

Polysomnography Literature and Scientific Review

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1. Executive Summary

Of the many different sleep disorders, Obstructive Sleep Apnea (OSA) is the most prevalent. Often undiagnosed, OSA is a chronic disease in which pauses in breathing (apnea events) frequently interrupt sleep and potentially lead to severe motor and cognitive dysfunction.

Individuals with OSA often have no recollection of apnea events but may suffer with symptoms such as low energy, fatigue, lethargy and overall drowsiness during periods when they expect to be awake. Excessive daytime sleepiness, the hallmark symptom of OSA, is known to increase the risk of motor vehicle accidents, workplace accidents, decreased productivity, and common comorbid diseases such as cardiovascular disease and obesity.

Historically, the gold standard for diagnosing sleep disorders, including OSA, has been polysomnography, a monitored overnight sleep test that takes place in a laboratory. However, polysomnography is expensive, not available in all hospitals and, in British Columbia (BC), often has long wait times to see a specialist for consultation and referral to testing. These limiting factors have given rise to alternative testing methods such as portable monitoring, also known as home sleep apnea testing (HSAT), which is more accessible and, for a certain cohort of patients, equally reliable as overnight testing.

HSAT utilizes portable diagnostic devices that patients use overnight in their home. HSAT technology and effectiveness has evolved considerably over the past decade, however limitations exist; appropriate patient triage and referral are necessary for accurate diagnoses as, unlike polysomnography, HSAT is designed to detect only moderate to severe OSA in those who have high pre-test probability of disease with and no underlying co-morbid conditions.

Position statements from sleep medicine associations and individual sleep experts support increased use of HSAT for patients with a high pre-test probability of OSA. However, knowledge transition is a key aspect in adopting any new diagnostic technology into clinical practice, and challenges have emerged in sleep medicine as medical practitioners must be educated on the limitations of HSAT to ensure its appropriate use and patient safety.

The practice of diagnostic sleep testing is evolving. This review explores sleep study technologies; their current use in North America; socioeconomic considerations for selecting sleep studies; and best practices and guidelines on their use, with a focus on polysomnography and HSAT for diagnosis of the most common sleep disorder, OSA.

2. Introduction

Sleep is a natural and necessary part of every individual's life. Although the precise functions of sleep remain a mystery, getting an adequate amount of sleep is essential for normal motor and cognitive function. Lifestyle factors and undiagnosed or untreated sleep disorders may cause sleeping problems that are associated with difficulty concentrating, memory lapses, low energy, fatigue, lethargy, and emotional instability. Sleeping problems often cause a person to be sleepy at times when he or she expects to be awake, with serious consequences, such as drowsy driving or workplace accidents and errors.

Obstructive Sleep Apnea (OSA) is the most common sleep disorder, and in most populations, utilizes the most diagnostic resources of any sleep disorder. OSA is a chronic disease with a relatively low rate of diagnosis. Most people are not aware they may suffer from OSA, yet it has serious health consequences, leading to it being described as a "hidden health crisis" in North America¹. Events of apnea, which means 'no breathing' in Greek, are characteristic of this disease and those who suffer from OSA typically experience periods of very shallow breathing and/or brief cessations of breathing while asleep. These events can happen hundreds of times a night and breathing usually resumes with a loud gasp, snort or body jerk. With each event, blood oxygen levels are reduced, sleep is disturbed, and the sleeper will briefly wake (arousal) to resume breathing, however, the individual will not usually become fully awake and will often have no recollection that apnea events have taken place.² In severe cases of OSA, the sleeper can wake and fall asleep again repeatedly throughout the night, sometimes as many as 70 times per hour. This disrupts the normal sleep pattern, leading to chronic sleep deprivation and excessive daytime sleepiness, the major hallmarks of OSA.

In Canada, an estimated 858,900 (or 3 percent) of Canadian adults have reported being told by a health professional that they have sleep apnea³. However, a 2019 study on the prevalence of OSA estimates 24.5 percent of the Canadian population has some form of OSA, the majority of them being undiagnosed⁴. Sleep apnea may occur in young or old persons, male or female, and even children. Population-based studies have estimated the OSA prevalence in men at 10 percent among 30-49 year-olds and 17 percent among 50-70-year-olds. In women this prevalence is an estimated 3 percent among 30-49-year-olds and 9 percent among 50-70-year-olds⁵. Further, more than 1 in 4 (26 percent) of adult Canadians have reported symptoms and risk factors that are associated with a high risk of having or developing OSA⁶. These population data and estimates suggest that OSA is highly prevalent throughout Canada but under-diagnosed, emphasizing the importance of ensuring that an adequate capacity of appropriate, publicly-funded diagnostic sleep tests are available to British Columbians.

The gold standard for diagnosing sleep disorders has historically been polysomnography, a monitored overnight sleep test that takes place in a laboratory. In many jurisdictions, including BC, population growth and increasing public awareness of the symptoms and health implications of untreated OSA are fuelling demand for diagnostic procedures that can reliably indicate OSA⁷.

Polysomnography is expensive to provide, not available in all hospitals and is thought to have long waiting lists. To address these issues and maintain reasonable wait times for diagnostic sleep testing, health care providers have been exploring the suitability of home sleep apnea testing (HSAT) devices that can indicate OSA outside of a sleep lab^{8,9}. As HSAT technology has advanced and gained support in the medical science community as a reliable alternative to polysomnography¹⁰, long-standing best practices on diagnostic sleep testing have been revised to acknowledge the suitability of HSAT in diagnosing OSA for certain patient groups¹¹. However, knowledge transition is a key aspect in adopting any new diagnostic technology into clinical practice, and challenges have emerged in sleep medicine as medical practitioners must be educated on the limitations of HSAT to ensure its appropriate use and the maintenance of patient safety.

3. Obstructive Sleep Apnea

Practitioners, policy makers, insurance providers and health care authorities have been searching for viable approaches towards achieving a new set of service delivery best practices for OSA diagnosis, and this review highlights progress made thus far and the challenges that remain. Diagnosis of OSA requires objective diagnostic testing. Bed partner history of snoring and witnessed apneas is thought to be correct only 64 percent of the time and subjective healthcare provider impressions following consultation correctly identify only 50 percent of sleep apnea patients¹². Thus, clinical history and prediction algorithms alone have a low level of accuracy for diagnosing OSA and must be supported by robust diagnostic testing.

Early recognition and treatment of OSA can improve patient quality of life, lower rates of motor vehicle accidents and reduce risk of chronic health consequences associated with untreated OSA¹³, reducing the overall impact to the healthcare system. Economic predictions have highlighted a decrease in healthcare costs associated with early diagnosis and treatment of OSA^{14,15}. In the past decade, the availability of HSAT technologies that simplify the equipment required to make a diagnosis, eliminate the need for monitoring by a trained sleep technician, and potentially expedite the diagnostic process have shown the potential to reduce costs and allow more appropriate use of limited, comprehensive diagnostic resources for sleep studies.

3.1. Sleep Testing Classification in North America

In North America, sleep studies are categorized based on the technical complexity of the test being offered and described based on the level of sleep study corresponding to the type of test performed. Table 1 below summarizes the categories of sleep studies used in North America. In this classification system, Level I, in-laboratory tests are the most complex sleep study, requiring the greatest resources, while Level IV testing is the simplest, requiring the least resources. Table 1 provides more detail regarding each of the four levels of sleep studies.

Level I and Level III studies are currently the primary tools for diagnosing sleep disorders in Canada and are the primary focus of this review. Although Level II and IV studies may be used in certain situations, many jurisdictions do not offer coverage for these studies under their public medical services plan.

Table 1: Portable studies for sleep apnea evaluation: classification scheme (6-hour overnight recording minimum)

	Level I	Level II	Level III	Level IV
Description	In-laboratory, technologist attended, polysomnography	Full (unattended) polysomnography	Portable monitoring with three or more channels, including pulse oximetry and heart rate	Portable monitoring with only one or two channels including pulse oximetry
Parameters	Minimum of 7: EEG, EOG, chin EMG, ECG, airflow, respiratory effort, oximetry	Minimum of 7: EEG, EOG, chin EMG, ECG or HR, airflow, respiratory effort, oximetry	Minimum of 4: ventilation (respiratory movement and airflow) HR or ECG, oximetry	Minimum of 1: (typically oximetry or airflow)
Body position	Documented or objectively measured	Can be objectively measured	Can be objectively measured	Not measured
Leg movement	EMG or motion sensor (optional)	EMG or motion sensor (optional)	May be recorded	Not recorded
Personnel attendance	Constant	None	None	None
Interventions Possible	Yes	No	No	No

Abbreviations: ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; HR = heart rate.

From: Ferber R, Millman R, Coppola M, *et al.* Portable recording in the assessment of obstructive sleep apnea. ASDA standards of practice. Sleep 1994; 17(4):378-92.

3.2. Socioeconomic Impact of OSA

In the United States of America (USA), the rising prevalence of OSA prompted the American Academy of Sleep Medicine (AASM) in 2015 to commission the global research firm, Frost and Sullivan, to conduct an analysis into the economic impact of undiagnosed OSA. The Frost and Sullivan report¹⁶ estimates that 29.4 million people (12 percent of the population) in the USA suffer from OSA, with only 5.9 million (roughly 20 percent of OSA sufferers) having been diagnosed. Excessive daytime sleepiness, the hallmark symptom of OSA, is known to increase the risk of motor vehicle accidents, workplace accidents, decreased productivity, and comorbid diseases common in OSA sufferers, such as cardiovascular disease and obesity. In the Frost and Sullivan report, it was estimated that the large undiagnosed population of OSA sufferers in the USA placed an estimated economic burden of \$150 billion on the economy (Figure 1). The Frost and Sullivan report also found that the economic costs associated with untreated OSA may largely be mitigated through early diagnosis and treatment. Treatments for OSA are known to be highly effective in most cases and the Frost and Sullivan report estimated the cost burden associated with treatment, illustrated in Table 2 at \$2,105 per person, whereas the economic burden of persons with undiagnosed OSA is estimated at \$6,366 per person, highlighting that leaving OSA untreated is far more costly than treatment costs.

To predict the monetary impact of undiagnosed OSA, the Frost and Sullivan report included an economic forecast. The report predicts that diagnosis and treatment of every OSA patient in the USA would create an annual cost savings of just over \$100 billion and underlines the importance of addressing this disease to the benefit of overall population health and reduced health care spending in the long-term.

Drivers with OSA are particularly at risk, and studies indicate that drivers with sleep apnea have a 7-fold increased risk of injury when compared to healthy drivers¹⁷ and that almost 20 percent of all serious car crash injuries in the general population are associated with driver sleepiness, independent of alcohol effects¹⁸. In a separate report, Sassani *et al*, estimated that in the year 2000, more than 800,000 drivers in the US were involved in sleep apnea-related vehicle crashes, those events costing an estimated \$15.9 billion dollars and 1,400 lives in the year 2000¹⁹. Sassani *et al* estimated that treatment for all drivers suffering from OSA in the USA would cost 3.18 billion dollars, annually saving 980 lives and 11.1 billion dollars in collision costs.

Figure 1: In the USA the estimated economic cost of undiagnosed obstructive sleep apnea was nearly \$150 billion in 2015²⁰.

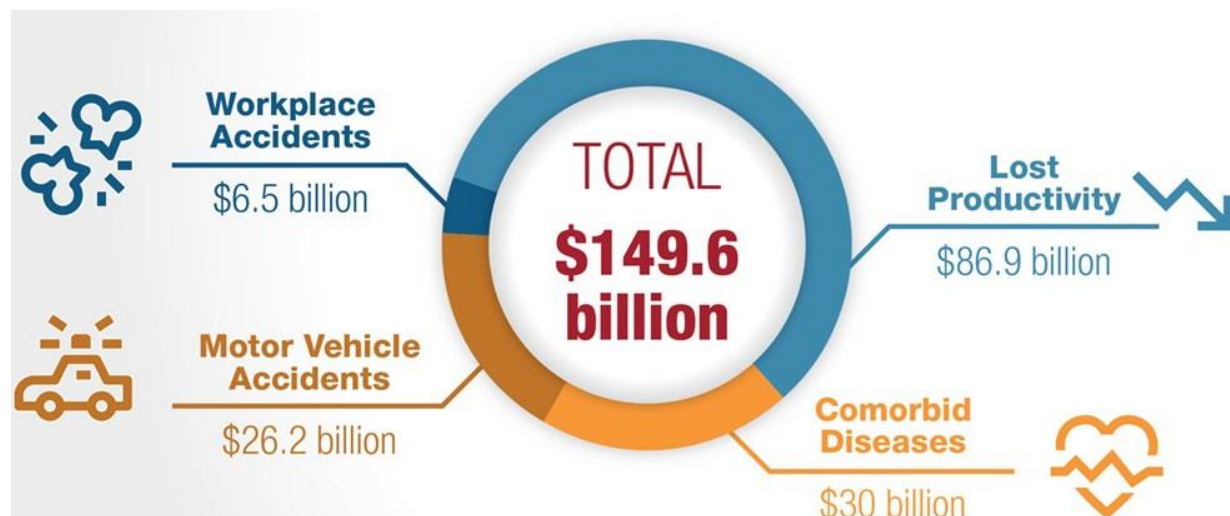


Table 2: Cost burden of OSA in undiagnosed versus diagnosis and treatment costs in the USA (2015)²¹

	Undiagnosed		Diagnosed
# People with OSA	23,500,000		5,900,000
	Cost of Undiagnosed OSA (\$US Bil)		Cost of Diagnosed OSA (\$US Bil)
Comorbidities & Mental Health	\$30.0	Diagnosis, Testing and Follow-up	\$0.8
Motor Vehicle Accidents	\$26.2	Non-surgical Treatment (PAP and Oral Appliances)	\$6.2
Workplace Accidents	\$6.5	Surgical Treatment	\$5.4
Lost Productivity	\$86.9		
Total Costs (\$US Bil)	\$149.6		\$12.4
Cost per Person	\$6,366		\$2,105

3.3. Treatment of OSA

Treatment options for adult OSA include behavioral therapy (sleep hygiene, exercise, weight loss, etc.), use of mechanical devices, and surgery to increase airway size. Overall, adherent use of a Positive Airway Pressure (PAP) device is the treatment of choice for mild, moderate and severe OSA, and this device, combined with patient education and follow-up, should be offered as an option to all patients²².

Treatment methods for OSA can be divided into three groups:

- Positive Airway Pressure (PAP), which are proven to be the most efficient, but may not be accepted by patients due to the need of wearing an uncomfortable mask during sleep.
- Use of the mandibular repositioning devices, which are less efficient than positive airway pressure, but more willingly accepted by patients; these methods have proven quite successful in treating mild to moderate OSA.
- Surgical methods which can be very efficient, but at the same time, can cause danger to the patient's life²³.

Continuous Positive Airway Pressure (CPAP) is the most efficacious in complete resolution of sleep apnea and in improving the indices of saturation during sleep²⁴. Although CPAP devices are uncomplicated, sleep experts recommend that all patients starting CPAP receive a high level of intensive instruction that stresses the importance of adherence to CPAP as a critical aspect of successful OSA treatment²⁵.

3.4. Level I Study: Attended Polysomnography

In North America, a Level I sleep study, also called polysomnography, is defined as an in-laboratory, monitored sleep study that measures several parameters at once. Polysomnography provides comprehensive recording of the bio-physiological changes that occur during sleep and is usually performed at night, when most people sleep. Level I studies are considered to be the gold standard in sleep testing as they provide neurophysiological measurements that can accurately distinguish periods of sleep from periods of wakefulness to help to chart sleep-wake cycles and diagnose a wide range of sleep disorders²⁶. For sleep disordered breathing, polysomnography produces a measure called the apnea-hypopnea index (AHI) which indicates the severity of the patients' condition.

The AHI is calculated by dividing the number of apnea events by the number of hours of sleep and AHI values for adults are categorized as follows:

- Normal: $AHI < 5$
- Mild sleep apnea: $5 \leq AHI < 15$
- Moderate sleep apnea: $15 \leq AHI < 30$
- Severe sleep apnea: $AHI \geq 30$

For children, because of their different physiology, an AHI in excess of 1 is considered abnormal. Pediatric patients presenting with AHI of 2 or greater will often be referred for treatment. Since the AHI produced during a Level I study is based on actual sleep time, polysomnography is considered more accurate than other types of sleep studies, which rely on predicted sleep times.

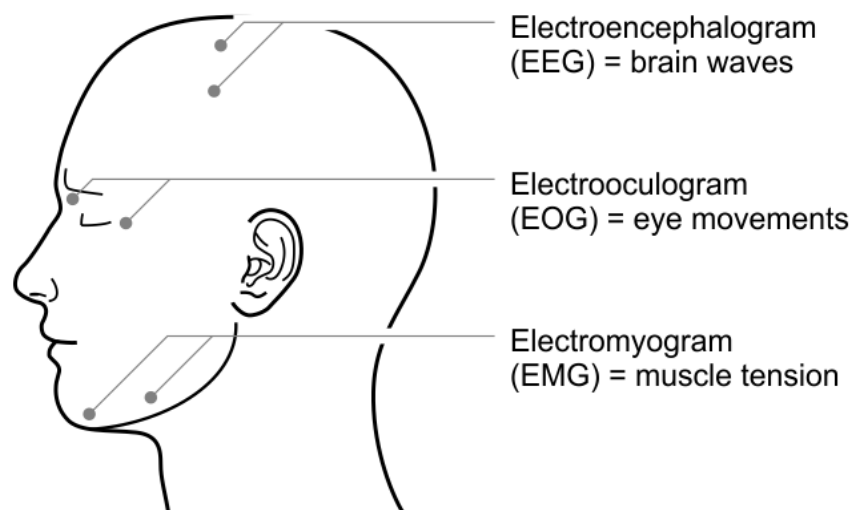
Monitored Parameters

Polysomnography includes signals from seven or more inputs, however modern polysomnograms typically measure 12 or more channels at once, requiring a minimum of 22 wire attachments to the patient. In addition to channels that measure respiration during sleep, other measurements provide important information to assess sleep quality. Although there may be laboratory-specific differences in how polysomnography is performed, all Level I devices include the following channels, many of which require multiple electrode attachments to the patient (*Figure 2*) for measuring bioelectrical signals:

- Brain rhythms by electro-encephalography (EEG)
- Heart rhythms by electrocardiography (EKG)
- Movement of body muscles by electromyography (EMG), usually limb muscles
- Eye movements during sleep by electro-oculography (EOG)
- Oxygen levels in blood recorded continuously (pulse oximeter)
- Respiratory effort at thorax and abdomen
- Air flow through the nose measured by special flow meters
- Audio/video recordings for analysis of sleep quality, snoring and movements

Measurement and recording of these parameters are followed by computational analyses to assess data and diagnose sleep disorders, including OSA²⁷.

Figure 2: *Electrode attachment locations on a patient undergoing polysomnography to monitor bioelectric signals associated with indicated polysomnographic parameters²⁸.*



Sleep Disorders Diagnosed Using Level I Studies

Diagnosis by polysomnography is indicated for medical, neurological and psychiatric sleep-related disorders. These include narcolepsy, sleep-related seizure disorders, bruxism, restless legs syndrome, periodic limb movement disorder, REM sleep behavior disorder, chronic insomnia and OSA²⁹.

However, in the USA, private insurance plans³⁰ and public health associations³¹ are increasingly recommending that a Level I study be used as an initial test only when a Level III study is contraindicated. Further, some insurers in the USA have developed specific criteria to determine when a Level III study is considered “medically necessary” and preferred to a Level I study, i.e. situations in which coverage for Level I studies is not provided by the plan³².

Accuracy/Precision

Level I sleep studies (polysomnography) are the best technology available for diagnosing sleep disorders. Therefore, when other sleep tests are evaluated for their accuracy and/or precision, polysomnography is typically used as the standard for comparison.

Although advances in sleep testing technologies have the potential to reduce the reliance on Level I studies for certain diagnoses, many sleep disorders, such as narcolepsy, continue to use polysomnography as the primary diagnostic tool. Furthermore, Level I studies are the only recommended diagnostic tool for diagnosing sleep disorders in children, elderly, those with special needs and patients with significant comorbid disorders³³. Thus, it is not expected that in-laboratory Level I studies will be replaced as the most accurate means of diagnosing a patient for any given sleep disorder.

Table 3 provides an overview on the reliability of different diagnostic sleep studies, indicating their sensitivity and specificity relative to in-laboratory polysomnography.

Table 3: Sensitivity and specificity of different levels of sleep studies when compared to in-laboratory, attended polysomnography for the diagnosis of obstructive sleep apnea.

		Operating characteristics for sleep testing modality	
Sleep test	Indications for use	AHI≥5 events/h	AHI≥15 events/h
Polysomnography			
Attended (Level I study)	Low-to-moderate probability of OSA Nondiagnostic HSAT/oximetry and suspected OSA Suspected sleep disorder other than OSA Suspected CSA or hypoventilation	Gold standard	Gold standard
Unattended (Level II study)	Predominantly used for research purposes	Sn: 0.88–0.97 Sp: 0.50–0.56	Sn: 0.94–0.95 Sp: 0.76–0.77
Home sleep apnea testing			
Level III study	Moderate-to-high probability of OSA without comorbidity	Sn: 0.90–1.00 Sp: 0.30–0.67	Sn: 0.66–0.88 Sp: 0.62–1.00
Two- or three-channel study	Unable to perform PSG because of immobility or infirmity	Sn: 0.80–0.96 Sp: 0.65–0.83	Sn: 0.66–0.88 Sp: 0.62–1.00
Single-channel study	Confirm treatment efficacy	Sn: 0.96† Sp: 0.82†	Sn: 0.55–0.91 Sp: 0.70–0.82
Peripheral arterial tone study		Sn: 0.96† Sp: 0.43†	Sn: 0.92–0.96 Sp: 0.77–1.00

Abbreviations: AHI = apnea–hypopnea index, CSA = central sleep apnea, HSAT = home sleep apnea testing, OSA = obstructive sleep apnea, PSG = polysomnography, Sn = sensitivity: proportion of people with OSA who are correctly identified as having OSA, Sp = specificity: proportion of healthy people who are correctly identified as not having OSA.

Note: All Sn and Sp values are measured predictive values relative to polysomnography (1.00).

*Operating characteristics of these testing modalities when compared with PSG and reported for high-prevalence populations (estimated prevalence 87%).

†Based on one validation study. Modified from Laratta *et al*, 2017.

Accessibility Issues in Canada

Many jurisdictions across Canada lack diagnostic capacity to serve the increasing number of individuals at risk for OSA³⁴. The number of Level I beds per 100,000 population varies greatly across Canada, ranging from zero in several provinces/territories to 4.78 beds per 100,000 in Ontario. In BC, there are currently 1.64 Level 1 polysomnography beds per 100,000 persons. Overall, the number of Level I beds in Canada increased to 2.0 per 100,000 in 2010 from the 1.4 estimated in 2004.³⁵

Clinical Practice Guidelines and Recommendations

The American Academy of Sleep Medicine (AASM) is the main North American professional society dedicated to the medical subspecialty of sleep medicine. In conjunction with the Choosing Wisely campaign, an initiative of the American Board of Internal Medicine Foundation, they have developed a list of statements aimed at reducing unnecessary testing and/or treatment for patients with suspected or diagnosed sleep disorders³⁶. These recommendations include two statements that speak to reducing use of polysomnography for initial assessment of some sleep disorders:

- **Avoid polysomnography in chronic insomnia patients unless symptoms suggest a comorbid sleep disorder.** Although polysomnography may confirm self-reported symptoms, it does not provide additional information necessary for diagnosis of chronic insomnia.
- **Do not use polysomnography to diagnose restless legs syndrome, except rarely when the clinical history is ambiguous, and documentation of periodic leg movements is necessary.** Restless legs syndrome is a neurologic disorder that can be diagnosed based on a patient's description of symptoms and additional clinical history. Polysomnography generally does not provide additional information necessary to make the diagnosis. The AASM recommends these statements be considered as guidelines to the requisition of sleep testing for patients with sleep disorders, including OSA.

Cost Considerations

Polysomnography in a sleep laboratory is the most costly type of sleep study. In addition to the specialized equipment needed, polysomnography studies require a long examination time (typically overnight), a qualified monitoring technician, and a sleep specialist for interpretation³⁷.

3.5. Level II Sleep Study

Level II studies, also known as unmonitored polysomnography, use equipment that is similar to a Level I study, however there is no attendant monitoring sleep movements and/or periods of wakefulness. Level II sleep equipment is sometimes referred to as a comprehensive portable device and these are theoretically capable of performing full polysomnography outside of the laboratory. Since this type of testing does not utilize an attendant to record periods of wakefulness, the sleep durations that are calculated using this method can be inaccurate, overestimating the duration of sleep while underestimating periods of wakefulness.

Monitored Parameters

Type II portable equipment monitors a minimum of 7 channels, including the following:

- Brain rhythms by electro-encephalography (EEG)
- Heart rhythms by electrocardiography (ECG)
- Movement of body muscles by electromyography (EMG), usually limb muscles
- Eye movements during sleep by electro-oculography (EOG)
- Oxygen levels in blood recorded continuously (pulse oximeter)
- Respiratory effort at thorax and abdomen
- Air flow through the nose measured by special flow meters

Equipment: Variations In/Types of

The types of equipment used as Level II devices are often capable of monitoring more than 12 channels. These machines are like those used for Level I studies with the exclusion of video monitoring and attendant-scored parameters.

Accuracy, Precision and Shortcomings

Since there is no video monitoring to accompany measurements obtained with Level II equipment, arousal measurements are used to imply periods of wakefulness and obtain an AHI value, providing an assessment of OSA and its severity. Despite this, periods of wakefulness may be underestimated and therefore Level II studies cannot reliably exclude OSA through a negative test result, a shortcoming that is shared with Level III studies. Furthermore, Level II monitoring tends to result in a greater number of total diagnostic tests performed for two reasons. First, split-night studies are not possible during unattended polysomnography and therefore a second session is necessary to obtain the data needed to determine PAP settings. Second, it has been estimated that 20 percent of unattended tests result in unusable data, triggering the need for subsequent, in-laboratory polysomnography³⁸. Since Level III studies have similar sensitivity and limitations and can be performed at a lower cost with less equipment, Level II studies have not been widely adopted for diagnosis of OSA.

Current State of Use

Billing for this service is not currently provided in BC and is not available in most Canadian jurisdictions due to lack of need as Level III studies are as accurate and easier to use without the need for additional complex equipment.

Benefits

The primary benefit of Level II studies is the ability to diagnose a range of sleep disorders outside of a sleep medicine laboratory. These studies are typically performed in a patient's home and benefit patients who have mobility concerns or difficulty sleeping in a laboratory.

3.6. Level III Sleep Study: Home Sleep Apnea Testing

Level III sleep studies, often referred to as home sleep apnea testing (HSAT) or portable monitoring, encompass a wide range of testing equipment that has been developed primarily to diagnose moderate to severe OSA.

Level III testing equipment has evolved considerably over the past decade as technology has created new methods for measuring physiological parameters. However, Level III sleep studies remain limited to the diagnosis of OSA and do not have the specificity to rule out OSA with a negative test, therefore the likelihood of false negatives should be considered by the referring physician when ordering a Level III study³⁹.

One of the major drawbacks of HSAT devices has been their inability to record signals needed to accurately determine sleep stages and/or sleep disruption. However, recent technological advances have led to the development of a proxy measurement for arousal that can adequately predict instances of sleep disruption during a Level III study, allowing the sensitivity of HSAT in diagnosing OSA to approach that of a Level I study (see Table 3).

Current research suggests that public funding models incorporating HSAT technology may offer economic advantages from the payer and patient perspectives when the test is used to diagnose patients with a high pretest likelihood of OSA⁴⁰. Level III testing is predicted to be less costly for the payer on a per-patient basis and the service is more accessible to patients when compared to Level I studies. However, an economic analysis⁴¹ that focused on the feasibility of providing Level III studies to a population, suggested that service providers (the facilities providing the service), are likely to face significant economic challenges when provision of Level III studies are the sole source of revenue as the provision of patient follow-up and monitoring that aligns with best practices challenges the profitability of HSAT providers.

Monitored Parameters

Although Level III devices are unattended, patient training is necessary to ensure accuracy and reproducibility of the data that they generate. These devices record four or more channels of physiologic variables, including:

- Two respiratory variables (i.e. respiratory movement and airflow)
- Cardiac variable (i.e. heart rate or an electrocardiogram)
- Arterial oxygen saturation

In contrast to polysomnography, HSAT devices typically do not include electroencephalography (EEG), electrooculography (EOG) or electromyography (EMG) sensors, all of which are required to define periods of sleep versus wakefulness.

Types of Equipment

The definition of respiratory events has evolved over time as advancing technology has allowed for improved detection of reduced airflow⁴². Level III devices now produce accepted proxies for arousal measurement, monitors to record snoring, light detection and means to determine body positioning and/or movements. In the absence of on-site video monitoring, HSAT devices are limited in their ability to determine sleep stages and sleep disruption as it is difficult to distinguish periods of sleep (when apnea events can occur) from wakefulness (when apnea events cannot occur). These periods of sleep and wakefulness are critical to determining the metric that is used to diagnose OSA, which is expressed as the average number of apnea events per hour of sleep.

The past decade has seen extensive research and development on unattended portable monitors for the diagnosis of OSA, particularly devices that can accurately recognize periods of sleep. Although no single device has emerged as a solution, some portable devices monitor autonomous nervous function by the measurement of peripheral arterial tone (PAT) on the finger, using this measurement to correlate the subcortical arousals that accompany apneas to periods of wakefulness that typically follow. Although the PAT signal cannot replace a polysomnogram, the additional information that they provide may be used as a proxy for respiratory disturbances. According to the 2017 AASM guideline, PAT used in combination with oximetry and actigraphy is “technically adequate” to diagnose OSA in patients likely to have the condition who do not present with comorbidities⁴³.

Accuracy, Precision and Shortcomings

As shown in Table 3, Level III studies have excellent sensitivity for identifying true positives, however they lack the ability to rule out OSA through a negative test. While polysomnography identifies the severity of sleep-disordered breathing based on actual sleep time, most HSAT devices produce a severity estimate called the respiratory event index, that is based on monitoring time. Thus, if a person wakes during an HSAT, the time it takes them to fall back asleep (a period during which hypopnea events typically do not occur) is not considered, leading to an underestimation of disease severity. Furthermore, the conventional sensors used in HSAT devices also are unable to detect hypopnea events that are only associated with cortical arousal, another limitation that may cause HSAT to underestimate the severity of OSA⁴⁴.

Current State of Use and Patient Experience

Research indicates that uncomplicated adult patients who present with a high risk of severe OSA may not require full polysomnography⁴⁵ and that HSAT is similarly effective for such patients⁴⁶, representing a cost-effective option that could change established clinical practice for diagnosis of OSA⁴⁷.

Patient preference for polysomnography or HSAT will differ depending on the individual. In clinical research facilities where both HSAT and polysomnography were performed for each patient, 76 percent preferred HSAT⁴⁸ and 24 percent preferred polysomnography. Unfortunately, there is insufficient data about diagnostic testing preferences in clinical practice, where preferences may differ from what is seen in the research setting. However, a taskforce commissioned to investigate patient preferences in sleep testing found that the availability of different options for diagnosis may increase satisfaction and when HSAT is used, patients valued accurate diagnosis, good clinical outcomes, and increased convenience⁴⁹. However, based on clinical judgment, patients prefer not having a repeat HSAT if the initial test result is negative, as repeated HSAT would be less likely to produce a definitive result and would unnecessarily inconvenience the patient. In this situation, proceeding directly to polysomnography, which has greater sensitivity to detect OSA, would be preferred by most patients⁵⁰.

Comparison of Home-Based and Hospital-Based OSA Treatment

In 2013, a randomized clinical trial was conducted to compare OSA patients who were treated based on HSAT dispensed at a primary care sleep facility to OSA patients treated based on a specialist model where polysomnography and follow-up were conducted at a sleep laboratory with specialist oversight⁵¹. In this study, sleepiness scores and general quality of life measures were not worse in patients using the HSAT model, suggesting that these two treatment models may result in comparable outcomes.

In a similar study, Andreu *et al*⁵² evaluated the efficacy of a home-based program using clinical response, compliance with treatment (continuous positive airway pressure, CPAP) and cost to evaluate outcomes in a population with high pre-test probability of suffering from OSA. In this study, patients were randomized into three groups: Group A: HSAT with home follow-up; Group B: laboratory polysomnography with hospital follow-up; and Group C: HSAT with hospital follow-up. Following a six-month evaluation of the groups, the study demonstrated that OSA patients can be diagnosed and treated in a home setting, with a high level of CPAP compliance and lower cost than either a laboratory/hospital-based approach or an HSAT/hospital follow-up approach.

Several randomized, controlled trials have shown that a strategy of HSAT followed by auto-titrating CPAP is as effective as a sleep laboratory-based strategy^{53, 54, 55, 56, 57}. Summarizing the evidence that HSAT is a reasonable substitute for in-laboratory polysomnography, a 2014 Cochrane meta-analysis of comparative studies that evaluate accuracy of Level III versus Level I sleep tests in adults with suspected OSA confirmed that Level III portable devices show good diagnostic performance compared to Level I sleep tests, specifically in patients with a high pretest probability of moderate-to-severe OSA⁵⁸.

The aforementioned studies focused on patients who had a high pretest probability of OSA, were diagnosed with moderate to severe disease and were treated with CPAP only. Based on these trials, professional guidelines have been developed by the AASM and these recommend the use of HSAT for evaluation of uncomplicated patients that have a high pretest probability of OSA⁵⁹.

Established HSAT Guidelines

Canadian Guidelines

In 2010, the Canadian Sleep Society and Canadian Thoracic Society published a position paper (the CTS Position Paper) on the use of portable monitoring (HSAT) for the diagnosis of obstructive sleep apnea/hypopnea. Indications in this paper state that:

- Complete laboratory polysomnography remains the gold standard for the evaluation of sleep-disordered breathing;
- HSAT can be used to confirm a diagnosis of OSA in patients with a moderate to high pretest probability of this disorder;
- The package of care accompanying HSAT should include a comprehensive sleep evaluation by a qualified sleep physician; and
- HSAT should be used with back-up availability of monitored, laboratory polysomnography.

Further, this Position Paper states that when HSAT is used for case selection in OSA, a medical evaluation and referral prior to testing is of primary importance to the diagnostic process. This evaluation is to include a complete patient history and examination sufficient to determine:

- A best estimate of the probability of OSA;
- The presence of any significant cardiopulmonary, vascular or neurological comorbidities;
- The presence of any significant comorbid sleep disorders (periodic limb movement disorder; central apnea or insomnia); and
- Triage information, and identification of patients working in safety-critical occupations.

Oversight and Accreditation

The CTS Position Paper highlights oversight by an accredited sleep medicine clinic or hospital sleep medicine program as a defining feature of any program that includes HSAT as a diagnostic tool and that such a program must include all steps from patient selection to completion of the HSAT report. Further to this, CTS guidelines state:

- Any individual or group performing HSAT should do so in partnership with or under supervision of an accredited Level I facility and sleep medicine specialist physician, or a specialist physician with recognised training in sleep medicine.
- The HSAT program should, within the same facility or by formal agreement with another facility, have access to refer to Level I studies so that specific HSAT technologies can be validated in the context of the local population, and so patients with equivocal HSAT results can be expeditiously referred for Level I studies as clinically indicated⁶⁰;

- When access to a Level I facility is not available, HSAT may be performed within the context of what is available in the local community, provided that all policies and procedures for performing the test are followed, as recommended⁶¹.

Importantly, the CTS Position Paper outlines that the ability to interpret HSAT studies should not be limited by physician specialty, provided appropriate training and experience has been obtained and the physician is associated with an accredited sleep facility. The CTS Position Paper states that where there is no regional Level I sleep facility, interpreting physician collaboration with the nearest sleep centre is strongly recommended. Physician training for HSAT interpretation includes training in sleep medicine and Level I sleep study interpretation (certification by American Board of Medical Specialties – Sleep Medicine, or equivalent training) or a specialist physician with recognized training in sleep medicine. Considerations for technical staff and technology used to perform HSAT are also detailed in the CTS Position Paper⁶².

American Guidelines

In 2007, the AASM appointed the Portable Monitoring Task Force to develop clinical guidelines for the use of HSAT in the diagnosis and management of OSA. The key features of these guidelines include⁶³:

- HSAT may be used as an alternative to polysomnography for the diagnosis of OSA in patients:
 - with a high pretest probability of moderate-to-severe OSA.
 - for whom in-laboratory polysomnography is not possible due to immobility or critical illness.
- HSAT is not appropriate for the diagnosis of OSA in patients:
 - with significant comorbid medical conditions such as advanced cardiopulmonary disease that may degrade its accuracy.
 - with evaluation showing suspected of having comorbid sleep disorders.
 - with screening of belonging to an asymptomatic population.
- At a minimum, HSAT must record air flow, respiratory effort, and pulse oximetry.
- HSAT application, education, testing, scoring, and interpretation must be performed under an AASM-accredited comprehensive sleep medicine program.
- A negative or technically inadequate HSAT in patients with a high pretest probability of moderate-to-severe OSA should prompt in laboratory polysomnography.

In 2017, the AASM updated the Clinical Practice Guideline for diagnostic testing for adult obstructive sleep apnea to include HSAT as a recommended equivalent to polysomnography for uncomplicated patients⁶⁴. This guidelines states that technically adequate HSAT⁶⁵, may be used for the diagnosis of OSA in uncomplicated adult patients with signs and symptoms that indicate an increased risk of moderate to severe OSA.

Updated recommendations in the Clinical Practice Guidelines are based on studies where:

1. An uncomplicated patient is defined by the absence of:
 - a. Conditions that place the patient at increased risk of non-obstructive sleep-disordered breathing (e.g. central sleep apnea, hypoventilation and sleep related hypoxemia). Examples include significant cardiopulmonary disease, potential respiratory muscle weakness due to neuromuscular conditions, stroke history and chronic opiate use.
 - b. Concern for significant non-respiratory sleep disorder(s) that require evaluation (e.g. disorders of central hypersomnolence, parasomnias, sleep related movement disorders) or interfere with accuracy of HSAT (e.g. severe insomnia).
 - c. Environmental or personal factors that preclude the adequate acquisition and interpretation of data from HSAT.

2. HSAT is to be administered by an accredited sleep center under the supervision of a board-certified sleep medicine physician, or a board-eligible sleep medicine provider.
3. A technically adequate HSAT device incorporates a minimum of the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or else PAT with oximetry and actigraphy. For additional information regarding HSAT sensor requirements, refer to The AASM Manual for the Scoring of Sleep and Associated Events.⁶⁶

In situations where a single HSAT is negative, inconclusive or technically inadequate, the AASM Clinical Practice Guidelines strongly recommend that in-laboratory polysomnography be performed. This recommendation is in line with the CTS Position Paper.

To further define the AASM position on HSAT devices, updated position statements were published December 2018⁶⁷, stating that:

- Only a medical provider can diagnose medical conditions such as OSA and primary snoring;
- The need for, and appropriateness of, an HSAT must be based on the patient's medical history and a face-to-face examination by a medical provider, either in person or via telemedicine;
- An HSAT is a medical assessment that must be ordered by a medical provider to diagnose OSA or evaluate treatment efficacy;
- An HSAT should not be used for general screening of asymptomatic clinical populations;
- Diagnosis, assessment of treatment efficacy, and treatment decisions must not be based solely on automatically scored HSAT data, which could lead to sub-optimal care that jeopardizes patient health and safety; and
- The raw data from the HSAT device must be reviewed and interpreted by a physician who is either board certified in sleep medicine or overseen by a board-certified sleep medicine physician.

Cautions/Limitations of Use

As reported by the American Academy of Sleep Medicine, HSAT may underestimate the seriousness of sleep apnea compared to a full night attended sleep laboratory polysomnography.⁶⁸

The Canadian Thoracic Society identifies that a portable monitoring device should not be used for⁶⁹:

- screening asymptomatic patients;
- evaluation of individuals with comorbid medical conditions (pulmonary disease, neuromuscular disease or congestive heart failure);
- evaluation of individuals suspected of having a sleep disorders other than OSA (insomnia, periodic limb movement disorder, central sleep apnea); or
- the pediatric population.

It is not recommended to use HSAT in patients who have any of the following attributes:

- | | |
|----------------------------------|--|
| •Severe pulmonary disease | •Asymptomatic patients |
| •Body Mass Index greater than 40 | •Individuals suspected of having other sleep disorders |
| •Narcotic analgesic use | •Individuals who work in safety-critical occupations |
| •Raynaud's Syndrome | •Pediatric populations |
| •Neuromuscular disease | •Inability to cooperate |
| •Stroke | |
| •Congestive heart failure | |
| •Lack of dexterity | |

Conflict of Interest Guidelines

In the USA, conflict of interest guidelines pertaining to Medicare-funded reimbursement for OSA therapy equipment have been established. In the USA, the Medicare CPAP payment prohibition states:

“No Medicare payment will be made to the supplier of a CPAP device if that supplier, or its affiliate, is directly or indirectly the provider of the sleep test used to diagnose the beneficiary with obstructive sleep apnea.”⁷⁰

However, in Canada, the CTS Position Paper appears to recommend flexibility in this regard, describing that, given the limited availability of medical and facility resources in certain jurisdictions, some communities may need to rely on a home care therapy supplier for diagnostic testing such as HSAT. In such circumstances, the CTS Position Paper recommends that standards of care should be maintained in accordance with provincial guidelines and full disclosure of any conflict of interest must be made clear to the patients and referring physicians by written public disclosure.

Sleep Disorders Diagnosed Using Level III Tests

OSA is currently the only sleep disorder that can be diagnosed using a Level III sleep study (HSAT).

Advantages and Cost Considerations

The principle benefits of home-based sleep studies are patient comfort and convenience, due to the reduced need to travel and greater accessibility of HSAT. Importantly, while payer cost is reduced compared to Level I studies (Table 4), patient outcomes are not worsened when HSAT is used as the primary means of diagnosing OSA in patient with a moderate to high probability of OSA.

Use of HSAT in Pediatrics

The 2017 AASM position paper outlines that the use of HSAT is not recommended for diagnosis of OSA in pediatrics patients younger than age 18 years⁷¹. This position is supported by research indicating that diagnostic measurements from portable testing/HSAT are not sufficiently reliable to exclude OSA in children.⁷² The CTS Position Paper also recommends that portable monitoring (HSAT) not be used for pediatric population.

Table 4: Outcomes and costs of different diagnostic and therapeutic strategies for obstructive sleep apnea among 1000 hypothetical Medicaid patients referred for testing and treated for 1 year if positive⁷³

Measure	Diagnostic Strategies		Diagnostic and Therapeutic Strategies Test-and-Treat		
	PSG (gold standard)	Type 3 monitor alone (PT)	PSG + fixed titration CPAP (gold standard)	Home monitor (PT) + autotitrating CPAP	Home monitor (PT): followed by split-night PSG, fixed titration CPAP if PT positive
Total cost (\$)	652,830	200,700	1,244,905	811,129	1,112,731
Cost difference of PT vs PSG alone (\$)	N/A	452,130	—	—	—
Cost differences of PT + APAP vs sleep laboratory strategy (\$)	—	—	N/A	433,776	132,174

All numbers are for 1000 patients at high risk of OSA diagnosis. For the diagnostic testing, the cost-savings for the diagnosis of OSA using PT was \$452,130 compared with PSG. For the test-and-treat strategies, cost savings for PT followed by auto-PAP compared with in-laboratory split-night PSG followed by CPAP titration was \$433,776.

Abbreviation: N/A, not applicable.

Telemedicine for OSA Diagnosis by HSAT

Telemedicine is a way to remotely communicate medical information and data that may save time and reduce costs when managing patients that are amenable to home care service for chronic diseases⁷⁴. Clinical studies have evaluated the effectiveness of telemedicine interventions on adherence to CPAP treatment^{75,76}. In comparison to traditional, hospital-based care, telemedicine coupled with telemonitoring systems saved operating costs and managed several patients simultaneously⁷⁷.

In 2015 the AASM published a position paper on the use of telemedicine for the diagnosis and treatment of sleep disorders⁷⁸. This paper, an output of the sleep medicine taskforce convened by the AASM Board of Directors in 2014, defines key features, processes, and standards for telemedicine specific to sleep medicine. Since there is currently a substantial shortage of certified sleep medicine providers across North America, with large regions grossly underserved or not served at all, more efficient and accessible ways to provide services beyond the traditional office model are needed. As this trend continues, telehealth applications, and telemedicine specifically, are increasingly seen as tools to deliver cost-effective care while increasing accessibility. Sleep medicine already utilizes telehealth applications for diagnosis and monitoring of sleep apnea and CPAP therapy through home sleep testing and monitoring technologies. Recent studies have indicated broad acceptance of telemedicine and patient satisfaction in OSA management models including diagnosis via tele-consultation and optimization of management via remote CPAP controls⁷⁹.

3.7. Level IV Study: Overnight Oximetry

In the past, home sleep testing was performed with a Level IV portable monitor. This is an unattended test with a device that monitors a minimum of three channels. Level IV devices must provide channels that allow direct calculation of an AHI or RDI (Respiratory Disturbance Index) as the result of measuring airflow or thoracoabdominal movement. Monitoring devices record one or two variables and can be used without a technician. Typically channels include:

- Arterial oxygen saturation - Measures the amount of saturated hemoglobin in tissue capillaries by transmitting a beam of light through the tissue to a receiver. As the amount of saturated hemoglobin alters the wavelengths of the transmitted.
- Light - Analysis of the received light is translated into a percentage of oxygen saturation of the blood.
- Airflow – Measures or predicts the quantity of air entering and exiting a patient’s lungs either using an oral device or by thoracoabdominal movement.

4. Discussion

4.1. Improving Access to Sleep Testing in British Columbia

A 2010 health technology assessment report by the Canadian Agency for Drugs and Technologies in Health illustrated that results obtained from modelling different strategies showed a trade-off between HSAT and polysomnography for time to diagnosis and CPAP therapy versus test accuracy⁸⁰.

While HSAT cannot reliably exclude an OSA diagnosis, its high sensitivity for detecting OSA sufferers and quick turnaround time from testing to diagnosis and treatment may provide a key advantage over Level I studies in regions where wait time for polysomnography are excessive. In BC, where patient access to Level I studies is known to be an issue due to access to consulting sleep specialists, population distribution and potentially high wait times, the use of HSAT may particularly benefit patients with a high pretest probability of moderate-to-severe OSA.

These patients are highly likely to be diagnosed with OSA and polysomnography does not result in better outcomes in terms of diagnosis, determining therapeutic device parameters, or response to CPAP therapy, when compared to an approach using HSAT⁸¹.

In BC, sleep testing facilities applying for a polysomnography Certificate of Approval currently must provide for a minimum capacity of three beds appropriate for the purpose of overnight sleep testing in order to be considered for approval. Since HSAT facilities in BC are not accredited to provide Level 1 studies, they are not able to be approved under the current policy framework. Guidelines from Canadian and American Sleep Medicine experts agree that accreditation by a governing body and oversight by an expert in sleep medicine are both essential elements to an effective HSAT program.

To determine the impact of sleep specialist consultation on patient outcomes, a 2016 study was conducted where a non-referred sample of OSA patients were diagnosed using HSAT but without involvement of a sleep medicine specialist. In that group of patients, OSA was not identified in only 5.8 percent of the sample, indicating that the probability of obtaining an accurate indication of disease severity using HSAT seems not to be influenced by the involvement of a specialist sleep physician⁸². This finding is significant considering the current situation in BC, where the broad population distribution and limited number of sleep specialists have led to a situation where patients may wait a significant amount of time for a specialist consult prior to diagnostic sleep testing. Further analysis is required in order to assess the patient risks in the situation where there is no direct interaction between the patient and a sleep medicine specialist prior to diagnostic testing.

4.2. Socioeconomic Considerations

In the USA, the increase in the prevalence and incidence of OSA is a challenge for healthcare systems. With the obesity epidemic and increasing recognition of OSA, billing for overnight polysomnography has been one of the fastest-growing charges for third-party payers. In response, there has been a push by private insurers to reduce costs by adopting HSAT as the primary test to diagnose OSA in uncomplicated patients⁸³.

An ongoing and implicit assumption of healthcare programs has been that a shift towards HSAT as the primary test for the diagnosis of OSA would be cost-saving for both payers and providers. However, an analysis conducted by Kim *et al*⁸⁴ shows that the economic implication of this shift clearly depends on the perspective taken.

When evaluating home-based vs laboratory-based diagnosis of OSA at facilities operating in the USA, under a scenario where diagnostic testing was the only service provided and the facilities did not draw revenue from any other source, Kim *et al* predict that facilities function at a financial deficit when providing either laboratory-based diagnosis¹ or at-home diagnostic testing².

The study assumes that all facilities provided services in accordance with AASM best practices while being reimbursed through Medicare for either polysomnography or HSAT. Importantly, the study goes one step further and predicts that service providers may also experience a net operating loss even if they draw revenue from the sale of therapeutic devices (*Figure 3*), citing the costs of ongoing patient monitoring, higher frequency of inadequate tests compared to polysomnography and the inability to determine optimal therapeutic device settings through HSAT devices alone.

¹ -\$247, 95% confidence interval (CI) = -\$262, -\$232

² -\$502, 95% CI = -\$535, -\$471

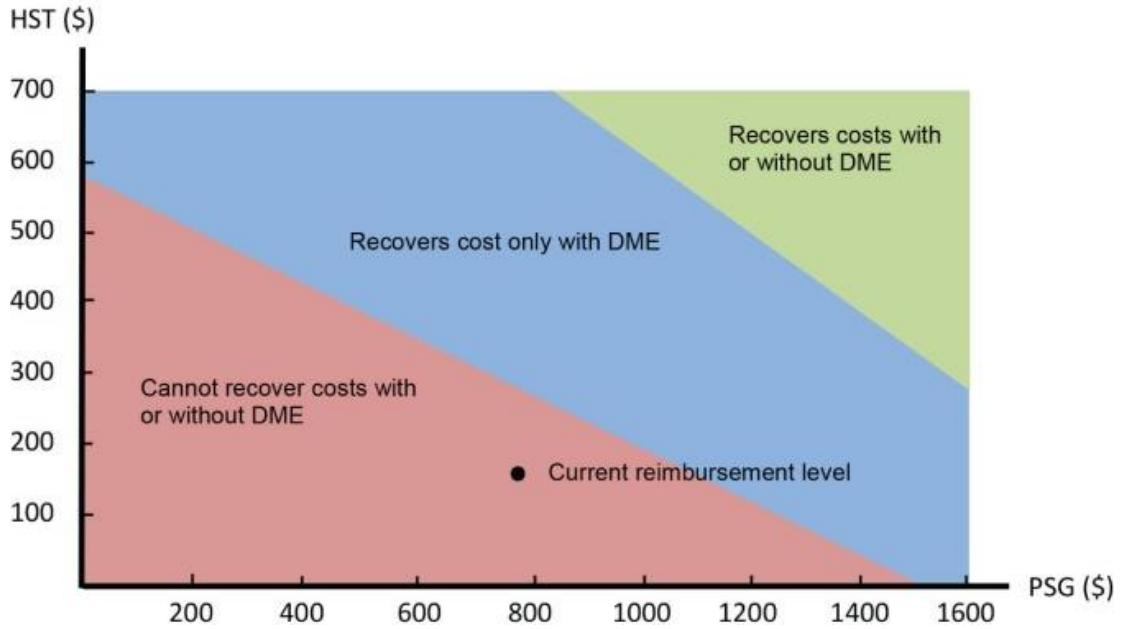
For the medical services payer/plan, however, Kim *et al* found that home-based testing results in cost savings compared to polysomnography, due to a lower reimbursement level for Level III testing. These cost savings were found even under a testing strategy where all negative and technically inadequate home-based tests were repeated in the laboratory setting, and almost three-quarters of all positive, laboratory-based polysomnography tests were performed while gathering both diagnostic and therapeutic data during a single overnight session.

The finding that a home-based diagnostic strategy offers significant cost savings predominantly from the payer perspective suggests that payers will be more motivated than providers to move toward a home-based strategy for OSA.

Although the authors advise that HSAT is a maturing technology that may improve upon its current cost and diagnostic performance, the identified disparity in costs between payers and providers can create a situation whereby third-party vendors are financially motivated to provide HSAT services outside the context of established patient management pathways. In these situations, processes designed to provide high-quality care may be circumvented, raising concerns that both patient outcomes and cost-effectiveness may suffer.

The findings by Kim *et al* raise awareness that as stand-alone home sleep testing facilities are brought under an accreditation standard, the details of such standards may negatively impact the profitability of these facilities, while the payer may realize a cost-savings, due to moving a percentage of Level I reimbursements to the lower Level III testing payment rate.

Figure 3: Operating Margin for Facilities that provide HSAT and a home-based model for PAP treatment



Two-way sensitivity analysis of reimbursement. This two-way sensitivity breakpoint analysis shows the combinations of laboratory and home sleep reimbursement where the sleep laboratory has different levels of profitability, assuming all patients are initially tested at home (some with follow-up PSG) and subsequently treated at home. The pink region indicates the combinations of reimbursement where a sleep laboratory realizes a net operating loss even after assuming the sleep laboratory is reimbursed for providing every patient with CPAP/auto titrating positive airway pressure equipment (i.e. durable medical equipment [DME]). The blue region is where the sleep laboratory has a positive net operating margin only after DME reimbursement for all patients. The green region is where the sleep laboratory has a positive net operating margin before DME reimbursement is considered. Medicare reimbursement for FY2011 are used. HST, home sleep testing.

4.3. Education and Standardization in Level III Studies

Currently, facilities in BC that provide stand-alone Level III testing are not accredited and operate without standardized patient support frameworks or other consistent standards of practice. However, optimal patient outcomes for any diagnostic service, are dependant on the development, implementation and ongoing improvement of standardized patient care frameworks.

The development of accreditation standards has achieved these goals for other diagnostic studies and the development of such standards for Level III sleep testing is one key element for ensuring the best possible experience with diagnostic sleep studies for BC patients.

4.4. Conclusions

Taken together, recent research and position statements from sleep medicine associations and individual experts illustrate that Level III HSAT devices are reliable, cost-effective tools for diagnosing OSA and highlight the potential for Level III sleep studies to address accessibility and capacity issues in adult patient populations. Importantly, sleep researchers continue to identify situations where a Level III sleep study is contraindicated; this knowledge, coupled with ongoing research, continues to inform best practices and clinical practice guidelines as this technology develops.

Level III sleep studies are a medically-appropriate and proven alternative to in-laboratory polysomnography, provided the following criteria are carefully considered:

- Studies must be performed only on a specific group of patients (i.e. those who have a high pretest probability of having sleep apnea and do not have coexisting sleep or cardiopulmonary disorders);
- Studies must be accompanied by an element of personalized medicine to ensure proper administration of testing in certain populations where implications of an inaccurate test are severe, such as commercial drivers;
- Studies must be part of an integrated and collaborative sleep-care delivery model to ensure appropriate follow-up and adherence to treatment.

Although HSAT is a maturing technology that may improve upon its current cost and diagnostic performance, economic modeling suggests that Level III testing, when conducted in accordance with best practices (i.e. adhering to clinical standards, acquiring facility accreditation), may not be economically viable for HSAT providers even with revenue from therapeutic device sales.

Considering this, compensation levels for Level III studies may need to be reviewed in future and consideration given to an ongoing ability for Level III facilities to sell therapeutic devices, as clinically appropriate, with consideration to conflict of interest guidelines that may be developed as part of the facility accreditation process.

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