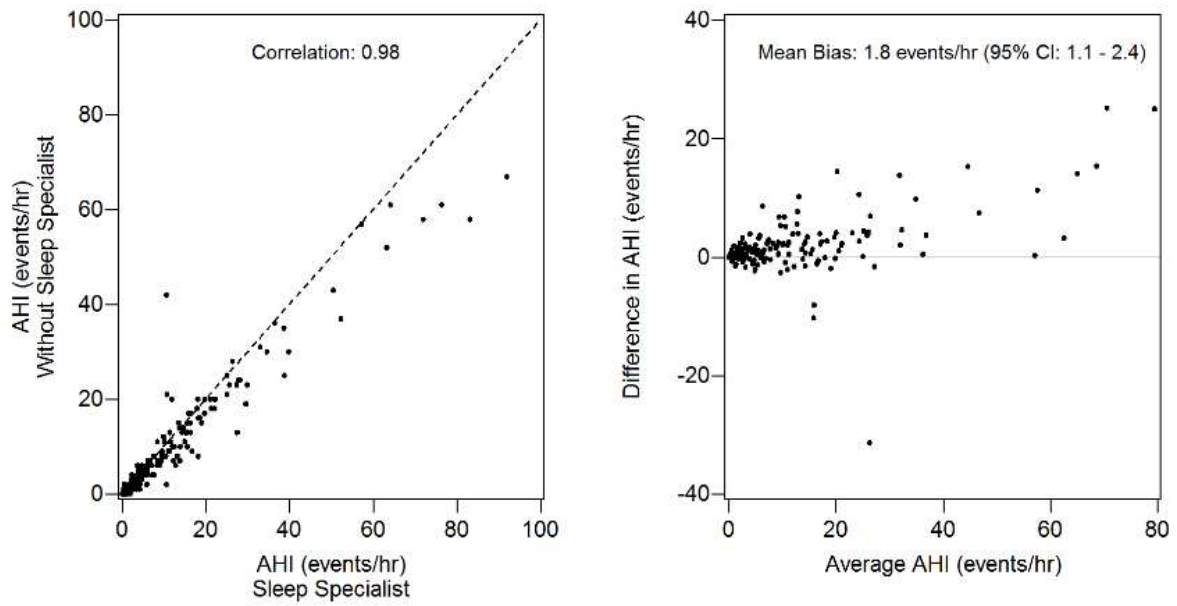


Figure 2: Classification of obstructive sleep apnea (OSA) severity (top panel) and concordance (bottom panel) with and without sleep specialist involvement.

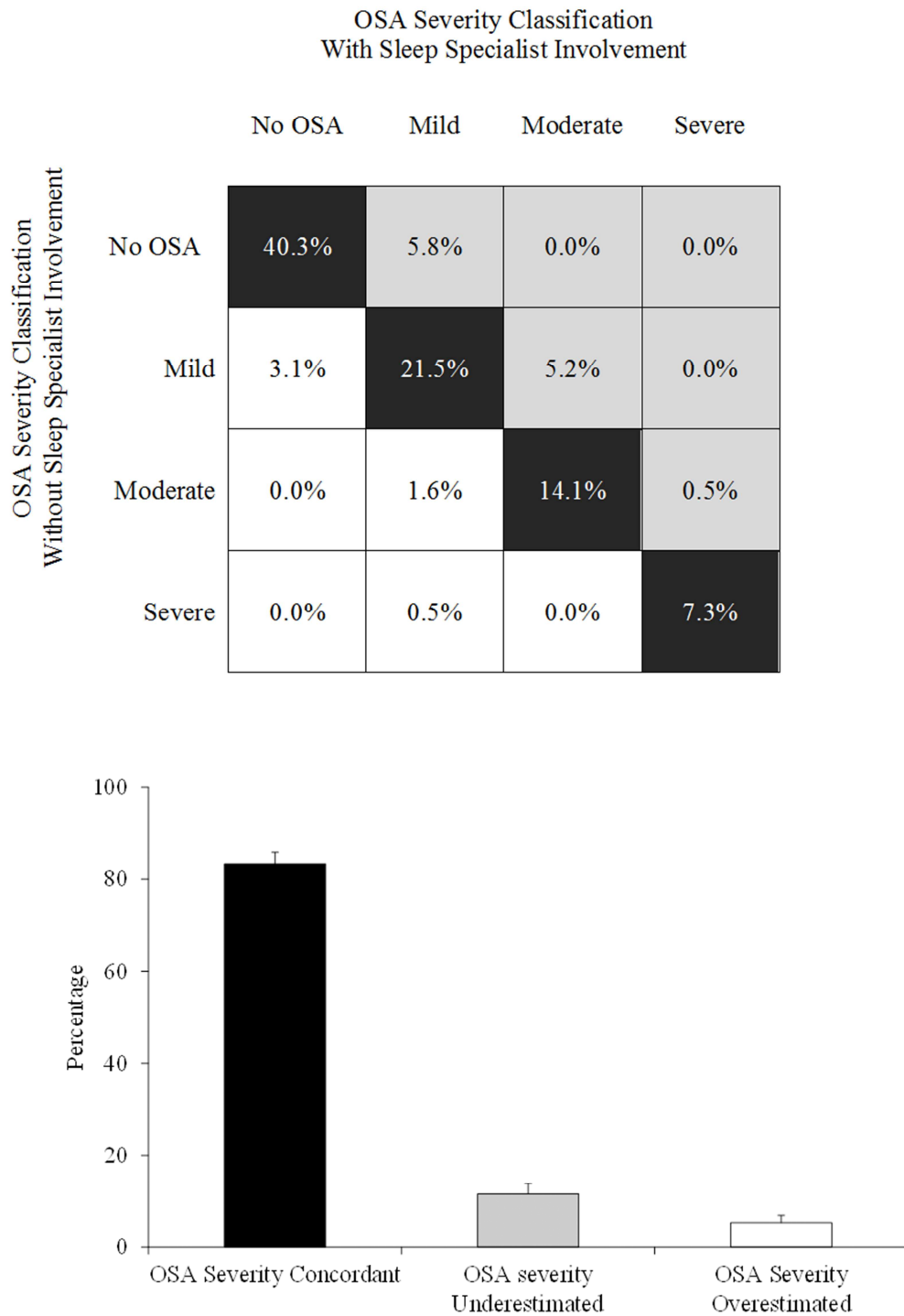
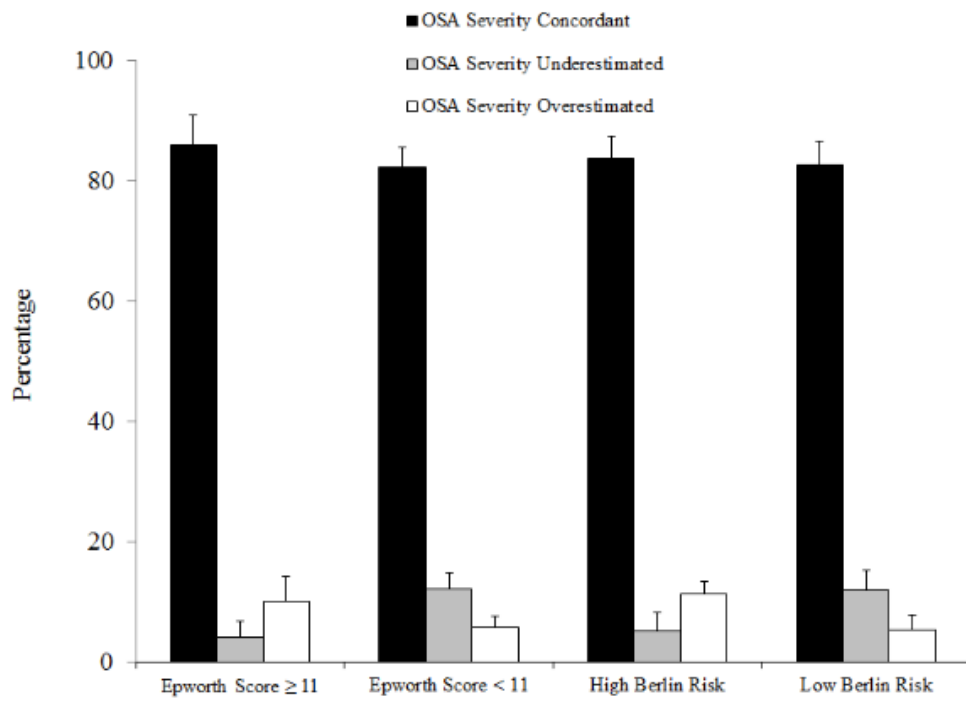


Figure 3: Percent concordance with and without sleep specialist involvement stratified by subjective sleepiness and OSA risk based on the Berlin questionnaire.



- Identification of obstructive sleep apnea using home sleep testing in a non-referred sample without involvement of a sleep specialist has not been routinely performed.
- Obstructive sleep apnea was missed in less than 6% when home sleep testing was conducted without a sleep specialist.
- Pretest probability of obstructive sleep apnea or subjective sleepiness does not alter diagnostic accuracy of home sleep testing when a sleep specialist is not involved.