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A WIRELESS PATCH-BASED POLYSOMNOGRAPHY SYSTEM FOR SLEEP STUDIES: EFFECT OF THE 2016 AASM RULES ON AHI IN NORMAL INDIVIDUALS

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Introduction: Current home sleep test (HST) devices are limited by an absence of EEG, or by being too cumbersome to use. We developed a wireless PSG system (Onera Health, NL) consisting of four disposable patches to record EEG, EOG, EMG, SaO2, ECG, bioimpedance derived respiratory airflow and effort, airflow via nasal cannula, snoring sounds, body position, actigraphy, and leg movements. Signals are stored on reusable electronic modules attached to each patch.
Methods: We measured PSG hook-up time in 15 healthy laypersons (6 male, 9 female, age 18-to-70 yrs, BMI 29.7±5.2 kg/m2). We also enrolled 6 additional asymptomatic healthy volunteers (2 male, 4 female, age 27-to-33 yrs, BMI 24.3±5.7 kg/m2) with history of occasional snoring, on which we scored the apnea-hypopnea index (AHI) using data from our patch-based PSG system recorded at home. We evaluated scoring using the 2016 AASM rules for hypopneas in comparison to the 2007 AASM rules requiring a greater than 3% fall in SaO2 for obstructive hypopneas.
Results: Mean hook-up time for applying all four patches and electronic modules was 4:42 ± 1:20 min. Mean home sleep efficiency was 89.5 SE 1.9% with an average REM% of 20 SE 6.7%. When comparing the 2016 vs 2007 AASM rules for scoring hypopneas, the AHI increased more than threefold during NREM (9.0 SE 2.0/h vs 2.7 SE 0.8/h; $p<0.03$) and minimally during REM (11.7 SE 2.3/h and 7.1/h SE 1.8/h; $p<0.01$), implying an overall increase in the AHI from 3.7 SE 0.8/h to 9.9 SE 1.9/h; $p<0.02$. One subject changed AHI category from normal to mild (3.6 to 14.4/h), another from mild to moderate (12.7 to 26.3/h) using the 2016 AASM rules.
Conclusion: Our wireless patch-based PSG system is an easy solution for sleep studies at home or in the sleep lab, lowering the burden to conduct large scale epidemiologic sleep studies. The presence of standard EEG signals allows to determine NREM and REM statistics, respiratory and non-respiratory arousal indices, AHI and RERA's by sleep stages. Preliminary study results show that using cortical arousal criteria for hypopneas, the AHI increase is more pronounced in NREM compared to REM sleep.
Support (if any):

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COMPARATIVE STUDY OF WIRELESS SENSORS VERSUS TYPE III HOME SLEEP APNEA TEST FOR HOME-BASED DIAGNOSIS OF OBSTRUCTIVE SLEEP APNEA

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Introduction: More than 22 million Americans are estimated to have obstructive sleep apnea (OSA), though this disease remains perpetually underdiagnosed. Undiagnosed OSA contributes to poor clinical outcomes, large healthcare costs and an economic burden in excess of $150 billion dollars annually. While polysomnography (PSG) is considered the gold standard to diagnose OSA home sleep apnea testing (HSAT) is now used for most patient cohorts. Wireless sensors may offer a lower cost and less burdensome approach to home testing than traditional HSAT.
Methods: We performed a fully remote, national, single-arm, open-label, prospective clinical study to evaluate the performance of a wireless, two sensor experimental system (ANNETM One, Sibel Health) against a Type III HST system. A total of 154 individuals completed screening with 62 screening in as high risk for OSA using the STOP-BANG questionnaire. Ultimately 60 participants were enrolled, and 46 completed a successful home testing night wearing both the commercially available HSAT (Philips Alice NightOne Home Sleep, Koninklijke Philips N.V) and the wireless experimental system. A board-certified sleep medicine physician determined the apnea-hypopnea index (AHI) for the HSAT defined by American Academy of Sleep Medicine v2.6 guidelines. Two study investigators, blinded to the HSAT results, scored the experimental system to determine AHI based on similar guidelines. An independent study investigator conducted the final analysis of comparative performance. Participants completed a psychometric survey of their preferences, experience, and usability of the two testing systems.
Results: We demonstrated a high level of agreement between the HSAT and experimental system for AHI ($r2=0.81$, $p<0.0001$). The sensitivity and specificity of the experimental system to diagnose moderate and severe OSA (AHI>15) was 85% and 95%, respectively. The experimental system had a significantly higher Systems Usability Scale score compared to HSAT (61 vs 48, $p<0.0001$) and more than 85% of participants preferred the experimental system.
Conclusion: This study provides compelling evidence that the experimental system was highly acceptable and comparable to a currently used HSAT. Continued innovation in reliable, cost-effective, low profile technologies will be critical to address the unmet needs of sleep diagnostic testing.
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SLEEP-DISORDERED BREATHING IN NATIVE HAWAIIANS/PACIFIC ISLANDERS WITH ASSOCIATED COMORBIDITIES AND ADHERENCE TO THERAPY

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Introduction: Sleep-disordered breathing in Native Hawaiians and Pacific Islanders (NHPIs), its relationship to type 2 diabetes mellitus (DM), chronic renal, and heart disease, is not well known. NHPIs comprise only 1.3% of Utah's population, but have the highest rates of DM and deaths due to diabetic kidney disease in Utah. This study assessed the nature of sleep-disordered breathing, its association with demographic variables, and comorbidities, and adherence patterns to positive airway pressure (PAP) therapy.
Methods: University of Utah sleep clinics patient databases from 2014 were evaluated to identify NHPIs using first/last names. Electronic medical records were reviewed to confirm patient ethnic origin, demographic data, and comorbidities. The most recent PAP downloads were obtained.
Results: Of 106 NHPIs were identified, data available for 104 patients (71 males, 33 females) was analyzed. Mean age of males was 47 + 13 years and females 48±13 years. Prevalence rates of obesity were 13% (female 9%, male 15%) with BMI≥30, 33% (female 24%, male 23%) with BMI≥35, and 49% (female 58%, Male 23%) with BMI≥40). Majority of patients had severe OSA (61% males with AHI≥30; 39% females with ≥ 30), with overall mean AHI of 47±38. A high prevalence of comorbidities was noted: 61% hypertension (male 58%; female 67%), diabetes 54% (male 48%, female 67%),