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Polysomnography in patients with obstructive sleep apnea: an evidence-based analysis

[Medical Advisory Secretariat](#)

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Abstract

Objective: The objective of this health technology policy assessment was to evaluate the clinical utility and cost-effectiveness of sleep studies in Ontario.

Clinical need: TARGET POPULATION AND CONDITION Sleep disorders are common and obstructive sleep apnea (OSA) is the predominant type. Obstructive sleep apnea is the repetitive complete obstruction (apnea) or partial obstruction (hypopnea) of the collapsible part of the upper airway during sleep. The syndrome is associated with excessive daytime sleepiness or chronic fatigue. Several studies have shown that OSA is associated with hypertension, stroke, and other cardiovascular disorders; many researchers believe that these cardiovascular disorders are consequences of OSA. This has generated increasing interest in recent years in sleep studies.

The technology being reviewed: There is no 'gold standard' for the diagnosis of OSA, which makes it difficult to calibrate any test for diagnosis. Traditionally, polysomnography (PSG) in an attended setting (sleep laboratory) has been used as a reference standard for the diagnosis of OSA. Polysomnography measures several sleep variables, one of which is the apnea-hypopnea index (AHI) or respiratory disturbance index (RDI). The AHI is defined as the sum of apneas and hypopneas per hour of sleep; apnea is defined as the absence of airflow for ≥ 10 seconds; and hypopnea is defined as reduction in respiratory effort with $\geq 4\%$ oxygen desaturation. The RDI is defined as the sum of apneas, hypopneas, and abnormal respiratory events per hour of sleep. Often the two terms are used interchangeably. The AHI has been widely used to diagnose OSA, although with different cut-off levels, the basis for which are often unclear or arbitrarily determined. Generally, an AHI of more than five events per hour of sleep is considered abnormal and the patient is considered to have a sleep disorder. An abnormal AHI accompanied by excessive daytime sleepiness is the hallmark for OSA diagnosis. For patients diagnosed with OSA, continuous positive airway pressure (CPAP) therapy is the treatment of choice. Polysomnography may also be used for titrating CPAP to individual needs. In January 2005, the College of Physicians and Surgeons of Ontario published the second edition of Independent Health Facilities: Clinical Practice Parameters and Facility Standards: Sleep Medicine, commonly known as "The Sleep Book." The Sleep Book states that OSA is the most common primary respiratory sleep disorder and a full overnight sleep study is considered the current standard test for individuals in whom OSA is suspected (based on clinical signs and symptoms), particularly if CPAP or surgical therapy is being considered. Polysomnography in a sleep laboratory is time-consuming and expensive. With the evolution of technology, portable devices have emerged that measure more or less the same sleep variables in sleep laboratories as in the home. Newer CPAP devices also have auto-titration features and can record sleep variables including AHI. These devices, if equally accurate, may reduce the dependency on sleep laboratories for the diagnosis of OSA and the titration of CPAP, and thus may be more cost-effective. Difficulties arise, however, when trying to assess and compare the diagnostic efficacy of in-home PSG versus in-lab. The AHI measured from portable devices in-

home is the sum of apneas and hypopneas per hour of time in bed, rather than of sleep, and the absolute diagnostic efficacy of in-lab PSG is unknown. To compare in-home PSG with in-lab PSG, several researchers have used correlation coefficients or sensitivity and specificity, while others have used Bland-Altman plots or receiver operating characteristics (ROC) curves. All these approaches, however, have potential pitfalls. Correlation coefficients do not measure agreement; sensitivity and specificity are not helpful when the true disease status is unknown; and Bland-Altman plots measure agreement (but are helpful when the range of clinical equivalence is known). Lastly, receiver operating characteristics curves are generated using logistic regression with the true disease status as the dependent variable and test values as the independent variable. Thus, each value of the test is used as a cut-point to measure sensitivity and specificity, which are then plotted on an x-y plane. The cut-point that maximizes both sensitivity and specificity is chosen as the cut-off level to discriminate between disease and no-disease states. In the absence of a gold standard to determine the true disease status, ROC curves are of minimal value. At the request of the Ontario Health Technology Advisory Committee (OHTAC), MAS has thus reviewed the literature on PSG published over the last two years to examine new developments.

Review strategy: There is a large body of literature on sleep studies and several reviews have been conducted. Two large cohort studies, the Sleep Heart Health Study and the Wisconsin Sleep Cohort Study, are the main sources of evidence on sleep literature. To examine new developments on PSG published in the past two years, MEDLINE, EMBASE, MEDLINE In-Process & Other Non-Indexed Citations, the Cochrane Database of Systematic Reviews and Cochrane CENTRAL, INAHTA, and websites of other health technology assessment agencies were searched. Any study that reported results of in-home or in-lab PSG was included. All articles that reported findings from the Sleep Heart Health Study and the Wisconsin Sleep Cohort Study were also reviewed. **DIFFUSION OF SLEEP LABORATORIES:** To estimate the diffusion of sleep laboratories, a list of sleep laboratories licensed under the Independent Health Facility Act was obtained. The annual number of sleep studies per 100,000 individuals in Ontario from 2000 to 2004 was also estimated using administrative databases.

Literature review: A total of 315 articles were identified that were published in the past two years; 227 were excluded after reviewing titles and abstracts. A total of 59 articles were identified that reported findings of the Sleep Heart Health Study and the Wisconsin Sleep Cohort Study.

Prevalence: Based on cross-sectional data from the Wisconsin Sleep Cohort Study of 602 men and women aged 30 to 60 years, it is estimated that the prevalence of sleep-disordered breathing is 9% in women and 24% in men, on the basis of more than five AHI events per hour of sleep. Among the women with sleep disorder breathing, 22.6% had daytime sleepiness and among the men, 15.5% had daytime sleepiness. Based on this, the prevalence of OSA in the middle-aged adult population is estimated to be 2% in women and 4% in men. Snoring is present in 94% of OSA patients, but not all snorers have OSA. Women report daytime sleepiness less often compared with their male counterparts (of similar age, body mass index [BMI], and AHI). Prevalence of OSA tends to be higher in older age groups compared with younger age groups. **DIAGNOSTIC VALUE OF POLYSOMNOGRAPHY:** It is believed that PSG in the sleep laboratory is more accurate than in-home PSG. In the absence of a gold standard, however, claims of accuracy cannot be substantiated. In general, there is poor correlation between PSG variables and clinical variables. A variety of cut-off points of AHI (> 5, > 10, and > 15) are arbitrarily used to diagnose and categorize severity of OSA, though the clinical importance of these cut-off points has not been determined. Recently, a study of the use of a therapeutic trial of CPAP to diagnose OSA was reported. The authors studied habitual snorers with daytime sleepiness in the absence of other medical or psychiatric disorders. Using PSG as the reference standard, the authors calculated the sensitivity of this test to be 80% and its specificity to be 97%. Further, they concluded that PSG could be avoided in 46% of this population. **OBSTRUCTIVE SLEEP APNEA AND OBESITY:** Obstructive sleep apnea is strongly associated with obesity. Obese individuals (BMI >30 kg/m²) are at higher risk for OSA compared with non-obese individuals and up to 75% of OSA patients are obese. It is hypothesized that obese individuals have large deposits of fat in the neck that cause the upper airway to collapse in the supine position during sleep. The observations reported from several studies support the hypothesis that AHIs (or RDIs) are significantly reduced with weight loss in obese individuals. **OBSTRUCTIVE SLEEP APNEA AND CARDIOVASCULAR DISEASES:** Associations have been shown between OSA and comorbidities such as

diabetes mellitus and hypertension, which are known risk factors for myocardial infarction and stroke. Patients with more severe forms of OSA (based on AHI) report poorer quality of life and increased health care utilization compared with patients with milder forms of OSA. From animal models, it is hypothesized that sleep fragmentation results in glucose intolerance and hypertension. There is, however, no evidence from prospective studies in humans to establish a causal link between OSA and hypertension or diabetes mellitus. It is also not clear that the associations between OSA and other diseases are independent of obesity; in most of these studies, patients with higher values of AHI had higher values of BMI compared with patients with lower AHI values. A recent meta-analysis of bariatric surgery has shown that weight loss in obese individuals (mean BMI = 46.8 kg/m²; range = 32.30–68.80) significantly improved their health profile. Diabetes was resolved in 76.8% of patients, hypertension was resolved in 61.7% of patients, hyperlipidemia improved in 70% of patients, and OSA resolved in 85.7% of patients. This suggests that obesity leads to OSA, diabetes, and hypertension, rather than OSA independently causing diabetes and hypertension. (ABSTRACT TRUNCATED)

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Figures

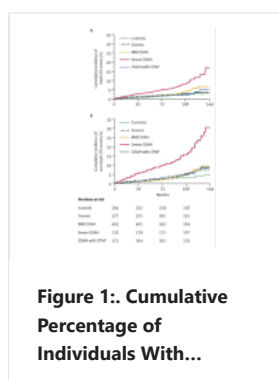


Figure 1:. Cumulative Percentage of Individuals With...

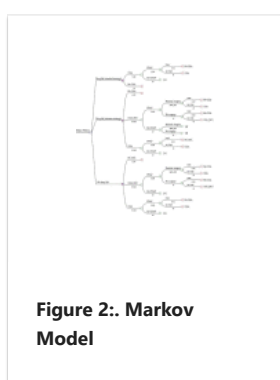


Figure 2:. Markov Model

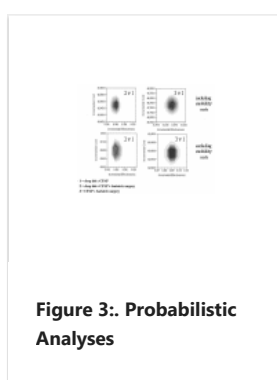


Figure 3:. Probabilistic Analyses

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