Comparison of the NovaSom QSG™, a new sleep apnea home-diagnostic system, and polysomnography

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Abstract

Background: Obstructive sleep apnea (OSA) is a serious, common, and underdiagnosed disorder that challenges health care resources. While polysomnography (PSG) represents the standard diagnostic test for OSA, portable devices provide an alternative diagnostic tool when issues of cost, time, geographic availability, or other constraints pose impediments to in-lab testing. This study compares the NovaSom QSG™, a new sleep apnea home diagnostic system, to PSG both in the laboratory and in the home.

Methods: Fifty-one consecutive adults referred to the sleep lab for suspicion of OSA underwent one night of in-lab, simultaneous recording of PSG and NovaSom QSG in addition to using the NovaSom QSG at home for three nights. Two separate comparisons were made using the apnea–hypopnea index (AHI): in-lab PSG to in-lab NovaSom QSG and in-lab PSG to home NovaSom QSG.

Results: Using a clinical cut-off of AHI = 15, the sensitivity and specificity of the in-lab NovaSom QSG vs. PSG were 95% and 91%, respectively. For home NovaSom QSG vs. in-lab PSG, the sensitivity was 91% and specificity was 83%. The intra-class correlation coefficient for the agreement between three separate nights of NovaSom QSG home data was 0.88.

Conclusions: In a patient population suspected of having OSA, the NovaSom QSG demonstrated acceptable sensitivity and specificity both in the lab and self-administered in the home, when compared to PSG.

Keywords: Home monitoring; Three nights; Unattended; Self-administered; Obstructive sleep apnea; Diagnosis; Polysomnography

1. Introduction

Obstructive sleep apnea (OSA) is a common disorder with significant morbidity and potential mortality occurring in 2–4% of middle-aged adults [1]. Patients with untreated OSA have a six- to 15-fold increased risk of motor vehicle accidents [2]. OSA is associated with a reduced quality of life [3], and is a contributor to hypertension [4–6] and cardiovascular events [7,8].

Diagnosis and treatment of OSA can result in significant short-term and lifetime cost savings [9]. One study found that in the 10 years prior to diagnosis, OSA patients used approximately twice as many health care services as non-OSA patients [10]. Another group reported that in the year prior to diagnosis, medical costs were twice as much for untreated sleep apnea patients compared to age and sex matched controls [11].

Despite the clear advantages of diagnosis and treatment of OSA, certain potential limitations of in-lab polysomnography (PSG), the most commonly used diagnostic sleep procedure, may at times impede the diagnostic process. Some of these potential limitations include: the high cost of this technician-dependent procedure, patient acceptance of in-lab testing [12], potential for lengthy waiting periods, limited access in geographically remote regions, significant inter-scorer variability [13,14], night-to-night variability in the apnea–hypopnea index (AHI) [15], and the tendency for predominantly supine PSGs to overestimate AHI due to the effect of position on breathing [16]. In addition, in many regions there are not enough sleep labs to address the demand using PSG. It is estimated that 1.17 million PSGs are performed each year in the US [17]. Given the
perform the study \[20,22\]. Even with technical assistance, current devices require the patient to be hooked up in the lab at home, where these devices are usually used. Most of these studies were performed only in a lab setting \[18–21\], which is a controlled environment compared to the in the sleep lab were simultaneous recordings of in-lab PSG and home NovaSom QSG. First, simultaneous recordings of in-lab PSG and NovaSom QSG were obtained for three nights \[23,25\]. A second set of comparisons was made between in-lab PSG and home NovaSom QSG. For each subject, separate home recordings were obtained for three nights since it is commonly used as a cut-off value for treatment. The value 15 was chosen as a ‘gold standard’. The value 15 was used to compare in-lab PSG-determined AHI to each subject’s average AHI across all nights of home AHI measurement is based on total recording time as opposed to total sleep time. All subjects had standard PSG processed through analog amplifiers and recorded by computer. The NovaSom QSG airflow respiration signal was wired into an empty channel on the polysomnogram montage for start time calibration. The technologist was blinded to the NovaSom QSG signal both during recording and scoring of the data.

Two separate sets of comparisons were made between in-lab PSG and NovaSom QSG. Instructions for Use, a Quick Guide and an instructional video were provided with the NovaSom QSG system in addition to a 24 h help line.

The NovaSom QSG, manufactured by Sleep Solutions Incorporated, is a five-channel home diagnostic system. The NovaSom QSG measures nasal and oral airflow (using sound), oxygen saturation, heart rate, respiration effort and snoring sound intensity. The NovaSom QSG consists of a bedside unit, a patient module (worn on the patient’s wrist) and three body sensors: airflow, finger oximeter and respiration effort. It is self-administered and used unattended in the home to record three nights of data. The system uses voice alerts to wake the patient if any of the sensors become dislodged during the night. The NovaSom QSG does not differentiate between wake and sleep, so the AHI measurement is based on total recording time as opposed to total sleep time. All subjects had standard PSG [24] processed through analog amplifiers and recorded by computer. The NovaSom QSG airflow respiration signal was wired into an empty channel on the polysomnogram montage for start time calibration. The technologist was blinded to the NovaSom QSG signal both during recording and scoring of the data.

Two separate sets of comparisons were made between in-lab PSG and NovaSom QSG. First, simultaneous recordings of in-lab PSG and NovaSom QSG were compared using AHI with a clinical cut-off of 15 in order to establish the validity of NovaSom QSG. This was accomplished by estimating the kappa coefficient to quantify the beyond-chance agreement of the measurement methods and by estimating the sensitivity, specificity, and positive and negative predictive values of NovaSom QSG using the PSG as a ‘gold standard’. The value 15 was chosen since it is commonly used as a cut-off value for treatment \[23,25\]. A second set of comparisons was made between in-lab PSG and home NovaSom QSG. For each subject, separate home recordings were obtained for three nights within seven days of the lab test. A clinical cut-off of AHI = 15 was used to compare in-lab PSG-determined AHI to each subject’s average AHI across all nights of home testing.

Patients with AHI values of 15 or more are classified as positive and patients with values less than 15 are classified as negative. The kappa coefficient compares the number of subjects positive or negative by both PSG and NovaSom QSG to the number expected if the measurement methods were independent of each other. If there is complete agreement, then kappa = 1. If the observed agreement is greater than chance, then kappa is \(>0\).

The test–retest reliability of the NovaSom QSG home data was estimated using the intra-class correlation coefficient (ICC). The ICC is a widely used measure of inter-subject reliability for quantitative data.

<table>
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<th>Subject characteristics ((n = 51))</th>
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<td>Gender (M/F)</td>
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<td>Age (years)</td>
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| Prevalence of OSA, the current in-lab capacity cannot meet the need for diagnosis. The significant increase in public and professional awareness of the increased costs, quality of life issues and dangers of untreated OSA has driven the need to find cost effective, clinically validated tests to supplement the current approach to diagnosis. One frequently considered strategy is to refer patients with a high pre-test probability of having OSA (e.g. regular loud snoring with witnessed apnea and high Epworth Sleepiness Score) for in-home evaluation.

There are many publications regarding ambulatory diagnostic systems and their validation to PSG. However, most of these studies were performed only in a lab setting \[18–21\], which is a controlled environment compared to the home, where these devices are usually used. Most of the current devices require the patient to be hooked up in the lab or require technical assistance in the home in order to perform the study \[20,22\]. Even with technical assistance, the data loss due to poor signal quality or signal loss was higher than if these studies had been performed in a lab setting \[23\]. We recently became aware of a new device specifically designed for self-administered home use, the NovaSom QSG, which we evaluated for reliability and validity in this study.

2. Materials and methods

Fifty-one consecutive adults referred to the sleep lab by a large pool of community physicians due to a clinical suspicion of OSA, based on symptoms including snoring, witnessed apnea and excessive daytime sleepiness, and scheduled for overnight in-lab PSG, signed informed consent to participate in the study. See Table 1 for subject characteristics and frequency of symptoms. All forms and procedures were approved by the Sequoia Hospital Institutional Review Board.

Patients performed a home NovaSom QSG study either before or after their in-lab study. All recordings performed in the sleep lab were simultaneous recordings of in-lab PSG and NovaSom QSG. Patients received a NovaSom QSG system from the sleep lab and were instructed to use the system at home for three nights but received no instructions on how to use the NovaSom QSG. Instructions for Use, a Quick Guide and an instructional video were provided with the NovaSom QSG system in addition to a 24 h help line.

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The test–retest reliability of the NovaSom QSG home data was estimated using the intra-class correlation coefficient (ICC). The ICC is a widely used measure of inter-subject reliability for quantitative data.
Some of the in-lab NovaSom QSG/PSG recordings were interrupted due to a split night protocol [26]. Each subject agreed to use NovaSom QSG at home for three nights, although ten subjects used it for less than three nights (two nights by seven subjects, one night by three subjects). To minimize order bias, half the NovaSom QSG home recordings were performed before the in-lab recordings and half were performed after the in-lab recordings according to the order of referral to the Sleep Disorders Center. The first half of the subjects referred for sleep study used NovaSom QSG at home before their lab test and the second half used NovaSom QSG at home after their lab test.

PSG included two channels of electroencephalogram (EEG), electrooculogram (EOG), submentalis electromyogram (EMG), electrocardiography, anterior tibialis EMG, diaphragmatic EMG, microphone (snoring sounds), end tidal CO₂, nasal–oral airflow (thermocouple), abdominal and thoracic respiration using piezo sensors, and oximetry (Novametrix), all processed through a Grass polygraph and recorded by a Sandman Diagnostics System.

Each polysomnogram was staged for sleep according to the Rechtschaffen and Kales criteria [27] by a trained, blinded technologist. Respiratory events from the polysonmogram recording were manually scored by the technologist (RPSGT). The NovaSom QSG scoring of events is automated. For both systems, an apnea was defined as cessation of airflow for 10 s or longer and hypopnea was defined as a ≥50% reduction in airflow for 10 s or longer accompanied by a ≥2% decrease in oxygen hemoglobin saturation.

PSG traditionally divides the sum of hypopneas and apneas by total hours of sleep to produce the AHI. Since total-hours-of-recording is the denominator used by NovaSom QSG, we compared NovaSom QSG lab and NovaSom QSG home AHI, both calculated with total recording time, to PSG AHI calculated with total sleep time.

The NovaSom QSG system utilizes patented audio digital-signal processing (DSP) technology to sense, analyze, and convert the patient’s respiratory sounds to airflow. The airflow sensor, which is worn on the patient’s upper lip, houses two microphones. One microphone captures the snoring sounds and ambient noise while the other microphone captures the respiration sounds. These two signals are processed by the adaptive noise canceling filters in the DSP to subtract the snoring and ambient noise from the respiration. The result is a pure respiration signal that has a fast response time and a linear correlation with measured airflow. The NovaSom QSG utilizes proprietary algorithms for automated scoring and the generation of a diagnostic report.

The NovaSom QSG effort sensor is thin Tygon™ tubing placed around the chest and is connected to a pressure transducer in the patient module. The finger sensor used by the NovaSom QSG is a Nonin Adult Flexi-form 7000A. The NovaSom QSG testing was unattended and self-administered by the subject in the home.

3. Results

Because no differences were present between subjects first using the NovaSom QSG at home vs. those first having in-lab testing, the data were pooled for analyses.

Of the 51 subjects, 45 completed in-lab PSG plus home NovaSom QSG. Six of the 51 subjects had no home data: three subjects returned their home systems unused and three subjects’ NovaSom QSG data were lost due to a faulty memory chip. Forty-four of the 51 subjects had both PSG and in-lab NovaSom QSG data; seven subjects were missing NovaSom QSG in-lab data: three due to a technician procedure error and four subjects’ data were lost due to an error made when the NovaSom QSG data was being uploaded. Forty of the 44 in-lab recordings were split night studies.

The demographic data for all subjects are summarized in Table 1. The average laboratory recording length was 239 min (range 62–409 min; SD 118). The average home recording length was 379 min (range 58–467 min; SD 123).

3.1. NovaSom QSG lab vs. PSG: AHI 15 as threshold

We used the kappa coefficient to estimate the beyond-chance agreement between NovaSom QSG lab and PSG AHI results. The value of kappa was 0.864 ± 0.076 SE.
which represents excellent agreement beyond chance [28]. This measure of agreement directly compares the two methods without assuming the polysomnogram values should be used as a ‘gold standard’ of comparison. With the in-lab results, among 44 subjects, 20 were positive and 21 were negative by both measuring modalities. Thus, the observed agreement equals $\frac{41}{44} = 0.932$. However, by chance alone this proportion is expected to equal $\frac{22}{44} = 0.50$. The kappa coefficient is defined as the difference of these proportions divided by the maximum possible beyond-chance proportion, i.e. for the example kappa $= (0.932 - 0.50)/ (1.0 - 0.50) = 0.864$.

Using PSG as the gold standard, the sensitivity and specificity of NovaSom QSG lab was $95 \pm 5\%$ and $91 \pm 6\%$, respectively, the negative predictive value was $96 \pm 4\%$ and the positive predictive value was $91 \pm 6\%$ (see Table 2).

Fig. 1 shows a Bland Altman plot of the difference in AHI against the mean AHI for PSG vs. in-lab NovaSom QSG.

3.2. NovaSom QSG home vs. PSG: AHI 15 as threshold

The kappa coefficient between each subject’s average NovaSom QSG home and lab PSG AHI results was $0.734 \pm 0.101$ SE. Referring to PSG as the gold standard, the sensitivity and specificity of NovaSom QSG home was $91 \pm 6\%$ and $83 \pm 8\%$. The negative predictive value was $91 \pm 6\%$ and the positive predictive value was $83 \pm 8\%$ (see Table 2). As expected, these results are somewhat lower than for the in-lab comparisons, since the in-lab night and home nights were not the same.

Fig. 2 shows a Bland Altman plot of the difference in AHI against the mean AHI for PSG vs. home NovaSom QSG.

3.3. NovaSom QSG lab vs. NovaSom QSG home

Sensitivities and specificities were compared between NovaSom QSG lab and average NovaSom QSG home using AHI with a clinical cut-off of 15 and PSG as the gold standard. Eighteen subjects had both in-lab and home values when the PSG was positive. The sensitivity of NovaSom QSG lab was $94 \pm 5\%$ SE and NovaSom QSG home was $89 \pm 7\%$ SE. The difference in the sensitivities equals $5.5 \pm 5.4\%$ SE with a $P$ value of 0.31. Twenty subjects had both in-lab and home values when the PSG was negative. The specificity of NovaSom QSG lab was $90.0 \pm 6.7\%$ and NovaSom QSG home was $80.0 \pm 8.9\%$. The difference in the specificities equals $10.0 \pm 6.7\%$ with a $P$ value of 0.14.

The agreement of the NovaSom QSG home AHIs was determined using an ICC. The ICC for the night-to-night home data was $0.88 \pm 0.034$, representing excellent night-to-night reliability.

Fig. 3 shows a Bland Altman plot of the difference in AHI against the mean AHI for in-lab NovaSom QSG vs. home NovaSom QSG.

3.4. Patient use at home without technician assistance

Ninety-four percent of the subjects (45/48) successfully used the NovaSom QSG system at home without technician assistance. Three subjects returned the device unused. The three subjects whose data were lost due to a faulty memory chip could not be included in the analysis because it could not be determined that the systems were properly used. There were no subjects who were unable to use the NovaSom QSG and there were no invalid home studies due to misapplied sensors. A 24 h help line was not utilized by any of the patients.

4. Discussion

This study attempts to compare the NovaSom QSG diagnostic system in the home and lab with conventional in-lab PSG. The study also examines the reliability of the
NovaSom QSG by assessing the agreement among findings obtained on separate home study nights.

The data showed very high concordance between the in-lab NovaSom QSG and PSG when performed simultaneously in the lab. Sensitivity and negative predictive values of 95% and 96%, respectively, indicate that the NovaSom QSG is capable of accurately determining negative cases, i.e., ruling out sleep apnea over a wide range of values. The home NovaSom QSG sensitivity and negative predictive values were 91%. These home values are slightly lower than the in-lab values, and may be attributable to night-to-night variance in sleep patterns and AHI. The negative prediction capability is important when home study is used as a diagnostic study rather than a screening device.

The simultaneous in-lab NovaSom QSG/PSG specificity and positive predictive values were 91%, which is clinically acceptable. There were four false positives in the home NovaSom QSG vs. PSG which reduced the specificity and positive predictive values to 83%. If the cut-off value was 18 rather than 15, all four home NovaSom QSG false positive cases would have been eliminated, yielding a specificity and positive predictive value of 100%. This observation points out the arbitrary nature of cut-offs, however necessary to estimate performance of methods. While these four cases are statistically categorized as false positives, the clinical decision whether or not to treat is based on many factors in addition to the AHI and the difference between an AHI of 15 and 18 is clinically insignificant.

Two subjects had a false negative (below 15) AHI result in the home. In both cases, the majority of respiratory events scored by the technician on PSG were hypopneas as opposed to apneas (one subject had all hypopneas). The discrepancy in both cases could be due to the difference in signals and scoring methodology or night-to-night variability.

There has been much debate about how to use home devices. Due to the relatively high specificity of the NovaSom QSG a three night home sleep study would be useful if a high probability of sleep apnea is suspected. The usual clinical clues include snoring, witnessed apneas, and concomitant corroborating signs and symptoms. In this case the diagnosis is mainly clinical and the in-home test corroborates the diagnosis and gives an indication of the severity.

The NovaSom QSG also demonstrated a high sensitivity in our patient population where OSA was suspected. Our patient population did not allow us to test whether NovaSom QSG sensitivity would remain high in subjects with a low probability of OSA. Future studies need to include a wider range of disease severity to test this hypothesis.

Home sleep studies are also convenient means of assessing treatment, i.e. post-surgical, post-weight reduction, positional therapy, dental appliances, etc.

The NovaSom QSG differs from currently available home systems in several ways. The system is sent directly to the patient's home, uses voice alerts to guide the patient during application of the sensors and during recording, and provides multiple nights of data. This gives the physician information about night-to-night variability [15,29] as well as access to additional information not obtainable with a one-night study, e.g. by altering night-to-night variables such as alcohol intake or sleeping position. Finally, the automated scoring eliminates the problem of inter-scorer variability [14] and regional differences in AHI criteria.

Two drawbacks of the NovaSom QSG compared to PSG are evident. The NovaSom QSG does not have a body position sensor, therefore position-related apnea cannot be determined. However, many patients with position-related apnea are ultimately treated with CPAP, as the long-term effectiveness of position-modification training is unknown. The NovaSom QSG does not record EEG, therefore sleep onset is not definitely known and sleep staging is not possible. Nonetheless, despite the lack of EEG, the overall AHI comparisons were very good.

As has been pointed out in previous publications, there are some inherent flaws in comparing devices across nights and in different environments [30]. Night-to-night variability can occur in both sleep patterns and AHI. Therefore, it is expected that the agreement between the two devices on different nights would be lower than the agreement between the two devices on the same night in the same environment.

There are some limitations of PSG (the current 'gold standard'): high overhead costs due to the need for dedicated rooms and full-time technologists, the requirement of night-shift workers, variable scoring criteria from sleep lab to sleep lab, inter-scorer variability, and the unfamiliar lab environment which alters the patient's sleep architecture. While there seems to be a transition occurring from the use of thermistors to nasal cannula/pressure transducers, no true gold standard for respiratory airflow currently exists.

In conclusion, the NovaSom QSG is a sensitive and reliable home diagnostic system that could be used in the diagnosis of OSA.

Acknowledgements

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