Washington State Health Care Authority, HTA Program
Final Key Questions and Background
Sleep Apnea Diagnosis and Treatment

Introduction

HTA selected Sleep Apnea Diagnosis and Treatment to undergo a health technology assessment where an independent vendor will systematically review the evidence available on the safety, efficacy, and cost-effectiveness. HTA posted the topic and gathered public input on all available evidence. HTA posted the key questions for public comment and 3 responses were received. Disposition of the comments is included at the bottom of this document.

This topic is scheduled for review in March 2012.

In this case, a federal research agency, AHRQ, also selected this topic. AHRQ has posted key Questions. HTA strives to make economical use of state resources and to not duplicate other systematic reviews where current reports meet our statutory mandate and are timely.

Key Questions *(As specified in AHRQ report)*

Diagnosis

KQ1: How do different available tests compare to diagnose sleep apnea in adults with symptoms suggestive of disordered sleep?

    a. How do the different tests compare in different subgroups of patients, based on: race, gender, body mass index (BMI), existing non-insulin dependent diabetes mellitus (NIDDM), existing cardiovascular disease (CVD), existing hypertension (HTN), clinical symptoms, previous stroke, or airway characteristics?

KQ2: In adults being screened for obstructive sleep apnea, what are the relationships between apnea-hypopnea index (AHI) or oxygen desaturation index (ODI) and other patient characteristics with long term clinical and functional outcomes?

KQ3: How does phased testing (screening tests or battery followed by full test) compare to full testing alone?

KQ4: What is the effect of pre-operative screening for sleep apnea on surgical outcomes?

Treatment

KQ5: What is the comparative effect of different treatments for obstructive sleep apnea (OSA) in adults?

    a. Does the comparative effect of treatments vary based on presenting patient characteristics, severity of OSA, or other pre-treatment factors? Are any of these characteristics or factors predictive of treatment success?

        o Characteristics: Age, sex, race, weight, bed partner, airway and other physical characteristics, specific comorbidities

        o OSA severity or characteristics: Baseline questionnaire (etc.) results, formal testing results (including hypoxemia levels), Baseline QoL; positional dependency, REM dependency

   o   Other: specific symptoms

   b. Does the comparative effect of treatments vary based on the definitions of OSA used by study investigators?

KQ6: In OSA patients prescribed non-surgical treatments, what are the associations of pre-treatment patient-level characteristics with treatment compliance?

KQ7: What is the effect of interventions to improve compliance with device (CPAP, oral appliances, positional therapy) use on clinical and intermediate outcomes?

Additional Key Question:

Cost

KQ8: What evidence exists of the cost and cost-effectiveness for the identified strategies of sleep apnea diagnosis and treatment?

Technology Background (*from AHRQ Background- see below for link to this report*)

Sleep apnea is a common disorder that affects all ages. The American College of Chest Physicians estimates the prevalence of obstructive sleep apnea (OSA) in the United States to be between 5-10 percent and asserts that as many as one in four American adults could benefit from evaluation for OSA. The condition is characterized by periods of disturbed airflow patterns during sleep time, namely reduced airflow (hypopnea) or airflow cessation (apnea). It is postulated that both types of airflow disturbance have similar pathophysiology and bear the same clinical significance. OSA is by far the most common type of the condition; apneas and hypopneas of central and mixed central and obstructive etiology comprise the other forms. OSA has been associated with a variety of adverse clinical outcomes, such as mortality secondary to cardiovascular disease, decreased quality of life, cardiac disease and stroke, hypertension, and noninsulin-dependent diabetes and other metabolic abnormalities. It also is associated with an increased likelihood for motor vehicle and other accidents.

Diagnosis

The severity of sleep apnea is typically quantified by the number of apneas and hypopneas per hour of sleep, a quantity that has been termed the apnea-hypopnea index (AHI). The symptom of excessive daytime sleepiness is quite variable and is not always present in patients with OSA; thus, in most patients, the condition remains undiagnosed and untreated.

There is a large amount of clinical uncertainty surrounding this condition, including inconsistencies in the definition of the disease. While in-laboratory polysomnography is considered the gold standard in clinical practice to diagnose obstructive sleep apnea, it is not without constraints such as cost, interlaboratory variation in hardware and assessment methods. The standard measurement of AHI (and by extension, the diagnosis of sleep apnea) requires a comprehensive, technologist-attended sleep study with multichannel polysomnography, which is performed in specialized sleep laboratories. Laboratory-based polysomnography records a variety of neurophysiologic and cardiorespiratory signals and is interpreted by trained technologists and sleep physicians after the sleep study has been completed.

However, it is acknowledged that it is not a definitive test to either diagnose or rule out obstructive sleep apnea. In part, this is due to a lack of robust standardized criteria as to the test parameters measured and the thresholds of the parameters used to make the diagnosis.

Since in-laboratory polysomnography is costly, resource intensive, and burdensome to the patient, other diagnostic tools have been developed, including portable tests and questionnaires for pre-screening patients. There are different types of portable monitors, which gather different neurophysiologic and respiratory information and may synthesize the accumulated data differently. Different screening questionnaires exist to pre-screen patients for further testing or treatment. The value of the different tests and of the questionnaires and other screening tools remains unclear. There is also lack of clarity as to whether the tests can be accurately used to predict the clinical severity of patients' sleep apnea and their likelihood of clinically important sequelae.

Treatment

Continuous positive airway pressure (CPAP) is the standard 1st-line therapy for most patients diagnosed with obstructive sleep apnea. Obstructive sleep apnea occurs when the upper airway closes or becomes overly narrow as the muscles in the oropharynx (mouth and throat) relax during sleep. This results in inadequate or stopped breathing, which reduces oxygen in the blood and causes arousal from sleep. The CPAP machine counteracts this sequence of events by delivering compressed air to the oropharynx, splinting the airway (keeping it open with increased air pressure) so that unobstructed breathing becomes possible, reducing and/or preventing apneas and hypopneas.

For many patients, using CPAP results in immediate improvement in sleep and improvement in quality of life largely related to decreased daytime somnolence. However, it has been suggested that approximately one-quarter to one-half of patients with obstructive sleep apnea will either refuse the offer of CPAP therapy, will not tolerate it, fail to use the machine properly, or for other reasons do not comply with CPAP use. These patients are essentially untreated and receive little or no benefit from the device.

When CPAP is refused or not tolerated, a number of 2nd-line treatments are available including, uvulopalatopharyngoplasty (UPPP), radiofrequency ablation, jaw surgery, and bariatric surgery, for eligible candidates. UPPP, radiofrequency ablation, and jaw surgery are surgical techniques to remove or shrink and scar redundant tissue that is causing the obstruction or to otherwise minimize the obstruction. The goal of bariatric surgery is to reduce body weight and fat, which may shrink the oropharyngeal tissue causing the obstruction. However, life-threatening complications have been associated with sleep apnea surgery. Fatalities have been related to upper airway collapse or obstruction secondary to pharmacological sedation and surgical edema.

Other less invasive techniques include oral appliances, which are worn overnight and aim to mechanically splint the oropharynx open; positional therapy, devices to prevent lying supine during sleep, a position that for many patients exacerbates the obstruction; pharyngeal or laryngeal exercises to improve muscle tone; non-surgical weight loss programs; and physical-exercise programs.

Another management approach is to provide interventions that will increase compliance with CPAP use. These include structured education about the value of CPAP and how to use and adjust the CPAP; structured individual follow-up to correct any problems; group support; and relieving nasal congestion or dryness caused by the CPAP machine.

Public comment and Response

HTA received 3 timely public comments; one comment included evidence. All comments, references and evidence have been forwarded to the technology assessment center for consideration in the assessment of this topic. A summary of the comments follows:

One commenter provided evidence in the form of references relevant to each key question and written response to address/answer each key question. Response: No change to key questions. Commenter did not provide recommendations or comments on the key questions.

One commenter noted the need for varied approach in the diagnosis and treatment of sleep apnea due to the broad spectrum of potential patients and felt a "common guideline" would be helpful to establish diagnostic and surgical criteria. Response: No change to key questions. Commenter did not provide recommendations or comments on the key questions.

One commenter asked if cost-effectiveness analysis will include consideration of morbidities associated with different treatments for sleep apnea. Response: No change to key questions. All cost-effectiveness analyses that meet report inclusion criteria will be included in the assessment.

AHRQ Report Reference and Link

Balk EM, Moorthy D, Obadan NO, Patel K, Ip S, Chung M, Bannuru RR, Kitsios GD, Sen S, Iovin RC, Gaylor JM, D'Ambrosio C, Lau J. Diagnosis and Treatment of Obstructive Sleep Apnea in Adults. Comparative Effectiveness Review No. 32. AHRQ Publication No. 11-EHC052-EF. Rockville, MD: Agency for Healthcare Research and Quality. July 2011. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.