

Objective: This research was aimed to validate a novel sleep test based on cardiopulmonary coupling to detect sleep apnea.

Methods: This multicenter prospective study was conducted at three tertiary medical centers in Taiwan. Adult subjects who were scheduled for an attended polysomnography in the sleep centers of the three hospitals were enrolled after obtaining informed consent. Clinical data including demographics were collected. Enrollees received a standard full-channel overnight polysomnography and Largan sleep test simultaneously to provide a head-to-head comparison. The Largan sleep test was carried out with a wireless ECG Holter (LARGAN CPC®) attached to the testee's left, anterior chest, which collected and recorded ECG signals continuously through the whole period of sleep. The data were further analyzed by the Largan Sleep Apnea and Sleep Quality Examination System, which was developed using CardioPulmonary Coupling (CPC) technology from BIDMC/Harvard Medical School to achieve automatic sleep staging and detecting events of sleep apnea/hypopnea. The respiratory event index (REI) independently derived from the system was compared with the apnea-hypopnea index (AHI) derived from the standard polysomnography. The correlation analysis and a ROC (receiver operating characteristic curve) curve analysis were also conducted.

Results: A total of 479 subjects were enrolled and completed the study. Characteristics of the enrollees were age: 42 years (IQR:33-54), female: 22%, BMI: 27.5 kg/m² (24.8-30.9), AHI: 15 (4.3-39.4). REI were significantly correlated to AHI (Spearman's rho: 0.888, p<0.001). The median difference between REI and AHI was 0.50 (-3.3~6.6). The sensitivity, specificity and diagnostic accuracy at a cut-off of REI=5/hr to detect sleep apnea (AHI≥5/hr) were 88.1%, 79.1%, and 85.6%, respectively. The area under the ROC curve was 0.923 (95% CI: 0.900~0.946, p<0.001). At a cut-off of REI=30/hr to detect severe sleep apnea (AHI≥30/hr), the area under the ROC curve was 0.967 (95% CI: 0.953~0.982, p<0.001).

Conclusion: The novel sleep test based on cardiopulmonary coupling is a device of promise to detect sleep apnea.

中文題目：The Effectiveness of a Novel Sleep Test based on Cardiopulmonary Coupling to Detect Sleep Apnea -A Multi-Center Prospective Study

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