Introduction:

Sleep is a topic near and dear to everyone’s heart. It is both essential and wonderful; however, optimal, restful sleep requires rotation through all stages with minimal interruptions. The effects of poor sleep can be a burden on not only a person’s psyche and mental well-being with symptoms ranging from forgetfulness to depression, but may also cause physical manifestations such as weight gain, skin aging, and increasing a person’s risk for overall mortality. As our understanding of sleep increases, it becomes equally important to develop methods of testing for poor sleep quality with increasing efficiency, reliability, and access.

The importance of sleep has been long acknowledged, but the scope of its true value has only recently been explored. Attempts have been made to estimate its cause dating back as early as 500 BC when the Greek philosopher/scientist Alcmaeon wrote that sleep was just a loss of consciousness when blood drains from vessels on the surface of the body. As archaic and simplistic as that view seems to us now, variations of that belief and equally simplistic views of sleep corroborated even by Hippocrates. In fact, it wasn’t even until 163 AD when another Greek, Galen, recognized that consciousness resided in the brain, not the heart, without which would have made studying the stages of sleep very difficult.

Stages of Sleep:

All sleep is not equal. It has been subdivided into several stages which help the body’s physiology in different ways, these individual stages are characterized by a unique constellation of traits which can be quantified and measured with polysomnography. There are 2 broad categories, namely sleep involving rapid eye movement (REM) and sleep without rapid eye movement (NREM). The latter is further divided into 3 sub stages.

NREM Stage 1:

This is the transition from the waking world to sleep. It is the stage where the person is not quite awake and not yet asleep. It is characterized on EEG by alpha waves, which are the waves which predominate during wakefulness. All muscles are active in this stage of sleep and
the eyes are free to move; however, these eye movements differ from those present in REM sleep.

**NREM Stage 2:**
In stage 2 sleep, it becomes more difficult to rouse the sleeper. Alpha waves give way to theta activity whereupon alpha waves are interrupted with sleep spindles and K complexes. These are key findings not present in other forms of sleep and are interesting in their own right. Sleep spindles coming from the thalamus are theorized to have a relationship with maintaining a tranquil state in the sleeper in the presence of external noise. Additional theories as to their importance includes neural mapping in children while the brain tries to solidify conduction pathways and discover which nerves control which muscle groups. K complexes also aid in suppressing the arousal of the sleeper in response to external stimuli. Additionally K complexes are linked to sleep-based memory consolidation. They are the highest amplitude finding on a healthy human EEG.

**NREM Stage 3:**
This stage was previously divided into stage 3 and 4 and has since been consolidated. Stage 3 is what is referred to as “slow wave sleep” and is predominated by higher amplitude, lower frequency perturbations in the EEG tracing. During this stage of sleep, the majority of external stimuli will produce no physical response within the sleeper.

**REM:**
REM sleep is referred to as paradoxical sleep as this is the stage where the sleeper is the most difficult to awaken; however, the brain activity is the most vigorous. The tracing resembles that of an awake person and oxygen consumption by the brain during this stage of sleep is even higher than that of the wakeful state. A key difference is that the muscles are paralyzed during REM sleep; ensuring that a person thrash during some of the vivid dreams possible during this stage of sleep. This is of particular importance concerning obstructive sleep apnea as, due to the paralysis of the muscles, mechanical airway obstruction and thus, obstructive sleep apnea is at its worst during this stage of sleep.

**Sleep Disorders:**
Of the litany of possible disorders affecting sleep, sleep disordered breathing (SDB) is the one most commonly leading to referrals to the otolaryngologist. SDB ranges from simple snoring, that is to say snoring with no associated parasomnias or additional disturbances to the patient, to obstructive sleep apnea (OSA) which requires objective studies to definitively diagnose and distinguish from less severe SDB. SBD is quite common, and has a self-reported incidence of 37% of adults with slightly increased prevalence in males vs females according to the national sleep foundations 2002 survey. OSA can be incredibly deleterious to a person’s health and can manifest with psychological problems including depression and or physical disturbances such as cardiovascular disease. It has been shown to increase the overall mortality of a person as an independently tracked variable. Due to the devastating potential effects of OSA on a patient, it becomes that much more important to be able to accurately classify and quantify.
Polysomnography:

The polysomnogram (PSG) is the way by which sleep stages and sleep disorders may be diagnosed and quantified, often times lowering the differential diagnosis to a single root cause. Such evaluation would not have been possible without the development of the EEG, and the term (Elektrenkephalogramm) was coined by Hans Berger the first person to successful use the apparatus on the human brain. The EEG consists of a series of electrodes attached to the skin overlying areas on the skull and measuring voltage potentials from the underlying neuronal depolarization activity. This allows for determination of brain activity on a real time basis and is the way that a PSG can know which stage of sleep a patient is in. From this initial metric, methods for quantifying other sleep parameters were added including eye movements (EOG), heart rhythm (EKG), muscle activity (EMG), respiratory airflow, respiratory effort, and pulse oximetry.

The setup typically has 12 leads devoted to any of the above metrics which involves no small amount of straps, tubes and wires. When a patient is fully hooked up to the central recording device, it can appear quite daunting and feel quite uncomfortable at first, and it is surprising that people are able to cooperate well enough to get definitive data the majority of the time.

In terms of quantifying the tracings of the PSG to not only diagnose, but also determine the severity of OSA, several values are often calculated from the raw data. These include chiefly the apnea-hypopnea index (AHI) and the respiratory disturbance index (RDI).

The AHI consists of the number of apneic and the number of hypopneic episodes divided by the amount of time spent asleep. The RDI consists of the number of apneic episodes, hypopneic episodes and respiratory effort related arousals (RERAs) divided by the total amount of time spent asleep. The total sleep time is often represented in minutes for both convenience and convention reasons, thus the formulas for AHI and RDI appear as follows:

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AHI = \frac{(\text{No. of apneas} + \text{No. of hypopneas}) \times 60 \text{min}}{\text{Total sleep time in minutes}}
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RDI = \frac{(\text{No. of apneas} + \text{No. of hypopneas} + \text{No. of RERAs}) \times 60 \text{min}}{\text{Total sleep time in minutes}}
\]

The formulas are relatively straight forward; however, the key in calculation of AHI and RDI lay with what events are classified as apneas, hypopneas, and RERAs.

Respiratory Criteria:

Accurately calculating the endpoints for diagnosis of OSA requires that disturbances in sleep be accurately identified within the raw tracings. It helps to have a consensus definition of what findings within the tracings are pathologic. In adults, an apnea is defined as a 90% decrease in respiratory flow rate for >10s and a hypopnea is defined as a 50-75% decrease in
respiratory flow rate for >10s. It is clear that the hypopnea is less precisely defined and thus can skew the results of the AHI/RDI calculations from interpreter to interpreter. RERAs are classified as arousals from sleep due to a respiratory disturbance that does not meet criteria for apnea or hypopnea. Following accurate calculation of the AHI, the degree of OSA may be stratified into severity.

- AHI from 5-14 = mild OSA
- AHI from 15-29 = moderate OSA
- AHI from >30 = severe OSA

Of note, many insurance companies will require an AHI indicative of moderate OSA to authorize payment for treatments, or an AHI indicative of mild OSA with greater than 2 comorbidities including: hypertension, congestive heart failure, coronary artery disease, atrial fibrillation, asthma, stroke, diabetes, obesity, reflux, or nocturia.

The respiratory criteria for identifying apneic events and diagnosis of OSA in adults vs children are not identical. Since the respiratory rate of children is normally higher than adults, less time is required for an event to register as an apneic event, generally an apnea in a child is defined as a 90% decrease in respiratory air flow for 6-8s. Once this information is gathered; however, there is no consensus view as to what AHI is considered diagnostic of OSA in children, although the generally accepted value is >1 prior to puberty.

**Types of PSG:**

When a PSG is ordered, there are several different variations available depending on which sleep disorder the physician is testing for. For instance, a multiple sleep latency test is a type of PSG where the patient is observed falling asleep multiple times, generally 4-5 20 minute nap opportunities with 2 hours in between. This is used to diagnose narcolepsy by gauging the sleepiness of a patient by measuring the amount of time it takes to fall asleep (normal is 15-20 minutes).

In otolaryngology, however, when examining for OSA the typical PSG undertaken will be a “whole night study”. This means that the diagnostic PSG, from which AHI and RDI are calculated is performed over the entire night and the titration of the CPAP pressure required to significantly reduce the AHI/RDI and improve sleep quality is performed over the course of a completely separate night. This is the defacto gold standard for sleep studies for the diagnosis and treatment of OSA. There has been a movement for “split night studies” whereupon the diagnostic PSG and CPAP titration occur during the same night. As one would expect this decreases the burden on sleep labs, decreasing wait times for studies, inconveniencing patients for 1 less night, and decreasing the latency to CPAP treatment. However, this practice has never been definitively validated when compared to whole night studies as of the writing of this chapter. Investigations have been made to try to determine the accuracy of split night vs whole, and the only conclusion was that failure to document OSA during the first portion of the night cannot reliably exclude the disease. What this means is that in a split night study, if the
diagnosis of OSA cannot be made within the first half of the night, then the study is converted to a whole night PSG to better clarify the findings of the test.

Contraindications to PSG?

It is important to note that there are no absolute contraindications to PSG testing. There are however some things to consider, such as, it the person in question really healthy enough to undergo the testing and transfer to the sleep lab? Generally in outpatient diagnosis and management of OSA, the answer to this question will be a resounding yes. Other possible concerns are whether the patient has any allergies to adhesives or whether the patient has any known seizure disorders and are they currently appropriately treated for it. There are ways in which PSG can still be obtained safely in patient with these latter 2 conditions; however, it is still clearly much more beneficial to be aware of these conditions prior to undergoing the PSG.

Home Sleep Testing:

Home sleep testing is similar to PSG in many ways, there are several key differences however, namely the patients are able to sleep in their own beds while undergoing the test and the EEG leads are conspicuously absent. The remaining equipment is very similar including, often times, the same pulse oximetry, chest and abdominal belts for measurement of respiratory effort and airflow monitors.

The home sleep devices can be nearly as complex as the PSG or quite a bit simpler depending on the number of desired leads. Typically the home sleep study will have 4 channels or less including leads for respiratory effort, respiratory flow, pulse/pulse oximetry. Given the absence of the numerous other leads present in a PSG, one would anticipate that the home sleep study more closely approximate that of the patient’s natural sleep, especially since very few people would prefer to go to sleep wearing EEG leads.

The absence of the EEG leads may lead to problems in using home sleep study for diagnosis of various sleep studies including insomnia etc. However, the otolaryngologist will oftentimes only need the sleep study to diagnose obstructive sleep apnea. Due to the high interpreter variability in the EEG, respiratory data is used for making the diagnosis of OSA the majority of the time and the EEG becomes superfluous. The inability to accurately determine which stage of sleep the patient is in does not change the calculation of AHI or RDI in any manner which would affect the eventual treatment of a patient. Instead of using the total sleep time for home studies, as is used with a PSG to calculate AHI/RDI, the home sleep study can offer only total test time which depends on accurate management of the home device by the patient.

The process of setting up a home sleep study is relatively straightforward and will start with an initial consultation where the patient is oriented to the device and testing protocol. This does not legally need to be done by a physician, but should be done by someone with experience using the home testing apparatus. During this meeting, the patient device will be demonstrated and the patient will be instructed in how to hook up the home leads and how to turn the device on when they are sleepy. The importance of stopping the recording when they are done sleeping will also be enforced as failure to accurately record the total test time (close gauge of total sleep
time) would lead to flawed calculation of AHI. The device is set up with the patient in the office if need be so that they are fully comfortable in the setup, and the device is sent home with the patient. When they are getting ready for bed, they attach the leads and when they are nearly ready to sleep, they will start the data recording. Since it takes 15-20 minutes to fall asleep in a normal person with no sleepiness issues, over the course of an 8 hour night this extra time will matter very little. Factor in that often times these patients will be excessively sleepy, and will fall asleep sooner, and this makes the effect of sleep latency on the results of the test even less significant.

The patient is allowed to keep the machine for several days and try it multiple nights if need be, which will increase the likelihood of getting useful data from the nightly recordings. When they return the device the data may then be downloaded from the device and interpreted. Interpretation of the data can be time intensive and the amount of data manipulation is linked to the type of device.

**Types of Home Devices:**

There are numerous types of home sleep testing devices which have similar properties and consist of similar components. These components typically include 1) Data recorder/storage device, 2) Leads; nearly always including nasal cannula to measure airflow and chest belt to measure respiratory effort. These devices often come with their own proprietary software for interpreting the results even with the ability to autoscore their own results and allow for physician oversight to alter the software’s automatic interpretation.

Some examples of the many that are offered are:

1) **Embletta:** Made by ResMed with availability of up to 14 channels for the measurement of patient sleep parameters. The disposable parts of the device cost roughly $7 per patient; however the device itself costs $3500 up front.

2) **ApneaLink:** Made by ResMed with availability of 4 channels. The disposable parts cost roughly $10 per patient. The device costs $2500 up front.

3) **Somte Sleep Recorder:** Up to 13 available channels. The cost of disposables is roughly $9 per patient; however, the device costs $4500.

All of the above devices have similar structure and require monitoring of airflow and respiratory effort by nasal cannula. There is a unique device known as the WatchPAT which incorporates its own proprietary technology measuring peripheral arterial tone via a fingertip device. Utilizing this method the device is able to correctly interpret when a patient is sleeping, which allows for accurate determination of sleep time (and not merely test time) when calculating an AHI. The disposables associated with this device are $60 per patient and the device itself cost $4400.

Each of the devices listed above requires upfront costs and interpretation of the patient sleep data. This is not the case for all devices. For instance, NovaSom offers use of their device and interpretation of their own data for a fee. The NovaSom device has 5 channels and is mailed to the patient, at the end of the day trial, the patient mails the device back and the data is interpreted. Reports are sent to the physician office within a few weeks. The main benefit of
this is that there is no need to personally take time to review the data and there are no upfront costs for the clinic. The cost pre study with interpretation is nearly $1200 and they don’t work with all insurance carriers; namely Medicaid, unless Medicaid is being used as a secondary form of insurance. The total billed to the patient can be as low as $50 with Medicare, and secondary form of insurance which includes device fee and interpretation. They typically do not contract with Medicaid unless it is being used as a secondary insurance type.

**Insurance:**

Coverage of PSG and home sleep studies varies by provider with each having specific criteria. One thing is for certain though. A PSG can cost an extraordinary amount of money. A split night or whole night PSG may cost more than $2000 and that cost may be transferred to the patient if criteria are not met. Medicaid typically has the strictest criteria for qualification.

For an **attended** PSG, Medicaid requires the patient to be presenting with narcolepsy, sleep apneas, snoring, parasomnias, periodic limb movement disorder, or chronic insomnia. For patients with sleep apneas, the cessation of breathing must last for >10s. For snoring the patient must additionally have daytime somnolence, excessive fatigue, or apneic breathing. Given the typical patient presenting to the otolaryngologist with concern for SOA, these criteria are relatively easy to satisfy.

For an **unattended** sleep study, i.e. **home sleep study**:

1) An appropriate device must be used (there are numerous, including those mentioned above)

2) The interpreter must have certification or subspecialty certification in sleep medicine and be an active staff member of an accredited sleep lab

3) All raw data must be interpreted by the physician/interpreter, this means that the software autoscore is not allowable

4) Test must gather 6 hours of data during normal sleep hours

5) Patient must have high pretest probability and have 4 of the following symptoms:
   a. Habitual snoring
   b. Witnessed apneas
   c. Morning headaches
   d. Daytime somnolence
   e. BMI >35

6) No other sleep disorders other than OSA may be suspected

7) Age >18y
Following satisfaction of the above criteria, the costs transferred to the patient are relatively low provided they have insurance coverage of some sort, including national health plans.

**Advantages of Home Sleep Study:**

Despite the fact that Medicaid won’t pay for an unattended sleep study in patients under the age of 18 years old (seen as purely investigational, not diagnostic in this population), there are several distinct advantages for home sleep study over the attended PSG:

1) **Comfort** - The patient has the distinct pleasure of sleeping in their own bed and in their own home during the test, with much fewer wires than found in the attended PSG. This will certainly more closely approximate the patient’s natural sleeping condition.

2) **Reportable results** - The results obtained from the test are directly comparable to those of PSG and the results may be reported in terms of AHI and RDI which are familiar endpoints. Research has shown that the RDI of the home sleep study tends to be 10% lower on the average than the attended PSG result which, in the vast majority of patients, will not affect the diagnostic implications for treatment.

3) **Cost** – The cost of the home sleep study has been shown to be significantly lower than that of the attended PSG and has been shown to be anywhere from 38% to 88% cheaper than an in-lab PSG. American sleep labs have been seen to charge upwards of $2000 for a test and any respite is welcomed by patients.

4) **Access** - Home sleep study improves access to diagnostic testing in places without sleep labs or with overwhelmed infrastructure where it would take too long to be scheduled for a test to make it feasible. Busy labs often require scheduling over 1 month ahead of the test time and some schedule out even further.

**Summary:**

Home sleep study provides similar diagnostic information to attended sleep studies; however, they are strictly for the diagnosis and quantification of severity of OSA in patients with sleep disordered breathing. The calculated RDI for Home sleep study is typically lower than that of their attended counterpart, thus leading to the possibility of underestimating disease. However, this is clinically insignificant in the majority of cases. The main hurdle regarding home sleep testing is that of coverage and, in that regard, access. Insurances are shifting coverage of a number of previously supported procedures and test, the leaders in this regard remain the federal payment plans such as Medicaid. However, if there is strong pretest concern, there is relatively little difficulty in satisfying the coverage criteria of various carriers. Access to home sleep reduces cost to the patient and insurance payers and improves access to those who would otherwise be unable to obtain diagnostic sleep testing. It is a viable diagnostic modality for the diagnosis of OSA.
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