Summer 8-19-2016

Psychometric Properties of Obstructive Sleep Apnea Screening Measures in Patients Referred to a Sleep Clinic

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PSYCHOMETRIC PROPERTIES OF OBSTRUCTIVE SLEEP APNEA SCREENING MEASURES IN PATIENTS REFERRED TO A SLEEP CLINIC

by

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A DISSERTATION

Presented to the Faculty of the University of Nebraska Graduate College in Partial Fulfillment of the Requirements for the Degree of Doctor of Philosophy

Nursing Graduate Program

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August, 2016

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Acknowledgements

Thank you to my advisor, Dr. Ann Malone Berger, for her mentorship, consistent support, words of encouragement, and for being an exceptional role model for nursing and sleep scholarship.

I would also like to thank my co-advisor, Dr. Paula Schulz, for introducing me to the BSN to PhD program at UNMC, serving as a supervisor for my research graduate assistantship, providing words of encouragement, and support throughout the PhD program.

And thank you to my supervisory committee for guidance: Dr. Lani Zimmerman, Dr. Kevin Kupzyk, Dr. Bunny Pozehl, and Dr. Debra Romberger.

I want to acknowledge the creator of the STOP Bang, Dr. Francis Chung and faculty from the Department of Anesthesiology at the University of Toronto, for granting me permission to study the measure.

I have received awards and scholarships that have been vital to my success. Thank you to the Ann Malone Berger, PhD and Thomas Berger Nursing Scholarship, the Nancy Bergstrom Graduate Nurse Fellowship Fund, the Nellie House Craven Scholarship for an Academic Nursing Career Award, Dean's Award for Poster Presentation at Midwest Nursing Research Society, and Sigma Theta Tau International, Gamma Pi Chapter-At-Large Research Award.

I want to acknowledge the support for my dissertation that I received from the physicians and staff at Nebraska Pulmonary Specialties, in Lincoln, NE.

I attribute much of my success to the support from my husband. Thank you for your humor, understanding, patience, kindness, and encouragement during this journey together. I also want to thank other my other friends and family members who have supported me along the way

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Background: Obstructive Sleep Apnea (OSA) contributes to all-cause and cardiac mortality. There are no current guidelines for OSA screening in outpatient settings. An American Academy of Sleep Medicine task force is focusing on improving detection and categorization of OSA symptoms and severity to promote screening, assessment, and diagnosis of the disorder. The purpose of this study was to identify the psychometric properties of three self-report OSA screening measures (Berlin, Epworth Sleepiness Scale (ESS), STOP Bang) and an objective portable sleep monitor (PSM) compared to apnea-hypopnea index (AHI) levels (≥5, ≥ 15, and ≥ 30) from polysomnogram (PSG).

Methods: A methodological design was used. Patients referred to a sleep specialist for an OSA consultation were recruited and enrolled at initial sleep evaluation. Participants completed the three OSA self-report screening measures and those participants who met inclusion criteria were sent home with a PSM for one night measurement. Automatic scoring was used. PSGs were ordered by the physician and AHI results were obtained from the medical record.

Results: Participants (N=170) were enrolled (88 male, 82 female; age 54.5, SD 5.0 years). Almost all participants completed the self-report OSA screening measures, approximately half completed PSM measurement, and the majority completed laboratory PSG. The STOP Bang had the highest levels of sensitivity; the ESS had the lowest. The ESS had the highest specificity and reliability level. The PSM measure had the highest positive predictive value (PPV). The PSM measure had the strongest psychometric properties of the screening measures.

Conclusions: The STOP Bang was the preferred self-report OSA screening measure because of high sensitivity levels**.** A positive STOP Bang warrants assessment for OSA. The ESS is the least desirable screening measure. If a patient qualifies, further screening with a PSM is indicated.

PSM measurement consistently predicted the presence of OSA but at the expense of low sensitivity at AHI levels ≥ 30. PSM results can guide the referral process from primary or specialty clinicians to sleep specialists

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Chapter I: Background

Obstructive sleep apnea (OSA) is a common, yet underdiagnosed, sleep-related breathing disorder that significantly contributes to all-cause (Kendzerska, Gershon, Hawker, Leung, & Tomlinson, 2014; Qaseem et al., 2014) and cardiac mortality (Kendzerska et al., 2014). The estimated prevalence rate of moderate to severe OSA in the United States is approximately 10% to 20%. The rate is thought to be influenced by the obesity epidemic and to have increased dramatically over the past two decades (Peppard et al., 2013).

Essential features of OSA include a repetitive partial (hypopnea) and/or complete (apnea) obstruction of the upper airway, marked by upper pharyngeal collapse with continuing efforts to breathe. Events can last 10 seconds to a minute in duration, resulting in intermittent desaturations in oxyhemoglobin levels and sleep fragmentation. Respiratory-effort related arousals (RERAs) are sequences of breaths with increased pressure for at least 10 seconds preceding an arousal with more normal pressures. The results of apneas, hypopneas, and RERAs are intermittent hypoxia, activation of oxygen free radicals, and an oxidative stress response (Berry et al., 2014). Long-term inflammatory processes result in changes in the vascular endothelium, leading to atheroma formation and vascular events (Almendros et al., 2011; Xie, Pan, Ren, Du, & Guo, 2013).

A study by Torres et al. found that gender, age, body mass index, nocturnal heart rate, and night and day-time blood pressure can be predictive of OSA. Other studies report a relationship between OSA and tachyarrhythmias (Holmqvist et al., 2015; Kohli, Balachandran, & Malhotra, 2011), reduced left ventricular stroke volume (Yumino et al., 2013), stroke (Lipford et al., 2015), cognitive impairment (Aaronson et al., 2015), and insulin resistance (Heffner, Rozenfeld, Kai, Stephens, & Brown, 2012).

Patients present to their health care providers with daytime sleepiness and/or known OSA risk factors, such as obesity and CVD, but are not screened for symptoms, assessed, or

referred to a sleep specialist for diagnosis and treatment for the disorder (Jennum, Ibsen, & Kjellberg, 2013).

The American Academy of Sleep Medicine (AASM) released a call for volunteers to serve on an OSA Assessment Tools Task Force. Two main goals for the task force are to evaluate the current OSA screening measures and to recommend whether the AASM needs to develop additional measures that improve detection of the disorder (American Academy of Sleep Medicine, 2016).

The self-report screening measures used commonly to detect OSA are the Berlin Questionnaire (Berlin) (Netzer, Stoohs, Netzer, Clark, & Strohl, 1999) and the Epworth Sleepiness Scale (ESS) (Johns, 1991). The STOP Bang questionnaire has been used to predict airways obstructive events in pre-operative patients in the acute care setting but more outpatient validation studies are needed (Chung et al., 2008a). The increased need for polysomnography (PSG) services encouraged the development of an objective screening measure, the portable sleep monitors (PSM). Level III PSM, with four channels, are used for OSA screening and diagnosis in patients who meet criteria. Reporting of the apnea hypopnea index (AHI) or respiratory distress index (RDI) after PSM is mandatory for OSA diagnosis (Department of Health and Human Services & Centers for Medicare & Medicaid Services, 2013). PSG remains the gold standard for generating AHI levels ≥ 15 to diagnose OSA.

Theoretical Background

Kohli, Balachandran, and Malhotra (2011) developed a pathophysiologic model that visually depicted the long-term effects of OSA on the cardiovascular system, titled "Effects of Obstructive Sleep Apnea on the Cardiovascular System" (Figure 1). The construction of the model was supported by epidemiological research. In the model, OSA is shown to have three main effects: arousal, decreased partial pressure of oxygen (pO_2) and increased partial pressure of carbon dioxide (pCO_2), and decreased intrathoracic pressure.

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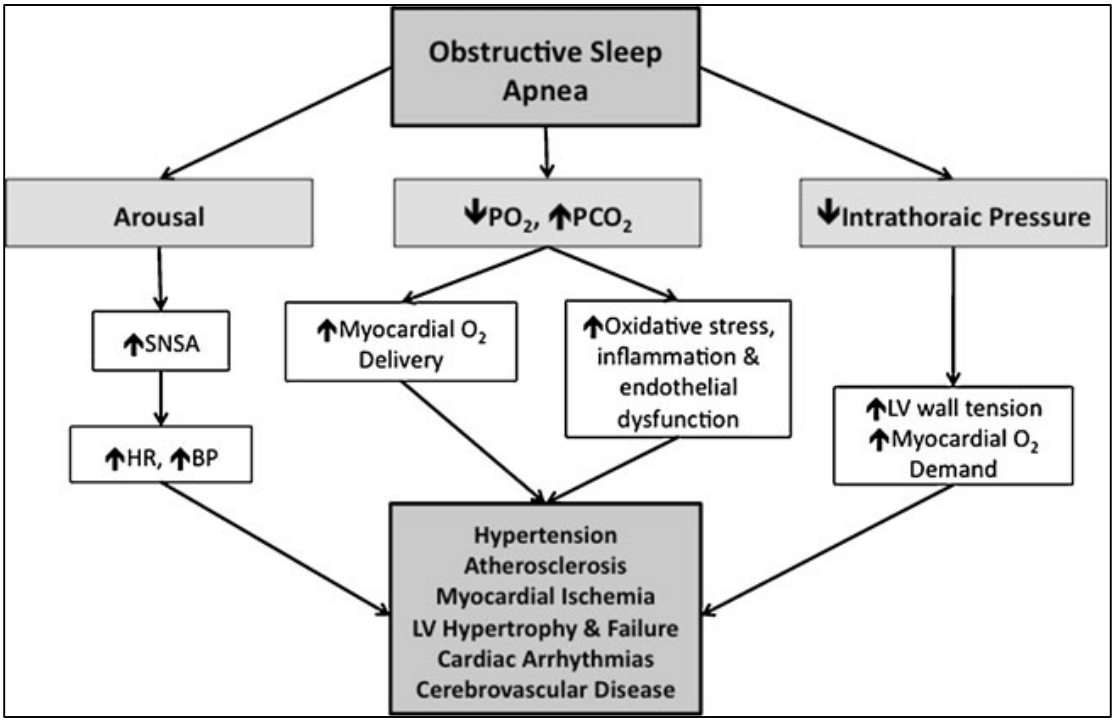
Arousals are important to OSA because the diagnosis of the disorder is based upon the number of apneas, hypopneas, RERAs, and/or respiratory distress index that are measured by PSG. The frequent arousals result in sympathetic nervous system activation that cascades into increased heart rate and blood pressure. The second main effect shown in the model is cyclic hypoxemia (decreased pO_2) and hypercapnia (increased CO_2). These two effects result in myocardial vasodilation and increased oxygen delivery as well as an increase in oxidative stress, inflammation, and endothelial dysfunction. Lastly, a decrease in intrathoracic pressure causes an increase in left ventricular wall tension and increased myocardial oxygen demand. The long-term effects of OSA, shown at the bottom of the model, are hypertension, atherosclerosis, myocardial ischemia, left ventricular hypertrophy and failure, cardiac arrhythmias, and cerebrovascular disease.

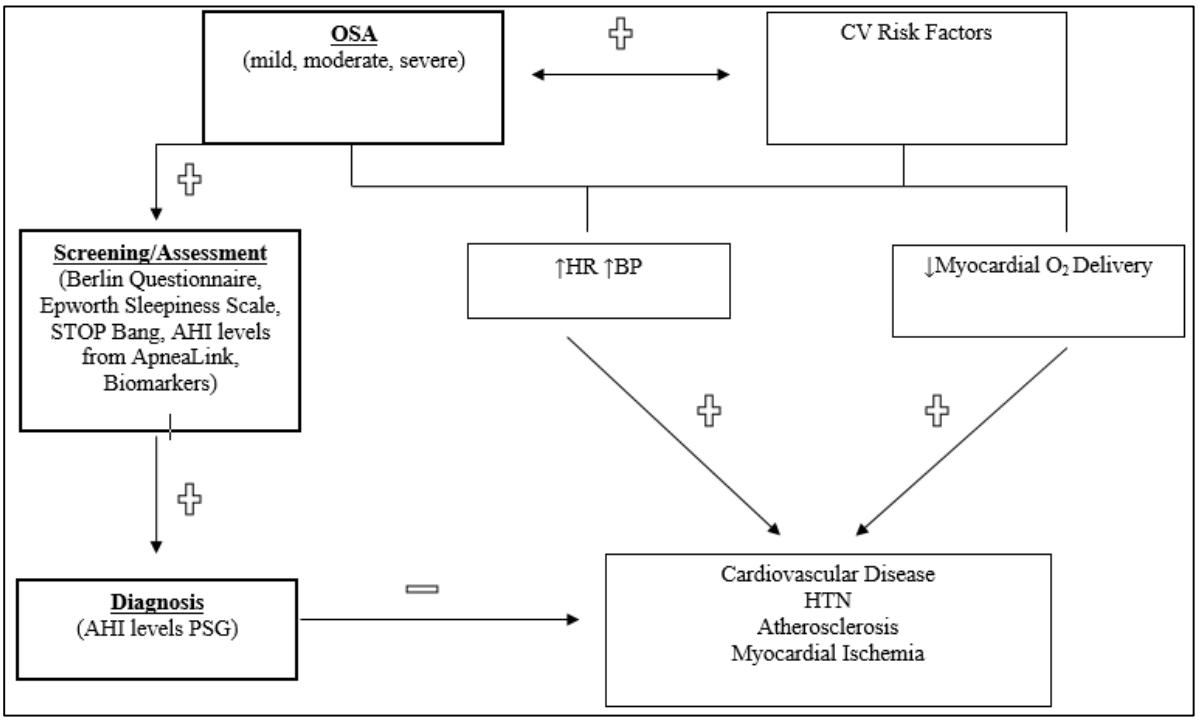
Figure 1: Effects of Obstructive Sleep Apnea on the Cardiovascular System (Kohli et al., 2011)



Conceptual Framework

The conceptual framework for this study (Figure 2) was adapted from Kohli's (Kohli et al., 2011). The pathophysiological effects of OSA need to be prevented or reduced. Figure 2 illustrates the need for screening, assessment, and diagnosis of OSA. It is important to determine which screening measurement(s) is/are the most reliable, valid and has the highest sensitivity and specificity levels compared to PSG. The second component of this framework illustrates the cardiovascular consequences of untreated OSA, which is not included in this study but will be in future research. OSA diagnosis begins with the screening and assessment process. The screening process is more efficient with the use of reliable and valid OSA screening measures. The OSA screening measures selected were the Berlin, ESS, STOP Bang and a PSM (ApneaLink Air). The screening measures were psychometrically compared with AHI levels from PSG.

Figure 2: Conceptual Framework Adapted from Kohli et al. (2011)



The cardiovascular consequences included in the framework include tachycardia and hypertension caused by systemic activation of the sympathetic nervous system. Because of the excess stress placed on the body's vascular system, blood pressure and heart rate increase along with decreased myocardial oxygen delivery. The result is development of cardiovascular disease (Kohli et al., 2011). Including the cardiovascular consequences of untreated OSA in the framework provides emphasis of the benefits of early screening and treatment of the sleep disorder.

The current practice pattern is inconsistent for screening and assessment of OSA. This framework informs the study by emphasizing the importance of identifying measures that are highly predictive of OSA. The knowledge gained from this study will determine which measurement(s) has the best predictability for identifying OSA in undiagnosed patients in a sleep clinic setting.

Definitions of Major Concepts

Obstructive sleep apnea

Essential features of OSA include a repetitive partial (hypopnea) and/or complete (apnea) obstruction of the upper airway, marked by upper pharyngeal collapse with continuing efforts to breathe (Berry et al., 2014). These events can last 10 seconds or up to a minute in duration, and result in intermittent desaturations in oxyhemoglobin levels and sleep fragmentation. In obese individuals, obstructive events in rapid eye movement sleep have been associated with lower oxyhemoglobin desaturations (Peppard, Ward, & Morrell, 2009).

An AASM task force listed symptoms of OSA as loud snoring between apneas, witnessed episodes of gasping for air, choking, and the presence of daytime sleepiness. The severity of OSA is categorized by an individual's AHI, indicating how many times an hour the patient experiences obstructive events during PSG testing (Epstein et al., 2009). AHI levels range from mild (≥ 5 and < 15), to moderate ($15 \geq$ and < 30), to severe (≥ 30) (Berry et al., 2014; Epstein et al., 2009; Guilleminault, Benbir, & Aktar, 2007). Daytime excessive sleepiness, fatigue and feeling

unrefreshed after sleep are common in most individuals with OSA and symptoms are exacerbated by more frequent apnic and hypopenic events (Epstein et al., 2009), these can be detected using sensitive and specific screening methods.

Screening

The definition for screening is "the act of doing a test on a person… to look for evidence of a disease" (Merriam-Webster Dictionary, 2014b). OSA screening currently takes place via the review of systems process but providers often do not include questions to detect sleep disturbances (Grover et al., 2011; Senthilvel, Auckley, & Dasarathy, 2011). Screening needs to occur during a routine health maintenance assessment or as part of a comprehensive exam for high-risk patients (Epstein et al., 2009). Physiologic characteristics that place a person at high-risk of OSA are obesity (body mass index > 35), congestive heart failure, atrial fibrillation, hypertension, type II diabetes, stroke, pulmonary hypertension, and nocturnal cardiac arrhythmias (Epstein et al., 2009; Miller & Berger, 2016).

An OSA screening measure can be used to predict OSA and to determine whether an assessment is warranted. The AASM Clinical Guidelines Task Force (Epstein et al., 2009) reached "consensus" that several questions can be asked by the primary care provider (PCP) during routine health maintenance assessments. Asking about a history of snoring and daytime sleepiness lacks reliability and validity and has not resulted in increased referrals to sleep specialists. PCPs need to use sensitive and specific measures to identify, high-risk patients for referral to a sleep specialist.

Measurement

OSA screening measures have been developed to aid health care providers to screening quickly for moderate to severe OSA in a variety of health care settings (Abrishami, Khajehdehi, & Chung, 2010; Ramachandran & Josephs, 2009; Silva, Vana, Goodwin, Sherrill, & Quan, 2011). Using sensitive and specific screening measures offers a cost-effective way to predict the presence of OSA and highlights the need to refer the patient to a sleep specialist. Measures with

high positive predictive value are likely to predict the presence of a disease while those with high negative predicative values are likely to predict the absence of the disease. This section will discuss reliability and validity as well as provide a description of the OSA screening measures.

Reliability. Reliability testing helps determine whether the health outcomes under study can provide reproducible results in the population. The reliability of a measurement is concerned with controlling random error, which can be caused by inconsistent responses to questionnaires, data entry errors, poor training of data collectors, or coding/transcription errors (Furr & Bacharach, 2014).

Validity. DeVon et al. (2007) defined validity as "the ability of the instrument to measure the attributes of the construct under study" (p.155). Validity can be divided into three categories of measurement: (a) content, (b) criterion, and (c) construct validity (Kane & Radosevich, 2010). Content, or face validity refers to the comprehensiveness of the measurement that is established via content analysis. Criterion validity measures a correlation between an instrument and the gold standard of measurement. This category of validity can be subdivided into concurrent and predictive validity. Concurrent validity occurs when scores on a measure are correlated to related criterion at the same point in time. Predictive validity is the degree to which test scores predict performance on some future criterion, measured by sensitivity, specificity, positive predictive value, and negative predictive value. Sensitivity is the probability of a positive test among patients with a disease and specificity is the probability of a negative test among patients without a disease. Positive predictive value is the probability that subjects with a positive screen will truly have the disease and negative predictive value is the probability that subjects with a negative screen truly don't have the disease (Kane & Radosevich, 2010).

Construct validity uses scientific theory to support or refute a construct. Hypotheses can test operational definitions to determine whether the overarching theory supports the instrument being tested. Construct validity can be assessed by convergent/discriminant validity or known groups testing. Convergent validity compares two scales purporting to measure the same construct

that should be highly correlated/theoretically similar. Known groups testing uses a highly sensitive/specific measure (i.e. PSG) to determine differences in groups (DeVon et al., 2007; Kane & Radosevich, 2010).

Berlin questionnaire. The Berlin questionnaire (Netzer et al., 1999) was developed by primary care and pulmonary physicians to predict the presence of OSA. The measurement has three symptom categories; the first has five unique questions concerning frequency (rare to often) of snoring and apneas while sleeping. The second category has four unique questions concerning daytime sleepiness with a question about sleepiness while driving. A score is positive for category 1 and 2 when a patient selects two responses from the top levels. The third category has two questions. A positive response is when a patient has high blood pressure (> 140/90mmHg) or a body mass index (BMI) > 30kg/m^2. After scoring, the individual is considered to be high-risk if two or three of the categories are positive.

Epworth sleepiness scale. The ESS (Johns, 1991) was developed as a simple measure to quantify the level of daytime sleepiness in adults. The ESS is a brief scale that asks the subject to rate on a scale of 0-3 (0=none, 3=high chance of dozing) the level of sleepiness during eight daily activities. The sum of the eight questions is calculated and the higher the sum, the higher the sleep deficit (0-24). A score of ≥16 indicates a high level of daytime sleepiness (Johns, 1991). The ESS has been shown to be reliable in the test-retest sense. The measure has high internal consistency (Johns, 1992) but inconsistent sensitivity and specificity values (El-Sayed, 2012; Silva et al., 2011).

STOP Bang. The STOP Bang is an OSA screening measure that was developed to quickly and concisely screen for OSA in a pre-surgical population. The eight OSA predictor variables are snoring, tiredness, obstruction, high blood pressure, BMI, age, neck circumference, and gender. Scoring takes place on a Yes/No scale (Chung et al., 2008a). The person is given one point for each "yes" response. Scores range from 0 to 8, with ≥3 indicating a positive screen.

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ApneaLink Air. The ApneaLink Air™ (ResMed, San Diego, CA) is a level III, four channel, PSM that is prescribed by a health care provider. The device monitors (a) oxygen saturation, (b) heart rate, and (c) breathing patterns (apneas, hypopneas, snoring, probability of Cheyne-Stokes breathing). No known figures of test-retest reliability have been reported. An AHI level of ≥ 15 on the ApneaLink Air was the indicator of a positive screen (Collop et al., 2007).

Assessment

A more comprehensive sleep history is recommended when an OSA screen is positive or the physician determines that assessment is warranted (Epstein et al., 2009). Assessment is defined as "the act of making a judgment about something" (Merriam-Webster Dictionary, 2014a). No clinical measurement or assessment is absolutely predictive of the presence of OSA, but patients assessed as high-risk for the disorder should be referred to a sleep specialist for evaluation (Epstein et al., 2009).

Assessments included are BMI, neck circumference, blood pressure, and a visual examination of the oro-naso-pharynx. Determining a Mallampati score is helpful in assessing posterior pharyngeal crowding caused by increased upper airway soft tissue or abnormal facial structures. Higher scores have been correlated with OSA severity ($r= 0.351$, $p= 0.008$) and may predict nighttime obstructive events. A class 1 Mallampati score is visualization of the entire soft palate; severity ranges to a class 4, which is the inability to see any part of the soft palate (Epstein et al., 2009).

The assessment for OSA should include an examination of the cardiovascular and respiratory systems (Epstein et al., 2009). Untreated OSA is more likely to be present in persons with hypertension (Walia et al., 2014), or other cardiovascular conditions such as stroke (C. Chen et al., 2015) and Type II diabetes (Wang, Bi, Zhang, & Pan, 2013). Untreated OSA in the presence of dilated cardiomyopathy or ischemic heart disease can lead to the development of congestive heart failure (D. J. Gottlieb et al., 2010). Patients with severe untreated OSA, who also have chronic obstructive pulmonary disease, are at higher risk of developing pulmonary

hypertension and cor pulmonale. When screening and assessment indicate that a patient found is at high-risk for OSA, the referral process must be expedited for timely diagnosis and treatment (Epstein et al., 2009).

Diagnosis

Polysomnography. Under supervision of a sleep technician, laboratory PSG is the gold standard for OSA diagnosis. An AASM task force (2012) defined apnea events in adults as "a drop in the peak signal excursion by ≥ 90% of pre-event baseline using an oro nasal thermal sensor (diagnostic study), positive assisted pressure (PAP) device flow (titration study), or an alternative apnea sensor, for ≥ 10 seconds"(p. 606). Hypopnea events in adults are scored when "the peak signal excursions drop by ≥ 30% of pre-event baseline using nasal pressure (diagnostic study), PAP device flow (titration study), or an alternative sensor for ≥ 10 seconds in association with either ≥ 3% arterial oxygen desaturation or an arousal (Berry et al., 2012). The severity of OSA has been defined by AASM as "an individual's Apnea Hypopnea Index (AHI), which indicates how many times an hour the patient experiences obstructive events" (Epstein et al., 2009). AHI levels range from mild (≥ 5 and < 15), to moderate (15 ≥ and < 30), to severe (≥ 30) (Berry et al., 2014; Epstein et al., 2009; Guilleminault et al., 2007).

Introduction of Documents

This dissertation adds to the current knowledge of OSA screening, assessment, and diagnosis. The dissertation uses the three-manuscript option to present the current state of the science on this topic. Chapter II is an integrative literature review titled State of the Science: Screening and Assessment for Obstructive Sleep Apnea in Primary Care. Next, Chapter III is a focused literature review titled Methodological Challenges: Using Portable Sleep Monitoring in Research. Chapter IV.A. is the presentation of Aim 1 of the dissertation study as well as a discussion of its theoretical and conceptual framework titled Psychometric Properties of Obstructive Sleep Apnea Screening Measures in Patients Referred to a Sleep Clinic. Chapter IV.B. is the presentation of Aim 2 of the dissertation study, which is a multiple regression

analysis of demographic and clinical variables using AHI from laboratory PSG as the outcome variable titled Analysis of Demographic, Clinical, and Biomarker Characteristics to Determine Predictors of Apnea Hypopnea Index from Polysomnography in Midwestern Sleep Clinic Patients. Chapter V presents conclusions and discussion of the research and implications for research and practice.

Chapter II: State of the Science: Screening and Assessment for Obstructive Sleep Apnea in Primary Care

OSA is the most common sleep-related breathing disorder and contributes to increased morbidity and compromised cardiovascular outcomes. Sleep disorders are common but rarely reported and addressed by primary health providers. An American Academy of Sleep Medicine task force (2015) released quality measures for the care of adult patients with OSA; the first outcome is improved detection and categorization of OSA symptoms and severity to promote assessment and diagnosis of the disorder.

This state of the science integrative review aimed to evaluate the screening and assessment for OSA in primary care settings including the psychometric properties of OSA screening measures. This paper is the first to focus on this issue. Studies that met inclusion criteria were fourteen non-experimental and three experimental designs. OSA screening measures (Berlin Questionnaire, Epworth Sleepiness Scale, STOP Bang) with extensive validation studies were examined. A critical evaluation of the current state of the science is provided as well as recommendations for future interdisciplinary research.

Chapter III: Methodological Challenges in Using Portable Sleep Monitoring in Research

OSA in adults has been increasing over the last two decades. Currently, it is estimated that moderate to severe OSA (apnea hypopnea index [AHI] $\geq$ 15) is present in 10% of men aged 30-49, 17% of men 50-70 years old, and 9% of women 50-70 years old. PSM type of testing is not recommended for patients with co-morbid conditions such as moderate to severe pulmonary disease, neuromuscular disease, congestive heart failure, or who are suspected to have other sleep

disorders (central sleep apnea, periodic limb movement disorder, insomnia, parasomnias, circadian rhythm disorders, or narcolepsy) (Collop et al., 2007). Because of the increase in OSA prevalence, sleep laboratory and diagnostic services are in high demand; therefore, it was necessary to identify alternative means for screening and diagnosis of sleep disorder outside of the sleep laboratory.

The first practice parameters were released for PSM in 1994 (Ferber et al., 1994). By the mid 1990's, most devices measured snoring but did not meet diagnostic requirements for OSA. By the year 2000, PSM were updated to include oxygen saturation, heart rate, oral/nasal airflow, respiratory effort and body position (Cleveland Medical Devices Inc., 2016). In 2000, the Agency for Healthcare Research and Research Quality (AHRQ) performed a meta-analysis that stated broad use of PSM could not be supported due insufficient evidence (Ross et al., 2000). In 2007, the Portable Monitoring Task Force of the AASM released guidelines which stated patients could be screened and diagnosed with OSA in home settings with Level III PSMs (Collop et al., 2007). This encouraged device manufacturers to develop PSM that allow patients to be screened or diagnosed with OSA in home settings. PSM has increased in popularity in order to meet the challenges of decreased availability of sleep laboratory sources.

With the increased use of PSM in outpatient settings, it is important to understand the research that has been published on the topic using level III monitors and to be able to understand the methodological challenges that are common with the use of the devices in research. To provide a focused review on the methodological challenges when using portable sleep monitors in research, it was necessary to create two main objectives for this manuscript. The first purpose of this paper was to synthesize the literature of the methodological challenges in using level III PSM in research adult patents, in terms of: (a) participant sampling; (b) instrumentation issues; (c) clinical variables; (d) data processing options; and (e) patient acceptability. A second purpose was to identify methodological strategies to use to standardize PSM information in research reports.

After implementing the exclusion criteria, 33 publications were included in the focused review and the strategies were identified from them.

Chapter IV.A. Psychometric Properties of Obstructive Sleep Apnea Screening Measures in Patients Referred to a Sleep Clinic

There are no current guidelines for screening for OSA in outpatient settings due to methodological issues with available measures. The screening measures that are often used to detect OSA are the Epworth Sleepiness Scale (ESS) (Johns, 1991) and the Berlin Questionnaire (Berlin) (Netzer et al., 1999). The STOP Bang questionnaire has been used to predict airways obstructive events in pre-operative patients in the acute care setting but more outpatient validation studies are needed (Chung et al., 2008a). A clinical practice guideline from the American College of Physicians, released in 2014, discussed the use of screening questionnaires for individuals with unexplained daytime sleepiness but states that they are not ready to be used as diagnostic tools for OSA (Qaseem et al., 2014). As previously discussed, PSM allows patients to be screened or diagnosed with OSA in home settings but limited studies discuss validation with screening measures and laboratory PSG. The knowledge gained from this study contributes to science by identifying the sensitivity and specificity of OSA measures used in screening.

Therefore, in patients who have been referred to a sleep specialist for a sleep disordered breathing evaluation, the purpose of this methodological study was to identify the psychometric properties of OSA screening measures (Berlin, Epworth Sleepiness Scale, STOP Bang, ApneaLink Air) compared to AHI levels from PSG. Validation testing was completed with the screening measures and conclusions were drawn in terms of implications for research and practice.

Chapter IV.B. Analysis of Demographic, Clinical, and Biomarker Characteristics to Determine Predictors of Apnea Hypopnea Index from Polysomnography in Midwestern Sleep Clinic Patients

OSA can occur in any age group but is most prevalent in older men (Kendzerska et al., 2014) and post-menopausal women (Zhao et al., 2014). A recent population health study concluded that the incidence of OSA is increasing because of rising obesity rates (Adams et al., 2012). OSA has been associated with hypertension (D. J. Gottlieb et al., 2014), congestive heart failure (D. J. Gottlieb et al., 2010), stroke (D. Gottlieb, Quan, Punjabi, Redline, & Bertisch, 2014), vascular disease (Cassar et al., 2014), metabolic disorders (N. H. Kim et al., 2013), and coronary artery disease (Jennum et al., 2013; Young et al., 2008). Untreated OSA can exacerbate all of these comorbid conditions (Colten & Altevogt, 2006).

Aim 2's purpose was to examine if selected demographic (age, gender), clinical (diabetes, coronary artery disease, hyperlipidemia, myocardial infarction, stroke, lung disease, smoking history, alcohol intake), and biomarker (blood pressure, heart rate, BMI, neck circumference, Mallampati Score) variables predict AHI levels from PSG. Significant predictor variables from the model were discussed in the conclusion as well as implications for future research and practice.

Chapter V: Discussion and Conclusions of the Dissertation Research

This chapter provides additional insights into the understanding of the conclusions of these documents. Implications for research and practice are presented. Unique insights into expanding validity testing of the STOP Bang and PSM are provided.

References

Aaronson, J. A., van Bennekom, C., Hofman, W. F., van Bezeij, T., van den Aardweg, Joost G, Groet, E., . . . Schmand, B. (2015). Obstructive sleep apnea is related to impaired cognitive and functional status after stroke. *Sleep, 38*(9), 1431-1437.

Abrishami, A., Khajehdehi, A., & Chung, F. (2010). A systematic review of screening questionnaires for obstructive sleep apnea. *Canadian Journal of Anesthesia/Journal Canadien D'Anesthésie, 57*(5), 423-438.

Adams, R. J., Piantadosi, C., Appleton, S. L., Hill, C. L., Visvanathan, R., Wilson, D. H., & McEvoy, R. D. (2012). Investigating obstructive sleep apnoea: will the health system have the capacity to cope? A population study. *Australian Health Review, 36*(4), 424-429.

Almendros, I., Farré, R., Torres, M., Bonsignore, M. R., Dalmases, M., Ramírez, J., . . . Montserrat, J. M. (2011). Early and mid-term effects of obstructive apneas in myocardial injury and inflammation. *Sleep Medicine, 12*(10), 1037-1040. doi:10.1016/j.sleep.2011.07.009

American Academy of Sleep Medicine. (2016). Call for Volunteers: AASM seeks volunteers for new OSA assessment tools task force. Retrieved from http://www.aasmnet.org/articles.aspx?id=6212&utm_source=WeeklyUpdate&utm_medium=email&utm_campaign=wu4-7-16

Berry, R. B., Brooks, R., Gamaldo, C. E., Harding, S. M., Lloyd, R. M., Marcus, C. L., & Vaughn, B. V. (2014). for the American Academy of Sleep Medicine The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications. Darien, IL: American Academy of Sleep Medicine; 2014. Version 2.0.3. *American Academy of Sleep Medicine: Darien, IL, USA,*

Berry, R. B., Budhiraja, R., Gottlieb, D. J., Gozal, D., Iber, C., Kapur, V. K., . . . Quan, S. F. (2012). Rules for scoring respiratory events in sleep: update of the 2007 AASM manual for the scoring of sleep and associated events. *J Clin Sleep Med, 8*(5), 597-619.

Cassar, A., Morgenthaler, T. I., Rihal, C. S., Prasad, A., Lennon, R. J., Lerman, L. O., & Lerman, A. (2014). Coronary endothelial function in patients with obstructive sleep apnea. *Coronary Artery Disease, 25*(1), 16-22. doi:10.1097/MCA.0000000000000063 [doi]

Chen, C., Chen, C., Yu, C., Chen, T., Tseng, S., & Ho, C. (2015). *Association of inflammation and oxidative stress with obstructive sleep apnea in ischemic stroke patients*. Netherlands: Elsevier Science. doi:10.1016/j.sleep.2014.07.027

Chung, F., Yegneswaran, B., Liao, P., Chung, S. A., Vairavanathan, S., Islam, S., . . . Shapiro, C. M. (2008). STOP questionnaire: a tool to screen patients for obstructive sleep apnea. *Anesthesiology, 108*(5), 812-821. doi:10.1097/ALN.0b013e31816d83e4 [doi]

Cleveland Medical Devices Inc. (2016). Home Sleep Testing: Past, Present, and Future. Retrieved from https://clevemed.com/home-sleep-testing-past-present-future/

Collop, N., Anderson, W. M., Boehlecke, B., Claman, D., Goldberg, R., Gottlieb, D., . . . Schwab, R. (2007). Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. *J Clin Sleep Med, 3*(7), 737-747.

Colten, H. R., & Altevogt, B. M. (2006). In Colten H. R., Altevogt B. M. (Eds.), *Sleep disorders and sleep deprivation: An unmet public health problem.* Washington, DC, US: National Academies Press.

Department of Health and Human Services, & Centers for Medicare & Medicaid Services. (2013). Continuous and bi-level positive airway pressure devices: complying with

documentation and coverage requirements. Retrieved from https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/PAP_DocCvg_Factsheet_ICN905064.pdf

DeVon, H. A., Block, M. E., Moyle-Wright, P., Ernst, D. M., Hayden, S. J., Lazzara, D. J., . . . Kostas-Polston, E. (2007). A psychometric toolbox for testing validity and reliability. *Journal of Nursing Scholarship, 39*(2), 155-164.

El-Sayed, I. H. (2012). Comparison of four sleep questionnaires for screening obstructive sleep apnea. *Egyptian Journal of Chest Diseases and Tuberculosis, 61*(4), 433-441.

Epstein, L. J., Kristo, D., Strollo, P. J.,Jr, Friedman, N., Malhotra, A., Patil, S. P., . . . Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. (2009). Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 5*(3), 263-276.

Ferber, R., Millman, R., Coppola, M., Fleetham, J., Murray, C. F., Iber, C., . . . Sanders, M. (1994). Portable recording in the assessment of obstructive sleep apnea. ASDA standards of practice. *Sleep, 17*(4), 378-392.

Furr, M. R., & Bacharach, V. R. (2014). Empirical Estimates of Reliability. In R. Hester, & E. Oettinger (Eds.), *Psychometrics* (2nd ed., pp. 125-161). Thousand Oaks, CA: Sage.

Gottlieb, D. J., Punjabi, N. M., Mehra, R., Patel, S. R., Quan, S. F., Babineau, D. C., . . . Lewis, E. F. (2014). CPAP versus oxygen in obstructive sleep apnea. *New England Journal of Medicine, 370*(24), 2276-2285.

Gottlieb, D., Quan, S., Punjabi, N., Redline, S., & Bertisch, S. (2014). Obstructive Sleep Apnea And Incident Stroke: Sleep Heart Health 14-Year Follow-Up Study. *Am J Respir Crit Care Med, 189*, A6361.

Gottlieb, D. J., Yenokyan, G., Newman, A. B., O'Connor, G. T., Punjabi, N. M., Quan, S. F., . . . Shahar, E. (2010). Prospective study of obstructive sleep apnea and incident coronary heart disease and heart failure: the sleep heart health study. *Circulation, 122*(4), 352-360. doi:10.1161/CIRCULATIONAHA.109.901801 [doi]

Grover, M., Mookadam, M., Armas, D., Bozarth, C., Castleberry, T., Gannon, M., . . . Dueck, A. (2011). Identifying patients at risk for obstructive sleep apnea in a primary care practice. *Journal of the American Board of Family Medicine : JABFM, 24*(2), 152-160. doi:10.3122/jabfm.2011.02.100193 [doi]

Guilleminault, C., Benbir, G., & Aktar, N. (2007). Obstructive Sleep Apnea. In N. Butkov, & T. Lee-Chiong (Eds.), *Fundamentals of Sleep Technology* (pp. 113). Philadelphia, PA: Lippincott, Williams and Wilkins.

Heffner, J. E., Rozenfeld, Y., Kai, M., Stephens, E. A., & Brown, L. K. (2012). Prevalence of Diagnosed Sleep Apnea Among Patients With Type 2 Diabetes in Primary Care. *CHEST Journal, 141*(6), 1414-1421.

Holmqvist, F., Guan, N., Zhu, Z., Kowey, P. R., Allen, L. A., Fonarow, G. C., . . . Chang, P. (2015). Impact of obstructive sleep apnea and continuous positive airway pressure therapy on outcomes in patients with atrial fibrillation—Results from the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF). *American Heart Journal, 169*(5), 647-654. e2.

Jennum, P., Ibsen, R., & Kjellberg, J. (2013). Morbidity prior to a diagnosis of sleep-disordered breathing: a controlled national study. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 9*(2), 103-108. doi:10.5664/jcsm.2398 [doi]

Johns, M. W. (1991). A new method for measuring daytime sleepiness: the Epworth Sleepiness Scale. *Sleep, 14*(6), 540-545.

Johns, M. W. (1992). Reliability and factor analysis of the Epworth Sleepiness Scale. *Sleep, 15*(4), 376-381.

Kane, R., & Radosevich, D. M. (2010). Strategic Questions in the Selection of Health Outcomes Measures. In C. Heverling (Ed.), *Conducting Health Outcomes Research* (pp. 61-78). London, United Kingdom: Jones & Bartlett Learning Books.

Kendzerska, T., Gershon, A. S., Hawker, G., Leung, R. S., & Tomlinson, G. (2014). Obstructive sleep apnea and risk of cardiovascular events and all-cause mortality: A decade-long historical cohort study. *PLoS Medicine, 11*(2), e1001599.

Kim, N. H., Cho, N. H., Yun, C. H., Lee, S. K., Yoon, D. W., Cho, H. J., . . . Shin, C. (2013). Association of obstructive sleep apnea and glucose metabolism in subjects with or without obesity. *Diabetes Care, 36*(12), 3909-3915. doi:10.2337/dc13-0375 [doi]

Kohli, P., Balachandran, J. S., & Malhotra, A. (2011). Obstructive sleep apnea and the risk for cardiovascular disease. *Current Atherosclerosis Reports, 13*(2), 138-146.

Lipford, M. C., Flemming, K. D., Calvin, A. D., Mandrekar, J., Brown, R. D.,Jr, Somers, V. K., & Caples, S. M. (2015). Associations between Cardioembolic Stroke and Obstructive Sleep Apnea. *Sleep, 38*(11), 1699-1705. doi:10.5665/sleep.5146 [doi]

Merriam-Webster Dictionary. (2014a). Assessment. Retrieved from http://www.merriam-webster.com/dictionary/assessment

Merriam-Webster Dictionary. (2014b). Screening. Retrieved from http://www.merriam-webster.com/dictionary/screening

Miller, J. N., & Berger, A. M. (2016). Screening and assessment for obstructive sleep apnea in primary care. *Sleep Medicine Reviews, 29*, 41-51.

Netzer, N. C., Stoohs, R. A., Netzer, C. M., Clark, K., & Strohl, K. P. (1999). Using the Berlin Questionnaire to identify patients at risk for the sleep apnea syndrome. *Annals of Internal Medicine, 131*(7), 485-491.

Peppard, P. E., Ward, N. R., & Morrell, M. J. (2009). The impact of obesity on oxygen desaturation during sleep-disordered breathing. *American Journal of Respiratory and Critical Care Medicine, 180*(8), 788-793.

Peppard, P. E., Young, T., Barnet, J. H., Palta, M., Hagen, E. W., & Hla, K. M. (2013). Increased prevalence of sleep-disordered breathing in adults. *American Journal of Epidemiology, 177*(9), 1006-1014. doi:10.1093/aje/kws342 [doi]

Qaseem, A., Dallas, P., Owens, D. K., Starkey, M., Holty, J. C., & Shekelle, P. (2014). Diagnosis of obstructive sleep apnea in adults: a clinical practice guideline from the American College of Physicians. *Annals of Internal Medicine, 161*(3), 210-220. doi:10.7326/M12-3187

Ramachandran, S. K., & Josephs, L. A. (2009). A meta-analysis of clinical screening tests for obstructive sleep apnea. *Anesthesiology, 110*(4), 928-939. doi:10.1097/ALN.0b013e31819c47b6 [doi]

Ross, S. D., Sheinihait, I., Harrison, K. J., Kvasz, M., Connelly, J. E., Shea, S., & Allen, I. E. (2000). Systematic review and meta-analysis of the literature regarding the diagnosis of sleep apnea. *SLEEP-NEW YORK-, 23*(4), 519-534.

Senthilvel, E., Auckley, D., & Dasarathy, J. (2011). Evaluation of sleep disorders in the primary care setting: history taking compared to questionnaires. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 7*(1), 41-48.

Silva, G. E., Vana, K. D., Goodwin, J. L., Sherrill, D. L., & Quan, S. F. (2011). Identification of patients with sleep disordered breathing: comparing the four-variable screening tool, STOP, STOP-Bang, and Epworth Sleepiness Scales. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 7*(5), 467-472. doi:10.5664/JCSM.1308 [doi]

Walia, H. K., Li, H., Rueschman, M., Bhatt, D. L., Patel, S. R., Quan, S. F., . . . Mehra, R. (2014). Association of severe obstructive sleep apnea and elevated blood pressure despite antihypertensive medication use. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 10*(8), 835-843. doi:10.5664/jcsm.3946 [doi]

Wang, X., Bi, Y., Zhang, Q., & Pan, F. (2013). Obstructive sleep apnoea and the risk of type 2 diabetes: A meta-analysis of prospective cohort studies. *Respirology, 18*(1), 140-146. doi:10.1111/j.1440-1843.2012.02267.x

Xie, X., Pan, L., Ren, D., Du, C., & Guo, Y. (2013). Effects of continuous positive airway pressure therapy on systemic inflammation in obstructive sleep apnea: a meta-analysis. *Sleep Medicine, 14*(11), 1139-1150.

Young, T., Finn, L., Peppard, P. E., Szklo-Coxe, M., Austin, D., Nieto, F. J., . . . Hla, K. M. (2008). Sleep disordered breathing and mortality: eighteen-year follow-up of the Wisconsin sleep cohort. *Sleep, 31*(8), 1071-1078.

Yumino, D., Kasai, T., Kimmerly, D., Amirthalingam, V., Floras, J. S., & Bradley, T. D. (2013). Differing effects of obstructive and central sleep apneas on stroke volume in patients with heart failure. *American Journal of Respiratory and Critical Care Medicine, 187*(4), 433-438.

Zhao, L. P., Tan, A., Tai, B. C., Loo, G., Tan, H. C., & Lee, C. H. (2014). Effects of gender on the prevalence of obstructive sleep apnea in patients with coronary artery disease. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 10*(12), 1279-1284. doi:10.5664/jcsm.4276 [doi]

Chapter II: Screening and Assessment for Obstructive Sleep Apnea in Primary Care

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Published in *Sleep Medicine Reviews*, 29, pp 41-51.

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The authors report no financial support, conflicts of interest or investigational use of product in the development of this manuscript. Acknowledgements:

We greatly appreciate Douglas Fiedler, M.D., Debra Romberger M.D, and Cynthia Schmidt M.D, MLS for their assistance in preparation of this manuscript.

Summary

Obstructive sleep apnea (OSA) is the most common sleep-related breathing disorder and contributes to increased morbidity and compromised cardiovascular outcomes. Sleep disorders are common but rarely reported and addressed by primary health providers. An American Academy of Sleep Medicine task force (2015) released quality measures for the care of adult patients with OSA; the first outcome is improved detection and categorization of OSA symptoms and severity to promote assessment and diagnosis of the disorder.

This state of the science integrative review aimed to evaluate the screening and assessment for OSA in primary care settings including the psychometric properties of OSA screening measures. Studies that met inclusion criteria were fourteen non-experimental and three experimental designs. OSA screening measurements (Berlin questionnaire, Epworth sleepiness scale, STOP Bang) with extensive validation studies were examined. Conclusions are that the current practice model of screening and assessment for OSA in primary care is fragmented and ineffective. Primary care providers encounter patients with OSA symptoms but do not routinely screen, assess, or refer to a sleep specialist. More psychometric research is needed for the OSA screening measurements in primary care. The results of these studies can be translated into practice to increase detection of OSA.

Keywords: assessment; cardiovascular; evaluation; obstructive sleep apnea; measurement; screening; sleep related breathing disorders

Abbreviations: AHI, apnea hypopnea index; BMI, body mass index; EMR, Electronic medical record; ESS, Epworth sleepiness scale; PAP, positive airway pressure; PCP, primary care provider; PSG, polysomnography; OSA, obstructive sleep apnea; US, United States

Chapter II: Screening and Assessment for Obstructive Sleep Apnea in Primary Care

Introduction

Obstructive sleep apnea (OSA) is the most common sleep-related breathing disorder (National Heart, Lung, and Blood Institute, 2012) and contributes to increased morbidity and compromised cardiovascular outcomes (Campos-Rodriguez et al., 2012; Kendzerska et al., 2014; Qaseem et al., 2014). The pathologic cardiovascular changes associated with OSA result from multifactorial etiologies. Repetitive obstructive events during sleep are hypothesized to cause intermittent hypoxia, resulting in activation of oxygen free radicals and an oxidative stress response. A concurrent inflammatory process suggests that damage to the vascular endothelium leads to atheroma formation and vascular events (Almendros et al., 2011; Xie et al., 2013). Epidemiological studies have concluded that untreated severe OSA is a large public health burden in terms of cardiac morbidity and mortality (D. J. Gottlieb et al., 2013; Kendzerska et al., 2014). In 2015, an American Academy of Sleep Medicine (AASM) task force released quality measures for the care of adult patients with OSA. The first quality measure outcome is to improve detection and categorization of OSA symptoms and severity (Aurora et al., 2015).

Bailes and colleagues (2008; 2009) surveyed primary care and sleep clinic patients and found that sleep disorders are common but rarely addressed by primary care providers (PCP). A Canadian population-based study found that patients often do not report sleep disturbance consequences to their PCP because their symptoms are chronic and difficult to explain (Bartlett, Marshall, Williams, & Grunstein, 2008). Daytime functioning complaints or insomnia symptoms are not recognized as consequences of OSA (Bailes et al., 2009). Congruently, many PCPs do not routinely screen or assess for sleep disturbances (Burgess, Havryk, Newton, Tsai, & Whitelaw, 2013; Grover et al., 2011). Patients present with known OSA risk factors, such as obesity and CVD, but are not screened for symptoms, assessed, or referred to a sleep specialist for diagnosis and treatment for the disorder (Jennum et al., 2013). Because PCPs and other clinicians fall short

in recognizing OSA, more education is needed to detect patients at high-risk for the sleep disorder.

Background

OSA can occur in any age group, but is most prevalent in older men (Kendzerska et al., 2014) and post-menopausal women (Zhao et al., 2014). OSA may be poorly recognized in pre-menopausal women because symptoms are often nonspecific, such as insomnia, headaches, or fatigue (Attarian & Viola-Saltzman, 2006). A recent population health study concluded that the incidence of OSA is increasing in men and women due to rising obesity rates and practitioners need to adopt a proactive approach to diagnosis (Adams et al., 2012). Cardiovascular disease is the leading cause of mortality in the United States (US) (J. I. Kim, Sillah, Boucher, Sidebottom, & Knickelbine, 2013). Both the National Institutes of Health (2013) and the American Heart Association (2013) have emphasized the need to improve cardiovascular health nationwide. OSA is associated with cardiovascular disease (Cassar et al., 2014; D. J. Gottlieb et al., 2014; D. J. Gottlieb et al., 2010; N. H. Kim et al., 2013; Young et al., 2008) and can exacerbate comorbid conditions (Colten & Altevogt, 2006), placing a significant burden on US health care system.

The US Preventative Task Force, the American Academy of Family Physicians, and the Center for Disease Control have not made recommendations for OSA screening or assessment (Senthilvel et al., 2011). No OSA practice guidelines have been released from any major internal or family practice organizations regarding screening and assessment. This demonstrates that sleep is undervalued in healthcare. The 2014 American College of Physicians summary includes use of screening questionnaires for individuals with unexplained daytime sleepiness (Qaseem et al., 2014). However, daytime sleepiness is often not reported by patients with OSA and screening for other symptoms is warranted (Bailes et al., 2009).

New Healthy People 2020 guidelines (2015) were released by the Office of Disease Prevention and Health Promotion and “Sleep Health” was listed as a national priority. Three objectives that are pertinent to improving health outcomes in persons with OSA are: (SH-1)

increasing the proportion of persons with symptoms of OSA who seek medical attention; (SH-2) reduce the rate of vehicular crashes per 100 million miles traveled that are due to drowsy driving; and (SH-4) increasing the proportion of adults who get sufficient sleep (Office of Disease Prevention and Health Promotion, 2015). With PCPs managing chronic conditions and acute events, there is often inadequate time for screenings that are not recommended (Sorscher, 2008). Awareness of the long-term impact of undiagnosed OSA on the cardiovascular system needs to stimulate increased OSA screenings in primary care.

Multiple treatment options for OSA have been shown to improve quality of life in patients with high adherence levels; however, positive airway pressure (PAP) therapy is considered the first line treatment for moderate to severe OSA (American Sleep Apnea Association, 2015). The AASM recommends using PAP therapy to reduce levels of daytime sleepiness and improve patients' quality of life (Aurora et al., 2015). Understanding the benefit of OSA treatments highlights the importance of screening for the sleep disorder.

This state of the science integrative review aimed to evaluate the screening and assessment for OSA in primary care settings including the psychometric properties of OSA screening measures. This paper is the first to focus on this issue. A critical evaluation of the current state of the science is provided as well as recommendations for future interdisciplinary research.

Methods

An electronic literature search was conducted by the authors and a medical librarian using the databases of Cumulative index to nursing and allied health literature (CINAL), Cochrane, Excerpt medical database (EMBASE), and PubMed. Other relevant publications were found via obtained articles. The time frame from January 1991- June 2014 was used to include the original article of the Epworth sleepiness scale. Keywords in the literature search included but were not limited to: "Obstructive sleep apnea", "adults", "sleep-related breathing disorders",

"screening", "assessment", "primary care", "primary care providers", "health care providers", "internal medicine", and "OSA screening tools".

Specific journal articles were included in the literature review based on the following criteria: 1. published in the English language, 2. participants studied in primary care setting/internal medicine, 3. providers practicing in primary care/internal medicine, 4. included an OSA screening process, 5. compared OSA screening tools, and 6. used OSA assessment criteria. Studies were excluded if: 1. conducted in any setting other than primary care/internal medicine, 2. focused on sleep disorders other than OSA, 3. discussed long-term management of OSA in primary care settings, 4. focused on management of OSA patients by sleep physicians, and 5. used children as participants. Adult OSA screening in primary care and internal medicine settings is the focus of this article because early detection of the sleep disorder can improve health and reduce risk of cardiovascular diseases. PCPs often see patients on a regular basis, allowing time to screen and assess for risk of chronic health conditions.

Search Results

In the initial search, 2,869 records were found. After deleting 553 duplicates, 2,316 records remained. Relevant articles were reviewed by the first author and the medical librarian and verified by the second author from the following databases: 63 in CINAL, 0 in Cochrane, 804 in EMBASE and 1,450 in PubMed. After implementing the exclusion criteria, 17 articles met criteria for this integrative literature review (Figure 1).

Definitions

Obstructive sleep apnea

Essential features of OSA include a repetitive partial (hypopnea) and/or complete (apnea) obstruction of the upper airway, marked by upper pharyngeal collapse with continuing efforts to breathe (Berry et al., 2014). These events can last 10 seconds or up to a minute in duration, and result in intermittent desaturations in oxyhemoglobin levels and sleep fragmentation. In obese

individuals, obstructive events in REM sleep have been associated with lower oxyhemoglobin desaturations (Peppard et al., 2009).

An AASM task force listed symptoms of OSA as loud snoring between apneas, witnessed episodes of gasping for air, choking, and the presence of daytime sleepiness. The severity of OSA is categorized as an individual's Apnea Hypopnea Index (AHI), which indicates how many times an hour the patient experiences obstructive events during polysomnography (PSG) testing (Epstein et al., 2009). AHI levels range from mild (≥ 5 and < 15), to moderate (15 ≥ and < 30), to severe (≥ 30) (Berry et al., 2014; Epstein et al., 2009; Guilleminault et al., 2007). Daytime excessive sleepiness, fatigue and feeling unrefreshed after sleep are common in most individuals with OSA and symptoms are exacerbated by more frequent apnic and hypopnic events (Epstein et al., 2009), these can be detected using sensitive and specific screening methods.

Screening

Screening for OSA needs to take place in any adult who reports OSA symptoms (Table 1) (Epstein et al., 2009). The definition for screening is "the act of doing a test on a person… to look for evidence of a disease" (Merriam-Webster Dictionary, 2014b). In primary care settings, the patient will most likely be screened by a mid-level provider (nurse practitioner and/or physician's assistant) or physician to determine if he/she is experiencing OSA symptoms. OSA screening currently takes place via the review of systems process but providers often do not include questions to detect sleep disturbances (Grover et al., 2011; Senthilvel et al., 2011). Screening needs to occur during a routine health maintenance assessment or as part of a comprehensive exam for high-risk patients (Epstein et al., 2009). Physiologic characteristics that place a person at high-risk of OSA are listed in Table 2.

PCPs need to focus on signs and symptoms of sleep disturbances while conducting their review of systems (Epstein et al., 2009). If the patient reports these symptoms, occupation should be addressed. The Federal Motor Carrier Safety Administration has not released regulations for OSA screening (Hartenbaum, 2010), but a recent expert review board recommended further

evaluation of any commercial driver with a body mass index (BMI) of 33 or higher (Federal Motor Carrier Safety Administration, 2008). An OSA screening measure can be used to predict OSA and to determine whether an assessment is warranted. A progressive model of care in Australia involved early referral by PCPs of symptomatic high-risk patients to sleep specialists (Mansfield, Antic, & McEvoy, 2013). Increased detection of OSA will lead to higher demand for sleep specialist services in the US. Mid-level providers can be trained to specialize in sleep disorders accommodate for the influx of patients.

The AASM Clinical Guidelines Task Force (2009) reached "consensus" that several questions can be asked by the PCP during routine health maintenance assessments. Asking about a history of snoring and daytime sleepiness lacks reliability and validity and has not resulted in increased referrals to sleep specialists. PCPs need to use a sensitive and specific measurement to identify symptomatic, high-risk patients for referral to a sleep specialist.

Measurement

OSA screening measures have been developed to aid health care providers in quickly screening patients for moderate to severe OSA in a variety of health care settings (Abrishami et al., 2010; Ramachandran & Josephs, 2009; Silva et al., 2011). Using sensitive and specific screening measures offers a cost-effective way to predict the presence of OSA and highlights the need to refer the patient to a sleep specialist. Measures with high positive predictive value are likely to predict the presence of a disease while those with high negative predicative values are likely to predict the absence of the disease. Screening measurements with extensive validation studies are discussed in this review. See Table 3 for detailed psychometric information on the most widely tested OSA screening measurements.

Berlin questionnaire. The Berlin questionnaire (1999) was developed by primary care and pulmonary physicians to predict the presence of OSA. The measurement has three symptom categories; the first has five unique questions concerning frequency (rare to often) of snoring and apneas while sleeping. The second category has four unique questions concerning daytime

sleepiness with a question about sleepiness while driving. A score is positive for category 1 and 2 when a patient selects two responses from the top levels. The third category has two questions. A positive response is when a patient has high blood pressure (> 140/90mmHg) or a BMI > 30kg/m^2. After scoring, the individual is considered to be high-risk if two or three of the categories are positive. The measurement was compared to home PSG testing; internal reliability testing showed category 1 (snoring) was acceptable but Category 2 (daytime sleepiness) was low (Netzer et al., 1999). Chung et al. (2008b) and El-Sayed (2012) found this questionnaire to have higher levels of sensitivity when compared to specificity. Netzer et al. (1999) reported inconsistent sensitivity and specificity levels. Low sensitivity and inconsistent levels of positive and negative predicative values are limitations (El-Sayed, 2012; Netzer et al., 1999). This OSA screening measure has documented psychometric properties in primary care settings (Chung, 2011).

Epworth sleepiness scale. The ESS (1991) was developed as a simple measure to quantify the level of daytime sleepiness in adults. The ESS is a brief scale that asks the subject to rate on a scale of 0-3 (0=none, 3=high chance of dozing) the level of sleepiness during eight daily activities. The sum of the eight questions is calculated and the higher the sum, the higher the sleep deficit (0-24). A score of ≥16 indicates a high level of daytime sleepiness (Johns, 1991). The ESS has been shown to be reasonably reliable in the test-retest sense, have high internal consistency (Johns, 1992), and inconsistent sensitivity and specificity values (El-Sayed, 2012; Silva et al., 2011). El-Sayed (2012) reported that the ESS has high positive predictive values but lower negative predictive values. The ESS has been used by PCPs to identify patients with daytime sleepiness (Silva et al., 2011). This may be problematic if used alone because OSA severity does not always correlate with symptomatic sleepiness (Ramachandran & Josephs, 2009).

STOP and STOP Bang Measurements. The STOP is an OSA screening measure that was developed to quickly and concisely screen for OSA in a pre-surgical population. The four

OSA predictor variables are snoring, tiredness, obstruction and high blood pressure on a Yes/No scale (Chung et al., 2008a). A pilot study found that the STOP questionnaire was effective in identifying patients with OSA, but the addition of four variables (BMI > 35kg/m, age >50 years old, neck circumference > 40 cm, and male gender) increased the sensitivity of the measurement (Chung et al., 2008a; El-Sayed, 2012; Silva et al., 2011).

The new variables were added to the measurement, creating the eight "yes/no" question acronym STOP Bang (Chung et al., 2008a; Chung et al., 2012). The person is given one point for each "yes" response. Scores range from 0 to 8, with ≥3 indicating a positive screen. El-Sayed (2012) reported that the sensitivity of the STOP Bang stayed consistent from the previous STOP version. Higher scores have been shown to correlate with the individual's OSA severity (AHI>5, sensitivity 0.836, AHI>15, sensitivity 0.923, AHI>30, sensitivity 1.0) (Chung et al., 2008b). Data are limited on the reliability of the STOP Bang in primary care settings.

With the differences in patient populations, demographics, and ethnicities, scientists must be mindful of the limitations of the psychometric data.

Assessment

A more comprehensive sleep history is recommended when an OSA screen is positive or the physician determines that further assessment is warranted (Epstein et al., 2009). Assessment is defined as "the act of making a judgment about something" (Merriam-Webster Dictionary, 2014a). No clinical measurement or assessment is absolutely predictive of the presence of OSA, but patients deemed high-risk for the disorder should trigger a referral to a sleep specialist for further evaluation (Epstein et al., 2009).

Assessments recommended are BMI, neck circumference, blood pressure, and a visual examination of the oro-naso-pharynx. Determining a Mallampati score is helpful in assessing posterior pharyngeal crowding caused by increased upper airway soft tissue or abnormal facial structures. Higher scores have been correlated with OSA severity ($r= 0.351$, $p= 0.008$) and may predict nighttime obstructive events. A class 1 Mallampati score is visualization of the entire soft

palate; severity ranges to a class 4, which is the inability to see any part of the soft palate. A referral to a sleep specialist is indicated when the health care provider determines the patient is at-risk for OSA (Epstein et al., 2009).

The assessment for OSA should include an examination of the cardiovascular and respiratory systems (Epstein et al., 2009). Untreated OSA can occur in persons with hypertension (Walia et al., 2014), along with other conditions such as stroke (C. Chen et al., 2015) and Type II diabetes (Wang et al., 2013). Untreated OSA in presence of dilated cardiomyopathy or ischemic heart disease can lead to the development of congestive heart failure (D. J. Gottlieb et al., 2010). Patients with severe untreated OSA, who also have chronic obstructive pulmonary disease, are at higher risk of developing pulmonary hypertension and cor pulmonale. When screening and assessment indicate that a patient found is at high-risk for OSA, their referral process must be expedited for timely diagnosis and treatment (Epstein et al., 2009).

Findings

This state of the science integrative review aimed to evaluate the screening and assessment for OSA in primary care settings including the psychometric properties of OSA screening measures. The literature published in this area consists of 14 non-experimental and 3 experimental designs (Table 4). All studies were conducted in the US unless otherwise stated.

Non-Experimental Designs

Cross-sectional descriptive studies. Seven studies aimed to screen undiagnosed, high-risk populations for presence of OSA symptoms. Five studies focused on the importance of early screening in high-risk patient populations in several countries (Alam, Chengappa, & Ghinassi, 2012; BaHammam, Alrajeh, Al-Jahdali, & BinSaeed, 2008; BaHammam, Al-Rajeh, Al-Ibrahim, Arafah, & Sharif, 2009; Burgess et al., 2013; Haponik et al., 1996; Netzer et al., 2003). One Israeli primary care office developed a symptom checklist to assess PCPs awareness of OSA during patient interactions (Reuveni et al., 2004). Burgess et al.(Burgess et al., 2013), used a two channel OSA screening device in Australia.

PSYCHOMETRIC PROPERTIES

BaHammam and colleagues (2009), reported a 39% prevalence of severe OSA symptoms in middle aged Saudi women and 33.3% in middle aged Saudi men (BaHammam et al., 2008) using the Berlin questionnaire. Netzer et al. (2003) performed a standardized survey of primary care patients to assess OSA risk factors and symptom frequency in a variety of countries (US, Germany, Spain). The survey results indicated that adults in the US had a higher likelihood of being at high-risk compared to adults in the European countries. Alam and colleagues (2012) screened primary care patients with severe mental illness for OSA using the STOP Bang and ESS. A high percentage of the patients with severe mental illness screened positive for OSA using the STOP Bang when compared to the ESS. The majority of patients screened as high-risk for OSA had never discussed the disorder with their PCP (Alam et al., 2012).

Burgess et al. (2013) used an unattended 2- channel OSA screening device, called ApneaLink+O_2, in high-risk patients. A high diagnostic accuracy was found in the OSA moderate to severe range compared to PSG. Haponik et al. (1996) used medical interns to pose as primary care patients. The histories taken by PCPs were analyzed to determine if unsolicited questions were asked regarding snoring, non-restorative sleep, day time sleepiness, or witnessed apneas. PCPs did not ask about signs of OSA or educate the patients on risk factors for the disorder (Haponik et al., 1996).

Reuveni et al. (2004) assessed the awareness level of OSA symptoms in PCP in Israel by providing standardized patient scenarios to indicate the need for further sleep disordered breathing assessment. PCPs understood the algorithms for diagnosis of the disorder but could not identify patients in need of diagnosis and treatment. The authors recommended development of educational programs to increase PCP's knowledge of OSA (Reuveni et al., 2004).

Overall, the studies were consistent in reporting OSA symptoms and risk factors in primary care patients. PCPs often encounter patients who are in need of further assessment, diagnosis, and treatment but for various reasons, are referred to a sleep specialist.

Retrospective studies. Four studies were found that retrospectively examined OSA screening and assessment in primary care patients. A Canadian study used prospective and retrospective methods and encouraged participants to complete a sleep symptom checklist to discuss with their health care provider during a sleep screening process. Researchers followed-up after one year and found that 13.6% accepted further sleep evaluation and completed overnight PSG (Bailes et al., 2009). One retrospective chart review evaluated what sleep history questions were asked during the screening process. Kramer et al. (1999) found that only a small group of physicians ordered sleep studies and the patients that were referred tended to be obese and to have overt OSA symptoms. Sorscher (Sorscher, 2008) used a health database to determine if family medicine physicians asked sleep disorder questions such as hypersomnolence and sleep disordered breathing, insomnia, and parasomnias. Family medicine clinics didn't screen for sleep disorders as often as lifestyle/behavioral issues.

An Australian population-based survey described the prevalence of persons visiting their primary care physicians for insomnia and/or OSA symptoms. , A population-weighted prevalence for reporting a doctor visit for snoring/sleep apnea symptoms was 6.2% (Bartlett et al., 2008).

In summary, most of the studies found that PCPs rarely screen for OSA symptoms without prompting from the patient (Bailes et al., 2009; Bartlett et al., 2008; Sorscher, 2008). When screening did occur, very few patients were referred to a sleep specialist and many mentioned symptoms without follow-up from health care providers (Kramer et al., 1999).

Correlational descriptive studies. Two correlational descriptive design studies used at least one OSA screening measurement (Berlin questionnaire, Cleveland sleep habits questionnaire, ESS or STOP) to help identify patients who were at high-risk (Demede et al., 2011; Senthilvel et al., 2011). Senthilvel et al. (2011) found that only one of the 111 subjects was suspected of having OSA by the blinded physicians. The PCP's did not routinely screen for OSA, which may have been influenced by lack of time and reimbursement. The authors suggested PCP

use valid and reliable measurements to screen for OSA to better identify high-risk patients (Senthilvel et al., 2011).

Demede et al. (2011) studied the prevalence of resistant hypertension in African-American patients and determined if they were at high-risk for OSA using the ESS via an Apnea risk evaluation system. Patients with resistant hypertension were at 2.5 times higher risk for OSA than those with treatable hypertension; conclusions were that comorbid conditions are a public health concern in African-Americans. Diagnosing and treating patients with OSA reduces cardiovascular risk and improves outcomes for persons with resistant hypertension (Demede et al., 2011; Dernaika, Kinasewitz, & Tawk, 2009).

Mixed method study. Mold et al. (2011) used a mixed method design to determine the proportion of primary care patients at high-risk for OSA, the methods used by primary care clinicians to identify them, and the proportion of those at high-risk who were diagnosed and treated. Primary care offices were randomly selected in five US states to conduct physician and patient interviews/assessments using the Berlin questionnaire and chart audits. Sleep consultants were also interviewed to discuss referrals for OSA diagnostics. Findings were that OSA patients were more accurately detected with the Berlin Questionnaire. Less than 25% of the PCPs screened patients routinely for OSA using a review of systems method. According to the PCP qualitative interviews, 84% of patients referred to a sleep specialist were positive for OSA. Findings from this study indicate that 70-99% of primary care patients who were referred to a sleep specialist had untreated severe OSA. This study exemplifies scientific rigor in sleep research.

Overall, these studies reported that PCPs often did not detect OSA symptoms. Screening measures used in the studies assisted the PCPs in identifying at-risk patients (Demede et al., 2011; Senthilvel et al., 2011).

Experimental Designs.

The authors identified three experimental design studies that used different methodologies. Both Grover et al. (2011) and Namen et al (1999) used a prospective, two-group design. Grover et al (2011) studied adults undergoing preventative exams at family medicine clinics and determined whether a review of systems form identified sleep complaints. Approximately one-third of participants reported sleep problems on the review of systems form and less than one-fourth of complaints were documented by the PCPs. The review of systems form identified persons with OSA when used as a screening measure but few sleep complaints were investigated by PCPs. Namen et al. (1999), studied the frequency of sleep history documentation and assessed whether randomized chart reminders prompted physicians to conduct sleep histories. Each of the physicians were randomly assigned one chart with a sleep history prompt and one without. The chart reminders increased the number of documented sleep histories but sleep disturbance reports did not impact diagnosis or treatment of the patients' disorders.

Ball et al. (1997) aimed to increase recognition of sleep disorders by PCPs in rural western US via patient questionnaires, PSG, and chart reviews. The researchers held a training session for PCPs taught by sleep specialists, who then taught PCPs how to interpret sleep testing data. Prior to the intervention, few charts had documentation of a sleep-related condition. Post intervention, the majority of PCPs ordered PSGs for their patients. Using sleep specialists to train rural PCPs in sleep medicine is an example of a cost -effective way to use interdisciplinary teamwork to increase access to OSA diagnostic testing.

Overall, these studies demonstrated that interventions that used a review of systems form or chart reminders can increase documentation of sleep complaints. Likewise, specialized sleep training for PCPs may increase referrals for sleep consultations and PSGs.

Discussion

This integrative review will now discuss the strengths, limitations, and implications related to the state of the science of screening and assessment for OSA in primary care settings including the psychometric properties of OSA screening measures. The strengths of the literature

are the overall consensus that there needs to be routine screening and assessment for OSA in primary care settings. The results support findings that OSA is associated with exacerbation of comorbid conditions and risk for increased mortality and morbidity (Alam et al., 2012; BaHammam et al., 2008; BaHammam et al., 2009; Ball et al., 1997; Burgess et al., 2013; Haponik et al., 1996; Mold et al., 2011; Netzer et al., 2003). The authors conclude that there is a lack of recognition of OSA symptoms by PCPs, whether or not the patient complains of daytime sleepiness (Bailes et al., 2009; Bartlett et al., 2008; Namen et al., 1999; Sorscher, 2008). Even more concerning is the agreement that PCPs are aware of the need to improve cardiovascular health, but aren't proactive in screening and assessment for OSA (Demede et al., 2011; Grover et al., 2011; Kramer et al., 1999; Reuveni et al., 2004; Senthilvel et al., 2011). This may be because screening measures need to demonstrate higher sensitivity, specificity, and predictive values before PCPs will adopt them. Findings report inconsistent psychometric findings for OSA screening measures with a lack of validation research in primary care (Abrishami et al., 2010; El-Sayed, 2012; Ramachandran & Josephs, 2009; Silva et al., 2011). PCP must recognize the importance of referrals to sleep specialists to earlier diagnose and treat OSA and improve patient outcomes. Overall, this review showed that the current practice model of screening and assessment for OSA in primary care is fragmented and ineffective.

This state of the science on screening and assessment of OSA patients in primary care settings is not without limitations. Not all OSA screening measurements that have been reported to be reliable and valid in primary care settings were included. Some studies may have been missed during the literature search process. No studies reported information on patients' willingness to be referred to sleep specialists. Lastly, several included studies did not explicitly state the research design and only one used participant randomization.

Implications for Research

Currently, there is no guideline for OSA screening in primary care. Studies are needed to further test a review of systems form or chart reminders. Inadequate screening is due in part to

inconsistent psychometric results from current OSA screening measures. More validation testing of the OSA screening measures is needed in primary care before a conclusion can be made regarding which tool has the best OSA predictability. Before a guideline can be developed, the OSA measurements used in primary care need to have high levels of sensitivity, specificity, and positive predictive values to reliably screen patients for OSA. The testing of OSA screening instruments must be conducted in large-scale, nationwide, studies that assess implementation in primary care settings. Considerations for a reference standard might include identification of adults with signs and symptoms, or conditions, associated with high risk for OSA. The development of an OSA screening guideline might reduce cardiovascular mortality in at-risk patients as long as the patient is adherent to the prescribed treatment. This is an area where research can have a large impact on cardiovascular health nationwide.

The AASM (2015) has recommended the integration of screening for sleep disorders in the Electronic medical record (EMR) as a health care priority. A task force is currently developing a series of sleep-related data fields. Future screening and assessment protocols may be integrated into the EMR to standardize the process. Translational research needs to provide evidence for using the EMR as a database for OSA screening and referrals from PCPs to sleep specialists.

Conclusion

Screening and assessment for OSA needs to be a priority in primary care settings. PCPs need to use measurements that accurately predict the presence of OSA. The STOP Bang and Berlin questionnaires serve as the current best measures to predict the presence of moderate to severe OSA (Ramachandran & Josephs, 2009; Silva et al., 2011). The ESS is a measure of daytime sleepiness (Johns, 1991) that can be used to help determine the level of daytime impairment. The STOP Bang and the Berlin questionnaires have the highest sensitivity of the measurements studied but at the expense of specificity (El-Sayed, 2012). The measurements do not perform well at excluding low risk for OSA. It is unclear at this time due to inconsistencies of

the psychometric properties which screening measure best predicts OSA in the primary care setting. More research is needed to determine psychometric properties of OSA screening measurements in primary care. The results from these studies can be translated into practice to better detect OSA in primary care patients.

PCPs need to be educated on how to detect OSA and its long-term effects on cardiovascular morbidity and mortality. Increased use of reliable and sensitive OSA screening tools in primary care will lead to earlier and more frequent detection of the sleep disorder and to a higher demand of sleep specialists' services. More mid-level providers (nurse practitioners and physician assistants) will need to be trained in sleep medicine to care for the influx of patients.

It is important to diagnose and treat OSA and cardiovascular disease as co- morbid conditions. By screening and assessing patients who are at risk for OSA in primary care settings, cardiovascular outcomes may stabilize and/or improve. Few studies have reported the screening and assessment process of OSA in primary care settings. The current state of the science will benefit from research on the psychometric properties of OSA screening measures in primary care settings.

PSYCHOMETRIC PROPERTIES

Practice Points

1. Adults often present with signs and symptoms or conditions associated with high risk for OSA but are not screened, assessed, or referred to a sleep specialist for diagnosis and treatment.

2. When an OSA screen is positive recommendations are to assess BMI, neck circumference, blood pressure and Mallampati score.

3. Reliable and valid measurements offer a cost effective way to screen for OSA and, when indicated, to expedite referral to a sleep specialist.

Research Agenda

1. Conduct more validation testing of the OSA screening measures in primary care before a conclusion is made of which tool has strongest predictability

2. Develop an evidence-based OSA screening guideline to promote earlier detection of the disorder.

3. Determine whether embedding OSA screening and assessment guideline in the EMR results in increased number of patients screened, assessed, diagnosed, and treated.

References

Abrishami, A., Khajehdehi, A., & Chung, F. (2010). A systematic review of screening questionnaires for obstructive sleep apnea. *Canadian Journal of Anesthesia/Journal Canadien D'Anesthésie, 57*(5), 423-438.

Adams, R. J., Piantadosi, C., Appleton, S. L., Hill, C. L., Visvanathan, R., Wilson, D. H., & McEvoy, R. D. (2012). Investigating obstructive sleep apnoea: will the health system have the capacity to cope? A population study. *Australian Health Review, 36*(4), 424-429.

Alam, A., Chengappa, K., & Ghinassi, F. (2012). Screening for obstructive sleep apnea among individuals with severe mental illness at a primary care clinic. *General Hospital Psychiatry, 34*(6), 660-664.

Almendros, I., Farré, R., Torres, M., Bonsignore, M. R., Dalmases, M., Ramírez, J., . . . Montserrat, J. M. (2011). Early and mid-term effects of obstructive apneas in myocardial injury and inflammation. *Sleep Medicine, 12*(10), 1037-1040. doi:10.1016/j.sleep.2011.07.009

American Academy of Sleep Medicine. (2015). EHR Integration Task Force: Committee Members. Retrieved from http://www.aasmnet.org/emrtaskforce.aspx

American Sleep Apnea Association. (2015). Varieties of OSA Surgery. Retrieved from http://www.sleepapnea.org/treat/treatment-options/surgery.html

Attarian, H. P., & Viola-Saltzman, M. (2006). *Sleep Disorders in Women* Springer.

Aurora, R. N., Collop, N. A., Jacobowitz, O., Thomas, S. M., Quan, S. F., & Aronsky, A. J. (2015). Quality Measures for the Care of Adult Patients with Obstructive Sleep Apnea.

Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, doi:jc-00031-15 [pii]

BaHammam, A. S., Al-Rajeh, M. S., Al-Ibrahim, F. S., Arafah, M. A., & Sharif, M. M. (2009). Prevalence of symptoms and risk of sleep apnea in middle-aged Saudi women in primary care. *Saudi Medical Journal, 30*(12), 1572-1576.

BaHammam, A. S., Alrajeh, M. S., Al-Jahdali, H. H., & BinSaeed, A. A. (2008). Prevalence of symptoms and risk of sleep apnea in middle-aged Saudi males in primary care. *Saudi Medical Journal, 29*(3), 423-426.

Bailes, S., Baltzan, M., Rizzo, D., Fichten, C. S., Amsel, R., & Libman, E. (2008). A diagnostic symptom profile for sleep disorder in primary care patients. *Journal of Psychosomatic Research, 64*(4), 427-433.

Bailes, S., Baltzan, M., Rizzo, D., Fichten, C. S., Grad, R., Wolkove, N., . . . Libman, E. (2009). Sleep disorder symptoms are common and unspoken in Canadian general practice. *Family Practice, 26*(4), 294-300. doi:10.1093/fampra/cmp031 [doi]

Ball, E. M., Simon, R. D.,Jr, Tall, A. A., Banks, M. B., Nino-Murcia, G., & Dement, W. C. (1997). Diagnosis and treatment of sleep apnea within the community. The Walla Walla Project. *Archives of Internal Medicine, 157*(4), 419-424.

Bartlett, D. J., Marshall, N. S., Williams, A., & Grunstein, R. R. (2008). Predictors of primary medical care consultation for sleep disorders. *Sleep Medicine, 9*(8), 857-864.

Berry, R. B., Brooks, R., Gamaldo, C. E., Harding, S. M., Lloyd, R. M., Marcus, C. L., & Vaughn, B. V. (2014). for the American Academy of Sleep Medicine The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical

Specifications. Darien, IL: American Academy of Sleep Medicine; 2014. Version 2.0.3. *American Academy of Sleep Medicine: Darien, IL, USA,*

Burgess, K. R., Havryk, A., Newton, S., Tsai, W. H., & Whitelaw, W. A. (2013). Targeted case finding for OSA within the primary care setting. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 9*(7), 681-686. doi:10.5664/jcsm.2838 [doi]

Campos-Rodriguez, F., Martinez-Garcia, M. A., de la Cruz-Moron, I., Almeida-Gonzalez, C., Catalan-Serra, P., & Montserrat, J. M. (2012). Cardiovascular mortality in women with obstructive sleep apnea with or without continuous positive airway pressure treatment: a cohort study. *Annals of Internal Medicine, 156*(2), 115-122.

Cassar, A., Morgenthaler, T. I., Rihal, C. S., Prasad, A., Lennon, R. J., Lerman, L. O., & Lerman, A. (2014). Coronary endothelial function in patients with obstructive sleep apnea. *Coronary Artery Disease, 25*(1), 16-22. doi:10.1097/MCA.0000000000000063 [doi]

Chen, C., Chen, C., Yu, C., Chen, T., Tseng, S., & Ho, C. (2015). *Association of inflammation and oxidative stress with obstructive sleep apnea in ischemic stroke patients*. Netherlands: Elsevier Science. doi:10.1016/j.sleep.2014.07.027

Chung, F. (2011). Screening for obstructive sleep apnea syndrome in the preoperative patients. *The Open Anesthesiol J, 5*, 7-11.

Chung, F., Subramanyam, R., Liao, P., Sasaki, E., Shapiro, C., & Sun, Y. (2012). High STOP-Bang score indicates a high probability of obstructive sleep apnoea. *British Journal of Anaesthesia, 108*(5), 768-775. doi:10.1093/bja/aes022 [doi]

Chung, F., Yegneswaran, B., Liao, P., Chung, S. A., Vairavanathan, S., Islam, S., . . . Shapiro, C. M. (2008a). STOP questionnaire: a tool to screen patients for obstructive sleep apnea. *Anesthesiology, 108*(5), 812-821. doi:10.1097/ALN.0b013e31816d83e4 [doi]

Chung, F., Yegneswaran, B., Liao, P., Chung, S. A., Vairavanathan, S., Islam, S., . . . Shapiro, C. M. (2008b). Validation of the Berlin questionnaire and American Society of Anesthesiologists checklist as screening tools for obstructive sleep apnea in surgical patients. *Anesthesiology, 108*(5), 822-830. doi:10.1097/ALN.0b013e31816d91b5 [doi]

Colten, H. R., & Altevogt, B. M. (2006). In Colten H. R., Altevogt B. M. (Eds.), *Sleep disorders and sleep deprivation: An unmet public health problem*. Washington, DC, US: National Academies Press.

Demede, M., Pandey, A., Zizi, F., Bachmann, R., Donat, M., McFarlane, S. I., . . . Ogedegbe, G. (2011). Resistant hypertension and obstructive sleep apnea in the primary-care setting. *International Journal of Hypertension, 2011*, 340929. doi:10.4061/2011/340929 [doi]

Dernaika, T. A., Kinasewitz, G. T., & Tawk, M. M. (2009). Effects of nocturnal continuous positive airway pressure therapy in patients with resistant hypertension and obstructive sleep apnea. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 5*(2), 103-107.

El-Sayed, I. H. (2012). Comparison of four sleep questionnaires for screening obstructive sleep apnea. *Egyptian Journal of Chest Diseases and Tuberculosis, 61*(4), 433-441.

Epstein, L. J., Kristo, D., Strollo, P. J.,Jr, Friedman, N., Malhotra, A., Patil, S. P., . . . Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. (2009). Clinical guideline for the evaluation, management and long-term care of obstructive sleep

apnea in adults. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 5*(3), 263-276.

Federal Motor Carrier Safety Administration. (2008). Expert panel recommendations on obstructive sleep apnea and commercial motor vehicle driver safety. Retrieved from http://www.mrb.fmcsa.dot.gov/documents/Final_Meet_Min_Jan28_2008_MRB_Meet_Revised_Upd_2-19-09.pdf

Gottlieb, D. J., Punjabi, N. M., Mehra, R., Patel, S. R., Quan, S. F., Babineau, D. C., . . . Lewis, E. F. (2014). CPAP versus oxygen in obstructive sleep apnea. *New England Journal of Medicine, 370*(24), 2276-2285.

Gottlieb, D. J., Craig, S. E., Lorenzi-Filho, G., Heeley, E., Redline, S., McEvoy, R. D., & Duran-Cantolla, J. (2013). Sleep apnea cardiovascular clinical trials-current status and steps forward: The international collaboration of Sleep Apnea Cardiovascular Trialists. *Sleep, 36*(7), 975-980. doi:10.5665/sleep.2790 [doi]

Gottlieb, D. J., Yenokyan, G., Newman, A. B., O'Connor, G. T., Punjabi, N. M., Quan, S. F., . . . Shahar, E. (2010). Prospective study of obstructive sleep apnea and incident coronary heart disease and heart failure: the sleep heart health study. *Circulation, 122*(4), 352-360. doi:10.1161/CIRCULATIONAHA.109.901801 [doi]

Grover, M., Mookadam, M., Armas, D., Bozarth, C., Castleberry, T., Gannon, M., . . . Dueck, A. (2011). Identifying patients at risk for obstructive sleep apnea in a primary care practice. *Journal of the American Board of Family Medicine : JABFM, 24*(2), 152-160. doi:10.3122/jabfm.2011.02.100193 [doi]

Guilleminault, C., Benbir, G., & Aktar, N. (2007). Obstructive Sleep Apnea. In N. Butkov, & T. Lee-Chiong (Eds.), *Fundamentals of Sleep Technology* (pp. 113). Philadelphia, PA: Lippincott, Williams and Wilkins.

Haponik, E. F., Frye, A. W., Richards, B., Wymer, A., Hinds, A., Pearce, K., . . . Konen, J. (1996). Sleep history is neglected diagnostic information. *Journal of General Internal Medicine, 11*(12), 759-761.

Hartenbaum, N. P. (2010). The commercial motor vehicle driver medical examination: practical issues. *American Family Physician, 81*(8), 975-980.

Jennum, P., Ibsen, R., & Kjellberg, J. (2013). Morbidity prior to a diagnosis of sleep-disordered breathing: a controlled national study. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 9*(2), 103-108. doi:10.5664/jcsm.2398 [doi]

Johns, M. W. (1991). A new method for measuring daytime sleepiness: the Epworth Sleepiness Scale. *Sleep, 14*(6), 540-545.

Johns, M. W. (1992). Reliability and factor analysis of the Epworth Sleepiness Scale. *Sleep, 15*(4), 376-381.

Kendzerska, T., Gershon, A. S., Hawker, G., Leung, R. S., & Tomlinson, G. (2014). Obstructive sleep apnea and risk of cardiovascular events and all-cause mortality: A decade-long historical cohort study. *PLoS Medicine, 11*(2), e1001599.

Kim, J. I., Sillah, A., Boucher, J. L., Sidebottom, A. C., & Knickelbine, T. (2013). Prevalence of the American Heart Association's "ideal cardiovascular health" metrics in a rural, cross-

sectional, community-based study: the Heart of New Ulm Project. *Journal of the American Heart Association, 2*(3), e000058-e000058. doi:10.1161/JAHA.113.000058

Kim, N. H., Cho, N. H., Yun, C. H., Lee, S. K., Yoon, D. W., Cho, H. J., . . . Shin, C. (2013). Association of obstructive sleep apnea and glucose metabolism in subjects with or without obesity. *Diabetes Care, 36*(12), 3909-3915. doi:10.2337/dc13-0375 [doi]

Kramer, N. R., Cook, T. E., Carlisle, C. C., Corwin, R. W., & Millman, R. P. (1999). The role of the primary care physician in recognizing obstructive sleep apnea. *Archives of Internal Medicine, 159*(9), 965-968.

Mansfield, D. R., Antic, N. A., & McEvoy, R. D. (2013). How to assess, diagnose, refer and treat adult obstructive sleep apnoea: a commentary on the choices. *Med J Aust, 199*, 21-26.

Melvin, C. L., Corbie-Smith, G., Kumanyika, S. K., Pratt, C. A., Nelson, C., Walker, E. R., . . . Ricketts, T. C. (2013). Developing a research agenda for cardiovascular disease prevention in high-risk rural communities. *American Journal of Public Health, 103*(6), 1011-1021. doi:10.2105/AJPH.2012.300984

Merriam-Webster Dictionary. (2014a). Assessment. Retrieved from http://www.merriam-webster.com/dictionary/assessment

Merriam-Webster Dictionary. (2014b). Screening. Retrieved from http://www.merriam-webster.com/dictionary/screening

Mold, J. W., Quattlebaum, C., Schinnerer, E., Boeckman, L., Orr, W., & Hollabaugh, K. (2011). Identification by primary care clinicians of patients with obstructive sleep apnea: a practice-based research network (PBRN) study. *Journal of the American Board of Family Medicine : JABFM, 24*(2), 138-145. doi:10.3122/jabfm.2011.02.100095 [doi]

Namen, A. M., Wymer, A., Case, D., & Haponik, E. F. (1999). Performance of Sleep Histories in an Ambulatory Medicine ClinicImpact of Simple Chart Reminders. *CHEST Journal, 116*(6), 1558-1563.

National Heart, Lung, and Blood Institute. (2012). What is Sleep Apnea? Retrieved from http://www.nhlbi.nih.gov/health/health-topics/topics/sleepapnea

Netzer, N. C., Hoegel, J. J., Loube, D., Netzer, C. M., Hay, B., Alvarez-Sala, R., & Strohl, K. P. (2003). Prevalence of symptoms and risk of sleep apnea in primary care. *CHEST Journal, 124*(4), 1406-1414.

Netzer, N. C., Stoohs, R. A., Netzer, C. M., Clark, K., & Strohl, K. P. (1999). Using the Berlin Questionnaire to identify patients at risk for the sleep apnea syndrome. *Annals of Internal Medicine, 131*(7), 485-491.

Office of Disease Prevention and Health Promotion. (2015). Healthy People 2020: Sleep Health. Retrieved from http://www.healthypeople.gov/2020/topics-objectives/topic/sleep-health/objectives

Peppard, P. E., Ward, N. R., & Morrell, M. J. (2009). The impact of obesity on oxygen desaturation during sleep-disordered breathing. *American Journal of Respiratory and Critical Care Medicine, 180*(8), 788-793.

Qaseem, A., Dallas, P., Owens, D. K., Starkey, M., Holty, J. C., & Shekelle, P. (2014). Diagnosis of obstructive sleep apnea in adults: a clinical practice guideline from the American College of Physicians. *Annals of Internal Medicine, 161*(3), 210-220. doi:10.7326/M12-3187

Ramachandran, S. K., & Josephs, L. A. (2009). A meta-analysis of clinical screening tests for obstructive sleep apnea. *Anesthesiology, 110*(4), 928-939. doi:10.1097/ALN.0b013e31819c47b6 [doi]

Reuveni, H., Tarasiuk, A., Wainstock, T., Ziv, A., Elhayany, A., & Tal, A. (2004). Awareness level of obstructive sleep apnea syndrome during routine unstructured interviews of a standardized patient by primary care physicians. *Sleep, 27*(8), 1518-1525.

Senthilvel, E., Auckley, D., & Dasarathy, J. (2011). Evaluation of sleep disorders in the primary care setting: history taking compared to questionnaires. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 7*(1), 41-48.

Silva, G. E., Vana, K. D., Goodwin, J. L., Sherrill, D. L., & Quan, S. F. (2011). Identification of patients with sleep disordered breathing: comparing the four-variable screening tool, STOP, STOP-Bang, and Epworth Sleepiness Scales. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 7*(5), 467-472. doi:10.5664/JCSM.1308 [doi]

Sorscher, A. J. (2008). How is your sleep: a neglected topic for health care screening. *Journal of the American Board of Family Medicine : JABFM, 21*(2), 141-148. doi:10.3122/jabfm.2008.02.070167 [doi]

Walia, H. K., Li, H., Rueschman, M., Bhatt, D. L., Patel, S. R., Quan, S. F., . . . Mehra, R. (2014). Association of severe obstructive sleep apnea and elevated blood pressure despite antihypertensive medication use. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 10*(8), 835-843. doi:10.5664/jcsm.3946 [doi]

Wang, X., Bi, Y., Zhang, Q., & Pan, F. (2013). Obstructive sleep apnoea and the risk of type 2 diabetes: A meta-analysis of prospective cohort studies. *Respirology, 18*(1), 140-146. doi:10.1111/j.1440-1843.2012.02267.x

Xie, X., Pan, L., Ren, D., Du, C., & Guo, Y. (2013). Effects of continuous positive airway pressure therapy on systemic inflammation in obstructive sleep apnea: a meta-analysis. *Sleep Medicine, 14*(11), 1139-1150.

Young, T., Finn, L., Peppard, P. E., Szklo-Coxe, M., Austin, D., Nieto, F. J., . . . Hla, K. M. (2008). Sleep disordered breathing and mortality: eighteen-year follow-up of the Wisconsin sleep cohort. *Sleep, 31*(8), 1071-1078.

Zhao, L. P., Tan, A., Tai, B. C., Loo, G., Tan, H. C., & Lee, C. H. (2014). Effects of gender on the prevalence of obstructive sleep apnea in patients with coronary artery disease. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 10*(12), 1279-1284. doi:10.5664/jcsm.4276 [doi]

Figure 1: Literature Search Results

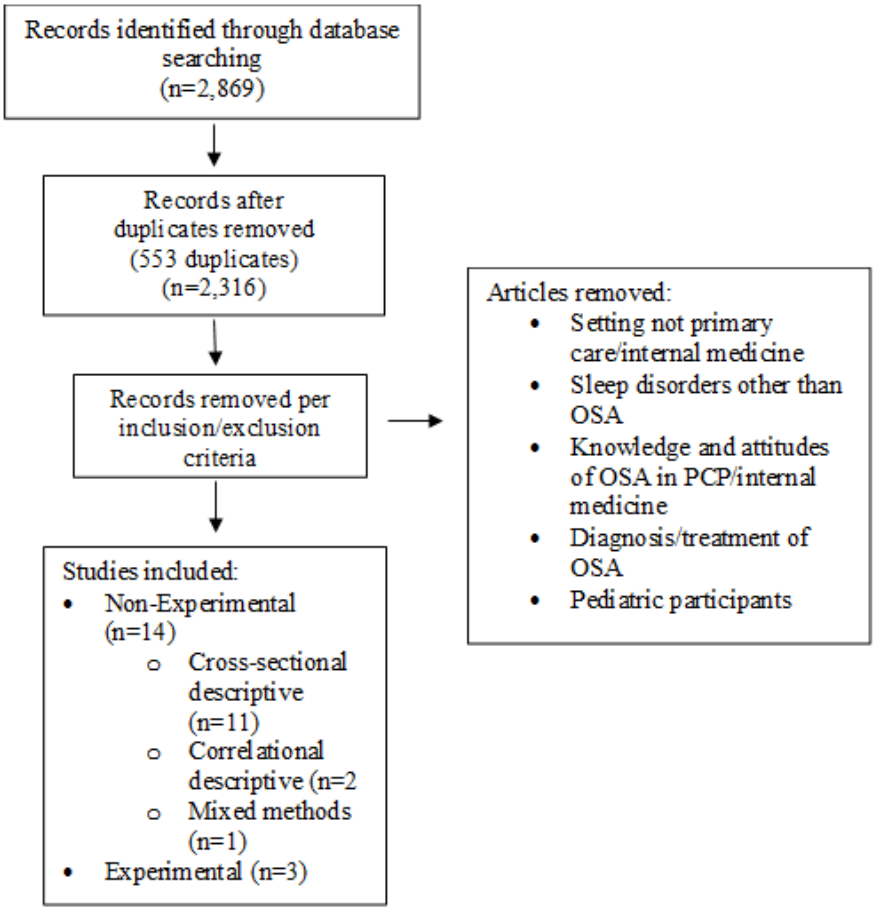

Table 1

OSA Signs and Symptoms

a. Snoring

b. Witnessed apneas

c. Nocturnal gasping/choking

d. Unexplained daytime sleepiness

e. Large neck size (≥ 17 inches for men, ≥ 16 inches for women)

f. Sleep fragmentation/insomnia

g. Non refreshing sleep

Adapted from Epstein et al. (2009)

Table 2

Conditions Associated with High Risk of Obstructive Sleep Apnea

a. Obesity (BMI>35)

b. Cardiac or metabolic comorbid conditions (congestive heart failure, atrial fibrillation, hypertension, Type 2 Diabetes, nocturnal cardiac dysrhythmias, stroke, pulmonary hypertension)

c. Pre-operative bariatric surgery

Adapted from Epstein et al. (2009)

Table 3

Psychometric Properties of OSA Screening Measurements

OSA instruments (year), Country	**Population /Country**	**Number of items**	**Reliability (95% CI)**	**Sensitivity/Specificity (95% CI) (AHI ≥ 15)**	**PPV/NPV (95% Cl) (AHI ≥ 15)**
Berlin questionnaire (1992), Germany[41]	Primary care, Germany[41]	Category 1 (5 questions)	Category 1 α = 0.92	0.54/0.97[41]	PPV=0.97[41]
			Category 2 α = 0.63[41]		
	Perioperative, Canada[42]	Category 2 (4 questions)		0.79 (0.67, 0.88)/ 0.51 (0.41, 0.62)[42]	0.51 (0.42, 0.61)/ 0.78 (0.67, 0.87)[42]
	Sleep clinic, Egypt[43]	Category 3 (1 question)[41]		0.95 (0.91, 0.98)/ 0.07 (0.01-0.24)[43]	0.87 (0.82, 0.91)/ 0.20 (0.03-0.56)[43]
Epworth sleepiness scale (ESS) (1991), Australia[45]	Persons with sleep disorders and controls, Australia[45]	8[45]	α= 0.88[46]	0.39, 0.71[40]	
	Medical students, Australia[46]			0.76 (0.69-0.82)/ 0.48 (0.29, 0.68)[43]	0.91 (0.85, 0.95)/ 0.23 (0.13, 0.36)[43]
	Persons with cardiovascular disease, United States[40]				
	Sleep clinic, Egypt[43]				

STOP (2008), Canada[47]	Perioperative, Canada[47,48] Persons with cardiovascular disease, United States[40] Sleep clinic, Egypt[43]	4[47]	Test-retest, k= 0.93 (0.82-1.00)[47]	0.74 (0.62, 0.84)/ 0.53 (0.43, 0.63)[47,48] 0.62/0.56[40] 0.95 (0.89, 0.97)/ 0.26 (0.11, 0.46)[43]	0.51 (0.41, 0.60)/ 0.76 (0.64,0.85)[47,48] 0.89 (0.84, 0.93)/ 0.41 (0.18, 0.67)[43]
STOP-Bang (2008), Canada[48]	Perioperative, Canada[48] Persons with cardiovascular disease, United States[40] Sleep clinic, Egypt[43]	8[48]	None reported	0.93 (0.84, 0.98)/ 0.43 (0.33, 0.53)[48] 0.87, 0.43[40] 0.98 (0.94, 0.99)/ 0.03 (0.006, 0.19)[43]	0.52 (0.43, 0.61)/ 0.90 (0.79, 0.97)[48] 0.87 (0.81, 0.91)/ 0.20 (0.03, 0.71)[43]

PPV, Positive Predictive Value
NPV, Negative Predictive Value

Table 4

OSA Screening and Assessment Practices in Primary Care

Author	Purpose	Participants	Measurement	Results
		Non Experimental Designs		
Cross-sectional Descriptive Studies				
Alam et al. (2012). [56] United States	Improve clinician knowledge and screening of OSA in persons with severe mental illness	Persons with severe mental illness in PC clinic (n=100)	STOP Bang and ESS	69 patients screened positive for OSA using STOP Bang; 20 using ESS; 68 patients in high-risk group reported OSA was never discussed by PCP
BaHammam et al. (2008).[53] Saudi Arabia	Assess prevalence of individuals who were at risk of OSA	Middle-aged Saudi males (n=578), PC setting	Berlin questionnaire	192 males were high risk. Symptoms included; BMI>30kg/m^2 (n=153), HTN (n=101), snoring (n=302), apnea>3 times/week (n=30), daytime sleepiness >once/week (n=205), and sleeping while driving (n=173).
BaHammam, et al. (2009).[55] Saudi Arabia	Assess the prevalence of symptoms and risk of OSA in women	Middle aged Saudi women (n=400), PC setting	Berlin questionnaire Answers stratified into three categories of OSA severity	156 women were high risk. Symptoms included; HTN (n=99), BMI > 30 (n=228), snoring (n=163), apnea>3times/week (n=90), day time sleepiness>1x/week (n=210), falling asleep in car (n=130).

PSYCHOMETRIC PROPERTIES

Burgess et al. (2013).[13] Australia	Determine feasibility of using an unattended 2-channel device for OSA screening in a population of high-risk patients	Adult patients at high risk for OSA (n=1,157) in Family practice clinics	ESS	Device results: AHI > 5 (n=821), AHI > 15 (n=382), and AHI >30 (n=185). 81 were unable to use accurately.
Haponik et al. (1996). [57] United States	Determine how often sleep history was obtained prior to diagnosis.	PCP (n=20), medical interns (n=23), and interns instructed on sleep (n=22) during routine health visit	Simulated patients (medical interns) trained to volunteer sleep problems if asked by the PCP	3 interns inquired about sleep problems but questions were not asked regarding snoring, non-restorative sleep, hypersomnia, and witnessed apnea. 18 interns asked questions more often.
Netzer et al. (2003).[54] United States, Germany, & Spain	Standardized survey of: a. PC patients, b. frequency of symptoms/risk for OSA, c. composite score for pretest probability for OSA	PC patients (n=6,223) in 40 offices and clinics in US (n=26), Germany (n=8) and Spain (n=6)	Used Berlin questionnaire, collected BMI, age, and sex.	Participants in US had higher probability of OSA vs. Europe and men > than women. Obesity rate was > in U.S vs. Europeans.
Reuveni et al. (2004).[58] Israel	Assess OSA awareness level of PCPs during patient-physician encounters	PCPs (n=30)	Used an investigator developed patient questionnaire and incorporated it into PCPs practice.	3 PCPs asked ≥ three sleep questions, 3 asked two questions, 9 asked 1 question, 15 asked no questions.

PSYCHOMETRIC PROPERTIES

Retrospective Studies

Bailes et al. (2009).[10] Canada	Discover what symptom presentation leads to a successful sleep clinic referral.	Two samples a. Older PC patients (n=191); Sleep clinic patients (n=138)	Sleep symptoms checklist completed by patients who stated which symptoms they discussed with physicians in past year, followed up with PSG referral.	PSG completers had higher AHI. Sleep clinic patients reported more sleep symptoms and explained symptoms directly.
Bartlett et al. (2008).[11] Australia	Describe prevalence/ risk factors for PC consultations for insomnia and/or snoring/sleep apnea	Adult PC patients (n=1421, 18-24 year olds) and (n=1879, 25-65 year olds).	a. Mailed questionnaire (sleep behavior/ medication, and driver safety/fatigue), b. 1 Question from Pittsburg Sleep Quality Index/ESS, c. OSA/insomnia questions, and d. medical exam.	2.9% of weighted respondents reported visiting their doctor for insomnia and OSA. Older patients reported more OSA symptoms to PCP (n=133).
Kramer et al. (1999).[59] United States	Evaluate percent of patients referred by PCP for sleep studies; characterize clinical features; compare with known OSA patients. Determine if PCP asked questions on	Patients (=69) referred to hospital based sleep center by internists or family practice	Investigator created worksheet PSG	65 had OSA; of 63 patients asked, 62 snored and 59 experienced daytime sleepiness.

	a worksheet to make OSA diagnosis.			
Sorscher (2008).[28] United States	Determine frequency of inquiry by PCPs of unhealthy sleep patterns/symptoms on questionnaires.	PC clinics (n=121) and family medicine physicians (n=935)	Health history database questionnaires	57% of health history database had no sleep health content. Two sites had sleep questions; one site had a question about snoring.
Correlational Descriptive Studies				
Demede et al. (2011).[60] United States	Determine the prevalence of RH and whether patients are at greater risk for OSA.	African American patients, PC setting (n=200)	Emanated from the Metabolic Syndrome Outcome Study. ESS via Apnea Risk Evaluation System	52 participants met criteria for RH. 80 screened as high risk for OSA. Patients with RH were at 2.5 times higher risk for OSA.
Senthilvel et al. (2011).[26] United States	Determine if PCPs screen for sleep disorders during clinical evaluation, compare to validated questionnaires.	New adult patient evaluations (n=101) PC clinic at tertiary care center	Cleveland Sleep Habits Questionnaire, Berlin questionnaire, ESS, and STOP	25 patients had ≥ one sleep symptom and limited sleep history. Questionnaires identified at risk patients more efficiently than PCPs. 9 patients had sleep disorder documentation. 2 were referred to sleep clinic.
Mixed Methods Study				
Mold et al. (2011).[62] United States	Determine proportion of PC patients at high risk for OSA and those who have been diagnosed	PC clinics (n=44), 5 states, sleep consultants (n=18) chart audits (n= 1744), patients (n=2091, n=1357	a. semi structured interviews with clinicians/sleep consultants, b. medical records, c. data from OSA	Of 662 younger patients, 299 discussed symptoms with PCP. 283 older patients were at risk for OSA and 132 discussed symptoms with PCP. OSA prevalence among

	and treated as well as methods used by PCPs to identify them.	ages 30-64, n=734 age> 65)	patients, d. Berlin questionnaire	the older adults was between 12 and 25%.
			Experimental Design	
Grover et al. (2011).[12] United States	Determine: a. if ROS form identifies sleep complaints, b. Frequency of PCPs investigating OSA complaints, c. Prevalence of patients at risk for OSA, d. How accurately ROS identifies OSA	Adult patients (n=249) undergoing preventative exams at family practice clinics (n=2)	ROS forms and Berlin questionnaire	At site 1, 92 patients reported sleep problems on ROS, 22 complaints were documented. 82 patients had increased risk of OSA. ROS responses were 57% sensitive and 73% specific for increased OSA compared to Berlin questionnaire. At site 2, 1of 20 sleep complaints were documented.
Namen et al. (1999).[63] United States	Estimate frequency of documented sleep histories by medical house officers and to assess whether a chart reminder influenced their performance	Ambulatory care patients in university, Physicians internal medicine clinic (n=118)	Chart reminders screened for a. hypersomnolence b. difficulty sleeping c. interference with daily functioning	Chart reminders increased frequency of sleep histories, from 6 to 29% over 3 years. 4 patients had sleep history recorded but had no impact management plan.

PSYCHOMETRIC PROPERTIES

Ball et al. (1997).[64] United States	Enhance recognition of sleep disorders by PCPs; transfer diagnostic testing and care of patients from tertiary care to the community; present PSG experience	Internal medicine patients (n=14330)	Sleep specialist educated PCPs on use of diagnostic equipment. Chart reviews, patient questionnaires, PSG data, and specialized reports were used.	Referrals increased from 2 out of 752 cases to 294 out of 14,330 cases over 2 yrs. CPAP was started on 228 of patients.

Chapter III: Methodological Strategies in Using Portable Sleep Monitoring in Research

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Abstract

Background/Purpose: Portable sleep monitors (PSM) have increased in popularity due to improvements in technology and accessibility. The American Academy of Sleep Medicine established guidelines for obstructive sleep apnea (OSA) using PSM. A comprehensive sleep evaluation and Level III PSM are required for OSA diagnosis. PSM must include least four channels; two respiratory (respiratory movement and airflow), one cardiac (heart rate or electrocardiogram), and oxygen saturation. Research studies using PSM have not consistently reported procedures and methodological challenges. The first purpose of this paper was to synthesize the literature on use of PSM in research of adults in terms of methodological challenges, including: (a) participant sampling; (b) instrumentation issues; (c) clinical variables; (d) data processing; and (e) patient acceptability. The second purpose was to identify methodological strategies to use to standardize PSM information in research reports.

Methods: The search strategy included studies of participants undergoing sleep testing for OSA using PSM. CINAHL, MEDLINE via PubMed, and Embase were search from 2000 to January 2016; some search terms used were “polysomnography”, “home”, “device(s)’, “level III’, “obstructive sleep apnea”, “portable sleep monitors”, and “out of center testing”. Of the 371 articles retrieved, 338 articles were excluded because Level III PSM were not used; 33 articles were included in this focused review.

Findings: The research articles were inconsistent in reporting methodological challenges. The authors identified five criteria to examine. Participants usually included samples who had OSA or were suspected of having OSA (n=20). Several different PSM (n=14) were used; the most commonly reported instrumentation issue was device malfunction. Almost all studies reported clinical variables (n=30). Data processing of the PSM data was discussed in the majority of the articles (n=19). Few studies (n=6) reported information on patient acceptability.

Conclusion: Ten methodological strategies are suggested for adoption when using PSM in research. Future studies need to address the methodological challenges and adopt more consistent procedures and reporting using these ten suggestions to advance knowledge.

Methodological Strategies in Using Portable Sleep Monitoring in Research

Introduction

Obstructive sleep apnea (OSA) in adults has been increasing in prevalence over the last two decades in the United States. The increase is attributed in part to the obesity epidemic (Peppard et al., 2013). Estimates are that moderate to severe OSA, defined as an apnea hypopnea index (AHI) ≥ 15 is present in 10% of men ages 30-49 years, 17% of men ages 50-70 years, and 9% of women ages 50-70 years. OSA contributes significantly to all-cause (Kendzerska et al., 2014; Qaseem et al., 2014) and cardiac (Kendzerska et al., 2014) mortality. The gold standard for OSA diagnosis is level 1 testing by laboratory polysomnography (PSG). During laboratory PSG testing, surface electrodes are positioned to measure electroencephalography, muscle activity, heart and respiratory physiology, and ocular movements (Marino et al., 2013). This type of testing is recommended in patients with co-morbid conditions such as moderate to severe pulmonary disease, neuromuscular disease, congestive heart failure, or suspected to have other sleep disorders (central sleep apnea, periodic limb movement disorder, insomnia, parasomnias, circadian rhythm disorders, or narcolepsy) (Collop et al., 2007). Because of the increase in OSA prevalence, sleep laboratory and diagnostic services are in high demand and alternative methods are needed to screen and diagnose sleep disorders.

In the late 1980's, clinicians began to recognize the need for ambulatory sleep studies but focused on arterial oxygen saturation (CleveMed & Cleveland Medical Devices Inc., 2016). The first practice parameters for portable sleep monitors (PSM) were released in 1994 (Ferber et al., 1994) and indications for PSG testing were published in 1997 (Chesson et al., 1997). At that time, most devices measured snoring but did not meet diagnostic requirements for OSA. In 2000, the Agency for Healthcare Research and Research Quality (AHRQ) reported results of a meta-analysis that stated broad use of PSM could not be supported due to insufficient evidence (Ross et al., 2000). PSM were further developed to include oxygen saturation, heart rate, oral/nasal airflow, respiratory effort and body position (CleveMed & Cleveland Medical Devices Inc.,

2016). In 2006, the AASM released a statement recommending that physicians who use PSM need to conduct a clinical assessment and a comprehensive patient evaluation. Further, PSM could only be used by AASM-accredited sleep centers or board-certified sleep physicians and treatment needed to be guided by the evaluation of study results and patient symptoms (American Academy of Sleep Medicine, 2006; Collop et al., 2007). These recommendations encouraged device manufacturers to develop PSM that met recommended criteria for screening and diagnosis of OSA in home settings.

PSM has increased in popularity due to technological improvements and accessibility. The Centers for Medicare and Medicaid (CMS) released standards for home testing requiring the apnea hypopnea index (AHI) or respiratory distress index (RDI) as mandatory for OSA diagnosis by PSM home testing (Department of Health and Human Services & Centers for Medicare & Medicaid Services, 2013). AASM created a task force (2007) to develop guidelines for PSM. These guidelines state that the diagnosis of OSA needs to be performed with a comprehensive sleep evaluation and with monitors that have level III diagnostic capability, including at least four channels; two respiratory variables (respiratory movement and airflow), cardiac measurement (heart rate or electrocardiogram), and oxygen saturation. The level III monitors must display raw data and allow for manual scoring, or editing of automatic scoring, by a sleep professional because PSM can underestimate AHI levels compared to PSG (Collop et al., 2007).

PSM allow patients access to a less expensive diagnostic option that can be completed in outpatient settings where sleep technologists are not present (Pereira, Driver, Stewart, & Fitzpatrick, 2013). PSM are valuable diagnostic measures for OSA but are not without disadvantages. Common issues with PSM include missing data due to equipment failure (Nickerson et al., 2015; Pereira et al., 2013) and lower sensitivity and specificity levels compared to PSG (Fredheim, Roislien, & Hjelmesaeth, 2014; Guerrero et al., 2014; Polese et al., 2013). There has been significant night to night AHI level variability in mild versus moderate OSA, when using PSM in home settings (Prasad et al., 2016). Researchers need to be knowledgeable of

published literature using level III monitors. Knowledge from this focused review will inform the readers regarding methodological challenges that are common with the use of the devices.

There are two main objectives for this manuscript. The first purpose was to synthesize the literature of methodological challenges in using level III PSM in research in adult patents. The second purpose was to identify methodological strategies to use to standardize PSM information in research reports.

Methods

Studies that included participants undergoing home sleep testing for obstructive sleep apnea diagnosis using PSM were identified by CINAHL, MEDLINE via PubMed, and Embase from the year 2000 to January, 2016. The year 2000 was chosen because literature from Level III PSM was not found prior to that date. Appropriate search terms for PSM were investigated by the first author. A medical librarian assisted in searching the literature using the following search terms: “polysomnography”; “home”; “device(s)”; “sleep disordered breathing”; “level III’; “obstructive sleep apnea”; “sleep disordered breathing”; “portable sleep monitors”; “home sleep testing devices for obstructive sleep apnea”; “out of center sleep testing”; “portable home sleep testing”. Articles included in the review met the following criteria: (a) primary research using PSM that reported methods, results, and findings, (c) Level III PSM examined, (c) sample size ≥ 30 participants, and (d) published in the English language. Studies were excluded if: (a) pediatric participants were included and (b) research was retrospective.

Search results

Of the 371 articles retrieved, 338 articles were excluded because Level III PSM were not used. Relevant articles were reviewed by the medical librarian and the first author and were subsequently verified by the co-authors. After implementing the exclusion criteria, 33 articles were included in this focused review of PSM.

Selection of pertinent variables: The authors reviewed the 33 articles and identified five challenges when using PSM in adult patients in research. These challenges included; (a)

participant sampling; (b) instrumentation issues; (c) clinical variables; (d) data processing methods; and (e) patient acceptability. Challenges were selected because they were the most common themes described in the 33 articles. A review of the articles organized by these the criteria is presented in Table 1.

Participant sampling. The sample and study settings were generally homogenous in nature and were conducted in a variety of countries. Slightly less than half of the studies [45%,(n=15)] had a sample size greater than or equal to 100 subjects (Abdel-Kader et al., 2012; Aurora, Swartz, & Punjabi, 2015; Dawson et al., 2015; Dingli et al., 2003; Gonçalves et al., 2007; Johansson, Alehagen, Svanborg, Dahlström, & Broström, 2012; Kuna, 2010; Masa et al., 2011; Nakayama-Ashida et al., 2008; Pereira et al., 2013; Senchak, Frey, & O'Connor, 2012; Skomro et al., 2010; Tedeschi et al., 2013; Tonelli de Oliveira et al., 2009; Weir et al., 2012). One-third (n=11) of the studies in this literature review were conducted in the United States (Abdel-Kader et al., 2012; Aurora et al., 2015; Dawson et al., 2015; Kuna et al., 2011; Lettieri, Lettieri, & Carter, 2011; Michaelson, Allan, Chaney, & Mair, 2006; Nickerson et al., 2015; Reichert, Bloch, Cundiff, & Votteri, 2003; Senchak et al., 2012; Su, Baroody, Kohrman, & Suskind, 2004; Weir et al., 2012). Studies were conducted in 11 other countries, including: Argentina (Nigro, Malnis, Dibur, & Rhodius, 2012), Brazil (Danzi-Soares et al., 2012; Gonçalves et al., 2007; Polese et al., 2013; Santos-Silva et al., 2009; Tonelli de Oliveira et al., 2009), Canada (Driver et al., 2011; Gjevre et al., 2011; Guerrero et al., 2014; Pereira et al., 2013; Skomro et al., 2010), China (H. Chen et al., 2009; Yin, Miyazaki, & Ishikawa, 2006), Italy (Maestri, La Rovere, Robbi, & Pinna, 2011; Tedeschi et al., 2013), Japan (Nakayama-Ashida et al., 2008), Scotland (Dingli et al., 2003), Spain (Masa et al., 2011), Sweden (Johansson et al., 2012; Zou, Grote, Peker, Lindblad, & Hedner, 2006), Taiwan (Yeh, Lin, Chiu, & Bai, 2015), and Turkey (Yuceege, Firat, Demir, & Ardic, 2013).

Most of the participants were sleep clinic patients who either had or were suspected of having OSA [61%, (n=20)] (H. Chen et al., 2009; Dawson et al., 2015; Dingli et al., 2003; Driver

et al., 2011; Gjevre et al., 2011; Guerrero et al., 2014; Kuna et al., 2011; Lettieri et al., 2011; Masa et al., 2011; Michaelson et al., 2006; Nigro et al., 2012; Pereira et al., 2013; Polese et al., 2013; Reichert et al., 2003; Santos-Silva et al., 2009; Skomro et al., 2010; Su et al., 2004; Tedeschi et al., 2013; Tonelli de Oliveira et al., 2009; Yin et al., 2006). Twelve studies included participants who had co-morbidities associated with OSA but met criteria for PSM (Abdel-Kader et al., 2012; Aurora et al., 2015; Danzi-Soares et al., 2012; Gonçalves et al., 2007; Johansson et al., 2012; Maestri et al., 2011; Nakayama-Ashida et al., 2008; Nickerson et al., 2015; Senchak et al., 2012; Weir et al., 2012; Yeh et al., 2015; Yuceege et al., 2013; Zou et al., 2006).

Instrumentation issues. There were 14 different PSM used in the studies. However, three models were used in more than half [55%, (n=18)] of the studies (Aurora et al., 2015; H. Chen et al., 2009; Danzi-Soares et al., 2012; Dawson et al., 2015; Dingli et al., 2003; Gjevre et al., 2011; Johansson et al., 2012; Kuna et al., 2011; Lettieri et al., 2011; Maestri et al., 2011; Nickerson et al., 2015; Nigro et al., 2012; Polese et al., 2013; Santos-Silva et al., 2009; Senchak et al., 2012; Skomro et al., 2010; Weir et al., 2012; Yin et al., 2006). Eleven PSM were used in the remainder of the studies (Abdel-Kader et al., 2012; Driver et al., 2011; Gonçalves et al., 2007; Guerrero et al., 2014; Masa et al., 2011; Michaelson et al., 2006; Nakayama-Ashida et al., 2008; Pereira et al., 2013; Su et al., 2004; Tedeschi et al., 2013; Tonelli de Oliveira et al., 2009; Yeh et al., 2015; Yuceege et al., 2013; Zou et al., 2006). Instrumentation related details included in these studies were level of monitor, model, and manufacturer.

More than half [n=17, (52%)] of the studies reported problems with overnight collection of sleep data such as: recordings less than minimum required time (Nakayama-Ashida et al., 2008; Nickerson et al., 2015), lack of air flow recordings (Dingli et al., 2003; Nakayama-Ashida et al., 2008; Tonelli de Oliveira et al., 2009; Yin et al., 2006), nasal cannula tube kinking (Driver et al., 2011), incomplete pulse oximetry (Yin et al., 2006), battery/download failure (Driver et al., 2011; Pereira et al., 2013; Polese et al., 2013; Reichert et al., 2003; Skomro et al., 2010), poor participant compliance (Maestri et al., 2011; Reichert et al., 2003; Tonelli de Oliveira et al.,

2009), overall device failure (Nakayama-Ashida et al., 2008; Tedeschi et al., 2013; Yeh et al., 2015), underestimation of AHI severity compared to PSG (Lettieri et al., 2011), or unstated reasons (Guerrero et al., 2014; Kuna et al., 2011; Yuceege et al., 2013).

Some studies [n=8, (24%)] reported engaging the participants in education of the PMS prior to the release of the device for home testing (Dingli et al., 2003; Guerrero et al., 2014; Nickerson et al., 2015; Pereira et al., 2013; Polese et al., 2013; Skomro et al., 2010; Yeh et al., 2015; Yin et al., 2006). Understanding PSM instrumentation issues is critical to the reliability of clinical variables. Data collected in a laboratory setting may have an environmental bias due to sleep technician supervision; PSM device failures are more likely to be recognized and corrected.

Clinical variables. Clinical variables recorded and reported by PSM included AHI, RDI, and ODI. AHI is the total number of apneas and hypopneas per hour of sleep. AHI levels range from mild (≥ 5 and < 15), to moderate (15 ≥ and < 30), to severe (≥ 30) (Berry et al., 2014; Epstein et al., 2009; Guilleminault et al., 2007). When using PSM, RDI is calculated as the number of apneas and hypopneas divided by total recording time (Epstein et al., 2009). ODI is the number of times per hour of sleep that the oxygen level in the blood drops by greater or equal to 3% from baseline (Berry et al., 2012).

AHI, RDI, and/or ODI were reported in 30 studies. The majority [(36%) (n=12] of studies calculated and compared AHI levels from PSM to PSG (Abdel-Kader et al., 2012; H. Chen et al., 2009; Danzi-Soares et al., 2012; Dingli et al., 2003; Guerrero et al., 2014; Masa et al., 2011; Polese et al., 2013; Reichert et al., 2003; Santos-Silva et al., 2009; Skomro et al., 2010; Tonelli de Oliveira et al., 2009; Yin et al., 2006). Four studies reported RDI and/or ODI (Dawson et al., 2015; Driver et al., 2011; Tedeschi et al., 2013; Zou et al., 2006); and two studies compared RDI and/or ODI from PSM to PSG (Pereira et al., 2013; Yuceege et al., 2013). Many studies [n=10, (30%)] psychometrically tested PSMs in the sleep laboratory (H. Chen et al., 2009; Dawson et al., 2015; Dingli et al., 2003; Driver et al., 2011; Michaelson et al., 2006; Polese et al.,

2013; Reichert et al., 2003; Santos-Silva et al., 2009; Su et al., 2004; Tonelli de Oliveira et al., 2009).

Each study had different research questions however, not all clinical variables were compared to PSG. One study compared AHI and RDI levels from PSMs to a device made by another manufacturer (Aurora et al., 2015). Another study compared AHI levels from a PSM to the Berlin Questionnaire and the Epworth Sleepiness Scale to demonstrate feasibility in military pre-deployment assessment (Senchak et al., 2012). Finally, one study compared AHI levels from a PSM to acetylcholine receptor antibodies in patients with myasthenia gravis to examine predictors for OSA (Yeh et al., 2015).

Data processing methods. According to the AASM, PSM must allow for the display of raw data for manual scoring or be able to be edited by a trained sleep technologist. For diagnostic purposes, review of the raw data must be completed by a certified sleep specialist or someone who meets eligibility criteria for the sleep medicine certification exam (Collop et al., 2007).

In this review, 18 of the 33 articles (55%) discussed PSM data scoring methods; however, one article did not state whether the data were scored automatically or manually (Kuna, 2010). A few studies [n=4, (12%)] used physicians to manually interpret overnight PSM data (Gonçalves et al., 2007; Guerrero, Masa, Embid, & Montserrat, 2014; Nigro et al., 2012; Tonelli de Oliveira et al., 2009); in two studies (6%) physicians reviewed data after it was manually scored by a sleep technician (Aurora et al., 2015; Gjevre et al., 2011). More commonly, studies used sleep technicians (Abdel-Kader et al., 2012; Aurora et al., 2015; Driver et al., 2011; Guerrero et al., 2014; Masa et al., 2015; Pereira et al., 2013; Santos-Silva et al., 2009), research personnel (Dingli et al., 2003), employees of PM manufacturers (Michaelson et al., 2006; Su et al., 2004), or unspecified persons (Johansson et al., 2012) to manually score data. Only 4 studies used automatic scoring techniques to analyze the PSM data (C. Chen et al., 2015; Nigro et al., 2012; Su et al., 2004; Yin et al., 2006).

Patient acceptability. Six studies (18%) asked participants to evaluate use of PSM. Five reported on ease of use and comfort of the PSM (Nickerson et al., 2015; Polese et al., 2013; Senchak et al., 2012; Skomro et al., 2010; Yin et al., 2006). Three studies measured sleep quality after using PSM (Gonçalves et al., 2007; Skomro et al., 2010; Yin et al., 2006) and two studies asked their participants to use sleep diaries (Gonçalves et al., 2007; Skomro et al., 2010). Only one study qualitatively measured how participants felt about PSM in terms of importance of OSA testing, ease of use, comfort, and if the participants understood how the monitor worked (Nickerson et al., 2015).

When analyzing research studies that used PSM as methodological instrument, it is important to understand the study's sampling, instrumentation issues, clinical variables, data processing methods, and patient acceptability. These topics are vital considerations when designing research studies using PSM.

Methodological Strategies for Using Portable Sleep Monitors in Research

There are many challenges when using PSM in research. Understanding and addressing the challenges when designing a research study is vital to obtaining full sets of data and achieving an accurate analysis of the clinical variables. Consistent standards of publishing can lead to easier comparability of results across studies. Clinical guidelines for the use of PSM in the diagnosis of OSA have been established (Collop et al., 2007) and should be used as a model when designing validation studies. Based on findings from the review, this section identifies methodological strategies to use to standardize PSM information in research reports (Table 2). Strategies were organized into five areas: participant sampling, instrumentation issues, clinical variables, data processing methods, and patient acceptability.

Participant sampling

Suggestion 1. Co-morbid conditions must be taken into account when selecting inclusion/exclusion criteria. According to the AASM task force, PSM testing is not appropriate in patients with significant co-morbid conditions (moderate to severe pulmonary disease,

neuromuscular disease, or congestive heart failure) due to the degradation of data accuracy. Likewise, PSM testing is not recommended in patients suspected of having other sleep disorders (central sleep apnea, periodic limb movement disorder, insomnia, parasomnias, circadian rhythm disorders, or narcolepsy) (Collop et al., 2007). Patients with these co-morbid conditions must receive laboratory PSG testing under direct supervision of a certified sleep technician in order to establish an OSA diagnosis.

Suggestion 2. Instruct participant on his/her role in data collection, such as wear time and recordings on specific days of the week. Each individual has a unique sleep schedule and patterns may vary depending on weekdays, weekends, and work schedules. Some participants may be hesitant to engage in research studies that include PSM because they have busy work and life schedules and changes in sleep habits may affect their level of daytime functioning. Some participants may engage in more social activities on the weekend that may include alcohol consumption, which increases the likelihood of pharyngeal collapse and apneic/hypopneic episodes. Consistency in assigning the same days, when feasible, is suggested to reduce variability and the length of recording time needed to analyze sleep data. The researcher is responsible to explain the importance of adequate wear time to reduce the amount of missing data.

Instrumentation issues

Suggestion 3. Monitors should be at least level III and include a minimum of four channels. Portable sleep testing has evolved over time and involves a wide range of available technology. Types of testing can range from the most thorough laboratory PSG (level I) which typically records nine physiologic channels (electroencephalogram, electrooculogram, electrocardiogram, chin electromyogram (EMG), limb EMG, respiratory effort at thorax/abdomen, airflow from nasal cannula, pulse oximetry, and ability to monitor continuous positive airway pressure or bi level positive airway pressure) to the least thorough unattended portable device, with two channels (oxygen saturation and airflow) (CleveMed & Cleveland

Medical Devices Inc., 2016). Monitors used in research should be at least level III capabilities with at least four channels, including: two respiratory variables (respiratory movement and airflow), cardiac measurement (heart rate or electrocardiogram), and oxygen saturation. Some PSM have features that record snoring, detect light, or can sense changes in body position; however, these channels are not mandatory for diagnostic testing (CleveMed & Cleveland Medical Devices Inc., 2016; Collop et al., 2007).

Suggestion 4. Cost of PSM supplies should be considered when designing a study. For research purposes, most PSM are available for rent (policies and cost differ between suppliers/ companies/ models / manufactures). Along with funding for the sleep monitor, researchers must take into account the purchase of the sensors that attach to the device, which vary depending on the model (typically nasal cannulas, oxygen probes, batteries, abdominal belts). All PSM used in the research study should be of the same type and model to ensure the validity and reliability of the data.

Clinical variables

Suggestion 5. AHI or RDI must be reported as the outcome variable from the PSM. Reporting of the AHI or RDI after PSM is mandatory for OSA diagnosis and reimbursement by Medicare & Medicaid standards; ODI may be reported but is not considered diagnostic for OSA (Department of Health and Human Services & Centers for Medicare & Medicaid Services, 2013).

Suggestion 6. Provide definition(s) of outcome variable(s). It is important for researchers to provide clear operational definitions of the variables being measured in order to compare findings and clinical applications. Providing definitions for AHI, RDI, or ODI orients the reader to the physiological importance of the data.

Data processing methods

Suggestion 7. Researchers must determine how PSM data will be stored, analyzed, and reported when designing the study. Many models of PSM may be used repeatedly, as the data can be stored, the device cleaned, and released quickly to a new participant. One of the

challenges is determining how data will be stored after use and how/who will analyze it. Prior to beginning the study, researchers need to identify secure places for data storage and accessibility according to IRB regulations/criteria. Once the PSM data is downloaded and stored in a secure area, many manufactures provide programs that allow for automatic or manual scoring. AAMS states that the PSM must display raw data and allow for manual scoring or editing of automatic scoring by a sleep professional (Collop et al., 2007). Automatic scoring is completed by downloading the PSM data to the manufacturer's software program that analyzes the data. Manual scoring must take place by a sleep professional who has been trained in scoring raw sleep data (sleep technologist or board certified sleep physician) (Collop et al., 2007), which can be labor intensive and require additional fees for researchers. Measuring and reporting interrater reliability is valuable when using more than one professional to manually score in order to assure concordance among raters (Hallgren, 2012).

The researchers must describe methods used for data entry, cleaning of data, and use of statistical software. Data analysis methods and the statistical analysis package should be reported to allow for comparisons between studies. Psychometric analysis of PSM should be conducted in comparison to PSG, the gold standard of OSA diagnosis. Reporting correlational analyses as well as sensitivity, specificity, positive predictive value, and negative predictive value are necessary when conducting validity testing. Percentage of missing data from equipment failure, inadequate wear time, or participant refusal must be reported.

Suggestion 8. Report the PSM by model, manufacturer, and use of software. PSM data recording and analysis may vary between manufacturers. Selecting a PSM should be based on the aims and methodology of the study. It is important to report the specific PSM model, manufacturer, and location, as well as the software used to provide transparency of data collection and analysis methods.

Patient acceptability

Suggestion 9. Provide PSM education using return demonstration methods. Participants need to receive in-depth training on the use of the PSM to obtain complete data. Researchers should have a PSM in their possession for demonstration purposes when participants are being enrolled into a study. The participant needs to understand how to use the PSM prior to enrollment. The researcher should demonstrate application of the sensors and the monitor on the participant so they know how the device should be worn during sleep. The researcher should request a return demonstration of how to apply the device and the how it is turned on and off. Participants should be told to feel free to ask questions about application or operation of the device.

Suggestion 10. Provide take-home PSM education materials that discuss possible technical difficulties and trouble-shooting techniques and research assistant contact information. Researchers need to be aware of technological difficulties that participants experience once they use the PSM at home. Many manufacturers have developed trouble-shooting and educational handouts that need to be given to participants to take home. It is important to provide information on how to contact a research assistant with questions when the PSM is being applied. This will allow participants to contact a staff member with questions and to decrease amounts of missing data from insufficient wear time or incorrect application of the PSM.

Conclusion

Many methodological challenges accompany the use of PSM in research. This review examined published research literature of PSM use and strategies used in research. The most consistent strategy described in these studies was the reporting of clinical variables. The majority reported AHI and less commonly RDI. Data processing was reported in most manuscripts and many used sleep professionals to complete manual scoring. The most commonly reported instrumentation issue was device malfunction resulting in loss of data. Only one-third of the studies included participants who were not enrolled from a sleep clinic. Few studies reported

using patient acceptability methods. None of the research articles addressed all five methodological strategies developed by the authors.

Sampling needs to be considered when designing studies using PSM. Participants' comorbid conditions should be taken into account as well their ability to complete data collection. Understanding the technological difficulties that can occur with PSM, such as device failure or problems with sensor misplacement, is needed because data inaccuracies in overnight sleep testing affect the analysis, reliability, and validity of the results, especially when compared to PSG. Researchers must determine whether data will be interpreted automatically or manually and will need to arrange for a qualified sleep professional to interpret findings accordingly. Finally, understanding the patient's perspective of PSM is important to achieving complete data. PSM can be perceived as cumbersome to wear during sleep and may cause anxiety for participants if they are not taught and involved in interactive teaching how to use the device.

Ten methodological strategies are suggested for adoption when using PSM in research. Future studies need to address the methodological challenges and adopt more consistent procedures and reporting using these ten suggestions to advance knowledge. The frequency of use of PSM in the clinical setting has increased because of the technological advancement and availability of the devices. Even though laboratory PSG continues to be the gold standard of OSA diagnosis, PSM are used for OSA screening and diagnosis in outpatient settings. The body of knowledge regarding PSM in research is growing rapidly but there has been no report discussing methodological strategies for PSM use in research outside a sleep laboratory. Awareness and action regarding these challenges will increase the validity of the data presented in research articles.

References

Abdel-Kader, K., Dohar, S., Shah, N., Jhamb, M., Reis, S. E., Strollo, P., . . . Unruh, M. L. (2012). Resistant hypertension and obstructive sleep apnea in the setting of kidney disease. *Journal of Hypertension, 30*(5), 960-966 7p.

American Academy of Sleep Medicine. (2006). Portable monitoring in the diagnosis of obstructive sleep apnea. *Journal of Clinical Sleep Medicine, 2*, 274.

Aurora, R. N., Swartz, R., & Punjabi, N. M. (2015). Misclassification of OSA severity with automated scoring of home sleep recordings. *Chest, 147*(3), 719-727. doi:10.1378/chest.14-0929 [doi]

Berry, R. B., Brooks, R., Gamaldo, C. E., Harding, S. M., Lloyd, R. M., Marcus, C. L., & Vaughn, B. V. (2014). for the American Academy of Sleep Medicine The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications. Darien, IL: American Academy of Sleep Medicine; 2014. Version 2.0.3. *American Academy of Sleep Medicine: Darien, IL, USA,*

Berry, R. B., Budhiraja, R., Gottlieb, D. J., Gozal, D., Iber, C., Kapur, V. K., . . . Quan, S. F. (2012). Rules for scoring respiratory events in sleep: update of the 2007 AASM manual for the scoring of sleep and associated events. *J Clin Sleep Med, 8*(5), 597-619.

Chen, C., Chen, C., Yu, C., Chen, T., Tseng, S., & Ho, C. (2015). *Association of inflammation and oxidative stress with obstructive sleep apnea in ischemic stroke patients*. Netherlands: Elsevier Science. doi:10.1016/j.sleep.2014.07.027

Chen, H., Lowe, A. A., Bai, Y., Hamilton, P., Fleetham, J. A., & Almeida, F. R. (2009). Evaluation of a portable recording device (ApneaLink™) for case selection of obstructive sleep apnea. *Sleep and Breathing, 13*(3), 213-219.

Chesson, A. L.,Jr, Ferber, R. A., Fry, J. M., Grigg-Damberger, M., Hartse, K. M., Hurwitz, T. D., . . . Sher, A. (1997). The indications for polysomnography and related procedures. *Sleep, 20*(6), 423-487.

CleveMed, & Cleveland Medical Devices Inc. (2016). Type I, type II, type III sleep monitors, CMS AASM guidelines. Retrieved from https://clevemed.com/cms-aasm-guidelines-for-sleep-monitors-type-i-type-ii-type-iii/

Collop, N., Anderson, W. M., Boehlecke, B., Claman, D., Goldberg, R., Gottlieb, D., . . . Schwab, R. (2007). Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. *J Clin Sleep Med, 3*(7), 737-747.

Danzi-Soares, N. J., Genta, P. R., Nerbass, F. B., Pedrosa, R. P., Soares, F. S., Cesar, L. A., . . . Lorenzi-Filho, G. (2012). Obstructive sleep apnea is common among patients referred for coronary artery bypass grafting and can be diagnosed by portable monitoring. *Coronary Artery Disease, 23*(1), 31-38. doi:10.1097/MCA.0b013e32834df5d0 [doi]

Dawson, A., Loving, R. T., Gordon, R. M., Abel, S. L., Loewy, D., Kripke, D. F., & Kline, L. E. (2015). Type III home sleep testing versus pulse oximetry: Is the respiratory disturbance index better than the oxygen desaturation index to predict the apnoea-hypopnoea index measured during laboratory polysomnography? *BMJ Open, 5*(6)

Department of Health and Human Services, & Centers for Medicare & Medicaid Services. (2013). Continuous and bi-level positive airway pressure devices: complying with

documentation and coverage requirements. Retrieved from https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/PAP_DocCvg_Factsheet_ICN905064.pdf

Dingli, K., Coleman, E. L., Vennelle, M., Finch, S. P., Wraith, P. K., Mackay, T. W., & Douglas, N. J. (2003). Evaluation of a portable device for diagnosing the sleep apnoea/hypopnoea syndrome. *European Respiratory Journal, 21*(2), 253-259.

Driver, H. S., Pereira, E. J., Bjerring, K., Toop, F., Stewart, S. C., Munt, P. W., & Fitzpatrick, M. F. (2011). Validation of the MediByte(R) type 3 portable monitor compared with polysomnography for screening of obstructive sleep apnea. *Canadian Respiratory Journal : Journal of the Canadian Thoracic Society, 18*(3), 137-143.

Epstein, L. J., Kristo, D., Strollo, P. J.,Jr, Friedman, N., Malhotra, A., Patil, S. P., . . . Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. (2009). Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 5*(3), 263-276.

Ferber, R., Millman, R., Coppola, M., Fleetham, J., Murray, C. F., Iber, C., . . . Sanders, M. (1994). Portable recording in the assessment of obstructive sleep apnea. ASDA standards of practice. *Sleep, 17*(4), 378-392.

Fredheim, J. M., Roislien, J., & Hjelmesaeth, J. (2014). Validation of a portable monitor for the diagnosis of obstructive sleep apnea in morbidly obese patients. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 10*(7), 751-757A. doi:10.5664/jcsm.3864 [doi]

Gjevre, J. A., Taylor-Gjevre, R. M., Skomro, R., Reid, J., Fenton, M., & Cotton, D. (2011). Comparison of polysomnographic and portable home monitoring assessments of obstructive sleep apnea in Saskatchewan women. *Canadian Respiratory Journal, 18*(5), 271-274.

Gonçalves, S. C., Martinez, D., Gus, M., de Abreu-Silva, E. O., Bertoluci, C., Dutra, I., . . . Fuchs, F. D. (2007). Obstructive sleep apnea and resistant hypertension: a case-control study. *Chest, 132*(6), 1858-1862 5p.

Guerrero, A., Embid, C., Isetta, V., Farre, R., Duran-Cantolla, J., Parra, O., . . . Masa, J. F. (2014). Management of sleep apnea without high pretest probability or with comorbidities by three nights of portable sleep monitoring. *Sleep, 37*(8), 1363-1373.

Guerrero, A., Masa, J. F., Embid, C., & Montserrat, J. M. (2014). Diagnosis, cost, and therapeutic decision-making of home respiratory poligraphy for patients without high suspicion of OSA or with comorbidity: Hospital polysomography in comparison with three nights of home respiratory polygraphy. *Chest, 145*(3)

Guilleminault, C., Benbir, G., & Aktar, N. (2007). Obstructive Sleep Apnea. In N. Butkov, & T. Lee-Chiong (Eds.), *Fundamentals of Sleep Technology* (pp. 113). Philadelphia, PA: Lippincott, Williams and Wilkins.

Hallgren, K. A. (2012). Computing Inter-Rater Reliability for Observational Data: An Overview and Tutorial. *Tutorials in Quantitative Methods for Psychology, 8*(1), 23-34.

Johansson, P., Alehagen, U., Svanborg, E., Dahlström, U., & Broström, A. (2012). Clinical characteristics and mortality risk in relation to obstructive and central sleep apnoea in community-dwelling elderly individuals: a 7-year follow-up. *Age & Ageing, 41*(4), 468-474 7p.

Kendzerska, T., Gershon, A. S., Hawker, G., Leung, R. S., & Tomlinson, G. (2014). Obstructive sleep apnea and risk of cardiovascular events and all-cause mortality: A decade-long historical cohort study. *PLoS Medicine, 11*(2), e1001599.

Kuna, S. T. (2010). Portable-monitor testing: an alternative strategy for managing patients with obstructive sleep apnea. *Respiratory Care, 55*(9), 1196-1215 20p.

Kuna, S. T., Gurubhagavatula, I., Maislin, G., Hin, S., Hartwig, K. C., McCloskey, S., . . . Atwood, C. W. (2011). Noninferiority of functional outcome in ambulatory management of obstructive sleep apnea. *American Journal of Respiratory & Critical Care Medicine, 183*(9), 1238-1244 7p. doi:10.1164/rccm.201011-1770OC

Lettieri, C. F., Lettieri, C. J., & Carter, K. (2011). Does home sleep testing impair continuous positive airway pressure adherence in patients with obstructive sleep apnea? *Chest, 139*(4), 849-854 6p. doi:10.1378/chest.10-1060

Maestri, R., La Rovere, M. T., Robbi, E., & Pinna, G. D. (2011). Night-to-night repeatability of measurements of nocturnal breathing disorders in clinically stable chronic heart failure patients. *Sleep & Breathing = Schlaf & Atmung, 15*(4), 673-678. doi:10.1007/s11325-010-0418-4 [doi]

Marino, M., Li, Y., Rueschman, M. N., Winkelman, J. W., Ellenbogen, J. M., Solet, J. M., . . . Buxton, O. M. (2013). Measuring sleep: accuracy, sensitivity, and specificity of wrist actigraphy compared to polysomnography. *Sleep, 36*(11), 1747-1755. doi:10.5665/sleep.3142 [doi]

Masa, J. F., Corral, J., Pereira, R., Duran-Cantolla, J., Cabello, M., Hernández-Blasco, L., . . . Montserrat, J. M. (2011). Effectiveness of home respiratory polygraphy for the diagnosis of sleep apnoea and hypopnoea syndrome. *Thorax, 66*(7), 567-573.

Masa, J. F., Duran-Cantolla, J., Capote, F., Cabello, M., Abad, J., Garcia-Rio, F., . . . Spanish Sleep Network. (2015). Efficacy of home single-channel nasal pressure for recommending continuous positive airway pressure treatment in sleep apnea. *Sleep, 38*(1), 13-21. doi:10.5665/sleep.4316 [doi]

Michaelson, P. G., Allan, P., Chaney, J., & Mair, E. A. (2006). Validations of a portable home sleep study with twelve-lead polysomnography: comparisons and insights into a variable gold standard. *Annals of Otology, Rhinology & Laryngology, 115*(11), 802-809 8p.

Nakayama-Ashida, Y., Takegami, M., Chin, K., Sumi, K., Nakamura, T., Takahashi, K., . . . Kadotani, H. (2008). Sleep-disordered breathing in the usual lifestyle setting as detected with home monitoring in a population of working men in Japan. *Sleep, 31*(3), 419-425.

Nickerson, J., Lee, E., Nedelman, M., Aurora, R. N., Krieger, A., & Horowitz, C. R. (2015). Feasibility of portable sleep monitors to detect obstructive sleep apnea (OSA) in a vulnerable urban population. *Journal of the American Board of Family Medicine : JABFM, 28*(2), 257-264. doi:10.3122/jabfm.2015.02.140273 [doi]

Nigro, C. A., Malnis, S., Dibur, E., & Rhodius, E. (2012). How reliable is the manual correction of the autoscoring of a level IV sleep study (ApneaLink) by an observer without experience in polysomnography? *Sleep & Breathing = Schlaf & Atmung, 16*(2), 275-279. doi:10.1007/s11325-011-0524-y [doi]

Peppard, P. E., Young, T., Barnet, J. H., Palta, M., Hagen, E. W., & Hla, K. M. (2013). Increased prevalence of sleep-disordered breathing in adults. *American Journal of Epidemiology, 177*(9), 1006-1014. doi:10.1093/aje/kws342 [doi]

Pereira, E. J., Driver, H. S., Stewart, S. C., & Fitzpatrick, M. F. (2013). Comparing a combination of validated questionnaires and level III portable monitor with polysomnography to diagnose and exclude sleep apnea. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 9*(12), 1259-1266. doi:10.5664/jcsm.3264 [doi]

Polese, J. F., Santos-Silva, R., de Oliveira Ferrari, P. M., Sartori, D. E., Tufik, S., & Bittencourt, L. (2013). Is portable monitoring for diagnosing obstructive sleep apnea syndrome suitable in elderly population? *Sleep & Breathing = Schlaf & Atmung, 17*(2), 679-686. doi:10.1007/s11325-012-0742-y [doi]

Prasad, B., Usmani, S., Steffen, A. D., Van Dongen, H., Pack, F. M., Strakovsky, I., . . . Weaver, T. E. (2016). Short-Term Variability in Apnea-Hypopnea Index During Extended Home Portable Monitoring. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine,* doi:jc-00380-15 [pii]

Qaseem, A., Dallas, P., Owens, D. K., Starkey, M., Holty, J. C., & Shekelle, P. (2014). Diagnosis of obstructive sleep apnea in adults: a clinical practice guideline from the American College of Physicians. *Annals of Internal Medicine, 161*(3), 210-220. doi:10.7326/M12-3187

Reichert, J. A., Bloch, D. A., Cundiff, E., & Votteri, B. (2003). Comparison of the NovaSom QCG™, a new sleep apnea home-diagnostic system, and polysomnography. *Sleep Medicine, 4*(3), 213-218.

Ross, S. D., Sheinihait, I., Harrison, K. J., Kvasz, M., Connelly, J. E., Shea, S., & Allen, I. E. (2000). Systematic review and meta-analysis of the literature regarding the diagnosis of sleep apnea. *SLEEP-NEW YORK-*, *23*(4), 519-534.

Santos-Silva, R., Sartori, D. E., Truksinas, V., Truksinas, E., Alonso, F. F., Tufik, S., & Bittencourt, L. R. (2009). Validation of a portable monitoring system for the diagnosis of obstructive sleep apnea syndrome. *Sleep*, *32*(5), 629-636.

Senchak, M. A., Frey, W. C., & O'Connor, P. D. (2012). Use of portable sleep monitors to diagnose sleep apnea during predeployment assessment. *Military Medicine*, *177*(10), 1196-1201.

Skomro, R. P., Gjevre, J., Reid, J., McNab, B., Ghosh, S., Stiles, M., . . . Cotton, D. (2010). Outcomes of home-based diagnosis and treatment of obstructive sleep apnea. *Chest*, *138*(2), 257-263 7p. doi:10.1378/chest.09-0577

Su, S., Baroody, F. M., Kohrman, M., & Suskind, D. (2004). A comparison of polysomnography and a portable home sleep study in the diagnosis of obstructive sleep apnea syndrome. *Otolaryngology - Head and Neck Surgery*, *131*(6), 844-850.

Tedeschi, E., Carratù, P., Damiani, M. F., Ventura, V. A., Drigo, R., Enzo, E., . . . Resta, O. (2013). Home unattended portable monitoring and automatic CPAP titration in patients with high risk for moderate to severe obstructive sleep apnea. *Respiratory Care*, *58*(7), 1179-1183.

Tonelli de Oliveira, A. C., Martinez, D., Vasconcelos, L. F., Cadaval Gonçalves, S., do Carmo Lenz, M., Costa Fuchs, S., . . . Danni Fuchs, F. (2009). Diagnosis of obstructive sleep apnea

syndrome and its outcomes with home portable monitoring. *Chest, 135*(2), 330-336 7p. doi:10.1378/chest.08-1859

Weir, I. D., Ahmed, K. M., Korbuly, S., Achaen, A., O'Malley, M., O'Malley, E., . . . Winter, S. M. (2012). Detection of postoperative sleep-disordered breathing using a portable monitoring device. *Sleep & Breathing = Schlaf & Atmung, 16*(3), 881-886. doi:10.1007/s11325-011-0590-1 [doi]

Yeh, J. -., Lin, C. -., Chiu, H. -., & Bai, C. -. (2015). Home sleep study for patients with myasthenia gravis. *Acta Neurologica Scandinavica,*

Yin, M., Miyazaki, S., & Ishikawa, K. (2006). Evaluation of type 3 portable monitoring in unattended home setting for suspected sleep apnea: Factors that may affect its accuracy. *Otolaryngology - Head and Neck Surgery*, *134*(2), 204-209.

Yuceege, M., Firat, H., Demir, A., & Ardic, S. (2013). Reliability of the Watch-PAT 200 in detecting sleep apnea in highway bus drivers. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 9*(4), 339-344. doi:10.5664/jcsm.2584 [doi]

Zou, D., Grote, L., Peker, Y., Lindblad, U., & Hedner, J. (2006). Validation a portable monitoring device for sleep apnea diagnosis in a population based cohort using synchronized home polysomnography. *Sleep*, *29*(3), 367-374.

Table 1

Focused Review of Methods Included in Research of PSM

Author (Year)	1. Sample	2. Instrumentation Issues	3. Clinical Variables	4. Data Processing	5. Acceptability
Abdel-Kader et al. (2012)	X		X	X	
Aurora et al. (2014)	X		X	X	
Chen et al. (2009)			X	X	
Danzi-Soares et al. (2012)	X		X		
Dawson et al. (2015)			X		
Dingli et al. (2003)		X	X	X	
Driver et al. (2011)		X	X	X	
Gjevre et al. et al. (2011)			X	X	
Goncalves et al. (2007)	X		X	X	X
Guerrero et al. (2014)	X	X	X	X	
Johansson et al. (2012)	X			X	
Kuna et al. (2011)		X		X	
Lettieri et al. (2011)		X			
Maestri et al. (2011)	X	X	X		
Masa et al. (2011)			X	X	
Michaelson et al. (2006)			X	X	
Nakayama-Ashida et al.(2007)	X	X	X		
Nickerson et al. (2015)	X	X	X		X
Nigro et al. (2012)				X	
Pereira et al. (2013)		X	X	X	
Polese et al. (2013)		X	X		X
Reichert et al. (2003)		X	X		
Santos-Silva et al. (2009)			X	X	
Senchak et al. (2012)	X		X		X
Skomro et al. (2010)		X	X		X
Su et al. (2004)			X	X	
Tedschi et al. (2013)		X	X		
Tonelli de Oliveira et al. (2009)		X	X	X	
Weir et al. (2012)	X		X		
Yeh et al. (2015)	X	X	X		
Yin et al. (2006)		X	X	X	X
Yuceege et al. (2013)	X	X	X		
Zou et al. (2006)	X		X		

Table 2

Methodological Strategies to use to Standardize PSM Information in Research Reports

Sampling
Co-morbid conditions must be taken into account when selecting inclusion/exclusion criteria.
Instruct patient on his/her role in data collection, such as wear time and recordings on specific days of the week.
Instrumentation Issues
Monitors used should be at a least level III and include a minimum four channels
Cost of PSM supplies should be considered when designing a study
Clinical Variables
AHI or RDI must be reported as the outcome variable from the PSM.
Provide definition of outcome variable
Data Processing Methods
Researchers must determine how PSM data will be stored, analyzed, and reported when designing the study.
Report PSM by model, use of software, and manufacturer
Patient Acceptability
Provide PSM education using return demonstration methods
Provide take-home PSM education materials that discuss possible technical difficulties and trouble-shooting techniques and research assistant contact information.

Chapter IV.A.: Psychometric Properties of Obstructive Sleep Apnea Screening Measures in Patients Referred to a Sleep Clinic

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Abstract

Background: Obstructive Sleep Apnea (OSA) contributes to all-cause and cardiac mortality but there are no current guidelines for OSA screening in outpatient settings due to inconsistent measurement psychometric properties. An American Academy of Sleep Medicine task force is focusing on improving detection and categorization of OSA symptoms and severity to promote screening, assessment, and diagnosis of the disorder. The purpose of this study was to identify the psychometric properties of three self-report OSA screening measures (Berlin, Epworth Sleepiness Scale (ESS), STOP Bang) and an objective portable sleep monitor (PSM) compared to AHI (apnea-hypopnea index) levels (≥5, ≥ 15, and ≥ 30) from polysomnogram (PSG).

Methods: A methodological design was used. Patients referred to a sleep specialist for an OSA consultation were recruited and enrolled at initial sleep evaluation. Participants completed the three OSA self-report screening measures and those participants who met inclusion criteria were sent home with a PSM for one night measurement. Automatic scoring was used. PSGs were ordered by the physician and AHI results were obtained from the medical record.

Results: Participants (N=170) were enrolled (88 male, 82 female; age 54.5, SD 5.0 years). Almost all participants (168) completed the self-report OSA screening measures, approximately half (91) completed PSM measurement, and the majority (142) completed laboratory PSG. The STOP Bang had the highest levels of sensitivity; the ESS had the lowest. The ESS had the highest specificity and reliability levels; the STOP Bang had the lowest. The PSM measure had the highest positive predictive value (PPV) but when AHI was ≥ 30, the PPV was unacceptable. The PSM measure had the strongest psychometric properties of the screening measures.

Conclusions: The STOP Bang was the preferred self-report OSA screening measure because of its high levels of sensitivity**.** A positive STOP Bang warrants assessment for OSA. The ESS is the least desirable screening measure. If a patient qualifies, further screening with a PSM is indicated. PSM measurement consistently predicted the presence of OSA but at the expense of low

sensitivity at AHI levels ≥ 30. PSM results can guide the referral process from primary or specialty clinicians to sleep specialists.

Psychometric Properties of Obstructive Sleep Apnea Screening Measures in Patients Referred to a Sleep Clinic

Introduction

Obstructive sleep apnea (OSA) is a sleep-related breathing disorder that significantly contributes to all-cause (Kendzerska et al., 2014; Qaseem et al., 2014) and cardiac mortality (Kendzerska et al., 2014). The estimated prevalence rate of moderate to severe OSA in the United States is approximately 10% to 20%. The rate is thought to be influenced by the obesity epidemic and to have increased dramatically over the past two decades (Peppard et al., 2013).

Repetitive obstructive breathing events are caused by increased volume in upper airway structures (Peppard et al., 2009) and result in intermittent hypoxia, activation of oxygen free radicals, and an oxidative stress response. An inflammatory process is believed to damage the vascular endothelium, leading to atheroma formation and vascular events (Almendros et al., 2011; Xie et al., 2013). The long-term results of these physiological events are development of hypertension, tachyarrhythmias (Bradley & Floras, 2003; Kohli et al., 2011), reduced left ventricular stroke volume (Yumino et al., 2013), stroke (Lipford et al., 2015), cognitive impairment (Aaronson et al., 2015), and insulin resistance (Heffner et al., 2012). Thus, OSA is a large public health burden (D. J. Gottlieb et al., 2013; Kendzerska et al., 2014).

Despite the evidence, OSA screening measures are not used consistently in primary care or specialty clinics to guide the patient referral process. An American Academy of Sleep Medicine (AASM) task force recently released quality measures for the care of adult patients with OSA. The first quality measure outcome listed was to improve detection and categorization of OSA symptoms and severity (Aurora et al., 2015). The United States Preventative Services Task Force released final recommendations for OSA screening in adults; more research needs to be conducted in terms of OSA screening and health outcomes, the accuracy of multi-step screening in outpatient populations, and home based sleep testing (U.S. Preventative Services Task Force, 2016).

PSYCHOMETRIC PROPERTIES

It is clear that the United States' health care system needs to develop a more streamlined approach to OSA screening, assessment, and diagnosis. The current gold standard for OSA diagnosis is the overnight laboratory polysomnogram (PSG) with a sleep technologist in attendance. Surface electrodes are applied to the patient's body prior to falling asleep to measure electroencephalography, electromyography, cardiac rhythms, respiratory effort, and ocular movements (Marino et al., 2013). Data gathered from the laboratory PSG are analyzed by a physician trained in interpreting PSG results; apnea hypopnea index (AHI) levels (≥ 15) is diagnostic for OSA. Given the labor-intensive nature of PSG testing and the limited number of sleep laboratory resources, it was necessary to develop a less expensive option for OSA screening, assessment, and diagnosis in outpatient populations.

The increased need for PSG services has encouraged sleep experts and monitor manufacturers to develop PSM that allow patients to be screened or diagnosed with OSA in home settings. A recent trend in OSA diagnosis includes the use of level III portable sleep monitors (PSM) that record oxygen saturation, heart rate, and breathing patterns (apneas, hypopneas, snoring, probability of Cheyne-Stokes breathing) (CleveMed & Cleveland Medical Devices Inc., 2016). PSM that can be used for diagnostic purposes are of level III capabilities and have four channels. The Centers of Medicare and Medicaid have released standards in home testing. Reporting the AHI or respiratory distress index (RDI) after PSM is mandatory for OSA diagnosis for home testing (Department of Health and Human Services & Centers for Medicare & Medicaid Services, 2013).

There are no current guidelines for screening for OSA in outpatient settings; thus, screening is performed inconsistently. The screening measures that are often used to detect OSA are the Epworth Sleepiness Scale (ESS) (Johns, 1991) and the Berlin Questionnaire (Berlin) (Netzer et al., 1999). The STOP Bang questionnaire has been used to predict airway obstructive events in pre-operative patients in the acute care setting but more outpatient validation studies are needed (Chung et al., 2008a).

The knowledge gained from this study contributes to science by identifying the most sensitive and specific OSA measures to use in screening. Therefore, in patients who have been referred to a sleep specialist for a sleep disordered breathing evaluation, the purpose of this methodological study was to evaluate the psychometric properties of three self-report OSA screening measures (Berlin, Epworth Sleepiness Scale, STOP Bang) and an objective PSM (ApneaLink Air™; ResMed, San Diego, CA) compared to AHI levels from PSG.

Methods

Research Design

The design was a methodological study. The study was approved by the University Institutional Review Board.

Sample/Setting

A convenience sample of adults who were being evaluated for OSA (n=173) were invited and (n=170) were recruited from a Midwestern sleep clinic over a five month period. The clinic has nine physicians specializing in pulmonary and critical care medicine; seven are board certified in sleep medicine and averages 20-25 new consultations for OSA a week.

Inclusion/Exclusion Criteria

Inclusion criteria for the study were: (a) patients ≥ 19 years old scheduled for OSA consultation at sleep clinic, and (b) able to communicate in writing and over the telephone in English.

Patients were excluded from the study if they: (a) were using a continuous positive airway pressure (CPAP) device, (b) could not undergo PSG, (c) were unable to repeat back procedures of the research study, and (d) were pregnant.

Exclusion criteria for collecting PSM data per AASM's recommendations were: (a) persons with significant comorbid conditions such as moderate to severe pulmonary disease, neuromuscular disease, or congestive heart failure; or (b) suspected to have other sleep disorders

including central sleep apnea, periodic limb movement disorder, insomnia, parasomnia, circadian rhythm disorders, or narcolepsy (Collop et al., 2007).

Conceptual Framework

The conceptual framework used was adapted from a framework of relationships between OSA and cardiovascular risk factors (Kohli et al., 2011) (Figure 1). This framework emphasizes the need for screening, assessment, and diagnosis of OSA, which is the main-focus of this study. The current practice model for screening and assessment of OSA is inconsistent. The second component of this framework displays the cardiovascular risk factors, consequences, and diseases that result from untreated OSA. Cardiovascular risk factors that were measured in this study include elevated heart rate, blood pressure, and decreased myocardial oxygen delivery. This model informs the study by emphasizing the importance of identifying measures that are highly predictive of OSA.

Measurements

Several OSA screening measures have been developed to aid health care providers in quickly screening patients for moderate to severe OSA in a variety of health care settings (Abrishami et al., 2010; Ramachandran & Josephs, 2009; Silva et al., 2011). The OSA screening measures selected in this study were Berlin, ESS, STOP Bang and the ApneaLink Air for comparisons with AHI levels from PSG. The self-report OSA screening measures were chosen because they are most commonly used. This section will describe these measures and present content regarding the validity testing used to determine the psychometric properties of the measures.

Berlin. The measure (Netzer et al., 1999) was developed by primary care and pulmonary care physicians to predict the presence of OSA in patients. The measure has three symptom categories and a total of 11 items. The first category has five unique questions concerning frequency (rare to often) of snoring and apneas while sleeping. The second category has four unique questions concerning daytime sleepiness with a question about sleepiness while driving. A

score is positive for category 1 and 2 when a patient selects two responses from the top levels. The third category has two questions. A positive response indicates a patient has high blood pressure (>140/90 mmHg) or a BMI > 30kg/m^2. The screening measure was considered negative if none or one of the categories were positive and positive if two or three of the categories were positive. The Berlin has a Flesch-Kincaid reading level of 4th grade, which is acceptable as it is lower than the recommended 5th grade level (Tarescavage & Ben-Porath, 2014).

When the measure was compared to home PSG, internal reliability testing showed category 1 (snoring) was high (α=0.92) but Category 2 (daytime sleepiness) was low (α=0.63). When the question about sleeping behind the wheel was excluded, the category 2 Cronbach alpha level increased (0.86) (Netzer et al., 1999). Chung et al. (2008b) and El-Sayed (2012) found the Berlin had higher levels of sensitivity (0.79, 0.95) than specificity (0.51, 0.07) but Netzer et al. (1999) reported inconsistent results (sensitivity 0.54, specificity 0.97).

Epworth Sleepiness Scale (ESS). The measure (Johns, 1991) was developed as a simple questionnaire to quantify the level of daytime sleepiness in adults and is a brief, self-administered scale that asks the subject to rate their level of sleepiness (0= none to 3 =high chance of dozing) during eight daily activities. Once completed, the researcher calculates the sum of the eight questions and the higher the sum, the higher the sleep deficit (0-24). A score of 16 or more indicates a high level of daytime sleepiness (Johns, 1991) and is considered a positive screen. The ESS has been shown to have high internal consistency values (α=0.88) (Johns, 1992). Inconsistent sensitivity (0.76, 0.39) and specificity (0.48, 0.71) values have been reported (El-Sayed, 2012; Silva et al., 2011). El-Sayed (2012) stated that the ESS has high PPV (0.91) with lower NPV (0.23). The ESS has a Flesch-Kincaid reading level of 8th grade, which is higher than the recommended 5th grade level (Tarescavage & Ben-Porath, 2014).

STOP Bang. The measure is comprised of eight Yes/No questions. The questions are arranged in the acronym of STOP Bang (snoring, tiredness, obstruction, blood pressure, BMI, age, neck circumference (>17 inches for male, >16 inches for female), gender (male/female).

With every "yes" the person scores one point for that question. The scores can range from 0 to 8, with greater or equal to three equating to a positive screen (Chung et al., 2008a). Higher scores achieved on the measure have been shown to correlate with the individual's OSA severity (Chung et al., 2008b). In sleep patients, El-Sayed (2012) reported that the sensitivity of the measure stayed consistent between the STOP (0.95) and the STOP Bang (0.98), but Silva et al. (2011) reported an improvement (0.62 to 0.87). The measures PPV (0.52, 0.87) and NPV (0.9, 0.2) were inconsistent between studies (Chung et al., 2008a; Chung et al., 2008b; El-Sayed, 2012). The STOP Bang has a Flesch-Kincaid reading level of 3rd grade, which is an acceptable (Tarescavage & Ben-Porath, 2014).

ApneaLink Air™. The ApneaLink Air (ResMed, San Diego, CA) is a level III, four channel, overnight PSM that is prescribed by a health care provider. The device monitors (a) oxygen saturation, (b) heart rate, and (c) breathing patterns (apneas, hypopneas, snoring, probability of Cheyne-Stokes breathing). An AHI level of ≥ 15 on the ApneaLink Air was the indicator of a positive screen for OSA in this study (Collop et al., 2007). Fredheim, Roislein, Hjelmesaeth (2014) studied an ApneaLink monitor over two nights in morbidly obese patients. The average sensitivity (94%) and specificity (94%) of the instrument were high at an AHI level ≥ 15 and the night-to-night variability of the instrument was almost zero. Erman et al. (2007) compared the original ApneaLink monitor to laboratory PSG and reported acceptable sensitivity (76%) and specificity (94%) levels at AHI of ≥ 15 events per hour. Ragette, Weinreich, Teschler (2010) conducted a study with similar methods as Erman et al (2007), but reported higher sensitivity (92%) and slightly lower specificity (88%) levels. Night to night variability has been documented in PSM mild to moderate OSA (Prasad et al., 2016).

Polysomnography (PSG). Laboratory PSG under supervision of a sleep technician is the gold standard for OSA diagnosis. Surface electrodes are applied to the patient's body prior to falling asleep to measure electroencephalography, muscle activity, heart and respiratory physiology, and ocular movements (Marino et al., 2013). An AASM task force (2012) defined

apnea events in adults as "a drop in the peak signal excursion by ≥ 90% of pre-event baseline using an oronasal thermal senor (diagnostic study), positive assisted pressure (PAP) device flow (titration study), or an alternative apnea sensor, for ≥ 10 seconds" (p.606). Hypopnea events in adults were scored when "the peak signal excursions drop by ≥ 30% of pre-event baseline using nasal pressure (diagnostic study), PAP device flow (titration study), or an alternative sensor for ≥ 10 seconds in association with either ≥ 3% arterial oxygen desaturation or an arousal (Berry et al., 2012). The severity of OSA was defined by AASM as "an individual's Apnea Hypopnea Index (AHI), which indicates how many times an hour the patient experiences obstructive events" (Epstein et al., 2009). AHI levels range from mild (≥ 5 and < 15), to moderate (15 ≥ and < 30), to severe (≥ 30) (Berry et al., 2014; Epstein et al., 2009; Guilleminault et al., 2007). The AHI levels are an indirect measure of myocardial oxygen delivery. Laboratory PSG data were analyzed by a physician trained in interpreting results. AHI levels ≥ 15 from PSG were considered positive in this study as it is considered to be clinically significant when treating OSA.

Procedures

Patients were first approached by a staff member of the clinic and asked if they were interested in speaking to a researcher about a study. If they agreed, patients were interviewed to assess their eligibility to participate in the study by the first author. After the informed consent process, participants completed a demographics section and three self-report OSA screening measures: (a) Berlin (Netzer et al., 1999), (b) ESS (Johns, 1991), and (c) STOP Bang (Chung et al., 2012).

Next, participants were taught how to use the PSM at home and were asked to enact a return demonstration. They were asked to wear the Level III PSM for one full night. The equipment for the PSM consisted of an oxygen finger probe, a nasal cannula pressure sensor, and a thoracic band. Participants were instructed to attach the device when they were ready to go to sleep, turn it on, place tape over the finger probe to secure it, and to turn it off once they woke up.

After completing home sleep testing, most participants underwent PSG testing as prescribed by their sleep physician. PSGs were either conducted as diagnostic or split-night sleep studies. Some participants completed diagnostic PSG testing in their home, per insurance requirements. For split-night sleep studies, data were interpreted from the diagnostic portion of the study and not after application of OSA treatment. The PSGs were first scored by a sleep laboratory technician and then reviewed and dictated by a board certified sleep physician.

Data Analysis

Data from the self-report screening measures (Berlin, ESS, and the STOP Bang) were scored by the first author. There were minimal missing data on OSA screening measures. Non-parametric statistics were used to examine clinical utility data (time to score and appropriateness of the measures). Data collected from the ApneaLink Air were analyzed by the ResMed computerized scoring program. The findings of the four OSA screening measures were compared to PSG. Data from PSG testing were first scored by a sleep laboratory technician and interpreted by a board certified sleep physician. AHI levels were divided into three severity categories; mild (≥ 5) moderate (≥ 15), and severe (≥ 30). In order to assess the impact of different cut-points that have been considered in the literature, psychometric testing for each OSA screening measure was completed at each AHI level (≥ 5, ≥ 15, and ≥ 30) for sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Screening measures and PSG data were stored on a secure server. After data were collected and entered into an excel spreadsheet, data were cleaned and checked for outliers and missing data. Data were then analyzed using IBM SPSS statistical software, version 23.

Reliability testing was conducted using KR-20 values for the Berlin and the STOP Bang measures. Cronbach's alpha reliability was assessed on the Epworth Sleepiness Scale.

Table 1 displays several types of validity testing that were used to calculate psychometric properties of the OSA screening measure. The types of validity testing included calculation of criterion validity (predictive and concurrent) and construct validity (convergent and known

groups testing) for each of the OSA screening measures. Predictive validity testing (sensitivity, specificity, positive predictive value, and negative predictive value) compared the OSA screening measure scores to the AHI levels from PSG. Concurrent validity testing compared a positive and negative screen to AHI levels from PSG. Convergent validity testing correlated each OSA screening measures' score against the other measures. Known groups testing compared OSA measure scores in patients who did/did not have AHI ≥ 15 from PSG.

Bivariate concurrent, convergent, and known groups validity testing were completed between the OSA screening measures. Independent sample t-tests were used for known-groups validity analysis to compare the ESS, STOP Bang, and ApneaLink Air to AHI levels ≥ 15 from PSG. Because the Berlin has dichotomous scoring in the third category, chi-squared testing was used to compare the screening measure to AHI level ≥ 15 from PSG. Phi correlations were used for concurrent and convergent validity analysis, to correlate positive and negative screens on OSA screening measures compared to each other and AHI levels from PSG. Bivariate scoring was used to test the validity of the measures compared to each other and using AHI ≥ 15 cut point. Spearman's rho correlational analyses were conducted between the continuous scores of the OSA screening measures and AHI levels from PSG.

To assess measurement agreement of AHI levels from ApneaLink Air and PSG, a Bland-Altman plot of agreement was constructed (Bland & Altman, 1986). A single sample t-test of differences and regression analyses predicting differences from means were subsequently conducted to assess if AHI levels deviated from the null hypotheses of agreement and no proportional bias.

Results

This methodological study recruited 170 participants, 88 male and 82 female with an overall mean age of 54.5 (SD=15.0 years). All participants completed the Berlin Questionnaire and STOP Bang; almost all (n=168) completed the ESS. The majority of participants scored positive for OSA on the Berlin (n=143, 84%) and STOP Bang (n=149, 88%); less than one-

quarter scored positive on the ESS (n=37, 22%). The Berlin Category 1, questions 2 (n=21), 3 (n=18), and 4 (n=11) had the most amount of missing data because questions required information from a bed partner for a participant answer (i.e. loudness, frequency, and annoyance of snoring). The median score on the ESS was 10 (SD=5.4, range 1-24). The STOP Bang median score was 4 (SD =1.7, range 1-7). The average time to score the Berlin was 20 seconds but the measure was difficult for people to complete if they slept alone. The average time to complete the ESS was 4.6 seconds and the STOP Bang was 3.5 seconds.

Only about half of the participants (n=91, 53%) met criteria for home sleep testing per AASM guidelines (Collop et al., 2007). Almost all participants who met criteria completed sleep testing in their homes (n=87, 96%). However, 10 (15%) of the recordings were invalid due to insufficient data such as wearing less than two hours (n=8) and equipment failure (n=2). The PSM AHI levels ranged from 0 to 139 with a mean of 21.9 (SD=27.6).

A total of 142 (84%) participants completed physician ordered PSG; AHI levels ranged from 0 to 113.7 with a mean of 20.7 (SD=24.5). Slightly greater than half of the participants who underwent PSG testing (n=77, 54.2%) had AHI levels < 15. Therefore, AHI levels from PSG were positively skewed indicating an abnormal distribution, with most participants having lower OSA severity. Outliers (n=12) were found at high (≥ 60) AHI levels. No cases were deleted from the database. Less than half participants completed all OSA screening measures and PSG (n=73) (Table 2).

Reliability testing was conducted on the OSA screening measures. Both the Berlin (KR20=0.661) and STOP Bang (KR20=0.407) measures showed low reliability but the ESS's Cronbach's alpha was high (α= 0.845).

Table 3 displays the psychometrics of each OSA screening measure at AHI levels (≥5, ≥ 15, and ≥ 30). For a PSG AHI cut point of ≥5 events per hour, the Berlin and STOP Bang had high sensitivity levels but the ESS had the highest specificity level. The ApneaLink Air had the highest positive predictive value (PPV) and the ESS had second highest. These levels are

acceptable for psychometric testing. All negative predictive values (NPV) were low and unacceptable for psychometric testing.

At a PSG AHI cut point of ≥ 15 events an hour, the Berlin and the STOP Bang again had high sensitivity levels. The ApneaLink Air and ESS had similar acceptable specificity levels. The ApneaLink Air had the highest PPV and NPV and both levels were acceptable.

At a PSG AHI cut point of ≥ 30 events an hour, the Berlin and STOP Bang repeated their high sensitivity levels. The ApneaLink Air and the ESS again had high specificity levels. The ApneaLink Air had the highest PPV. The STOP Bang had the highest NPV.

Table 4 shows results of other validity testing, including PSG included known-groups, concurrent, and convergent testing. Known groups validity testing was completed with chi-square testing for the Berlin (χ^2 3.346, p=0.067). The independent sample t-test showed there was a significant difference in positive (M=5.12, SD=1.61) and negative (M=4.22, SD=4.55) scores for the STOP Bang [t (140) = 3.40, *p* = .001] and a significant difference in positive (M=38.37, SD=30.75) and negative (M=9.0, SD=17.25) AHI levels for the ApneaLink Air [t (58.50) = 5.12, *p* = .000]. The ESS did not show a significant difference in positive and negative scores [t (138)= 1.46, p = .146].

Phi-correlations were used to conduct bivariate concurrent and convergent validity testing. A significant but moderate correlation was detected between positive and negative AHI levels ≥ 15 from the ApneaLink Air and PSG (r=0.656, p=.01). A significant correlation was detected between positive and negative scores on the Berlin and STOP Bang (r=.375, p=.01).

Spearman's rho correlational analysis was completed between the continuous variables of the OSA screening measures and AHI levels from PSG. All OSA screening measures had a significant correlation to AHI from PSG ($p \leq 0.05$); however, the ApneaLink Air and the STOP Bang had the highest correlations. ApneaLink Air AHI levels had a strong linear relationship (r=0.750, p=0.01) and the STOP Bang had a moderate linear relationship (r=.327, p=.01) with AHI levels from PSG.

Figure 1 shows a Bland-Altman plot analyzing the mean difference between AHI levels from ApneaLink Air and PSG. Clustering occurred at the lower end of mean AHI scores because the majority of the participants had low OSA severity. Of the mean scores, 91% (n=68) fell within the limits of agreement (± 2 SD) and 9% (n=7) outside of the limits of agreement. The single sample t-test of differences, with a test value of zero, showed no significant differences [t (74) = .18, p = .86]. The regression analysis showed that differences were not predictable by the means as the regression coefficient was non-significant (B=-.06, p = .51). These analyses show there was no significant difference and no proportional bias between AHI mean scores from ApneaLink and PSG, supporting agreement.

In summary, the STOP Bang had the highest sensitivity while the ESS had the lowest. The ESS had the highest specificity and reliability levels while the STOP Bang had the lowest. Some questions on the Berlin may be difficult to answer for people who sleep alone. The ApneaLink Air had the highest PPV. However, when the AHI was ≥ 30, the PPV was unacceptable. AHI levels from the ApneaLink Air and STOP Bang were most highly correlated with AHI levels from PSG. The ApneaLink Air had the strongest psychometric properties of all OSA screening measures. No difference in mean AHI levels was shown using Bland-Altman testing.

Discussion

This study's purpose was to identify the psychometric properties of three self-report OSA screening measures (Berlin, Epworth Sleepiness Scale, STOP Bang) and an objective PSM (ApneaLink Air) compared to AHI levels from PSG. The desired outcome was to identify the most reliable and valid screening measure(s) in patients referred to a sleep clinic. The major finding was that the ApneaLink Air most consistently predicted AHI levels indicating the presence of OSA. A limitation of ApneaLink Air was the low sensitivity levels at AHI ≥ 30. A second major finding was that none of the self-report measures had entirely acceptable

psychometric properties to be used independently for OSA screening. The psychometric properties of the STOP Bang support it as the preferred self-report screening measure.

Regarding internal consistency reliability, the ESS had high levels but the Berlin and STOP Bang had low levels. Since our data were cross-sectional, stability over time was not measured. The stability is best supported by its ability to reproduce the same results at different time-periods.

Validity testing was completed between the OSA screening measures and AHI levels from PSG. Concurrent validity testing showed a significant but moderate correlation between AHI levels from the ApneaLink Air and PSG; Bland-Altman testing showed there was no significant difference in mean AHI scores from ApneaLink Air and PSG. Convergent validity testing showed a significant but weak correlation between the Berlin and STOP Bang. The STOP Bang and AHI levels from the ApneaLink Air were the most proficient at determining who did/did not have OSA when compared to AHI $\geq$ 15 from PSG.

The ApneaLink Air had the highest level of sensitivity at AHI $\geq$ 5 and was the lowest at AHI $\geq$ 30. This is concerning because 40% of persons with severe OSA were not identified as having the sleep disorder using the device. Specificity levels were lowest at AHI $\geq$ 5 but were high at moderate and severe OSA levels; this indicates that the ApneaLink Air was not proficient at ruling out OSA at low levels of severity. Several other studies reported higher levels of sensitivity and specificity across all ranges of OSA severity than found in this study using ApneaLink PSM (H. Chen et al., 2009; Fredheim et al., 2014; Senchak et al., 2012). This study's results may have been affected by the automatic data scoring of the PSM compared to manual scoring used in prior studies.

The Berlin has been tested in different outpatient populations and has documented inconsistent sensitivity and specificity results compared to PSG. Some studies have found higher sensitivity compared to specificity level (El-Sayed, 2012) but others have reported opposite results (Best, Fitzpatrick, Milev, Bowie, & Jokic, 2013; Chung et al., 2008a; Geiger-Brown et al.,

2013; Netzer et al., 1999). Both Netzer et al. (1999) and El-Sayed (2012) reported high levels of PPV (97%, 87%) for the questionnaire but Chung et al. (2008b) found the measure had lower PPV levels (51%) compared to NPV (78%). In this study, the Berlin had acceptable sensitivity levels but values were lower when compared to the STOP Bang. The measure produced unacceptable levels of specificity and inconsistent PPV and NPV. Overall, the measure performed inconsistently which could have been impacted by the amount of missing data from Category 1, questions two, three, and four.

The ESS has shown consistently low levels of sensitivity but higher levels of specificity when compared with other OSA screening measures (El-Sayed, 2012; Faria, da Costa, & Rufino, 2015; Silva et al., 2011). This study is unique in finding an inverse relationship between PPV and NPV in all of the OSA screening measures when compared to mild, moderate, and severe OSA. This finding may have been influenced by the positive skewness of the AHI levels from PSG. Using a screening measure with high levels of specificity, such as the ESS, allows for accurate identification of patients who do not have the disease. The ESS had the highest specificity levels at AHI ≥ 5, which means that 13% of patients who had moderate to severe OSA at AHI levels $\geq$ 15 and ≥ 30 were not identified. This leads one to ask if the strength of the specificity outweighs the weakness of missed OSA diagnoses.

The STOP Bang has shown consistently high levels of sensitivity and low levels of specificity when compared to PSG across many psychometric studies regardless of patient population (Abrishami et al., 2010; Boynton, Vahabzadeh, Hammoud, Ruzicka, & Chervin, 2013; Chung, 2011; Chung et al., 2012; El-Sayed, 2012; Farney, Walker, Farney, Snow, & Walker, 2011; B. Kim, Lee, Chung, Kim, & Lee, 2015; Nagappa et al., 2015; Pereira et al., 2013; Silva et al., 2011). The measures PPV and NPV have shown to be inconsistent between studies (Chung et al., 2008a; Chung et al., 2008b; El-Sayed, 2012). The high levels of sensitivity in this study can be explained by the scoring criteria of the measure; three positive scores indicate a positive screen and need for further evaluation. Using a screening measure with high sensitivity but low

specificity, such as the STOP Bang, can be useful when the test detects a disease that is serious but treatable. Therefore, the STOP Bang identified a high number of participants with the disease but at the cost of false positives.

The findings from this study are most similar to those of Pereira et al. (2013). Canadian sleep clinic patients were studied and completed OSA screening measures (Berlin, STOP Bang, and Sleep Apnea Clinical Score [SACS]) and level III PSM (MediByte). The diagnostic utility of the tools were compared to laboratory PSG. The STOP Bang and Berlin were found to have the highest sensitivity levels in all severities of OSA. Although Periera et al. reported PSM findings as a RDI, the monitors used in both studies had very similar sensitivity levels at mild, moderate, and severe OSA level. This study and Periera et al (2013) reported poor probability that the PSM would detect an AHI $\geq$ 30. Collop et al. (2007) stated that false negative rates may be as high as 17% in PSM studies. This could be influenced by scoring methods used by researchers or evidence of diagnostic limitations of the PSM. The calculation of total recording time rather than total sleep time could also affect results (Nickerson et al., 2015).

This study has several strengths in its design. First, a sample size of N=170 was calculated for the sample to have sufficient number of patients both with and without OSA and to be representative of the general population. This assumed that approximately 24-34 participants out of 170 would have a negative PSG. Second, this study compared three self-report and one objective screening measure to PSG and variety of validity tests. This expands the knowledge of validity testing of the OSA screening measures and adds to the current state of the science in this area. Lastly, the results of this study can be generalized to other sleep clinic populations due to the variety of settings patients were diagnosed in (home testing and three different sleep laboratories).

It is important to acknowledge the limitations of this study. The participants were recruited from a convenience sample at a Midwestern sleep clinic. The patients were referred from their primary care provider or from other health care specialties but our data did not

originate from a community based random sample. Another limitation of this study is the single night use of the ApneaLink Air and the use of automatic scoring technique. Some data were missing due to participant ineligibility, equipment failure, or inadequate wear time of the monitor.

Implications for Research

The AASM released a call in 2016 for volunteers to serve on a new OSA Assessment Tools Task Force that will evaluate screening, assessment, and evaluation of current measures. The task force will determine if measures used currently are reliable and effective at detecting OSA in undiagnosed persons as well as make recommendations regarding the development of new tools. The development of this committee encourages researchers to conduct more validation testing of OSA screening measures in order to determine which tool has the best predictability (American Academy of Sleep Medicine, 2016).

There are no current guidelines for OSA screening in outpatient settings. This is due in part by inconsistent reports of sensitivity, specificity, PPV, and NPV of current OSA screening measures. Further development of screening measures needs to include studying clinical variables that make patients high risk for OSA (Epstein et al., 2009; Miller & Berger, 2016). Continued improvement in technology will assist in more accurate identification of AHI levels and reduce health care costs.

Implications for Practice

Health care providers need increased education on the importance screening and assessment for OSA and encouragement to refer at-risk patients to sleep specialists for further evaluation. Many patients who are diagnosed with OSA have already developed hypertension, coronary artery disease, a stroke or have reduced left ventricular stroke volume. Early OSA screening and assessment may reduce the likelihood of developing these comorbid conditions. Screening measures are not ready to be used independently in a clinical setting. Therefore, clinicians need to integrate assessment for OSA risk factors into their practice, such as evaluation of patient's comorbid cardiovascular and respiratory conditions, BMI, conducting a Mallampati

score, and measuring a neck circumference. In addition, evaluating daytime sleepiness and functioning levels are clinically relevant (Epstein et al., 2009; Miller & Berger, 2016).

To help guide the referral process to sleep specialists, sleep screening and assessment can be followed by the use of a PSM. As evidenced in this study, PSM have been shown to be effective in both screening and diagnosing OSA in specific patient populations. However, only 53% of participants qualified for PSM per AASM guidelines because of comorbid conditions (Collop et al., 2007). Patients who are at risk for OSA need to be identified early in their disease trajectory, prior to development of cardiovascular disease. The use of PSM can assist clinicians in deciding which patients need to be referred to sleep specialists for OSA diagnosis. Patients who have AHI levels from PSM ≥ 5 and < 15 need an assessment of daytime sleepiness. If patients report excessive daytime sleepiness, a referral to a sleep specialist is necessary. Sleep specialists are trained to manually interpret PSM data and can determine if results are accurate for OSA diagnosis or if laboratory sleep testing is needed.

In conclusion, this study demonstrated that the STOP Bang questionnaire was the preferred self-report OSA screening measure as it had the highest level of sensitivity. The ESS was found to be the least psychometrically desirable. A positive screen on the STOP Bang warrants assessment for OSA. If a patient qualifies, further screening with a PSM is indicated. The ApneaLink Air had the most consistent ability to predict the presence of OSA but at the expense of low sensitivity levels at AHI ≥ 30, indicating some patients with severe OSA would have a missed diagnosis. PSM need to be used to guide the referral process from primary or specialty care to sleep specialist. Earlier screening and detection of OSA will reduce the development of cardiovascular conditions as well as all-cause mortality in adult patients.

References

Aaronson, J. A., van Bennekom, C., Hofman, W. F., van Bezeij, T., van den Aardweg, Joost G, Groet, E., . . . Schmand, B. (2015). Obstructive sleep apnea is related to impaired cognitive and functional status after stroke. *Sleep, 38*(9), 1431-1437.

Abrishami, A., Khajehdehi, A., & Chung, F. (2010). A systematic review of screening questionnaires for obstructive sleep apnea. *Canadian Journal of Anesthesia/Journal Canadien D'Anesthésie, 57*(5), 423-438.

Almendros, I., Farré, R., Torres, M., Bonsignore, M. R., Dalmases, M., Ramírez, J., . . . Montserrat, J. M. (2011). Early and mid-term effects of obstructive apneas in myocardial injury and inflammation. *Sleep Medicine, 12*(10), 1037-1040. doi:10.1016/j.sleep.2011.07.009

American Academy of Sleep Medicine. (2016). Call for Volunteers: AASM seeks volunteers for new OSA assessment tools task force. Retrieved from http://www.aasmnet.org/articles.aspx?id=6212&utm_source=WeeklyUpdate&utm_medium=email&utm_campaign=wu4-7-16

Aurora, R. N., Collop, N. A., Jacobowitz, O., Thomas, S. M., Quan, S. F., & Aronsky, A. J. (2015). Quality Measures for the Care of Adult Patients with Obstructive Sleep Apnea. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine*, doi:jc-00031-15 [pii]

Berry, R. B., Brooks, R., Gamaldo, C. E., Harding, S. M., Lloyd, R. M., Marcus, C. L., & Vaughn, B. V. (2014). for the American Academy of Sleep Medicine The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical

Specifications. Darien, IL: American Academy of Sleep Medicine; 2014. Version 2.0.3. *American Academy of Sleep Medicine: Darien, IL, USA,*

Berry, R. B., Budhiraja, R., Gottlieb, D. J., Gozal, D., Iber, C., Kapur, V. K., . . . Quan, S. F. (2012). Rules for scoring respiratory events in sleep: update of the 2007 AASM manual for the scoring of sleep and associated events. *J Clin Sleep Med, 8*(5), 597-619.

Best, M. W., Fitzpatrick, M., Milev, R., Bowie, C. R., & Jokic, R. (2013). Utility of the Berlin questionnaire for predicting obstructive sleep apnea in individuals with treatment-resistant depression. *Sleep and Breathing, 17*(4), 1221-1227.

Bland, J. M., & Altman, D. G. (1986). Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet (London, England), 1*(8476), 307-310.

Boynton, G., Vahabzadeh, A., Hammoud, S., Ruzicka, D. L., & Chervin, R. D. (2013). Validation of the STOP-BANG Questionnaire among Patients Referred for Suspected Obstructive Sleep Apnea. *Journal of Sleep Disorders--Treatment & Care, 2*(4)

Bradley, T. D., & Floras, J. S. (2003). Sleep apnea and heart failure: Part I: obstructive sleep apnea. *Circulation, 107*(12), 1671-1678. doi:10.1161/01.CIR.0000061757.12581.15 [doi]

Chen, H., Lowe, A. A., Bai, Y., Hamilton, P., Fleetham, J. A., & Almeida, F. R. (2009). Evaluation of a portable recording device (ApneaLink™) for case selection of obstructive sleep apnea. *Sleep and Breathing, 13*(3), 213-219.

Chung, F. (2011). Screening for obstructive sleep apnea syndrome in the preoperative patients. *The Open Anesthesiol J, 5*, 7-11.

Chung, F., Subramanyam, R., Liao, P., Sasaki, E., Shapiro, C., & Sun, Y. (2012). High STOP-Bang score indicates a high probability of obstructive sleep apnoea. *British Journal of Anaesthesia, 108*(5), 768-775. doi:10.1093/bja/aes022 [doi]

Chung, F., Yegneswaran, B., Liao, P., Chung, S. A., Vairavanathan, S., Islam, S., . . . Shapiro, C. M. (2008a). STOP questionnaire: a tool to screen patients for obstructive sleep apnea. *Anesthesiology, 108*(5), 812-821. doi:10.1097/ALN.0b013e31816d83e4 [doi]

Chung, F., Yegneswaran, B., Liao, P., Chung, S. A., Vairavanathan, S., Islam, S., . . . Shapiro, C. M. (2008b). Validation of the Berlin questionnaire and American Society of Anesthesiologists checklist as screening tools for obstructive sleep apnea in surgical patients. *Anesthesiology, 108*(5), 822-830. doi:10.1097/ALN.0b013e31816d91b5 [doi]

CleveMed, & Cleveland Medical Devices Inc. (2016). Type I, type II, type III sleep monitors, CMS AASM guidelines. Retrieved from https://clevemed.com/cms-aasm-guidelines-for-sleep-monitors-type-i-type-ii-type-iii/

Collop, N., Anderson, W. M., Boehlecke, B., Claman, D., Goldberg, R., Gottlieb, D., . . . Schwab, R. (2007). Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. *J Clin Sleep Med, 3*(7), 737-747.

Department of Health and Human Services, & Centers for Medicare & Medicaid Services. (2013). Continuous and bi-level positive airway pressure devices: complying with documentation and coverage requirements. Retrieved from https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/PAP_DocCvg_Factsheet_ICN905064.pdf

El-Sayed, I. H. (2012). Comparison of four sleep questionnaires for screening obstructive sleep apnea. *Egyptian Journal of Chest Diseases and Tuberculosis, 61*(4), 433-441.

Epstein, L. J., Kristo, D., Strollo, P. J.,Jr, Friedman, N., Malhotra, A., Patil, S. P., . . . Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. (2009). Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 5*(3), 263-276.

Faria, A. C., da Costa, C. H., & Rufino, R. (2015). Sleep apnea clinical score, Berlin questionnaire, or Epworth sleepiness scale: Which is the best obstructive sleep apnea predictor in patients with COPD? *International Journal of General Medicine, 8*, 275-281.

Farney, R. J., Walker, B. S., Farney, R. M., Snow, G. L., & Walker, J. M. (2011). The STOP-Bang equivalent model and prediction of severity of obstructive sleep apnea: relation to polysomnographic measurements of the apnea/hypopnea index. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 7*(5), 459-65B. doi:10.5664/JCSM.1306 [doi]

Fredheim, J. M., Roislien, J., & Hjelmesaeth, J. (2014). Validation of a portable monitor for the diagnosis of obstructive sleep apnea in morbidly obese patients. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 10*(7), 751-757A. doi:10.5664/jcsm.3864 [doi]

Geiger-Brown, J., Rogers, V. E., Han, K., Trinkoff, A., Bausell, R. B., & Scharf, S. M. (2013). Occupational screening for sleep disorders in 12-h shift nurses using the Berlin Questionnaire. *Sleep and Breathing, 17*(1), 381-388.

Gottlieb, D. J., Craig, S. E., Lorenzi-Filho, G., Heeley, E., Redline, S., McEvoy, R. D., & Duran-Cantolla, J. (2013). Sleep apnea cardiovascular clinical trials-current status and steps forward: The international collaboration of Sleep Apnea Cardiovascular Trialists. *Sleep, 36*(7), 975-980. doi:10.5665/sleep.2790 [doi]

Guilleminault, C., Benbir, G., & Aktar, N. (2007). Obstructive Sleep Apnea. In N. Butkov, & T. Lee-Chiong (Eds.), *Fundamentals of Sleep Technology* (pp. 113). Philadelphia, PA: Lippincott, Williams and Wilkins.

Heffner, J. E., Rozenfeld, Y., Kai, M., Stephens, E. A., & Brown, L. K. (2012). Prevalence of Diagnosed Sleep Apnea Among Patients With Type 2 Diabetes in Primary Care. *CHEST Journal, 141*(6), 1414-1421.

Johns, M. W. (1991). A new method for measuring daytime sleepiness: the Epworth Sleepiness Scale. *Sleep, 14*(6), 540-545.

Johns, M. W. (1992). Reliability and factor analysis of the Epworth Sleepiness Scale. *Sleep, 15*(4), 376-381.

Kendzerska, T., Gershon, A. S., Hawker, G., Leung, R. S., & Tomlinson, G. (2014). Obstructive sleep apnea and risk of cardiovascular events and all-cause mortality: A decade-long historical cohort study. *PLoS Medicine, 11*(2), e1001599.

Kim, B., Lee, E. M., Chung, Y., Kim, W., & Lee, S. (2015). The utility of three screening questionnaires for obstructive sleep apnea in a sleep clinic setting. *Yonsei Medical Journal, 56*(3), 684-690.

Kohli, P., Balachandran, J. S., & Malhotra, A. (2011). Obstructive sleep apnea and the risk for cardiovascular disease. *Current Atherosclerosis Reports, 13*(2), 138-146.

Lipford, M. C., Flemming, K. D., Calvin, A. D., Mandrekar, J., Brown, R. D.,Jr, Somers, V. K., & Caples, S. M. (2015). Associations between Cardioembolic Stroke and Obstructive Sleep Apnea. *Sleep, 38*(11), 1699-1705. doi:10.5665/sleep.5146 [doi]

Marino, M., Li, Y., Rueschman, M. N., Winkelman, J. W., Ellenbogen, J. M., Solet, J. M., . . . Buxton, O. M. (2013). Measuring sleep: accuracy, sensitivity, and specificity of wrist actigraphy compared to polysomnography. *Sleep, 36*(11), 1747-1755. doi:10.5665/sleep.3142 [doi]

Miller, J. N., & Berger, A. M. (2016). Screening and assessment for obstructive sleep apnea in primary care. *Sleep Medicine Reviews, 29*, 41-51.

Nagappa, M., Liao, P., Wong, J., Auckley, D., Ramachandran, S. K., Memtsoudis, S., . . . Chung, F. (2015). Validation of the STOP-Bang Questionnaire as a Screening Tool for Obstructive Sleep Apnea among Different Populations: A Systematic Review and Meta-Analysis. *PloS One, 10*(12), e0143697.

Netzer, N. C., Stoohs, R. A., Netzer, C. M., Clark, K., & Strohl, K. P. (1999). Using the Berlin Questionnaire to identify patients at risk for the sleep apnea syndrome. *Annals of Internal Medicine, 131*(7), 485-491.

Nickerson, J., Lee, E., Nedelman, M., Aurora, R. N., Krieger, A., & Horowitz, C. R. (2015). Feasibility of portable sleep monitors to detect obstructive sleep apnea (OSA) in a vulnerable urban population. *Journal of the American Board of Family Medicine : JABFM, 28*(2), 257-264. doi:10.3122/jabfm.2015.02.140273 [doi]

Peppard, P. E., Ward, N. R., & Morrell, M. J. (2009). The impact of obesity on oxygen desaturation during sleep-disordered breathing. *American Journal of Respiratory and Critical Care Medicine, 180*(8), 788-793.

Peppard, P. E., Young, T., Barnet, J. H., Palta, M., Hagen, E. W., & Hla, K. M. (2013). Increased prevalence of sleep-disordered breathing in adults. *American Journal of Epidemiology, 177*(9), 1006-1014. doi:10.1093/aje/kws342 [doi]

Pereira, E. J., Driver, H. S., Stewart, S. C., & Fitzpatrick, M. F. (2013). Comparing a combination of validated questionnaires and level III portable monitor with polysomnography to diagnose and exclude sleep apnea. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 9*(12), 1259-1266. doi:10.5664/jcsm.3264 [doi]

Prasad, B., Usmani, S., Steffen, A. D., Van Dongen, H., Pack, F. M., Strakovsky, I., . . . Weaver, T. E. (2016). Short-Term Variability in Apnea-Hypopnea Index During Extended Home Portable Monitoring. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine,* doi:jc-00380-15 [pii]

Qaseem, A., Dallas, P., Owens, D. K., Starkey, M., Holty, J. C., & Shekelle, P. (2014). Diagnosis of obstructive sleep apnea in adults: a clinical practice guideline from the American College of Physicians. *Annals of Internal Medicine, 161*(3), 210-220. doi:10.7326/M12-3187

Ramachandran, S. K., & Josephs, L. A. (2009). A meta-analysis of clinical screening tests for obstructive sleep apnea. *Anesthesiology, 110*(4), 928-939. doi:10.1097/ALN.0b013e31819c47b6 [doi]

Senchak, M. A., Frey, W. C., & O'Connor, P. D. (2012). Use of portable sleep monitors to diagnose sleep apnea during predeployment assessment. *Military Medicine, 177*(10), 1196-1201.

Silva, G. E., Vana, K. D., Goodwin, J. L., Sherrill, D. L., & Quan, S. F. (2011). Identification of patients with sleep disordered breathing: comparing the four-variable screening tool, STOP, STOP-Bang, and Epworth Sleepiness Scales. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 7*(5), 467-472. doi:10.5664/JCSM.1308 [doi]

Tarescavage, A. M., & Ben-Porath, Y. S. (2014). Psychotherapeutic outcomes measures: A critical review for practitioners. *Journal of Clinical Psychology, 70*(9), 808-830.

U.S. Preventative Services Task Force. (2016). Final research plan for obstructive sleep apnea in adults: screening. Retrieved from http://www.uspreventiveservicestaskforce.org/Page/Document/final-research-plan142/obstructive-sleep-apnea-in-adults-screening

Xie, X., Pan, L., Ren, D., Du, C., & Guo, Y. (2013). Effects of continuous positive airway pressure therapy on systemic inflammation in obstructive sleep apnea: a meta-analysis. *Sleep Medicine, 14*(11), 1139-1150.

Yumino, D., Kasai, T., Kimmerly, D., Amirthalingam, V., Floras, J. S., & Bradley, T. D. (2013). Differing effects of obstructive and central sleep apneas on stroke volume in patients with heart failure. *American Journal of Respiratory and Critical Care Medicine, 187*(4), 433-438.

Figure 1: Conceptual Framework of the Relationship between Obstructive Sleep Apnea and Cardiovascular Risk Factors Adapted From Kohli, Balachandran, & Malhotra

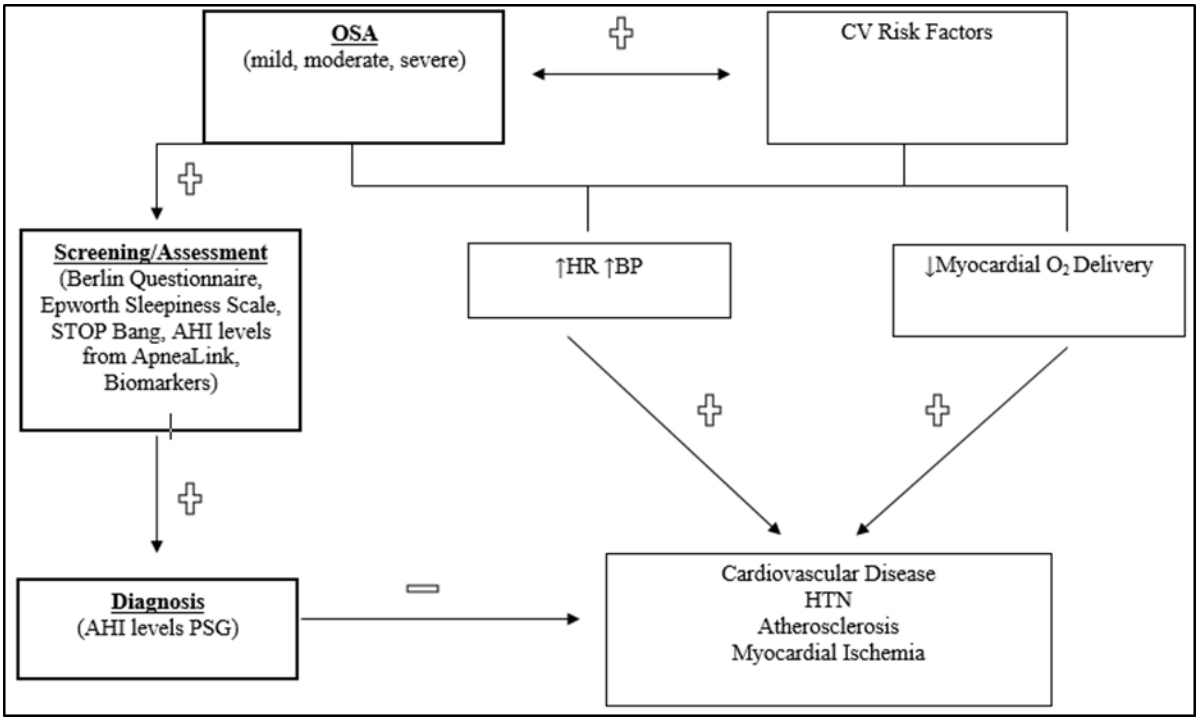

Figure 2: Bland-Altman Plot Examining the Difference Between ApneaLink Air and PSG AHI Levels

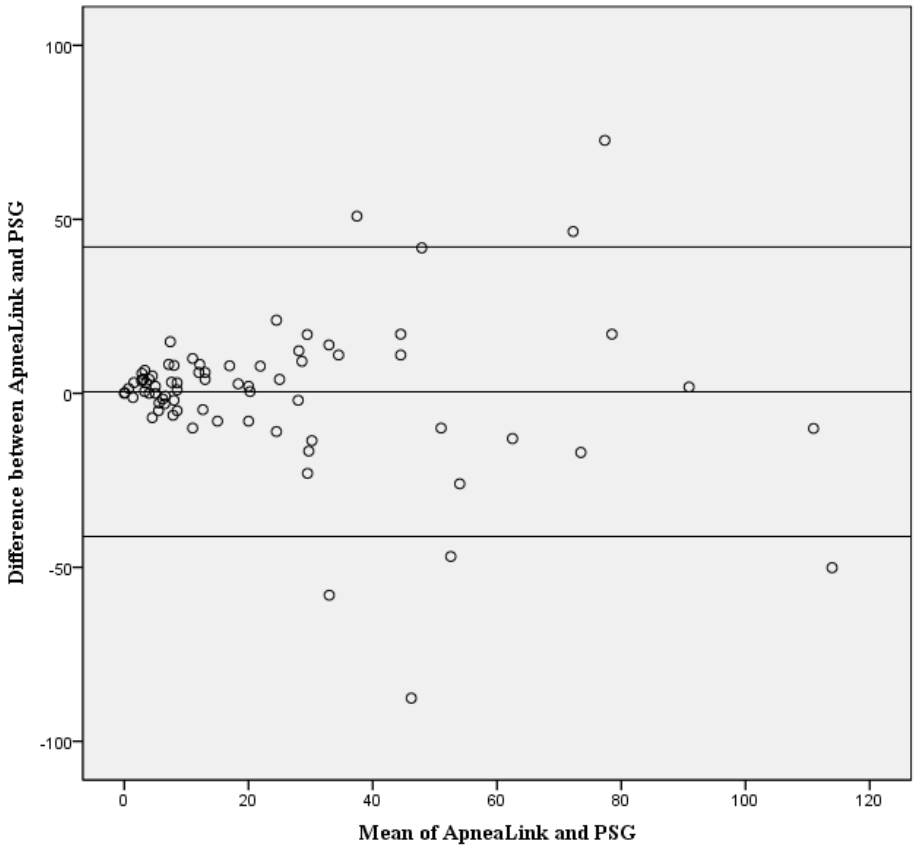

Table 1

Validity Testing

	Criterion Validity
Predictive	The degree to which the OSA screening measures predict PSG AHI levels ≥ 15 (sensitivity, specificity, positive predictive value, negative predictive value).
Concurrent	Correlating +/- screens on OSA measures scores to the AHI levels from laboratory PSG.
	Construct Validity
Convergent	Correlating each measure's +/- scores against the other OSA screening measures.
Known groups	Comparing each measure's +/- screen to patients who did/did not have PSG AHI ≥ 15

PSYCHOMETRIC PROPERTIES

Table 2

Number of Positive OSA Screening Measures and PSG (N=170)

Berlin (N=170)	ESS (n=168)	STOP Bang (N=170)	ApneaLink Air (n=87)	PSG (n=142)
n=143 (84%)	n= 37 (22%)	n= 149 (88%)	n=38 (44%)	n=65 (46%)

PSYCHOMETRIC PROPERTIES

Table 3

Predictive Validity Testing of OSA Screening Measures Compared to AHI Levels from PSG

Measure		Berlin (N=170)			ESS (n=168)	
Cut-point	5	15	30	5	15	30
Sensitivity	88.89%	92.31%	90.32%	17.92%	20.63%	31.03%
Specificity	20.59%	18.18%	14.41%	88.24%	87.01%	87.39%
PPV	78.05%	48.78%	22.76%	82.61%	56.52%	39.13%
NPV	36.84%	73.68%	84.21%	25.64%	57.26%	82.91%
Measure		STOP Bang (N=170)			ApneaLink (n=83)	
Cut-point	5	15	30	5	15	30
Sensitivity	94.44%	95.38%	96.77%	81.97%	78.95%	60.00%
Specificity	20.59%	12.99%	10.81%	57.14%	86.49%	87.27%
PPV	79.07%	48.06%	23.26%	89.29%	85.71%	63.16%
NPV	53.85%	76.92%	92.31%	42.11%	80.00%	85.71%

Berlin Questionnaire (Berlin); Epworth Sleepiness Scale (ESS); negative predictive value (NPV); positive predictive value (PPV)

PSYCHOMETRIC PROPERTIES

Table 4

Known Groups, Concurrent[a] ,and Convergent[b] Validity Testing of OSA Screening Measures Compared to AHI Levels ≥ 15 (PSG)

	Berlin[b] (n=170)	ESS[b] (n=168)	STOP-Bang[b] (n=170)	ApneaLink Air[b] (n=87)	PSG[a] (n=142)
Concurrent/Convergent					
PSG	.154	.103	.145	.656**	
Epworth	-.022		-.121	-.060	.103
STOP Bang	.375**	-.121		.196	.145
ApneaLink Air	.196	-.060	.196		.656**
Berlin		-.022	.375**	.196	.154
Known Groups	(χ^2 3.346, p=0.067)[c]	[t(138) = 1.46, p = .146][d]	[t(140) = 3.40 , p = .001][d]	[t(58.45) =5.12, p = <.001][d]	

Berlin Questionnaire (Berlin); Epworth Sleepiness Scale (ESS); polysomnogram (PSG)
** Correlation is significant at the 0.01 level (2-tailed).
a. Concurrent validity
b. Convergent validity
Chi-squared

Chapter 4.B.: Analysis of Demographic, Clinical, and Biomarker Characteristics to Determine Predictors of Apnea Hypopnea Index from Polysomnography in Midwestern Sleep Clinic Patients

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Chapter IV.B. Analysis of Demographic, Clinical, and Biomarker Characteristics to Determine Predictors of Apnea Hypopnea Index from Polysomnography in Midwestern Sleep Clinic Patients

Dissertation Aim #2

The second aim for this dissertation study was to examine if selected demographic (age, gender), clinical (diabetes, coronary artery disease, hyperlipidemia, myocardial infarction, stroke, lung disease, smoking history, alcohol intake), and biomarker (blood pressure, heart rate, body mass index (BMI), neck circumference, Mallampati score) variables predicted apnea hypopnea index (AHI) from polysomnography (PSG).

Methods

Research Design

The design is a descriptive, prospective, cross-sectional study. The study was approved by the University Institutional Review Board.

Sample/Setting

A convenience sample of adults (n=173) were invited and (n=170) were recruited. All patients were being evaluated for obstructive sleep apnea (OSA) were recruited from a Midwestern sleep clinic.

Chapter IV. A. Methods

Please see Chapter IV.A. for inclusion/exclusion criteria, informed consent, and procedures.

Data Analysis

An estimate of 15-20% of PSG results are negative at Nebraska Pulmonary Specialties, LLC for patients who undergo testing. A power analysis determined that a sample size of N=170 was a sufficient number of patients both with and without OSA and to be representative of the population. This calculation assumed that approximately 24-34 participants out of 170 would have a negative PSG result. For the regression analysis, n= 130 participants were included in the

model. A maximum of 15 variables could have been included in the model if all correlated with the outcome variable at p<.20. There were 15 demographic, clinical, and biomarker characteristics. Therefore, a multiple regression model with 15 predictors and 130 participants would provide 80% power to detect an effect size of $f^2 = .15$, which is a medium effect size. The planned sample size provided sufficient power to detect the effects of interest for this analysis.

First, data were entered into a secured Excel spreadsheet and rigorous procedures were followed for data entry and editing. Data were cleaned and checked for outliers and missing data; no outliers were removed. Descriptive statistics were performed on the sample of participants. Next, Spearman's correlational analyses were conducted; demographic (age, gender), clinical (diabetes, coronary artery disease, hyperlipidemia, myocardial infarction, stroke, lung disease, smoking history, alcohol history), and biomarker (blood pressure, heart rate, body mass index, neck circumference, Mallampati score) variables were compared to determine their relationship with AHI levels from PSG. Then, assumptions of multiple regression analysis (linearity, homoscedasity, normality, and multicollinearity) were assessed. Bivariate scatterplots were used to assess linearity and homoscedasity. Normality was evaluated by a) histograms to assess normal distributions and b) skewness and kurtosis values. Skewness was assessed by examining the symmetry of the distribution (positive or negative). The outcome variable was positively skewed, indicating an abnormal distribution of data, and a log transformation of AHI levels (PSG) was performed. Transformation of the AHI level scores (PSG) reduced the impact of the outliers. The transformation of the variables normalized distribution of the AHI levels (PSG).

Potential covariates associated with AHI levels from PSG were examined for inclusion in the multiple regression model. Prior to entering the variables into the model, correlational analyses also were conducted between the predictors. Multiple regression analyses were used to test a model of predictors of log AHI levels from PSG in participants (gender, comorbid health conditions, smoking history, current tobacco use, alcohol use/amount, systolic and diastolic blood pressure, heart rate, body mass index, neck circumference, and Mallampati score). Baseline

variables that correlated with log AHI levels from PSG, at a significance level of P<.20, were included in the model following a model-building strategy outlined by Hosmer and Lemeshow (Hosmer & Lemeshow, 2000).

Variables that met the Homser and Lemeshow (2000) criteria and that were not highly inter-correlated were entered into the multiple regression model. Using the model respecification technique, age, diabetes mellitus, coronary artery disease, heart attack, stroke, current or past tobacco use, alcohol use, diastolic blood pressure, heart rate, and Mallampati score were deleted from the model ($p > .05$). Interactions between variables were then tested.

Descriptive statistics and multiple regression analysis were performed using IBM SPSS Statistical Software, Version 23.

Results

This cross-sectional descriptive study took place in a sleep clinic and recruited patients who were referred for sleep evaluation (n=170). The sample consisted of approximately half males and half females. The means and standard deviations of clinical predictors were analyzed (Table 1). On average, the participants were middle aged, obese, and pre-hypertensive. The majority of patients reported using alcohol at least once a week. The most commonly self-reported co-morbid conditions were hyperlipidemia, lung disease and diabetes mellitus type II (Table 2).

Multi-collinearity was assessed for and confounding factors, correlations, and potential interactions were explored. Systolic and diastolic blood pressures were highly correlated with each other ($\rho=0.464$). Diastolic blood pressure was deleted from the model because it had a multicollinearity effect with systolic blood pressure. A slightly higher correlation was found between systolic blood pressure and AHI levels from PSG (Table 3). Interactions were tested between diastolic blood pressure and other variables and one was found with lung disease (Figure 1). If participants had lung disease, diastolic blood pressure did not predict OSA; however; if lung disease was not present, diastolic blood pressure had a positive relationship with PSG. The

Spearman's correlation between diastolic blood pressure and PSG was not significant for those with lung disease (ρ =-.071, p=.788, N=17) but for those without lung disease, there was a significant correlation (ρ =.32, p=.001, N=113).

Interactions in the model were tested between gender and other variables (high cholesterol, BMI, neck circumference, systolic blood pressure) (Table 4) and between systolic blood pressure and other variables (high cholesterol, BMI, neck circumference, and lung disease) (Table 5). In Table 4, there was a significant amount of variance accounted for by the variables in the model (F=3.07, p=.002, adjusted R^2=.138, R^2=.205) with 20.5% of the variability of the response variable accounted for by the predictors. Table 5 also supports a significant amount of variance accounted for by variables in the model (F=2.89, p=.003, adjusted R^2=.128, R^2=.196). No interactions occurred between gender or systolic blood pressure and other variables, meaning that the effects of the variables on AHI levels from PSG did not vary depending on gender or systolic pressure.

Of the 130 participants in the final regression model, 69 (53.1%) had an AHI < 15 and 61 (46.9%) had an AHI ≥15. The final model (Table 6) included gender, high cholesterol, lung disease, systolic blood pressure, body mass index, and neck circumference (n=130); the model predicted a significant level of variance in the continuous AHI levels by the variables in the model (F =4.57, p<.001, R^2=0.183, adjusted R^2=0.143). The significant predictors in the model included lung disease, systolic blood pressure, and body mass index. Systolic blood pressure and BMI independently predicted AHI levels from PSG. Lung disease was a negative predicator for AHI levels from PSG; therefore, persons with lung disease were less likely to have elevated AHI levels from PSG.

Discussion

This study found that participants BMI, systolic blood pressure, and lack of lung disease diagnosis were predictors for AHI levels ≥ 15 from PSG. The demographic, clinical, and biomarker variables that did not predict AHI levels from PSG were age, gender, diabetes,

coronary artery disease, hyperlipidemia, myocardial infarction, stroke, smoking history, alcohol intake, diastolic blood pressure, heart rate, neck circumference, and Mallampati Score. To our knowledge, this is the first study to compare this combination of variables to AHI levels from PSG.

BMI was shown to be a significant predictor for OSA and the relationship has previously been studied. Rogers et al. (2015) investigated OSA predictors among African American participants with metabolic syndrome (n=1,035). African American participants were at greater risk for OSA relative to other adults in developed countries; obesity was found to be the strongest independent predictor for OSA (OR=1.59, p <.001). Natsios et al.(2015) performed a retrospective cohort study using a university database (N=1501) to determine predictors of laboratory diagnosis of OSA for development of hypertension. BMI was found to be an accurate predictor of hypertension in patients with OSA (p<.001). Kendzerska et al. (2014) conducted a systematic review of the prognostic value of clinical and PSG characteristics of OSA for adverse long-term outcomes of untreated OSA in adult patients. OSA was found to be associated with all-cause and adverse cardiac outcomes (15 of 26 studies), including BMI (3 of 21 studies) and hypertension (5 of 21 studies).

Systolic blood pressure was shown to be a significant predictor of OSA. Other studies have confirmed the relationship between these two health conditions. Pedrosa et al. (2011) conducted a cross-sectional study (N=125) that found OSA was the most common condition (64%) associated with resistant hypertension. Pedrosa et al. (2013), studied the effect on blood pressure with the use of continuous positive airway pressure (CPAP) to treat OSA in patients with resistant hypertension (N=243). Findings were that the treatment of OSA with CPAP significantly reduced daytime systolic blood pressure levels (p<.05). Haas et al.(2005) studied the association between systolic and diastolic hypertension in relation to OSA. Findings supported that OSA was associated with systolic and diastolic hypertension (AHI 15 to 29.9, OR=2.38; AHI ≥30, OR=2.24) in participants less than 60 years old.

The finding that the absence of lung disease was a significant predictor for OSA was unique to this study. Most studies report a positive relationship between the presence of lung disease and OSA. Zidan, Dabbis, and Gharraf (2015) assessed the prevalence of OSA in a group of asthmatics (n=30) and controls (n=12). A regression analysis revealed that higher BMI ($p=0.03$), gastroesophageal reflux disease ($p=.034$), and asthma severity (FEV1%) ($p<.001$) were significant independent predictors for the development of OSA. Furthermore, the presence of OSA was significantly associated with worse asthma control ($p<.001$). In a similar experimental study, Greenberg-Dotan et. al. (2014) aimed to determine whether there is increased prevalence of obstructive lung diseases in patients with OSA (N=1,497) when compared to a control group (n=1,489). The study found that chronic obstructive pulmonary disease (COPD) ($p<0.0001$), asthma ($p<0.0001$), and COPD with asthma ($p<0.0001$) were more prevalent in patients with OSA across all AHI severities, compared to controls. One reason this study's results differ from prior studies may due to the small sample of participants recruited with lung disease (n=17).

Interpretation of the final model deserves further discussion due to its unique findings. In Table 6, the F-test was highly significant, thus we can assume that there is a relationship between the variables in the model and the outcome variable. R^2, also known as the coefficient of multiple determination, is a statistical measure of how close the data are to the fitted regression line and provides an estimate of strength of the relationship between the model and the response variable (Pagano, Gauvreau, & Pagano, 2000). In Table 6, $R^2= .183$ and adjusted $R^2=.143$, therefore 18.3% of variability of the response variable was accounted for by the predictors; however, the model was overall significant which shows that BMI, systolic blood pressure, and absence of lung disease are still associated with log AHI levels from PSG. This model can be subjectively considered significant because it is reasonable to assume that an individual's BMI, systolic blood pressure, and absence of lung disease can be affected by many other health conditions besides OSA; however, because the model was shown to be significant, the relationship between the comorbid conditions and OSA deserves further investigation.

This study had several strengths. All participants (N=170) completed the demographics and health history questionnaire. Participants were given adequate time and support to complete demographic questionnaires in private and were given adequate chances to ask questions. Also, the sample consisted of persons with chronic comorbid conditions.

A limitation of the study was that lung disease was measured via self-report from participants and was not validated using health records; this applies to all comorbid health conditions and demographic variables obtained. Also, chronic disease severity was not assessed, measured, or recorded. Only subjects who completed demographic, clinical, and biomarker variables, and had AHI levels from PSG were included in the model (N=130).

Chapter 5 includes conclusions and implications for future research and practice for this aim.

References

Greenberg-Dotan, S., Reuveni, H., Tal, A., Oksenberg, A., Cohen, A., Shaya, F. T., . . . Scharf, S. M. (2014). Increased prevalence of obstructive lung disease in patients with obstructive sleep apnea. *Sleep and Breathing, 18*(1), 69-75.

Haas, D. C., Foster, G. L., Nieto, F. J., Redline, S., Resnick, H. E., Robbins, J. A., . . . Pickering, T. G. (2005). Age-dependent associations between sleep-disordered breathing and hypertension: importance of discriminating between systolic/diastolic hypertension and isolated systolic hypertension in the Sleep Heart Health Study. *Circulation, 111*(5), 614-621. doi:111/5/614 [pii]

Hosmer, D. W., & Lemeshow, S. (2000). Introduction to the logistic regression model. *Applied Logistic Regression, Second Edition,* , 1-30.

Kendzerska, T., Gershon, A. S., Hawker, G., Leung, R. S., & Tomlinson, G. (2014). Obstructive sleep apnea and risk of cardiovascular events and all-cause mortality: A decade-long historical cohort study. *PLoS Medicine, 11*(2), e1001599.

Natsios, G., Pastaka, C., Vavougios, G., Zarogiannis, S. G., Tsolaki, V., Dimoulis, A., . . . Gourgoulianis, K. I. (2015). Age, Body Mass Index, and Daytime and Nocturnal Hypoxia as Predictors of Hypertension in Patients With Obstructive Sleep Apnea. *The Journal of Clinical Hypertension,*

Pagano, M., Gauvreau, K., & Pagano, M. (2000). *Principles of biostatistics* Duxbury Pacific Grove, CA:.

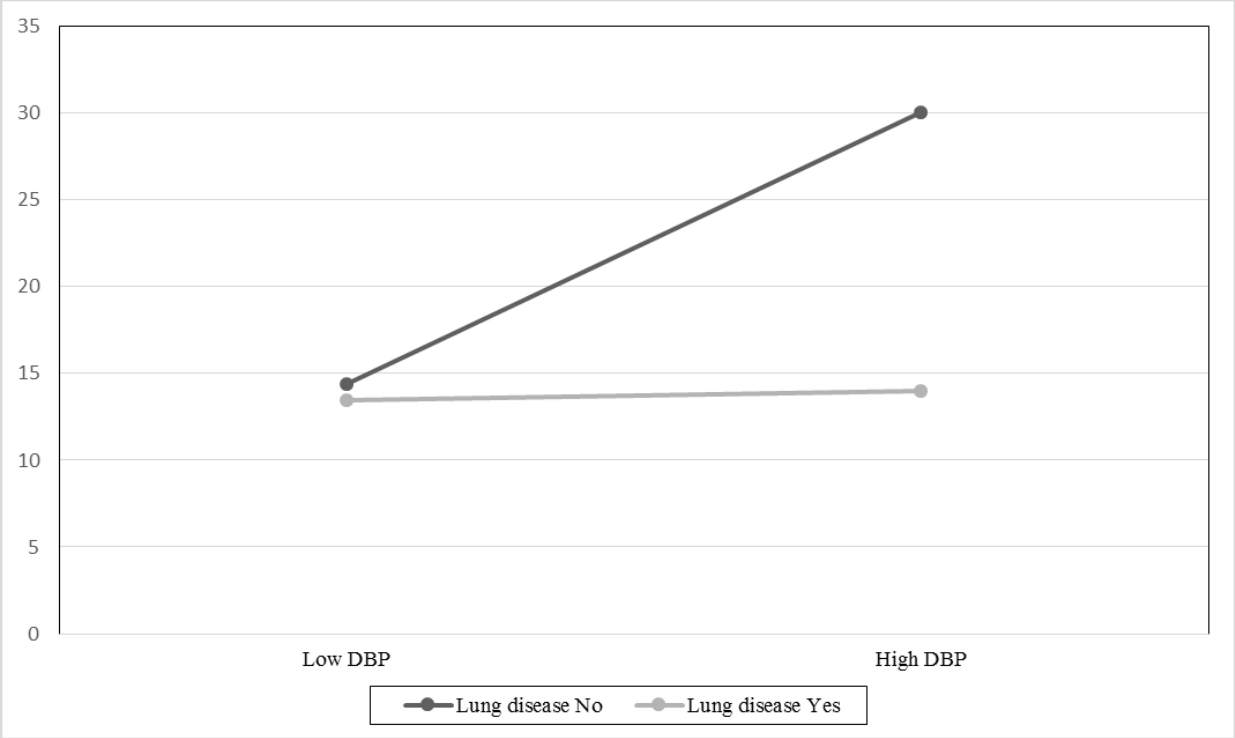
Pedrosa, R. P., Drager, L. F., de Paula, L. K., Amaro, A. C., Bortolotto, L. A., & Lorenzi-Filho, G. (2013). Effects of OSA treatment on BP in patients with resistant hypertension: a randomized trial. *CHEST Journal, 144*(5), 1487-1494.

Pedrosa, R. P., Drager, L. F., Gonzaga, C. C., Sousa, M. G., de Paula, L. K., Amaro, A. C., . . . Lorenzi-Filho, G. (2011). Obstructive sleep apnea: the most common secondary cause of hypertension associated with resistant hypertension. *Hypertension, 58*(5), 811-817. doi:10.1161/HYPERTENSIONAHA.111.179788 [doi]

Rogers, A., Ravenell, J., Donat, M., Sexias, A., Ogedegbe, C., McFarlane, S., & Jean-Louis, G. (2015). Predictors of Obstructive Sleep Apnea Risk among Blacks with Metabolic Syndrome. *Journal of Obesity and Overweight, 1*(1)

Zidan, M., Daabis, R., & Gharraf, H. (2015). Overlap of obstructive sleep apnea and bronchial asthma: Effect on asthma control. *Egyptian Journal of Chest Diseases and Tuberculosis, 64*(2), 425-430.

Figure 1: PSG AHI Diastolic Blood Pressure and Lung Disease Interaction



DBP, Diastolic blood pressure

Table 1

Mean and Standard Deviation of Participants' (N=170) Clinical Health Predictors

Clinical predictors	Mean ± SD	Range
Gender	(88M, 82F)	NA
Age	54.5 ± 15 years	20.4-89.5
Body mass index	34.8 ± 7.6 kg/m^2	20.2-65.1
Mallampati score	2.7 ± 1.1	1-4
neck circumference	16 ± 2.1 inches	12-23.5
heart rate	93 ± 18.4	41-137
systolic blood pressure	124 ± 15	94-190
diastolic blood pressure	73± 10	32-99

BMI: 18.5, Underweight; 18.5-24.9, Healthy weight; 25.0-29.9, Overweight; 30.0 or > Obese
Blood systolic blood pressure (mmHg): < 120, normal; 120-139, prehypertension; 140-159, stage 1 hypertension; 160-180, stage 2 hypertension; 180 or >, hypertensive crisis

Table 2

Number of Participants' Co-morbid Conditions (n=170)

Co-morbid conditions	N
Lung disease	25
Diabetes mellitus	25
Coronary artery disease	16
High cholesterol	71
Heart attack	12
Hypertension	80
Stroke	5
Current tobacco use	17
Current alcohol use	115

Note: individuals could report one or more medical conditions

Table 3

Correlational analyses between clinical variables and AHI levels from PSG (n=96-142)

	AHI levels per Polysomnography		
	Correlation Coefficient	Sig. (2-tailed)	N
Age	.065	.443	142
Gender (0-male, 1-female)	-.210*	.012	142
Diabetes mellitus	-.040	.635	142
Coronary artery disease	-.014	.870	142
High cholesterol	.110	.194	142
Heart attack	.065	.439	142
Stroke	-.052	.539	142
Lung disease	-.132	.132	132
Current tobacco use	-.001	.989	142
Previous smoking history	.055	.532	132
Current or Previous Smoker	.007	.935	142
Alcohol use	.078	.354	142
Amount of alcohol use	.051	.623	96
Systolic Blood Pressure	.256**	.002	140
Diastolic blood pressure	.232**	.006	140
Heart rate	.056	.514	140
BMI	.173*	.041	140
Neck circumference	.302**	.000	141
Mallampati Score	-.029	.740	132

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

Table 4

Interactions Tested Between Gender and High Cholesterol, BMI, Neck Circumference, and Systolic Blood Pressure (n=130)

	Sum of Squares	DF	Mean Square	F	p	Partial Eta Squared
Corrected Model	32.844	10	3.284	3.068	.002	.205
Intercept	.276	1	.276	.258	.613	.002
Gender	.355	1	.355	.332	.566	.003
High cholesterol	1.341	1	1.341	1.253	.265	.010
Lung disease	5.797	1	5.797	5.416	.022	.044
Systolic blood pressure	2.123	1	2.123	1.984	.162	.016
Body mass index	7.612	1	7.612	7.112	.009	.056
Neck circumference	1.325	1	1.325	1.238	.268	.010
Gender*High Cholesterol	.390	1	.390	.365	.547	.003
Gender*Body Mass Index	3.113	1	3.113	2.908	.091	.024
Gender*Neck Circumference	1.549	1	1.549	1.447	.231	.012
Gender*Systolic Blood Pressure	.138	1	.138	.129	.720	.001

R^2 = .205, adjusted R^2 = .138

Table 5

Interactions Tested Between Systolic Blood Pressure and High Cholesterol, BMI, Neck Circumference, and Lung disease (n=130)

	Sum of Squares	DF	Mean Square	F	p	Partial Eta Squared
Corrected Model	31.344	10	3.134	2.894	.003	.196
Intercept	.535	1	.535	.494	.483	.004
Gender	3.388	1	3.388	3.128	.080	.026
High cholesterol	.008	1	.008	.007	.933	.000
Lung disease	.351	1	.351	.324	.570	.003
Systolic blood pressure	.200	1	.200	.185	.668	.002
Body mass index	.294	1	.294	.271	.603	.002
Neck circumference	.948	1	.948	.876	.351	.007
High Cholesterol* Systolic Blood Pressure	.035	1	.035	.032	.858	.000
Systolic Blood Pressure * Body Mass Index	.063	1	.063	.058	.810	.000
Systolic Blood Pressure* Neck circumference	.974	1	.974	.899	.345	.007
Lung disease* Systolic blood pressure	.937	1	.937	.865	.354	.007

R^2 = .196, adjusted R^2 = .128

Table 6

Final Model of Multiple Regression with Respecification Analysis for Variables Predicting Continuous AHI Levels from PSG (n=130)

	b	SE (b)	B	t	p
Gender	-.491	.269	-.220	-1.826	.070
Body mass index	.040	.019	.245	2.162	.033*
Systolic blood pressure	.013	.006	.187	2.107	.037*
Neck circumference	-.005	.070	-.009	-.068	.946
Lung disease	-.662	.275	-.201	-2.406	.018*
High cholesterol	.164	.185	.073	.886	.377

R^2 = .183, adjusted R^2=.143, F = 4.579, p <.001

a. Dependent Variable: Log (PSG)

b. Gender: male, 0; female, 1

*Significant at .05 level.

Chapter V: Conclusions, Discussion, and Implications for Research and Practice

This dissertation study was developed from the progression of knowledge focusing on the current state of screening, assessment, and diagnosis of obstructive sleep apnea (OSA). Three manuscripts included in this document are the result of the learning process that occurred throughout the PhD program with the dissertation serving as the culmination of the doctoral processes. The following paragraphs are a summary of knowledge development presented in Chapters 1-4.B. followed by implications for future research, application to clinical practice, and the author's next steps in scholarship.

Chapter I: Introduction

Chapter 1 provided an introduction to the background and significance of the dissertation study. The theoretical background and conceptual framework for the study were provided. Definitions for major concepts (obstructive sleep apnea (OSA), screening, assessment, diagnosis) were discussed. A discussion of reliability and validity was provided. The most commonly used OSA screening measures (the Berlin Questionnaire (Berlin), Epworth Sleepiness Scale (ESS), and the STOP Bang) were addressed in terms of types of questions, scoring, and limitations of the tools. The description of OSA assessment and diagnosis was discussed. Lastly, an introduction to the dissertation documents was presented.

Chapter II: Screening and Assessment for OSA in Primary Care

Sleep disorders are common in primary care patients but are rarely self-reported and go unaddressed by primary health providers. This state of the science publication is an integrative review aimed at evaluating current evidence regarding the screening and assessment for obstructive sleep apnea (OSA) in primary care settings. This publication also includes a discussion of OSA screening measures and the published psychometric properties of each one. This is the first publication to discuss the current state of the science of screening and assessment for OSA in primary care (Miller & Berger, 2016).

Specific journal articles that were included in the literature review were based on the following criteria: (a) published in the English language; (b) participants studied in primary care setting/internal medicine; (c) providers practicing in primary care/internal medicine; (d) included an OSA screening process; (e) compared OSA screening tools; and (f) used OSA assessment criteria. Studies were excluded if: (a) conducted in any setting other than primary care/internal medicine; (b) focused on sleep disorders other than OSA; (c) discussed long-term management of OSA in primary care settings; (d) focused on management of OSA patients by sleep physicians; and (e) used pediatric participants. After implementing the exclusion criteria, 17 articles met criteria for this integrative literature review.

OSA screening measures were developed to aid health providers in quickly screening for OSA in variety of health care settings (Abrishami et al., 2010; Ramachandran & Josephs, 2009; Silva et al., 2011). As previously discussed, self-report screening measures are intended to identify the patients that are in need of further assessment and possible referral to sleep specialists. The screening measures with extensive validation studies that were discussed in the review were the Berlin Questionnaire (Netzer et al., 1999), the Epworth Sleepiness Scale (ESS) (Johns, 1991), and STOP Bang (Chung et al., 2008a).

Studies that met the inclusion criteria were 14 non-experimental and three experimental designs. The results of the integrative literature review support that OSA is associated with exacerbation of comorbid conditions and increased risk for morbidity and mortality. Methodological testing of the OSA screening measures is necessary in primary care. There is lack of consensus in the role that primary care providers can perform in screening, assessing, and referring patients to sleep specialists for OSA. The findings from the review confirm that the current practice model of screening and assessment for OSA in primary care is fragmented and ineffective.

Chapter III: Methodological Strategies in Using Portable Sleep Monitoring in Research

OSA in adults has been increasing in prevalence over the last two decades, which is attributed in part to the obesity epidemic (Kendzerska et al., 2014; Peppard et al., 2013; Qaseem et al., 2014). Because of the increase in OSA prevalence, sleep laboratory and diagnostic polysomnogram (PSG) services are in high demand. Use of portable sleep monitors (PSM) has increased in popularity due to technological improvements and accessibility. American Academy of Sleep Medicine (AASM) established clinical guidelines that state the diagnosis of OSA needs to occur with a comprehensive sleep evaluation and with Level III monitors with at least four channels (Collop et al., 2007). PSM allow patients and clinicians a less expensive diagnostic option for OSA in outpatient and home settings with satisfactory positive predicative value (PPV) when compared to PSG

There are two purposes of the focused review on the methodological strategies when using PSM in research. The first purpose was to synthesize the literature on use of level III PSM in adult patients, in terms of: (a) sampling; (b) instrumentation issues; (c) clinical variables; (d) data processing; and (e) patient acceptability. The second purpose was to identify methodological strategies to use to standardize PSM information in research reports. This is the first known focused review that presents suggestions for adoption when using PSM in research. Articles were retrieved from 2000 to 2016 (n=371). Most articles were excluded (n=337) because Level III PSM were not used. After implementing inclusion/exclusion criteria, 33 articles were included in the focused review.

The research articles were inconsistent in reporting strategies. The authors identified five criteria to examine. Samples of most studies included sleep participants who had OSA or were suspected of having OSA (n=20). The most commonly reported instrumentation issue was device malfunction. Scoring practices of the PSM data were discussed in the majority of the articles (n=19). Almost all studies reported clinical variables (n=30). Several different PSM (n=14) were used. Few studies (n=6) reported information on patient acceptability.

Ten suggestions were made for adoption when using PSM in research. The body of knowledge regarding PSM in research is growing rapidly. Future studies need to address the methodological challenges and adopt the ten suggestions to promote consistency of reports and advance knowledge.

Chapter IV.A.: Psychometric Properties of OSA Screening Measures in Patient Referred to a Sleep Clinic; Aim 1 of Dissertation Study

Repetitive obstructive breathing events are caused by increased volume in upper airway structures (Peppard et al., 2009) and result in intermittent hypoxia, activation of oxygen free radicals, and an oxidative stress response. The long-term effects are development of co-morbid vascular comorbid conditions (Aaronson et al., 2015; Heffner et al., 2012; Kohli et al., 2011; Lipford et al., 2015; Yumino et al., 2013). Despite the evidence, OSA screening measures are not used consistently in primary care or specialty clinics to guide the patient referral process.

An AASM task force is focusing on improving detection and categorization of OSA symptoms and severity to promote screening, assessment, and diagnosis of the disorder (Aurora et al., 2015). More psychometric testing of OSA screening measures was needed to determine how well they predicted OSA in outpatient populations. The purpose of this methodological study was evaluate the psychometric properties of three self-report OSA screening measures (Berlin, ESS, STOP Bang) and an objective PSM (ApneaLink Air) compared to AHI levels (≥ 5, ≥ 15, and ≥ 30) from PSG in patients referred to a sleep clinic.

Patients referred to a sleep clinic (n=170) were enrolled in this study. The majority completed all self-report screening measures (n=168). Only about half met criteria for home sleep testing per AASM guidelines (n=91), however some were invalid due to insufficient data (n=8) and equipment failure (n=2). Most participants completed physician ordered PSG testing (n=142). The number of participants with complete data was 73.

Reliability testing was completed on the self-report screening measures. The ESS had high Cronbach's alpha levels, however, the Berlin and STOP Bang had very low Kudar-

Richardson (KR-20) levels. Validity testing was completed between the OSA screening measures and AHI levels from PSG. The STOP Bang and ApneaLink Air AHI levels were best at predicting participants who did/did not have OSA compared to AHI ≥ 15 from PSG.

Findings were that the STOP Bang had the highest sensitivity of the self-report measures while the ESS had the lowest; however, the ESS had the highest specificity. The Berlin produced the second highest sensitivity levels. The ApneaLink Air AHI levels had the highest PPV. It is important to note that not one self-report OSA screening measure has the psychometric properties to be implemented on a standardized basis. However, sleep screening and assessment can be followed by the use of a PSM; patients can then be referred to a sleep specialists when indicated.

Chapter IV.B.: Analysis of Demographic, Clinical, and Biomarker Characteristics to Determine Predictors of Apnea Hypopnea Index from Polysomnography in Midwestern Sleep Clinic Patients

This manuscript focuses on Aim 2, to examine if selected demographic (age, gender), clinical (diabetes, coronary artery disease, hyperlipidemia, myocardial infarction, stroke, lung disease, smoking history, alcohol intake), and biomarker (blood pressure, heart rate, body mass index (BMI), neck circumference, Mallampati score) variables predicted apnea hypopnea index (AHI) from PSG. To our knowledge, this is the first study to compare these combinations of variables to AHI levels from PSG.

The sample (N=170) consisted of approximately half males and half females. The majority of the participants consumed alcohol, had pre-hypertension, and hyperlipidemia.

Multi-collinearity was assessed and confounding factors, correlations, and potential interactions were explored. Systolic and diastolic blood pressures were highly correlated with each other therefore diastolic blood pressure was deleted from the model because it had a multicollinearity effect. Interactions in the model were tested between gender and other variables (high cholesterol, BMI, neck circumference, systolic blood pressure) and between systolic blood pressure and other variables (high cholesterol, BMI, neck circumference, and lung disease). No

interactions occurred between gender or systolic blood pressure and other variables, meaning that the effects of the variables on AHI levels from PSG did not vary depending on gender or systolic pressure. Participants who completed the pertinent demographic, clinical, and biomarker variables, and had AHI levels from PSG, were included in the model (N=130).

The final model included gender, high cholesterol, lung disease, systolic blood pressure, BMI, and neck circumference. The entire model predicted a significant level of variance in the outcome by the variables in the model ($F = 4.573$, $p < .001$, $R^2 = .183$, adjusted $R^2 = .143$). This study found that participants BMI, systolic blood pressure, and lack of lung disease diagnosis were independent predictors for AHI levels from PSG. Systolic blood pressure and BMI independently predicted AHI levels from PSG. Lung disease was a negative predicator for AHI levels from PSG; therefore, persons with lung disease were less likely to have OSA.

A strength of this study was that all participants completed the demographics and health history questionnaire. A limitation of the study was that lung disease was measured via self-report from participants and was not validated against health records; this applies to all comorbid health conditions and demographic variables obtained.

Implications for Research

An AASM task force recently released quality measures for the care of adult patients with OSA as well to improve detection and categorization of OSA symptoms and severity (Aurora et al., 2015). AASM then released a call for volunteers to serve on a new OSA Assessment Tools Task Force that will evaluate screening, assessment, and evaluation of current measures. The task force will determine if measures used currently are reliable and effective at detecting OSA in undiagnosed persons. The goals of this task force are three fold: (a) evaluate current OSA screening measures pre and post continuous positive airway pressure titration to see if they are reliable and effective, (b) develop a resource to inform members of existing measures, and (c) recommend whether the AASM needs to develop additional screening measures and mechanisms for completing this task (American Academy of Sleep Medicine, 2016). The

development of this committee emphasizes the need for researchers to collaborate and conduct validation testing of OSA screening measures. One timely implication is to submit a rigorous manuscript to a high impact journal describing results of Aim 1 (Chapter IV.A.). A second timely implication is to contact AASM task force members to express interest in future collaborations that address these three goals.

Further research is needed to determine the psychometric properties of the STOP Bang and appropriate use of PSM in outpatient settings. The findings from this study support further research of the STOP Bang in primary care and specialty settings because its ability to be quickly scored, acceptable reading level, and high levels of sensitivity. However, the STOP Bang has shown high false positive rates for OSA. The use of Level III PSM has been studied primarily in sleep laboratory settings and needs more validation testing in outpatient settings

Potential future studies will now be presented that are appropriate for this author's career stage. The first study is planned as a sub analysis using data collected from for this dissertation study. Because the STOP Bang was shown to have high false positive rates with a score ≥ 3, the analysis would compare a score ≥ 5 to Level III PSM apnea hypopnea index (AHI), respiratory distress index (RDI), and oxygen desaturation index (ODI). These measures would then be psychometrically compared to PSG AHI, RDI, and ODI data to further test predicative, convergent, and concurrent validity. The results from the secondary analysis would test higher STOP Bang cut-off scores against data from PSM and PSG testing in hopes to improve the psychometrics of the measure.

To build on results of the sub analysis, a pilot study will take place in a primary care and/or specialty setting. Patients with hypertension, BMI ≥ 35, and/or atrial fibrillation will be screened for study eligibility that includes meeting AASM criteria for PSM testing. After participant enrollment, a chart review will be completed to track co-morbid conditions, medications, and vital signs. The clinic nurse will interview and gather data to complete and score the STOP Bang and ESS, to assess for daytime sleepiness. Although the ESS has proven to be

psychometrically inadequate for OSA screening, it is still a valuable measure for daytime sleepiness. Participants will then complete two-nights of home PSM testing. STOP Bang scores ≥ 5 and ESS total scores will be compared to AHI, RDI, and ODI from manually scored PSM data. Providers would be made aware of participants' STOP Bang, ESS, and PSM scores after testing were completed.

Participants who were referred to sleep specialists will be followed through completion of PSG. Data from STOP Bang ≥ 5, ESS, and manually scored PSM will be psychometrically compared to physician ordered PSG results (AHI, RDI, ODI). A chart review will be conducted on all participants who were not referred to a sleep specialist. The research team will conduct a six-month follow-up to collect data on OSA diagnosis, treatment, health status and vital signs. The longitudinal design of this study will allow researchers to follow patients who are at high-risk for OSA through his/her treatment plan, initiated in a primary care or specialty setting. This pilot study would be the first to test the OSA screening measures in this manner.

Implications for Practice

Screening and assessment for OSA needs to become a priority in primary care and specialty settings. Health care providers need education on the importance of early screening, assessment, and diagnosis of OSA and how early detection may reduce the development of co morbid conditions (Bailes et al., 2009; Collop & Shafazand, 2013). In this study, BMI, systolic blood pressure, and absence of lung disease were predictors of OSA. The first two co-morbid conditions are in congruence with other studies. Many of the participants had chronic cardiac and respiratory conditions that could possibly be reduced in severity with OSA treatment. While research continues, a three-step process has been identified to improve the screening, assessment, and referral process.

The first step emphasizes the importance of the clinic nurse identifying patients at high-risk for OSA in primary care settings. While obtaining the patient's health history and changes in medications, nurses would ask about signs and symptoms (snoring, witnessed apneas, nocturnal

gasping or choking) and check the medical record for certain co-morbid conditions associated with OSA (BMI > 35, congestive heart failure, atrial fibrillation, hypertension, type II diabetes) (Miller & Berger, 2016). If the patients states that he/she has a sign or symptom or co-morbid condition(s) making them high-risk for OSA, the nurse would administer a screening measure with high levels of sensitivity, such as the STOP Bang (Chung et al., 2008a). The measure would then be scored and patients with a positive OSA screen (≥ 5) would be flagged. The ESS would be administered to measure daytime sleepiness levels. A trained health care provider could then conduct a clinical assessment.

The second step includes an assessment conducted by a health care provider. The assessment for OSA includes an examination of cardiovascular and respiratory systems including visual inspection of the oral-naso-pharynx (Epstein et al., 2009). If the provider suspects the presence of OSA, the patient would be evaluated for possible use of PSM.

The third step involves OSA evaluation with PSM. Patients who are appropriate for PSM are outlined in the AASM Clinical Guidelines (Collop et al., 2007). If the patient is suspected of having OSA and had a co-morbid condition that excluded him/her from PSM, a referral to a sleep specialist must be provided. In patients who receive PSM in primary care or specialty settings, results from PSM may be automatically scored by the primary care provider or specialty clinician. If the results of the PSM indicate AHI levels ≥ 15, the patient should be referred a sleep specialist for further evaluation. From this point, the sleep specialist can interpret the PSM data and decide whether treatment can be prescribed from the study or if laboratory PSG testing is warranted. If AHI levels were < 15 and the patient is not experiencing daytime sleepiness symptoms, the clinician should encourage weight and blood pressure management. These patients should be flagged for re-evaluation for OSA in 6 months.

AASM suggests that treatment modalities for OSA should not be prescribed by primary care or specialty providers because a comprehensive sleep evaluation is needed. Only sleep

specialists should prescribe OSA treatment methodologies from AHI levels from PSM as they have been trained to analyze the data manually (Collop et al., 2007).

In conclusion, further testing of the STOP Bang is necessary in primary care and specialty settings. There is not one OSA screening measure that can be widely implemented across clinical settings without clinical assessment, but the STOP Bang has shown to have the highest levels of sensitivity. More education is needed in primary care and specialty clinics. PSM can aide in the referral process to sleep specialists but are not without flaws, such as equipment failure and misplacement of sensors. More PSM research is needed to further establish reliability and validity testing in outpatient settings. This three-step process for screening, diagnosis, and treatment of OSA is ready for testing in primary care and specialty settings.

References

Aaronson, J. A., van Bennekom, C., Hofman, W. F., van Bezeij, T., van den Aardweg, Joost G, Groet, E., . . . Schmand, B. (2015). Obstructive sleep apnea is related to impaired cognitive and functional status after stroke. *Sleep, 38*(9), 1431-1437.

Abrishami, A., Khajehdehi, A., & Chung, F. (2010). A systematic review of screening questionnaires for obstructive sleep apnea. *Canadian Journal of Anesthesia/Journal Canadien D'Anesthésie, 57*(5), 423-438.

American Academy of Sleep Medicine. (2016). Call for Volunteers: AASM seeks volunteers for new OSA assessment tools task force. Retrieved from http://www.aasmnet.org/articles.aspx?id=6212&utm_source=WeeklyUpdate&utm_medium=email&utm_campaign=wu4-7-16

Aurora, R. N., Collop, N. A., Jacobowitz, O., Thomas, S. M., Quan, S. F., & Aronsky, A. J. (2015). Quality Measures for the Care of Adult Patients with Obstructive Sleep Apnea. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine*, doi:jc-00031-15 [pii]

Bailes, S., Baltzan, M., Rizzo, D., Fichten, C. S., Grad, R., Wolkove, N., . . . Libman, E. (2009). Sleep disorder symptoms are common and unspoken in Canadian general practice. *Family Practice, 26*(4), 294-300. doi:10.1093/fampra/cmp031 [doi]

Chung, F., Yegneswaran, B., Liao, P., Chung, S. A., Vairavanathan, S., Islam, S., . . . Shapiro, C. M. (2008). STOP questionnaire: a tool to screen patients for obstructive sleep apnea. *Anesthesiology, 108*(5), 812-821. doi:10.1097/ALN.0b013e31816d83e4 [doi]

Collop, N., Anderson, W. M., Boehlecke, B., Claman, D., Goldberg, R., Gottlieb, D., . . . Schwab, R. (2007). Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. *J Clin Sleep Med, 3*(7), 737-747.

Collop, N., & Shafazand, S. (2013). Primary vs. specialist care in management of sleep apnea. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 9*(6), 625-627. doi:10.5664/jcsm.2770 [doi]

Epstein, L. J., Kristo, D., Strollo, P. J.,Jr, Friedman, N., Malhotra, A., Patil, S. P., . . . Adult Obstructive Sleep Apnea Task Force of the American Academy of Sleep Medicine. (2009). Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 5*(3), 263-276.

Heffner, J. E., Rozenfeld, Y., Kai, M., Stephens, E. A., & Brown, L. K. (2012). Prevalence of Diagnosed Sleep Apnea Among Patients With Type 2 Diabetes in Primary Care. *CHEST Journal, 141*(6), 1414-1421.

Johns, M. W. (1991). A new method for measuring daytime sleepiness: the Epworth Sleepiness Scale. *Sleep, 14*(6), 540-545.

Kendzerska, T., Gershon, A. S., Hawker, G., Leung, R. S., & Tomlinson, G. (2014). Obstructive sleep apnea and risk of cardiovascular events and all-cause mortality: A decade-long historical cohort study. *PLoS Medicine, 11*(2), e1001599.

Kohli, P., Balachandran, J. S., & Malhotra, A. (2011). Obstructive sleep apnea and the risk for cardiovascular disease. *Current Atherosclerosis Reports, 13*(2), 138-146.

Lipford, M. C., Flemming, K. D., Calvin, A. D., Mandrekar, J., Brown, R. D.,Jr, Somers, V. K., & Caples, S. M. (2015). Associations between Cardioembolic Stroke and Obstructive Sleep Apnea. *Sleep, 38*(11), 1699-1705. doi:10.5665/sleep.5146 [doi]

Miller, J. N., & Berger, A. M. (2016). Screening and assessment for obstructive sleep apnea in primary care. *Sleep Medicine Reviews, 29*, 41-51.

Netzer, N. C., Stoohs, R. A., Netzer, C. M., Clark, K., & Strohl, K. P. (1999). Using the Berlin Questionnaire to identify patients at risk for the sleep apnea syndrome. *Annals of Internal Medicine, 131*(7), 485-491.

Peppard, P. E., Ward, N. R., & Morrell, M. J. (2009). The impact of obesity on oxygen desaturation during sleep-disordered breathing. *American Journal of Respiratory and Critical Care Medicine, 180*(8), 788-793.

Peppard, P. E., Young, T., Barnet, J. H., Palta, M., Hagen, E. W., & Hla, K. M. (2013). Increased prevalence of sleep-disordered breathing in adults. *American Journal of Epidemiology, 177*(9), 1006-1014. doi:10.1093/aje/kws342 [doi]

Qaseem, A., Dallas, P., Owens, D. K., Starkey, M., Holty, J. C., & Shekelle, P. (2014). Diagnosis of obstructive sleep apnea in adults: a clinical practice guideline from the American College of Physicians. *Annals of Internal Medicine, 161*(3), 210-220. doi:10.7326/M12-3187

Ramachandran, S. K., & Josephs, L. A. (2009). A meta-analysis of clinical screening tests for obstructive sleep apnea. *Anesthesiology, 110*(4), 928-939. doi:10.1097/ALN.0b013e31819c47b6 [doi]

Silva, G. E., Vana, K. D., Goodwin, J. L., Sherrill, D. L., & Quan, S. F. (2011). Identification of patients with sleep disordered breathing: comparing the four-variable screening tool, STOP,

STOP-Bang, and Epworth Sleepiness Scales. *Journal of Clinical Sleep Medicine : JCSM : Official Publication of the American Academy of Sleep Medicine, 7*(5), 467-472. doi:10.5664/JCSM.1308 [doi]

Yumino, D., Kasai, T., Kimmerly, D., Amirthalingam, V., Floras, J. S., & Bradley, T. D. (2013). Differing effects of obstructive and central sleep apneas on stroke volume in patients with heart failure. *American Journal of Respiratory and Critical Care Medicine, 187*(4), 433-438.

Appendix A

Berlin Questionnaire

Scoring Berlin questionnaire

Adapted from: from Netzer, et al., 1999. (Netzer NC, Stoohs RA, Netzer CM, Clark K, Strohl KP.Using the Berlin Questionnaire to identify patients at risk for the sleep apnea syndrome. Ann Intern Med. 1999 Oct 5;131(7):485-91).

The questionnaire consists of 3 categories related to the risk of having sleep apnea.

Patients can be classified into High-Risk or Low Risk based on their responses to the individual items and their overall scores in the symptom categories.

Categories and scoring: Category 1: items 1, 2, 3, 4, 5. Item 1: if '**Yes**', assign **1 point**

Item 2: if '**c**' or '**d**' is the response, assign **1 point** Item 3: if '**a**' or '**b**' is the response, assign **1 point** Item 4: if '**a**' is the response, assign **1 point**

Item 5: if '**a**' or '**b**' is the response, assign **2 points**

Add points. Category 1 is positive if the total score is 2 or more points

Category 2: items 6, 7, 8 (item 9 should be noted separately). Item 6: if '**a**' or '**b**' is the response, assign **1 point**

Item 7: if '**a**' or '**b**' is the response, assign **1 point**

Item 8: if '**a**' is the response, assign **1 point**

Add points. Category 2 is positive if the total score is 2 or more points Category 3 is positive if the answer to item 10 is 'Yes' OR if the BMI of the patient is greater than 30kg/m2.

(BMI must be calculated. BMI is defined as weight (kg) divided by height (m) squared, i.e., kg/m2).

High-Risk: if there are 2 or more Categories where the score is positive

Low Risk: if there is only 1 or no Categories where the score is positive

Additional question: item 9 should be noted separately.

Berlin Questionnaire

Height (m)_____ Weight (kg)_____ Age_____ Male / Female Please choose the correct response to each question

CATEGORY 1

1. **Do you snore?**
_ a. Yes

_ b. No

_ c. Don't know

If you snore:

2. **Your snoring is:**
_ a. Slightly louder than breathing
_ b. As loud as talking
_ c. Louder than talking
_ d. Very loud – can be heard in adjacent rooms

3. **How often do you snore**
_ a. Nearly every day
_ b. 3-4 times a week
_ c. 1-2 times a week
_ d. 1-2 times a month
_ e. Never or nearly never

4. **Has your snoring ever bothered other people?**
_ a. Yes

_ b. No

_ c. Don't Know

5. **Has anyone noticed that you quit breathing during your sleep?**

_ a. Nearly every day
_ b. 3-4 times a week
_ c. 1-2 times a week
_ d. 1-2 times a month
_ e. Never or nearly never

CATEGORY 2

6. **How often do you feel tired or fatigued after your sleep?**
_ a. Nearly every day
_ b. 3-4 times a week
_ c. 1-2 times a week
_ d. 1-2 times a month
_ e. Never or nearly never

7. **During your waking time, do you feel tired, fatigued or not up to par?**
_ a. Nearly every day
_ b. 3-4 times a week
_ c. 1-2 times a week
_ d. 1-2 times a month
_ e. Never or nearly never

8. **Have you ever nodded off or fallen asleep while driving a vehicle?**
_ a. Yes

_ b. No

If yes:

9. **How often does this occur?**
_ a. Nearly every day
_ b. 3-4 times a week
_ c. 1-2 times a week
_ d. 1-2 times a month
_ e. Never or nearly never

CATEGORY 3

10. **Do you have high blood pressure?**
_ Yes

_ No

_ Don't know

The Epworth Sleepiness Scale

The Epworth Sleepiness Scale is widely used in the field of sleep medicine as a subjective measure of apatient's sleepiness. The test is a list of eight situations in which you rate your tendency to become sleepy on a scale of 0, no chance of dozing, to 3, high chance of dozing. When you finish the test, add up the values of your responses. Your total score is based on a scale of 0 to 24. The scale estimates whether you are experiencing excessive sleepiness that possibly requires medical attention.

How Sleepy Are You?

How likely are you to doze off or fall asleep in the following situations? You should rate your chancesof dozing off, not just feeling tired. Even if you have not done some of these things recently try to determine how they would have affected you. For each situation, decide whether or not you would have:

- No chance of dozing =0
- Slight chance of dozing =1
- Moderate chance of dozing =2
- High chance of dozing =3

Write down the number corresponding to your choice in the right hand column. Total your score below.

Situation	Chance of Dozing
Sitting and reading	
Watching TV	
Sitting inactive in a public place (e.g., a theater ora meeting)	
As a passenger in a car for an hour without a break	
Lying down to rest in the afternoon when circumstances permit	
Sitting and talking to someone	
Sitting quietly after a lunch without alcohol	
In a car, while stopped for a few minutes in traffic	

Total Score =

Analyze Your Score

0-7: It is unlikely that you are abnormally sleepy.

8-9: You have an average amount of daytime sleepiness.

10-15: You may be excessively sleepy depending on the situation. You may want to consider seeking medical attention.

16-24: You are excessively sleepy and should consider seeking medical attention.

Reference: Johns MW. A new method for measuring daytime sleepiness: The Epworth Sleepiness Scale. *Sleep*, 1991; 14(6):540

STOP-Bang Questionnaire

Property of University Health Network, for further info: www.stopbang.ca
Modified from Chung F et al. Anesthesiology 2008; 108:812-21, Chung F et al Br J Anaesth 2012; 108:768–75, Chung F et al J Clin Sleep Med Sept 2014

Yes	No	
○	○	**Snoring?** Do you **Snore Loudly** (loud enough to be heard through closed doors or your bed-partner elbows you for snoring at night)?
○	○	**Tired?** Do you often feel **Tired, Fatigued, or Sleepy** during the daytime (such as falling asleep during driving)?
○	○	**Observed?** Has anyone **Observed** you **Stop Breathing** or **Choking/Gasping** during your sleep?
○	○	**Pressure?** Do you have or are being treated for **High Blood Pressure**?
○	○	**Body Mass Index more than 35 kg/m^2?**
○	○	**Age older than 50 year old?**
○	○	**Neck size large? (Measured around Adams apple)** For male, is your shirt collar 17 inches/43 cm or larger? For female, is your shirt collar 16 inches/41 cm or larger?
○	○	**Gender = Male?**