VALIDATION STUDY OF AN ECG BASED SLEEP DIAGNOSTIC SYSTEM

Michael J. Decker[1,2], Zvika Shinar[3], Shulamit Eyal[3], Jeffrey S. Durmer[1], William C. Reeves[2], Clement Cahan[4]

1. Fusion Sleep, Suwanee, GA, USA.
2. Centers for Disease Control & Prevention, Atlanta, GA, USA.
3. HypnoCore, Netanya, Israel.
4. Share Zedek Medical Center, Sleep Disorders Clinic, Jerusalem, Israel.

Introduction: Recent algorithms developed at the Medical Physics Department at Tel Aviv University enable determination of sleep/wake architecture, cardiorespiratory activity and autonomic tone from standard ECG and pulse oximetry signals. In this study we defined levels of agreement between these ECG-derived values of sleep-wake architecture and cardiorespiratory parameters with those calculated from manually scored polysomnographic (PSG) recordings.

Methods: Polysomnographic recordings from 54 subjects were randomly selected from those obtained from a cohort of 254 subjects participating in a study of Chronic Fatigue Syndrome. All participants underwent standard PSG with all studies being scored manually by the same individual, according to Rechtschaffen & Kales criteria. The ECG and pulse oximtery signal were analyzed by the Hypnocore HC1000P to determine values for sleep time, sleep efficiency, % time awake, in NREM and REM sleep, and respiratory disturbance index (RDI).

Results: 53 of 54 PSG 's contained technically acceptable ECG and pulse oximetry signals. There was no significant (t test) difference between ECG and PSG derived values of total sleep time (396.5 ± 48.0 vs 387.9 ± 29.2 minutes), sleep efficiency (88.7% ± 7.6% vs 82.6% ± 4.3%), wake (15.6% ± 9.4 vs 15.6% ± 4.1), NREM (65.9% ± 7.8 vs 67.2% ± 4.9), and REM sleep (18.6% ± 6.3 vs 15.2% ± 4.8). Comparisons between RDI values yielded a correlation coefficient of R=0.96, providing a positive predictive value (PPV) of 90.6% and a negative predictive value (NPV) of 95.2%. Further comparisons between the two methods revealed a kappa of 0.84 for a RDI cutoff at 5, with a PPV of 93.8%, NPV 100%; for a RDI cutoff at 15, the kappa was 0.95. Using the Bland and Altman technique the level of agreement (mean ± 1 SD) between ECG & oximetry based RDI and manually scored RDI was PSG's 4.1 ± 3.9.

Conclusion: We assessed a novel algorithm that derives values of sleep/wake architecture, cardiorespiratory activity and autonomic tone from standard ECG and pulse oximetry signals. We found no difference between values of wakefulness, sleep, NREM, REM sleep and RDI calculated with this algorithm versus those derived from manually scored PSG recordings. We propose this unique algorithm will facilitate high throughput analysis of sleep/wake parameters and RDI that, when combined with clinical information, provides reliable and reproducible diagnosis of sleep disordered breathing as well as disorders of initiating and maintaining sleep.

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