Validation of an ECG and Oxygen Saturation Based Sleep Diagnostic System

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Introduction

- Obstructive sleep apnea is a prevalent disorder with significant health consequences, it is estimated at least 6% of the population is affected.¹,²
- It is widely undiagnosed and untreated due to the high cost and inconvenience of gold standard diagnostic practices.³,⁴
- New simplified methods to allow cost-effective diagnosis are under consideration.
- This study aimed to validate the HC1000P by HypoCore, a software device enabling evaluation of sleep architecture and diagnosis of Sleep Related Breathing Disorders (SBD) based on single-channel ECG and pulse oximetry recordings only.

Methods

- The HC1000P:
  - Detects respiratory events by ECG morphology (ECG Derived Respiration-EDR) and oximetry.⁵,⁶
  - In addition the system can identify sleep architecture, autonomic arousals and awakenings. This is based on the connection between sleep and differential autonomic nervous system modulation of instantaneous heart rate during different sleep stages.⁷,⁸
  - The study was based on 454 whole night polysomnograms performed on 234 subjects for a cohort study on Chronic Fatigue Syndrome at the CDC.⁹
  - 410 studies met the quality inclusion criteria and were free of extensive arousality. 79.6% Female, BMI 29.0 ± 4.9, Age 50 ± 9.0.
  - All recordings were scored manually according to R&K and ASDA criteria.¹⁰,¹¹
  - ECG and oximetry signals were blindly analyzed by the HC1000P to determine sleep architecture and quality, detect respiratory disturbances and calculate the Apnea/Hypopnea Index (AHI = respiratory events per hour of sleep).

Results

Respiratory evaluation:
- The total number of respiratory events highly correlated between the two methods with R = 0.87.
- AHI (apnea/hypopnea events per hour of sleep) highly correlated with R = 0.89 as can be seen in Figure 1.

Sleep architecture evaluation:
- Parameters of sleep architecture obtained by gold standard, manual methods were compared to those calculated automatically by HC1000P system. Results of the analysis show good overall agreement with regards to total sleep time, sleep efficiency, percentage of time spent in REM and NREM sleep (Figure 2).

Discussion & Conclusions

- The HC1000P allows for an accurate, specific and highly sensitive method to diagnose Obstructive Sleep Apnea (OSA).
- This novel method overcomes disadvantages of partial ambulatory tests by providing accurate evaluation of sleep architecture, efficiency and arousals.
- Results are accurate even at low AHIs, i.e. mild cases of OSA or normal individuals. This implies it can be used as a true diagnostic tool, not just a method of screening.
- The simplicity of the method allows for easy follow up studies which are not affordable by standard methods. Thus, compliance with CPAP might increase.
- The HC1000P may facilitate high throughput diagnosis of OSA including sleep/wake assessment.
- It is a cost-effective measure for mass diagnosis, of great importance for a disorder with a high prevalence of undiagnosed cases.

References