Sleep Apnea

An essential guide



WHAT IS SLEEP APNEA?

Overview:

Sleep disorders are caused by physiological and/or psychological factors. Most sleep disorders lead to reduced sleep quantity and poor sleep quality. Sleep disorders are subdivided into three broad categories,

including: Insomnias — disorders of initiating and/or maintaining sleep, Hypersomnias — disorders of daytime sleepiness, and Parasomnias — behaviors not related to sleep which occur during sleep. The two most prevalent sleep disorders in the adult population are insomnia and obstructive sleep apnea.

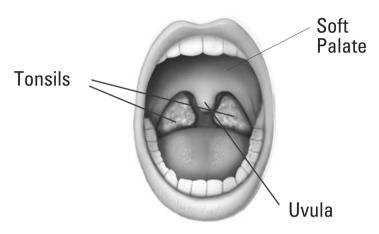


These disorders, though different in origin, signs and clinical manifestations, both have serious consequences in terms of physical and mental health, functioning and quality of life.

Sleep Apnea:

Sleep apnea or sleep disordered breathing is a serious, potentially life-threatening condition that is far more common than is generally appreciated. The most common type of sleep apnea, affecting about 85% of all cases, is called obstructive sleep apnea (OSA), and is caused by repetitive obstruction of the upper airway (including the throat and/or nose) despite ongoing respiratory efforts. Central sleep apnea (CSA) is a much less common syndrome (less that 15% of all cases) cased by failure of the respiratory center in the brain and involving complete or partial reduction of airflow with no respiratory effort

In some people, OSA occurs when the throat muscles and tongue relax during sleep and partially or completely block the opening of the airway. When the muscles of the soft palate and the uvula (the small fleshy tissue hanging down the center of the throat) relax and sag, the airway becomes blocked, making breathing labored and noisy, and possibly ceasing altogether.



For someone with OSA, breathing may be interrupted for at least 10 seconds over 10 times an hour, and in severe cases over 40 times an hour, during which air intake is reduced by more than 30% and blood oxygen levels are de-saturated by more than 4%. Typically, during these apneic events, the brain will trigger a gasping response as the sleeper struggles to breath, causing full or partial awakenings which reduce sleep time in general and deep, restorative sleep in particular. The heart will also start to beat harder and faster as it tries to maintain the flow of oxygen to the body during the apneic event.

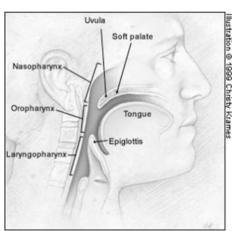
Who gets Obstructive Sleep Apnea?

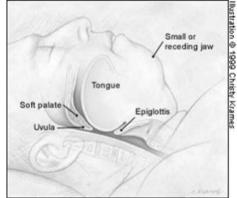
Obstructive Sleep Apnea occurs in all age groups and both genders, but is more common in men (though it may well be under diagnosed in women). It has been estimated that at least 5% of the western population have Obstructive Sleep Apnea — four percent of middleaged men and two percent of middle-aged women — accompanied by excessive daytime sleepiness.

When people reach middle age, they lose some of their muscle tone. If they also gain some weight, the air passage may become narrower. Consumption of alcohol or sedating medications before bedtime may also contribute to a loss of muscle tone and a narrowing of the throat during sleep. As the western population gets heavier, the incidence of OSA can be expected to increase.

How is Obstructive Sleep Apnea diagnosed?

The first indication of OSA is snoring, particularly loud snoring, which is caused by the vibration of the uvula against the palate. OSA also seems to run in families, suggesting a possible genetic component in the disorder. For many OSA patients, their spouses are the first ones to suspect that something is amiss — heavy snoring and gasping for breath are common bewildering signs often noticed by the spouse. Co-workers or friends of the OSA patient may notice that the individual falls asleep during the day at inappropriate times — such as in the middle of a conversation, at work, or even while driving. The patients themselves often ignore these warning signals and fail to relate their sleepiness to inadequate or problematic nighttime sleep





Diagnosis of OSA can only be made by a competent health professional. Previously, the only options available to the patient were polysomnography conducted in the sleep laboratory. Up until recently, testing a patient's sleep in a sleep clinic was an expensive affair, requiring the patient to spend the night inconveniently away from home.

Now, there are other reliable technologies enable the patient to sleep at home, with ambulatory testing equipment.

However, the crucial questions still remains – how to bring all suspected OSA patients for a sleep study? This is the main challenge that the medical sleep community is facing today.

The only current solution for screening the masses is the SleepStrip®. The SleepStrip® offers an alternative preliminary testing method. The SleepStrip is a single-use sleep apnea screener, which provides an easy, advanced and cost effective method for accurate home screening of sleep apnea. Accuracy of this device has been validated by leading international sleep experts.

SLEEP APNEA: A MAJOR HEALTH PROBLEM

Cardiovascular disease:

Over 50% of patients with impaired cardiac function suffer from sleep-related breathing disorders. Cardiovascular complications of OSA include systemic and pulmonary hypertension, coronary heart disease, heart failure, myocardial infarction, cardiac arrhythmias, stroke, transient ischemic attacks, and atherosclerosis. The relationships between OSA and some of these conditions are presented below:

Myocardial Infarction:

Sleep apnea has long been associated with heart attacks that occur in sleep, a third of which may be caused by over-exertion of the heart as it attempts to compensate for lack of oxygen caused by OSA. Today, research indicates that sleep apnea may contribute to the risk of heart attacks during waking hours as well.

Hypertention:

Substantial evidence has shown a high incidence of hypertension among OSA patients compared to non OSA individuals. Furthermore, OSA is also considered an independent risk factor for the development of hypertension.

Congestive Heart Failure (CHF):

OSA is considered a contributing factor to CHF, while central sleep apnea (CSA) is considered to be a consequence of CHF, which may also lead to further cardiac decline. Indeed, studies from several labs have shown high rates of OSA and CSA in CHF patients.

Obesity, Diabetes and the Metabolic Syndrome:

The relationship between OSA and obesity has been well established ever since early observations of the disorder were reported. Obesity is a major sign of OSA, and weight loss is considered the optimal treatment, though often unattainable. Researchers have also noted an association between OSA and diabetes, however, until recently, this association has been related to the common risk factors of both

conditions, i.e., obesity and hypertention. More recently, researchers are investigating the relationship between OSA and early signs of diabetes, including glucose intolerance and insulin resistance, in the context of systemic metabolic dysfunction, also known as metabolic syndrome. This syndrome is considered a significant risk factor for the development of atherosclerosis and cardiovascular disease.

Impotence:

There is growing evidence that the prevalence of erectile dysfunction (ED) is high in OSA patients, however, a causal relationship has not been proven. Although ED may be secondary to hypoxia and excessive sleepiness caused by OSA, it may be that both disorders (OSA and ED) are related to common comorbid conditions, i.e., obesity and cardiovascular disease. The Kinsey Foundation reports that 80% of men between the ages of 30 and 40, experience impotence as a result of fatigue. Research indicates that half of this fatigue is caused by insufficient sleep and the stress caused by sleep apnea.

Depression:

Studies have shown that OSA patients have an increased rate of psychiatric disorders in general and depression in particular, compared to individuals without OSA. Excessive daytime sleepiness has been suggested as the mediating factor between OSA and depression.

Workplace and motor accidents:

Fatigue and sleepiness due to sleep restriction, shift work and/or sleep disordered breathing have all been implicated as important causes of accidents both at the workplace and at the wheel. OSA attributes??? as much as a third of all workplace accidents and injuries to fatigue by equipment operators who have not had enough sleep.

Lost productivity:

The most conservative estimates by the U.S. Department of Labor are that 20% of all lost work hours due to illness are actually caused by sleep-related fatigue. The productivity lost by workers who actually show up for work but who are unable to perform at peak potential is difficult to measure - but the U.S. Department of Labor places that number at \$25 billion per year.

Automotive accidents:

The National Highway and Safety Administration estimates that annual toll from sleep-related driver fatigue is 400,000 accidents, 1,550 deaths (4% of the total U.S. highway accident mortality rate), and \$12.5 billion in financial losses. An OSA sufferer is three to four times more likely to be involved in a serious car accident.

ADHD in Children:

Children have increasingly been found to suffer from sleep disorders, no doubt a situation exacerbated by our "noisy" and "high anxiety" culture. Studies show that up to a third of children who have been diagnosed and treated for ADHD actually have an undiagnosed sleep disorder which is responsible for their behavior. Diagnosing children's sleep in a clinical setting presents an entire new array of problems, not the least of which being the difficulty children have in getting to sleep whenever they are placed in new surroundings.

THE TREATMENTS AVAILABLE FOR OSA

Once the patient has been tested and Obstructive Sleep Apnea has been diagnosed, treatment can be prescribed. The treatment available can be categorized on four levels of ascending complexity and severity: 1. behavior Therapy; 2. Mechanical Assistance Therapy; 3. Surgery; 4. Medication. In each category, the influence of the physician on the behavior of the patient and the treatment of the problem of OSA is significant.

MECHANICAL ASSISTANCE THERAPY

A patient's breathing can be assisted through the uses of a Continuous Positive Airway Pressure pump (or, "CPAP" — referred to as "seepap") worn during the sleeping hours, often for many years. One could also include in this category oral appliances where the intent is to maintain an open air passageway. These appliances and devices occupy a very small part of the sleep disorder treatment market.



Surgical Procedures and Medication.

A number of standard surgical procedures have shown themselves to be effective — uvulopatopharyngoplasty (UPPP); tracheostomy; upperairway enlargement; jaw advancement, tongue advancement; and somnoplasty. These were generally regarded as unattractive options because the surgeries were often painful, expensive, and caused scarring and bleeding. Two recent advances in this field have shown promises: In one procedure, the palate is reinforced by the insertion of a subcutaneous plastic wafer that keeps the palate rigid and hence the airway open. In the other — Laser Assisted Uvulopalatoplasty, or

 $\mathsf{LAUP}-\mathsf{a}$ laser is used to ablate tissue on and around the trauma of the traditional surgery.

Medications.

Medications used are often those used to treat depression (trazodone, citalopram, fluoxetine, or paroxetine). Though these often seem to be effective, in reality, they fail to address the physiological etiology of OSA and only mask the disease.

Disclaimer

As with all pre-screening devices a definitive diagnosis should not be based on the results of a single test and should always be confirmed with a qualified specialist.

Under no circumstances shall SLP be liable for any loss of revenue or damage direct, consequential, or incidental including loss of profit, property damage or personal injury arising from the use or the inability to use this product.



SleepStrip®

Disposable Sleep Apnea Screener With more than 80% of OSA patients still undiagnosed effective, low-cost screening is good news.

SleepStrip is the only product of its kind on the market. It's manufactured under ISO standards and has been cleared by the FDA and has CE approval. It has also been validated by leading international decision makers.

SleepStrip is a single use device. Before going to bed, just apply it on your face and go to sleep. Miniature flow sensors will monitor your respiration all through the night. The integrated microprocessor analyzes respiration patterns to detect and count each apnea and hypopnea event as it occurs. The morning after the study the SAS severity score is calculated based on your Apnea/Hypopnea Index (AHI) and permanently displayed on the built-in electrochemical display.

Because sleep apnea is a medical disorder, and needs to be officially diagnosed and treated by a physician, you must acquire physicians prescription to get a SleepStrip.

SleepStrip advantages:

- At-home study, in the patient's natural sleeping environment
- Easy to use, disposable, patient-applied test
- Low cost
- Accurate, strong correlation with sleep lab results
- Small, lightweight, can be sent by mail
- Instant, permanently displayed results
- No additional equipment necessary



S.L.P. Ltd.

P.O.Box 14014, Tel-Aviv, 61140, Israel

Tel: +972 3 5371281 Fax: +972 3 5371282

E-mail: info@slp-med.com www.slp-med.com

12