Sleep Diagnosis and Therapy Vol 7 No 7 November 2012, Daniel J. Levendowski and Phillip Westbrook

Expanding the Out-of-Center Sleep Testing Arsenal

Sleep Profiler: In-home Neuro-Cardio Assessment of Sleep Quality

A new system that enables sleep centers to expand beyond sleep apnea testing and improve quality of care for insomnia patients.

The Advanced Brain Monitoring (ABM) team is dedicated to helping clinicians make better decisions through access to accurate information. After success with the ARES™ in-home sleep apnea monitor, a close look at the market revealed an under-served population of people who had sleep problems, but did *not* have sleep apnea—specifically insomnia sufferers.

Insomnia is a different market segment with fewer diagnostic tools than sleep apnea. Daniel Levendowski, president of ABM, attributes the difference to the relative ease of acquiring and detecting apnea patterns. Patients can fairly easily apply a cannula and oximeter probe in their home and the interpretation of the associated signal patterns is well understood.

Objective assessment of sleep architecture and continuity on the other hand, requires measurement of electro-encephalography (EEG). "EEG acquisition is highly reliant on proper application and maintenance of the sensors, typically placed over hair, to obtain a good quality signal," he says. "Polysomnography is commonly used to obtain this information but is too costly and cumbersome for long-term and/or large-scale applications."

ABM has simplified the acquisition process with its forehead monitor, dubbed the Sleep Profiler. "Interpreting the signal patterns from Sleep Profiler is similar to staging sleep with electrooculography recordings," stated Philip Westbrook, MD, chief medical officer of ABM. "Our goal is to provide quantitative metrics that allow clinicians to differentiate those with sleep state misperception from those with sleep onset or sleep maintenance insomnia, and to provide additional information to help determine the source of non-restorative or poor sleep quality."

Clinical Case Builds

Beyond the obvious problems of daytime sleepiness, disrupted sleep plays an important role in cardiovascular, neurological, and psychiatric disorders. "It is an independent risk factor for type 2 diabetes and obesity, and is a predictor of increased mortality," says Levendowski from his California-based office. "The 2011 National Institute of Health Sleep Research Plan emphasized the importance of understanding the impact of sleep and circadian disorders, chronic sleep deficiency, and circadian disruption on human health."

Sleep Profiler attempts to address these unmet needs by providing a neuro-cardio assessment of sleep quality—particularly an accurate measure of sleep architecture and sleep continuity with patients sleeping comfortably at home. The "how" of Sleep Profiler involves physiological signals recorded with sensors self-applied by the patient to the forehead. The recorder is 2 inches by 1.5 inches and weighs 2.5 ounces. Sleep Profiler measures sensor impedances and provides voice messages to acquire high quality recordings for one or two nights.

Sleep records are analyzed with validated algorithms that provide automated detection of sleep stages, cortical, sympathetic and behavioural arousals (see accompanying research study page 51). The web-portal provides clinicians the capability to edit and interpret the full-disclosure recordings.

Market is Growing

Insomnia is a widespread sleep disorder, with many estimates pegging the malady as affecting approximately 30% of adults. The average cost for patients with insomnia is $1,250 greater than patients without insomnia, contributing over $100 billion annually in direct and indirect costs. Additionally, sedative hypnotics commonly prescribed for insomnia are expensive, cause dependency, and can magnify sleep problems when abused, misused, or taken too often.

Cognitive behavioral therapy, which is the recommended treatment for chronic insomnia, is currently being administered with limited objective measurement of therapeutic improvement. According to Westbrook, wrist actigraphy and sleep diaries provide therapists rudimentary estimates of total sleep time without any information about the quality of periods self-reported or labeled by actigraphy as sleep.

"Assessing improvements in the amount of slow wave sleep an insomnia patient receives may help us better assess the impact therapy has on other chronic diseases," adds Westbrook, past president of the American Academy of Sleep Medicine. "Abnormal REM patterns that present in patients with depression and post-traumatic stress syndrome are distinctive yet rarely objectively assessed. As a result, clinicians may sub-optimally treat patients who report overlapping symptoms."

The idea behind Sleep Profiler is to eliminate some of the guesswork and establish a cost-effective clinical protocol for improving the management of patients with insomnia. "The potential for reducing the long-term health care costs for these patients is high, given the annual cost of the medication and the high cost of treating other chronic co-morbid conditions exacerbated by insomnia," says Levendowski.

New research such as "The Associations of Insomnia With Costly Workplace Accidents and Errors: Results From the America Insomnia Survey" published in *The Archives of General Psychiatry*, part of the *Journal of the American Medical Association (JAMA) Network*, backs Levendowski up. Researchers pegged the cost of insomnia in the tens of billions—$31.9 billion to be exact.

Several news outlets reported the startling numbers that only add weight to the growing focus on sleep in the health care world. Researchers found that workplace mistakes related to insomnia were more costly than other kinds of errors, with

insomnia-related errors costing $32,062 compared with non insomnia-related errors costing $21,914, on average.

Incorporating Sleep Profiler into the out-of-center sleep testing paradigm ideally begins with an in-home SleepProfiler study performed on non-medicated patients to assess sleep duration and quality, autonomic nervous system activity, and behavioral arousals.

"A physician boarded in sleep medicine would review the sleep architecture patterns to confirm insomnia, rule out undiagnosed sleep apnea, and/or identify depression patterns which would require a different treatment path," explains Levendowski. "Cognitive behavioral therapy for insomnia (CBT-I) could be delivered by trained therapists or via web-based CBT-I sessions available through the Sleep Profiler portal. Upon completion of therapy a follow-up Sleep Profiler study would be performed to provide objective feedback for patient improvement, a critical component to improved outcomes."

Outcome measures available with Sleep Profiler include: total time and percentage sleep; REM, and SWS, sleep, REM, and SWS latency; sleep efficiency; total and average hourly number of cortical, sympathetic, and behavioral arousals; and frequency and intensity of snoring.

Daniel J. Levendowski co-founded Advanced Brain Monitoring and has served as its president since inception in 1997. As principal investigator for 17 National Institute of Health research grants, he managed over $8 million in funding used to create novel systems and implement predictive algorithms to diagnose and treat chronic diseases or monitor physiology and optimize performance. He has co-authored more than 20 journal articles and 15 papers needed for new product adoption. His contributions to product innovation has resulted in 18 patents or patents-pending. He received an M.B.A. from the Anderson School of Management at the University of California, Los Angeles.

Phillip Westbrook, MD, served as president of the American Academy of Sleep Medicine and member of the Board of Directors and Standards of Practice Committee, and was acknowledged with a Distinguished Service Award in 1992. He was honored by the National Sleep Foundation with a Lifetime Achievement Award in 2009. He is an Emeritus Clinical Professor of Medicine at UCLA, was a clinical fellow and Associate Professor of Medicine at Mayo Medical School in Rochester, MN and founding director of the Sleep Disorder Centers at the Mayo Clinic from 1980 through 1989 and at Cedars-Sinai Medical Center, Los Angeles, CA from 1989 through 1995.