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The Comparative Effectiveness, Harms, and Cost of Care Models for the Evaluation and Treatment of Obstructive Sleep Apnea (OSA): A Systematic Review

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PREFACE

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The ESP Centers generate evidence syntheses on important clinical practice topics. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The ESP disseminates these reports throughout VA and in the published literature; some evidence syntheses have informed the clinical guidelines of large professional organizations.

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Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP CC Program Manager, at Nicole.Floyd@va.gov.

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EXECUTIVE SUMMARY

INTRODUCTION

Obstructive sleep apnea (OSA) is a chronic condition that results from repeated closure of the upper airway during sleep resulting in reduced airflow (hypopnea) or complete airflow cessation (apnea) leading to cyclic sleep disruption. Patients with OSA frequently experience excessive daytime sleepiness and decreased quality of life. However, not all individuals have excessive daytime sleepiness and symptoms are not required to make a diagnosis or obtain treatment. OSA has also been associated with a higher risk of myocardial infarction, heart failure, stroke, and cognitive decline. Continuous positive airway pressure (CPAP) effectively reduces apneas and hypopneas in most patients with OSA, improves blood pressure, and – particularly in those with symptoms of excessive daytime sleepiness – improves quality of life and sleep symptoms. CPAP use is also associated with a reduced risk of motor vehicle accidents.

The estimated prevalence of mild to severe OSA in the United States (2007-2010 data) among 30- to 70-year-olds is 34% for men and 17% for women. Despite the data associating OSA with consequences to health and quality of life and the conclusions from other guideline groups, many persons with OSA remain undiagnosed. In 2010, among 1.8 million US Veterans receiving outpatient care at 136 Veterans Affairs (VA) facilities, 37.4% had a body mass index (BMI) ≥ 30 kg/m^2. Given the strong relationship between high BMI and OSA, these data suggest that a substantial portion of US Veterans are at high risk for OSA. A recent analysis of Veterans Administration Informatics and Computing Infrastructure (VINCI) data between 2000 and 2010 showed that among 9.8 million Veterans, the age-adjusted prevalence of diagnosed sleep apnea was 0.4% in 2000 and had increased to 3.0% in 2010 (a relative increase of 650%). As awareness of OSA by patients and providers continues to increase, and as BMI continues to increase in the US and globally, healthcare systems such as the VA need to develop strategies to manage the increasing demand for sleep services. One strategy is to target screening and testing to those most likely to derive benefit from OSA treatment (*eg*, those with significant unexplained daytime sleepiness), as suggested by the American College of Physicians (ACP). Another strategy is to improve efficiency within healthcare systems by implementing innovative, less resource-intense models of care for OSA.

The traditional model of OSA evaluation and care relies upon primary care providers to refer patients with suspected OSA to a sleep specialist physician (SSP) for consultation. After an initial consultative visit, the SSP can order formal, in-lab polysomnogram (PSG) for diagnostic purposes and for those with confirmed OSA, a PSG for titration of CPAP pressures. The SSP would typically initiate CPAP at the pressure suggested by the titration PSG, and then the patient would follow up with the SSP at regular intervals for assessment of treatment compliance and efficacy. Given the rapidly rising requests for OSA diagnostic and treatment services, this traditional model is increasingly viewed as unnecessarily expensive and inefficient for the evaluation and treatment of patients at high risk of OSA. Recent data also indicate a decreasing supply of SSPs to care for patients with known or suspected OSA.

Therefore, new models of OSA care have been proposed and implemented. These new models include home sleep testing (HST) for diagnostic purposes, followed by treatment with an autotitrating CPAP (APAP) device which has internal algorithms to adjust CPAP pressure to keep the airway open during sleep. These models reduce PSG-associated costs and logistical

barriers, yet typically still include consultation and follow up with a SSP. Other proposed models would reduce reliance on SSPs by including non-SSP providers such as nurses or primary care physicians to provide the bulk of OSA diagnosis and treatment.

Although several studies have been conducted to test some of these new models, systematic reviews are lacking. The Minneapolis VA's Evidence-based Synthesis Program (ESP) Center, in partnership with topic nominators and a Technical Expert Panel (TEP), was commissioned to systematically review the evidence regarding the comparative effectiveness, harms, and cost of these new models of OSA evaluation and treatment.

We addressed the following key questions (KQs):

Key Question 1. For adults with suspected OSA, what are the effectiveness/harms/resource utilization of case finding and care provided by practitioners who are not sleep physicians (including PCPs, PAs, NPs, technologists, nurses, and respiratory therapists), compared to case finding and care provided by sleep specialist physicians?

Key Question 2. For adults with suspected OSA, what are the effectiveness/harms/resource utilization of electronic consultation versus interactive (*eg*, in-person, telephone) consultation?

Key Question 3. For adults diagnosed with OSA, what are the effectiveness/harms/resource utilization (including cost avoidance) of using in-home autotitrating continuous positive airway pressure (APAP) technology compared to standard continuous positive airway pressure (CPAP) titrated by in-lab PSG?

METHODS

Data Sources and Searches

We searched MEDLINE (Ovid) and CINAHL for articles published between 2000 and May 2016. We obtained additional articles by hand searching the reference lists of related systematic reviews and included studies.

Study Selection

Abstracts were independently reviewed in duplicate by investigators and research associates. We included studies of any design, published in English, that reported on OSA care or case finding in adults with suspected or diagnosed OSA and took place in North America, Europe, Australia, or New Zealand. For KQ1 we excluded studies that did not include a comparison of a supervised practitioner or non-specialist licensed independent practitioner (*eg*, primary care physician, physician's assistant, nurse, technologist, or respiratory therapist) to a SSP. We excluded studies evaluating the role of dentists and anesthesiologists. For KQ2 we excluded studies that did not compare an electronic initial consultation without patient contact to an interactive initial consultation. For KQ3 we excluded studies that did not compare the use of APAP to CPAP for *titration* or *treatment* of OSA. Furthermore, in studies of *titration* we only included articles in which the APAP was used at home and CPAP was manually titrated in a lab. We also excluded studies if they did not report any of our outcomes of interest.

Full-text reports of studies identified as potentially eligible based on abstract review were obtained for further review. Each article was independently reviewed by 2 investigators or research associates with disagreements settled by a third.

Data Abstraction and Risk of Bias Assessment

Study characteristics (location, setting, intervention groups, follow-up, aim of study, treatments, inclusion/exclusion criteria, and patient characteristics) as well as intermediate and clinical outcomes were extracted onto evidence tables by one investigator or research associate and verified by another. Trained research methodologists rated the risk of bias of individual studies as low, moderate, or high risk.

We assessed strength of evidence for the following outcomes: access to care, quality of life, compliance (hours of use per night), and adverse events. Strength of evidence was rated as high, moderate, low, or insufficient based on precision, consistency, directness, and risk of bias of the individual studies.

Data Synthesis and Analysis

We summarized findings by Key Question. We were able to pool data for quality of life (SF-36 scores), Epworth Sleepiness Scale (ESS) scores, and compliance (hours per night of use) for KQ1 and KQ3 (*titration* and *treatment* studies).

RESULTS

Results of Literature Search

We reviewed 2,847 abstracts, 2,252 from MEDLINE, and 595 from CINAHL. We excluded 2,493 abstracts and reviewed the full-text of 354 references. During full-text review we excluded 323 articles, leaving 31 eligible for inclusion. Hand searching reference lists of pertinent trials and systematic review identified an additional 3 references.

Summary of Results for Key Questions

Key Question 1

Eight studies (n = 1,401; 4 randomized controlled trials [RCTs]) reported results for KQ1. Sleep physician care was compared to management by primary care in 4 studies (n = 564), sleep-specialist nurses in 3 studies (n = 434), and other non-sleep physicians in one study (n = 403). Patients were generally middle-aged and moderately obese with mild sleepiness and severe sleep apnea as determined by apnea-hypopnea index (AHI).

Case Finding

One retrospective study reported on the ability of a primary care pulmonologist to order the proper sleep test. There was good agreement between the primary care pulmonologist and SSP (kappa = .74) and 93% (89/96) of the referred patients were diagnosed with OSA.

Care

Seven studies reported treatment outcomes in patients being managed by providers other tha SSPs. Three of these studies compared SSP care to primary care (n = 468, 1 RCT), 3 to sleep specialist nurses (n = 434; 3 RCTs), and one compared SSP care to management by a variety of physicians who were not sleep specialists.

Three studies reported quality of life; all found that SF-36 scores were similar between patients being treated by primary care (k = 1) or sleep-specialist nurses (k = 2) as compared to SSPs. Two studies reporting patient satisfaction found overall satisfaction was similar between groups.

CPAP compliance was reported in 7 studies. Six of the 7 studies found no difference in compliance, regardless of measure used, when comparing patients receiving SSP care to those receiving care from non-SSPs. The final study found that patients who were referred for a sleep study by non-SSPs were significantly less compliant, with fewer hours per night and less regular use, than those patients who were referred by SSPs. Cost was reported, in various ways, by 5 of the studies. Three did not report the significance of cost differences between SSP and non-SSP care. Two studies, however, found that nurse-led OSA care was associated with significantly lower costs per patient and within-trial costs.

Five studies reported ESS scores; all found scores were similar between groups receiving care from different providers. AHI was reported by one study. Residual AHI on CPAP was significantly lower in patients referred for PSG by non-SSPs than in patients referred by SSPs (P<.001).

Occurrence of adverse events was similar in the SSP and nurse/primary care groups. Time to initiation of therapy was reported in 2 studies. One found that significantly fewer patients in the primary care group received CPAP within one month of PSG when compared to patients in the SSP group (P = .012). The other reported that while there was no significant difference between groups for satisfaction with time waiting (P = .706), patients receiving nurse-led care were more satisfied with their impression of wait time (P = .004).

Key Question 2

No articles were identified that met inclusion criteria for this question.

Key Question 3

Twenty-seven studies addressed KQ3 and KQ3a, including 4 that compared *titration* with APAP to *titration* with CPAP and 23 that compared *treatment* with APAP to *treatment* with CPAP. The mean age of patients enrolled was 52 years, 80% were male, baseline BMI was 33 kg/m^2, baseline ESS was 13, and baseline AHI was 44 events/hour.

Titration

Of the 4 studies comparing *titration* in-lab with CPAP to *titration* at home with APAP, 3 were RCTs and one was an observational study. Mean ESS scores at baseline ranged from 14.0 to 15.5.

Few studies reported clinical outcomes. Most frequently reported was quality of life with 2 studies finding CPAP *titration* and APAP *titration* to be similar while another found mixed results for different subscales of the SF-36. No study reported access to care.

Intermediate outcomes were more commonly reported. ESS scores and compliance were generally similar for the CPAP *titration* and APAP *titration* groups.

Treatment

Among the 23 studies comparing treatment with CPAP to treatment with APAP, there were 22 RCTs (15 using a crossover design) and one retrospective cohort study. Baseline ESS scores ranged from 6.4 to 17.4.

The most commonly reported clinical outcomes were quality of life (specifically SF-36 scores) and patient preference for one treatment over another. Quality of life was similar for the 2 treatment groups in 7 of 9 studies reporting that outcome. In 7 of 12 studies reporting treatment preference, APAP was preferred. No study reported a significantly higher preference for CPAP.

Intermediate outcomes, including ESS scores and compliance (hours per night and proportion of nights used) were generally similar for the CPAP and APAP treatment group. Adverse events, reported in 6 studies, were generally similar between groups.

DISCUSSION

Key Findings and Strength of Evidence (Executive Summary Table)

Key Question 1

Case Finding

- No studies assessed the diagnostic accuracy of non-sleep-specialist nurse for case finding and referral.

- One retrospective study reported good agreement between a primary care pulmonologist and a SSP on what sleep test to order for patients referred by their family physician.

Care

- Clinical (*ie*, patient-centered) outcomes were infrequently and inconsistently reported. When reported there was no significant difference in clinical outcomes between OSA treated by primary care/nurses and SSPs. The strength of evidence for quality of life was moderate.

- Intermediate outcomes were more commonly reported. Sleep symptom scores were similar between groups (moderate strength of evidence).

- There was little evidence that treatment compliance differed between patients treated by SSPs and those not, including the proportion of patients with 4 hours or more of CPAP use on 70% or more of nights (moderate strength of evidence).

- Very few studies reported other intermediate outcomes. One reported a significantly lower residual AHI on CPAP in patients referred for PSG by non-sleep specialists and another found that the proportion of patients receiving CPAP within one month of their PSG was significantly higher in patients cared for by a SSP. Strength of evidence for access to care and adverse events was insufficient.

Key Question 3

Titration

- Few studies compared clinical (*ie*, patient-centered) outcomes between in-lab CPAP *titration* and at-home APAP *titration*. In limited reporting, study groups were generally similar on measures of quality of life (moderate strength of evidence) and cognitive symptoms. Some differences were noted for resource utilization and patient preference.

- Intermediate outcomes (*ie*, sleep measures, blood pressure, adverse events, and compliance/adherence) were more commonly reported and generally similar. Strength of evidence for ESS was moderate and strength of evidence for compliance was low. Strength of evidence for adverse events was insufficient.

Treatment

- Twenty-three studies compared *treatment* with CPAP to *treatment* with APAP. The studies enrolled patients with a broad range of baseline AHI values.

- Few studies reported clinical (*ie*, patient-centered) outcomes other than quality of life and patient preference for one *treatment* approach over another. Quality of life, assessed with the SF-36, was generally similar between the CPAP and APAP groups (moderate strength of evidence). Patient preference was also generally similar or favored APAP in studies reporting statistical significance. Strength of evidence was insufficient for access to care.

- Intermediate outcomes including post-treatment ESS scores were frequently reported and generally similar for the 2 *treatment* approaches (moderate strength of evidence). Adverse events were mild and similar for APAP and CPAP (low strength of evidence).

- Compliance, reported as either hours per night or the proportion of nights the device was used, was also similar for the CPAP and APAP *treatment* groups (moderate strength of evidence).

Executive Summary Table. Strength of Evidence

Comparison	Outcome of interest	Strength of evidence[a]	Direction
KQ1: Sleep physician care compared to management by primary care, sleep-specialist nurses, or other non-sleep physicians	Access to care	Insufficient	
	Epworth Sleepiness Score	Moderate	**SIMILAR**
	Quality of life	Moderate	**SIMILAR**
	Compliance, hours per night	Moderate	**SIMILAR**
	Adverse events	Insufficient	
KQ3: Home APAP technology versus standard in-center manual CPAP *titration*	Access to care	Insufficient	
	Epworth Sleepiness Score	Moderate	**SIMILAR**
	Quality of life	Moderate	**SIMILAR**
	Compliance	Low	**SIMILAR**
	Adverse events	Insufficient	
KQ3: APAP versus CPAP *treatment*	Access to care	Insufficient	
	Epworth Sleepiness Score	Moderate	**SIMILAR**
	Quality of life	Moderate	**SIMILAR**
	Compliance	Moderate	**SIMILAR**
	Adverse events	Low	

APAP = Auto-adjusted (autoregulated) continuous positive airway pressure; CPAP = continuous positive airway pressure

[a]Strength of Evidence Definitions (Owens, DK et al, J Clin Epidemiol. 2010;63(5):523-523)

• High: Very confident that estimate of effect lies close to true effect. Few or no deficiencies in body of evidence, findings believed to be stable.

• Moderate: Moderately confident that estimate of effect lies close to true effect. Some deficiencies in body of evidence; findings likely to be stable, but some doubt.

• Low: Limited confidence that estimate of effect lies close to true effect; major or numerous deficiencies in body of evidence. Additional evidence necessary before concluding that findings are stable or that estimate of effect is close to true effect.

• Insufficient: No evidence, unable to estimate an effect, or no confidence in estimate of effect. No evidence is available or the body of evidence precludes judgment.

Limitations

We limited inclusion to English language studies and those performed in the United States, Canada, Western Europe, Australia, or New Zealand. This likely increases applicability of our findings to the VA healthcare system, but may reduce generalizability of our findings to other health settings. We also chose to exclude studies of dentists and anesthesiologists due to our

uncertainty whether or not these persons truly represent "Non-Sleep-Specialist Physicians" given that many dentists and anesthesiologists have substantial practices or background in sleep medicine. We also did not assess the role of surgery or mandibular assist devices for OSA treatment including referral of patients who may be more interested in or better candidates for these options.

A significant limitation is the paucity of high-quality literature regarding key questions 1 and 2. Although we are aware of the existence of clinical care models utilizing sleep respiratory therapists and behavioral sleep medicine providers to provide varying degrees of OSA care, we did not find any studies to address these particular type of practitioners. We also note that, importantly, the providers in many of these "primary care" studies were persons who had substantial experience in sleep medicine. Therefore, the generalizability of these findings to primary care providers with less experience in sleep medicine is not clear.

Applicability and Implementation

Most patients enrolled in studies were obese, middle-aged men, with severe OSA based on both high AHI levels and the presence of excessive daytime sleepiness. Our findings are most applicable to these individuals. We found only one study that was performed in a VA population for Key Question 3. One study was performed at Walter Reed Army Medical Center for key questions 1 and 3. While most studies were not specifically conducted in VA or military populations, because the patients enrolled in these studies were generally older, overweight men with OSA, we believe the findings of our systematic review should be applicable to the population of Veterans served by VA facilities.

Many of the study providers who were not SSPs had prior sleep training and therefore the results may not be fully generalizable to all primary care providers. While data are not conclusive, because our findings indicated similar Epworth Sleepiness Scores, quality of life, and treatment compliance scores among patients evaluated and treated by non-SSPs compared to SSPs it may be reasonable to consider expanded use of non-SSP providers who have received training in sleep medicine, especially where SSPs are in limited supply and demand for OSA services is high. Similarly, greater use of at-home APAP may lessen dependence on backlogged PSG laboratories, as most health outcomes were similar between groups.

Our report focused on methods that might improve the 'supply' side of OSA evaluation and treatment, through use of non-SSPs, electronic consultation, and at-home APAP *titration* and *treatment*. However, healthcare systems struggling to match supply to demand might also consider whether the 'demand' is truly appropriate. We found little to no data in screen-detected patients (*ie*, those found to have abnormal AHI either through direct referral to sleep laboratories or based on results of screening questionnaires such as the Berlin questionnaire but without excessive daytime sleepiness). The evidence to date indicates that the main benefit of OSA detection and treatment is improvement in patient-reported sleepiness symptoms among those with unexplained daytime somnolence. Therefore, VA healthcare providers and decision-makers could potentially achieve the highest value care, including resource use, by targeting case finding approaches and subsequent evaluation and treatment to individuals with unexplained daytime somnolence and who express interest in further evaluation and treatment. Theorectically, this referral approach could be readily be implemented by developing and using electronic medical record templates that describe the evidence-based rationale for the referral recommendations

while requesting that referring providers include information specifically about daytime somnolence and the patient's willingness for further evaluation and treatment in the consult.

Research Gaps/Future Research

Comparative effectiveness trials were lacking for all key questions. Key questions 1 and 2 would particularly benefit from trials to address the outcomes resulting from non-SSP care of sleep apnea patients (Key Question 1) and electronic consultation (Key Question 2). Limited available data suggest that care led by non-SSPs may potentially provide equivalent outcomes to care led by SSPs. Comparative effectiveness trials are needed in order to determine whether such results can be achieved in routine practice, outside of controlled research settings. The available data suggest that with some appropriate training, non-SSPs can potentially provide equivalent outcomes, but the operationalization of such training is unclear. Therefore, future comparative effectiveness trials should describe their training programs. Such trials should also collect clinical outcomes where possible.

As more healthcare systems implement comprehensive electronic medical records (EMRs), we anticipate Key Question 2 will become more feasible to study. In the current climate of increasing numbers of sleep referrals, yet a declining number of SSPs, EMR-based electronic consultation holds significant promise to provide equivalent outcomes in a more cost-effective, time-efficient manner. Although many systems have already implemented electronic consultation systems, evidence supporting this practice is largely lacking and further studies should be conducted. We think comparative effectiveness study designs such as stepped-wedge randomization (where sites are randomly assigned to the time point at which they implement electronic consultation) would allow the creation of good-quality evidence to quantify the risks, benefits, and economic impacts of electronic consultation for patients with known or suspected OSA.

We also note that blinding the intervention is not feasible in many of these randomized trials. However, we recommend that future studies make efforts to assess outcomes by persons blinded to treatment assignment and thereby mitigate the potential for biased assessments.

A large gap in evidence is related to the effectiveness of treatment for individuals without excessive daytime sleepiness (screen detected or case-finding in at-risk asymptomatic individuals) and on outcomes other than daytime sleepiness. For example, a recently published multi-site randomized trial showed that CPAP was not effective for secondary prevention of cardiovascular events in those with established cardiovascular disease and moderate to severe OSA. Additional information gaps include the effectiveness of treatment in those with mild AHI regardless of symptoms. These gaps are supported by recent evidence reports and accompanying clinical practice recommendations by the ACP and US Preventive Services Task Force (USPSTF) and described in greater detail in the introduction to the main report. These are critically important gaps to fill due to the dramatic increase in patients with, or suspected to have, OSA and thus being referred for evaluation and treatment.

Conclusions

Among patients suspected of having OSA, evidence suggests that primary care providers and sleep-specialist nurses might provide similar outcomes to SSPs, although the strength of this evidence was only moderate and many outcomes were inconsistently reported. Likewise, among

patients diagnosed with OSA, evidence suggests that at-home APAP *titration* and *treatment* provides similar outcomes to fixed pressure CPAP titrated in the PSG laboratory, although the strength of evidence was generally low to moderate.

We found no evidence addressing the topic of electronic consultation for the management of known or suspected OSA.

Future studies are needed to determine which patients derive the most benefit from treatment and should be prioritized for testing and treatment, whether newer models of care with less reliance on SSP time (either through utilization of other types of providers or electronic consultation) result in similar outcomes to traditional models, and if effective, how such models should be implemented.

ABBREVIATIONS TABLE

AHI	Apnea-Hypopnea Index
APAP	Auto-adjusting Positive Airway Pressure
BMI	Body Mass Index
CI	Confidence Interval
CPAP	Continuous Positive Airway Pressure
ESS	Epworth Sleepiness Scale
FOSQ	Functional Outcomes of Sleep Questionnaire
HbA1c	Hemoglobin A1c
HST	Home Sleep Testing
LIP	Licensed Independent Practitioner
MeSH	Medical Subject Heading
MID	Minimally Important Difference
ODI	Oxygen Desaturation Index
OSA	Obstructive Sleep Apnea
PSG	Polysomnogram/Polysomnography
PSQI	Pittsburgh Sleep Quality Index
RCT	Randomized Controlled Trial
RDI	Respiratory Disturbance Index
RR	Risk Ratio
SAQLI	Sleep Apnea Quality of Life Index
SASQ	Sleep Apnea Symptom Questionnaire
SF-36	Short Form-36, quality of life scale
SSP	Sleep Specialist Physician
US	United States
USPSTF	United States Preventive Services Task Force
VA	Department of Veterans' Affairs
VAS	Visual Analogue Scale
VINCI	Veterans Administration Informatics and Computing Infrastructure
VSQ-9	Visit-specific Satisfaction Instrument