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Sleep Assessment using a Passive Ballistocardiography-Based System: Preliminary Validation

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Abstract—**Quantitative sleep analysis through the use of polysomnography is a well established standard. Finding new ways to approach this, especially over multiple nights, is becoming more important due to a growing recognition of adverse effects from poor sleep and sleep disorders. The Non-Invasive Analysis of Physiological Signals (NAPS™) system is a ballistocardiography-based monitoring system developed to measure heart rate, breathing rate and musculoskeletal movement that shows promise as a general sleep analysis tool. Overnight sleep studies were conducted on 20 healthy subjects during a validation clinical trial which compared the NAPS system to actigraphy, using polysomnography as the gold standard. The NAPS system [$\kappa = 0.478$; 95% CI (0.463, 0.494); p-value < 0.001] outperformed actigraphy [$\kappa = 0.344$; 95% CI (0.324, 0.358); p-value < 0.001], largely due to better performance in distinguishing sleep onset times as determined by polysomnography [NAPS mean bias estimate: -2.5 epochs; 95% CI (-16.8, 11.9); p = 0.725 | Actigraphy mean bias estimate: -33.6 epochs; 95% CI (-57.4, -9.7); p = 0.016)].**

I. Introduction

Quantitiave analysis of sleep studies has been performed manually since Rechtshaffen and Kales set forth the first set of rules and standards in their 1968 manual on sleep staging [1]. Computer technology has facilitated advances in quantitative analysis and its supporting hardware. This has improved data acquisition and quality, but the fundamental quantitative approach to sleep assessment has seen little modification. Finding ways to quantify sleep more easily is a priority [2] to enable screening of wider populations in more natural settings. Some progress has been made in improving the portability of polysomnography instruments [3]. New technologies have not addressed the need for additional longitudinal data and the ability to easily gather data in the home. The current standard for providing longitudinal sleep monitoring is actigraphy, which uses a wrist-worn accelerometer to track the motion of a subject [4]. Its ability to monitor circadian rhythms and sleep patterns over time has made it a very useful tool, but it is limited in its analysis due to monitoring only the patient's limb movement.

We attempted to accomplish the goal of combining the convenience and longitudinal aspects of actigraphy with some important aspects of polysomnography through a system developed to record physiologic parameters passively. The Non-Invasive Analysis of Physiological Signals (NAPS™) system uses resilient pads placed on a bed to record minute movements associated with cardiac and respiratory functions. This technique, known as ballistocardiography, provides a passive way of recording the above fundamental parameters throughout the night without having to wear any sensors. By monitoring the changes in these parameters, it can potentially analyze sleep quantitatively [5-6].

Previous work [7] has quantified the validity of the NAPS system's ability to detect heart rate, against an electrocardiogram (ECG) and a pulse oximeter, and breathing rate, against respiratory inductance plethysmography (RIP). An algorithm has been developed to report details of sleep architecture, sleep patterns, and sleep efficiency based on heart and breathing rates, regularity of those two parameters, and musculoskeletal movement [9]. To determine the NAPS system's ability to report these parameters effectively, it was compared to both the clinical standard of polysomnography and the longitudinal standard of actigraphy. Specifically, conventional polysomnography was used as the gold standard to directly assess the NAPS system against actigraphy in differentiating wakefulness from sleep on an epoch-by-epoch basis and in describing basic sleep patterns and efficiency.

II. Materials and Methods

A. Study Design

The enrollment of 20 subjects from the Charlottesville general population was reviewed and approved by University of Virginia's Institutional Review Board (IRB) and the General Clinical Research Center (GCRC) Committee. All subjects were educated to the study specifics, and informed consents were obtained prior to their participation. Overnight sleep analyses were performed at the University of Virginia Health System's GCRC Sleep Laboratory on all 20 healthy participants. A NAPS system, using two resilient

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force-coupling pads and four temperature sensors, and conventional polysomnography were used to simultaneously monitor the subjects. An actigraph was also worn on each subject's non-dominant hand.

B. Subjects

Males and non-pregnant females between 18 and 79 years old were recruited by advertisement. Exclusion criteria included a history of cardiopulmonary disease, being a member of a vulnerable population (pregnant females, prisoners or cognitively impaired), history of seizures or epilepsy, use of prescription sleeping pills, tranquilizers, stimulants or anti-depressants, and use of over-the-counter sleeping aids, stimulant diet aids, or stimulants within 7 days prior to the study. A diverse population of subjects met the criteria, including 10 males and 10 non-pregnant females, whose racial demographic was similar to that of the surrounding geographical area obtained from recent census data [8]. The subjects' demographics and apnea-hypopnea index (AHI) are shown for both groups in Table I.

TABLE I
SUBJECT DEMOGRAPHICS

Parameter	Mean	Standard Deviation	Minimum	Maximum
Height (in)	68.4	3.8	61.4	73.1
Weight (lbs)	169.7	43.5	101.2	257.6
Age (yrs)	33.6	12.6	20.0	61.0
AHI[a]	9.6	11.7	0.1	51.3

a = Apnea-Hypopnea Index

C. Data Analysis

Data acquisition and synchronization of the three sleep analysis methods were performed as described previously [7] and the same process [7] was used to resolve the epoch definition of the three different techniques. All polysomnography data were recorded on a Sandman® Computerized Sleep System. The actigraphy data was obtained using the Actiwatch-64 (Respironics/Minimitter; Bend, OR) and interpreted using the accompanying software package (Actiware 5.0). The actigraphs were set to record data in 30-s intervals at the "medium" sensitivity setting to accurately perform the sleep analyses [10]. The NAPS data was analyzed using an automated set of algorithms developed previously [7, 9]. With one exception, only data recorded between the "lights off" and "lights on" times set by the polysomnography analyses were considered. Sleep pattern definitions had to be expanded outside of these times to maintain the independent nature of the techniques used. In all cases, the polysomnography analysis was considered the gold standard. The sleep architecture data from all three techniques were reported in 30-s epochs throughout the night. The sleep pattern and efficiency reporting were also based on these epoch divisions. During polysomnography, apneas were marked as distinct events, independent of the epoch distinctions, and their severity was reported by the technician using the AHI.

III. RESULTS

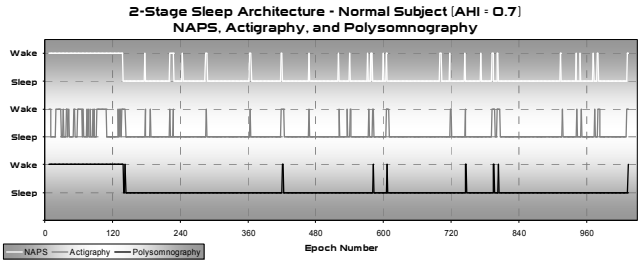

Fig. 1. Representative sleep architecture from three different methods for a normal subject. For each of these graphs, the top series shows data from NAPS, the middle from actigraphy, and the bottom from polysomnography.

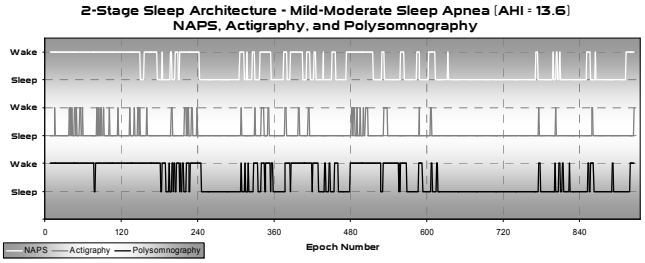

Fig. 2. Representative sleep architecture from three different methods for a subject with mild-moderate sleep apnea.

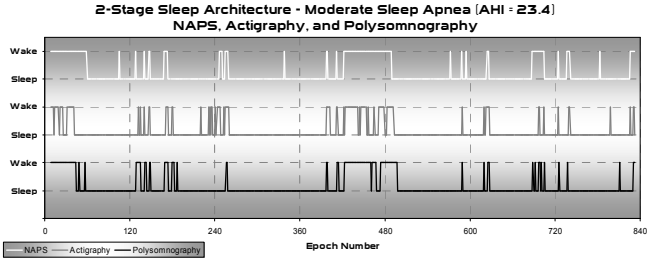

Fig. 3. Representative sleep architecture from three different methods for a subject with moderate sleep apnea.

Sleep architecture was examined using a 2-stage comparison, delineating only wakefulness from sleep. Conventional polysomnography was used as the gold standard to compare the effectiveness of the NAPS system and actigraphy. Three examples, each with different severities of sleep apnea present, were plotted in Figures 1, 2 and 3. Correspondence of the two systems with polysomnography is described in Tables II, III and IV using epoch-by-epoch percent agreement and the conventional Kappa statistic. Table II shows the overall agreement of both NAPS and actigraphy with polysomnography. Tables III and IV show data from each individual subject and also indicate each subject's severity of sleep apnea (using the AHI as determined by the polysomnography analysis). Table III details the results from the NAPS system while Table IV does so for actigraphy. According to Viera et al.'s [11] classification system for the Kappa statistic, the NAPS system has "moderate" agreement with polysomnography

[Kappa = 0.478; 95% CI (0.463, 0.494); p-value < 0.001]. Under the same system, actigraphy has "fair" agreement [Kappa = 0.344; 95% CI (0.324, 0.358); p-value < 0.001].

TABLE II
OVERALL COMPARISON TO POLYSOMNOGRAPHY

	Percent Agreement			Kappa Statistic			
Overall	Estimate	95% Conf. Interval		Estimate	95% Conf. Interval		p-value
NAPS	83.6%	60.1%	94.5%	0.478	0.463	0.494	p < 0.001
Actigraphy	84.6%	52.3%	96.5%	0.344	0.324	0.358	p < 0.001

17,521 total epochs examined across 20 subjects

TABLE III
INDIVIDUAL COMPARISON TO POLYSOMNOGRAPHY

NAPS System comparison to Polysomnography

UserID	Total Epochs	PSG AHI	Percent Agreed	Kappa Statistic
4001	914	52.1	70.6%	0.293
4002	897	10.2	81.0%	0.149
4003	886	14.3	93.0%	0.619
4004	882	13.9	78.6%	0.431
4005	812	5.3	64.5%	0.339
4006	866	0.8	94.3%	0.665
4007	861	1.8	81.2%	0.295
4008	820	1.7	89.9%	0.366
4009	850	15.6	90.2%	0.705
4010	826	23.4	88.6%	0.649
4011	834	5.6	80.6%	0.443
4013	872	1.2	81.2%	0.351
4014	846	6.3	73.3%	0.398
4015	870	0.5	78.2%	0.437
4016	868	7.4	84.7%	0.401
4017	785	12.3	80.4%	0.534
4018	982	0.1	86.0%	0.393
4019	911	8.2	72.2%	0.326
4020	912	13.6	77.9%	0.548
4021	1027	0.7	94.4%	0.787

PSG AHI = Polysomnography Apnea-Hypopnea Index

TABLE IV
INDIVIDUAL COMPARISON TO POLYSOMNOGRAPHY

Actigraphy comparison to Polysomnography

UserID	Total Epochs	PSG AHI	Percent Agreed	Kappa Statistic
4001	914	52.1	74.6%	0.334
4002	897	10.2	82.4%	0.184
4003	886	14.3	95.6%	0.691
4004	882	13.9	88.4%	0.489
4005	812	5.3	45.2%	0.136
4006	866	0.8	92.5%	0.302
4007	861	1.8	84.9%	0.319
4008	820	1.7	94.0%	0.430
4009	850	15.6	88.1%	0.590
4010	826	23.4	88.7%	0.602
4011	834	5.6	88.7%	0.549
4013	872	1.2	85.8%	0.370
4014	846	6.3	66.9%	0.154
4015	870	0.5	81.1%	0.324
4016	868	7.4	84.7%	0.247
4017	785	12.3	86.0%	0.403
4018	982	0.1	94.4%	0.553
4019	911	8.2	67.5%	0.181
4020	912	13.6	61.1%	0.154
4021	1027	0.7	88.3%	0.469

PSG AHI = Polysomnography Apnea-Hypopnea Index

Comparisons of basic sleep pattern characteristics, including time to sleep onset, duration of the sleep period (defined by sleep onset to final wake up prior to "lights on"), and sleep efficiency (defined as the percentage of actual sleep during the sleep period) were calculated. With the polysomnography system used as the gold standard, the NAPS system and actigraphy discrepancies from polysomnography were computed for the three characteristics. Statistically significant differences were found for actigraphy in all characteristics, as summarized in Table V. Additionally, correlations of the time from "lights off" to sleep onset (in epochs) of both the NAPS system and actigraphy with polysomnography are shown in Figure 4.

TABLE V
COMPARISON OF BASIC SLEEP CHARACTERISTICS

	Estimated Mean Bias	95% Conf. Interval Lower	Upper	Standard Deviation	Inter-Quartile Range Q (0.25)	Q (0.75)	p-value	Adjusted p-value
Sleep Onset	**All measures listed in epochs**							
NAPS-PSG	-2.5	-16.8	11.9	31.5	-5.0	12.8	0.725	*
ACT-PSG	-33.6	-57.4	-9.7	52.3	-48.3	-3.8	0.008	0.016
Sleep Period	**All measures listed in epochs**							
NAPS-PSG	11.2	-16.1	38.5	59.7	-14.5	4.0	0.400	*
ACT-PSG	50.2	16.4	84.0	74.1	3.0	49.5	0.006	0.012
Sleep Efficiency	**All measures listed as a percentage**							
NAPS-PSG	-0.6	-6.8	5.6	13.5	-7.4	4.2	0.843	*
ACT-PSG	11.9	4.6	19.1	15.8	3.1	13.9	0.003	0.006

PSG = polysomnography ACT = actigraphy * Indicates p-value not computed

Column Descriptions (Left to right): 1) Estimated Mean Bias: Indicates the estimate of the mean discrepancy from polysomnography. 2 and 3) 95% Confidence Interval: For the true mean discrepancy. 4) Standard Deviation: The estimated standard deviation for the measurement discrepancy. 5 and 6) Inter-Quartile Range: The numerical range for the middle 50% of the data, when sorted from minimum to maximum values. 7) p-value: The p-value for the null hypothesis that the true standard deviation for the within-subject measurement discrepancy is equal to zero. 8) Adjusted p-value: Same as the value listed in column 7, but adjusted for Type 1 error; p-values that already accepted the null hypothesis were not favorably biased.

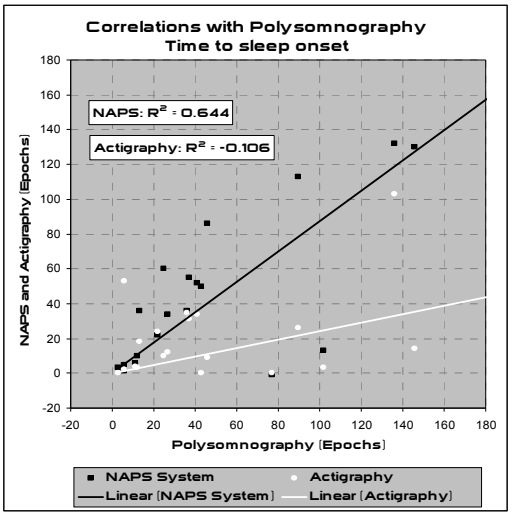

Fig. 4. NAPS and actigraphy sleep onset times compared with polysomnography. The lines represent a linear regression of each method.

The NAPS system's ability to detect if the subject left the bed (i.e. to use the bathroom) any time between the "lights off" and "lights on" times was also evaluated. Qualifying events were recorded by the polysomnography technician and compared to the NAPS system's automatic analysis. The NAPS system detected all 17 events across 12 subjects

with a standard deviation of 2 epochs. It detected the correct duration of these with a standard deviation of 2.7 epochs.

IV. Discussion

Estimating sleep staging without the use of electroencephalographs, electromyographs and electrooculograms is difficult. Perfect agreement with polysomnography may be unattainable due to the inter-rater variability due to technician scoring. As recently reviewed by the AASM [12], there tends to be variability between technicians who are scoring of the same dataset. However, that effect has been minimized to some extent by comparing the two automated approaches of the NAPS system and actigraphy to the same polysomnography data.

Simplifying the sleep architecture data to only delineate wakefulness and sleep was required to allow the two techniques to be compared directly. Actigraphy alone is incapable of examining REM or other stages of sleep. The NAPS system and actigraphy both performed well in making the distinction between sleep and wake on an epoch-by-epoch basis as compared to polysomnography. However, the NAPS system had better agreement overall as denoted by the distribution of the conventional Kappa statistic for each subject. This is due, in part, to NAPS System's superiority in detecting sleep onset times as compared to actigraphy. The NAPS system showed little or no bias in its detection of sleep onset while actigraphy showed a statistically significant negative bias that indicates it consistently places sleep onset earlier than polysomnography. This was also true for the related parameters of sleep period length and sleep efficiency. The NAPS system's ability to monitor heart rate and breathing rate allowed it to not solely rely on movement to determine sleep state. However, occasional postural movement is still required for the NAPS system to detect long wake periods.

The results show that the NAPS system is useful in studying subjects who experience longer sleep onset times or long wake periods throughout the night, including those who experience insomnia. The NAPS system's ability to obtain these characteristics without the need for sleep diaries or patient compliance in pushing a button to flag rest periods, as is the case with actigraphy, is another key advantage. Additionally, the NAPS system's ability to detect bed entry/exit provides additional information about when the subject is actually in bed, something impossible to detect with actigraphy alone.

V. Conclusion

The NAPS system outperformed actigraphy in distinguishing 2-stage sleep architecture, largely due to better performance in distinguishing sleep onset times. This was mainly due to the incorporation of heart rate, breathing rate and heart rate/breathing rate regularity, along with musculoskeletal movement information. Unlike other approaches, the NAPS system automatically recorded when the subject was out of bed without the need for a sleep diary or input from the subject. The NAPS system appears to be a promising tool for use in longitudinal, unattended home sleep studies.

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