Improving the Diagnosis and Treatment of Chronic Insomnia and Insomnia with Comorbid OSA or Depression

THE PROBLEM:

Chronic insomnia afflicts 20-30% of the population and between 10% and 50% of patients attending primary care\(^1\). Insomnia is associated with significant morbidity in terms of health problems and healthcare utilization, work absenteeism, and reduced productivity. In 2009, the average annual per-person direct and indirect healthcare costs was reported to be $5,010 for individuals with an insomnia syndrome, $1,431 with individuals presenting with insomnia symptoms, and $421 for good sleepers\(^2\). Insomnia has been associated with 7.2% of all costly workplace accidents; the average cost of insomnia-related accidents and errors ($32,062) is one-third greater than the other sources of accidents/errors\(^3\). In January 2013, the U.S. FDA issued a Drug Safety Announcement recommending that the nightly dosage for insomnia medications be cut by 50% in order to reduce the risk of next-morning impairment for activities that require complete mental alertness\(^4\).

Insomnia is classified as chronic disorder when the patient experiences difficulty initiating or maintaining sleep, or suffers from non-restorative sleep for at least one month. As many a 50% of Obstructive Sleep Apnea (OSA) patients also suffer from moderate to severe insomnia\(^5\). Untreated insomnia does not resolve with the treatment of OSA\(^6\) and untreated insomnia reduces CPAP compliance\(^9\). Insomnia is primarily diagnosed by clinical evaluation using a detailed medical, psychiatric, and sleep history (i.e., sleep diary)\(^11,12\). The subjectivity involved with the diagnosis of insomnia is problematic because over 5% of the clinical population and many patients with chronic insomnia underestimate their sleep duration\(^13\). The degree to which sleep diaries are distorted depends in large part on the personality type of the patient; those who are neurotic are more prone to underestimate their sleep duration\(^14\).

Clinical guidelines for the evaluation and management of chronic insomnia recommend quantification of sleep and sleep stages by polysomnography when the initial diagnosis is uncertain, treatment fails, or precipitous arousals occur with violent or injurious behaviour\(^11\). Additional laboratory testing is recommended for the insomnia patient when there is suspicion of comorbid disorders. Cognitive behavioural therapy for insomnia (CBT-I) is considered the first choice for treatment of chronic insomnia\(^8\). Internet-based CBT-I has been shown to be an effective, more convenient alternative to office-based CBT-I\(^15\). Hypnotic medications are only recommended as a short-term insomnia intervention due to a possibility of drug tolerance and drug dependency with long-term use\(^11,12\). In addition to safety concerns, hypnotic medications are expensive, costing as much as $1,500 per year.

New evidence supports use of overnight electroencephalography (EEG) as the means to improve treatment outcomes by objectively characterizing insomnia phenotypes. An insomnia patient with sleep misperception (i.e., EEG-based confirmation of normal sleep duration) provides a profile of high depression and anxiety and low ego strength\(^16\). It is recommended that this insomnia phenotype should be targeted with CBT-I. An insomnia phenotype suffering from short sleep duration (i.e., less than 6 hours) is likely to have an underlying medical disorder such as hypertension, type 2 diabetes, hypothalamic-pituitary-adrenal axis, and/or neurocognitive deficits\(^16,17\). Prescribing hypnotics to treat insomnia in this idiopathic group could mask recognition of the underlying condition that could be uncovered by additional laboratory testing\(^11\). Thus, improving insomnia outcomes requires objective assessment of sleep duration, continuity and architecture, metrics that can be reliably measured only with multi-night EEG recordings\(^18\).

Approximately 40% of patients with insomnia suffer from a psychiatric disorder\(^13\) and as many as 80% of patients with depression suffer from insomnia. Characterization of a genetic predisposition to depression by recognition of early onset and high density REM architecture in overnight EEG\(^19\) allows clinicians to safely and
more economically direct pharmacological interventions for comorbid insomnia and depression. Evidence suggests that early diagnosis and treatment of insomnia could, at least partially, prevent future depression\textsuperscript{20}. Delivery of cognitive behavioural therapy for insomnia (CBT-I) to those with symptoms of insomnia and depression guarantees a better treatment outcome than standard antidepressants alone \textsuperscript{21,22}.

**THE SOLUTION:**

The Sleep Profiler System provides an evidence-based, stepped-care solution for the assessment and management of insomnia and insomnia with comorbid depression. The pre-treatment Sleep Profiler assessment allows the clinician to compare with the patient differences in their objective measures of sleep architecture and sleep continuity with subjective impression of their sleep quality. Objective measures of total sleep time and sleep efficiency provide a more accurate and safer determination of the initial requirement for sleep restriction. These objective measures also allow clinicians to better assess the need for continued use of hypnotic sleeping medications. The clinician’s assessment of sleep architecture is used to identify patients susceptible to depression, which in turn allows a more informed determination of an appropriate pharmacological regimen which promotes the long-term health at a reduced cost. Comparison of pre- and post-treatment sleep quality metrics allow clinicians to monitor changes in sympathetic arousal and slow wave sleep patterns which impact hypertension\textsuperscript{23}, diabetes\textsuperscript{24}, and weight gain\textsuperscript{25}. Shifting acquisition of overnight EEG from one night in the laboratory to multi-nights in the home increases measurement accuracy while reducing costs.

For many insomnia patients, office CBT is unavailable due to the limited number of trained psychologists. Up to 50% of patients refuse office CBT due to the out-of-pocket cost or inconvenience of taking time off from work to undergo therapy. Sleep Profiler provides an alternative with delivery of on-line CBT-I, a therapeutic approach proven to be as effective as office CBT \textsuperscript{26-28}. The Sleep Profiler pre-treatment assessment is used to identify those appropriate for online CBT-I. Then, more than 70% of patients with insomnia can be successfully treated from the comfort of their home while clinicians monitor their patient’s therapeutic progress using the Sleep Profiler web-portal.
SLEEP PROFILER-BASED CLINICAL CONCLUSIONS:

If the patient has been taking hypnotics (Ambien, Edluar, and Zolpimist) for > 30 days:

- By conducting the study, we were able to comply with the FDA’s Drug Safety Communication - Risk of Next-morning Impairment After Use of Insomnia Drugs by objectively verifying the severity of the insomnia. This, in turn, allowed us to determine:
  - A refill was appropriate
  - The refill was not warranted
  - Based on the patient’s sleep latency, sleep efficiency, and wake after sleep onset, an alternative course of therapy “cognitive behavioral therapy for insomnia” (CBT-I) is recommended.

If the patient has been taking hypnotics (Ambien, Edluar, and Zolpimist) at a dosage greater than > 5 mg for females and 6.25 mg for males (typical dosages have been 10 and 12.5 mg respectively):

- By conducting the study, we were able to comply with the FDA’s Drug Safety Communication - Risk of Next-morning Impairment After Use of Insomnia Drugs by objectively verifying the severity of the insomnia. This, in turn, allowed us to effectively manage the patient while reducing the dosage by 50%.

To rule out comorbid disorders:

- The patient presented with insomnia as a primary complaint, however, we needed to objectively assess the patient’s sleep patterns in order to:
  - Determine if the disorder will likely be resolved by correction of behaviors which can be readily treated with “cognitive behavioral therapy for insomnia” (CBT-I), or
  - Rule out insomnia being caused by an undiagnosed comorbidity (i.e., hypertension, cancer, heart disease, diabetes, GI or urinary problem)

For patients with insomnia and comorbid depression/anxiety/PTSD disorders:

- We needed to determine the appropriate pharmacotherapy for a patient with overlapping symptoms. We need to provide a procedure which allowed us to assess which condition may be causing the other and/or to assess the degree to which the conditions are reciprocal. The overnight EEG provided the information to:
  - Confirm the presence of consolidated/fragmented REM sleep, which supports prescribed/continued use of selective serotonin reuptake inhibitors (SSRI).
  - Based on a lack of consolidated/fragmented REM sleep, introduction of selective serotonin reuptake inhibitors (SSRI) should be delayed until after insomnia therapy is introduced.
  - Based on the patient’s sleep latency, sleep efficiency, and wake after sleep onset, the patient requires a direct intervention for Insomnia independent of the depression/anxiety/PTSD and “cognitive behavioral therapy for insomnia” (CBT-I) is recommended.

For patients with insomnia and comorbid OSA:

- Because untreated insomnia contributes to non-compliant CPAP therapy, and because CPAP therapy does not resolve the insomnia, we needed to objectively assess the presence of insomnia while the patient was on their OSA therapy.
  - Based on the patient’s sleep latency, sleep efficiency, and wake after sleep onset while on OSA therapy, the patient requires a direct intervention for Insomnia independent of the OSA and “cognitive behavioral therapy for insomnia” (CBT-I) is recommended.

When CBT-I is prescribed as the therapeutic intervention for someone who drives to and from work or is in a safety-sensitive position:
• The overnight EEG provided us the objective information (i.e., total sleep time and wake after sleep onset) needed to select a sleep restriction window that limits the safety risk associated with excessive sleep deprivation.

**Acquisition of post-treatment study:**

• The first procedure was used to determine if the patient was appropriate for CBT-I and to rule out undiagnosed co-morbidities.
• The second procedure provided objective evidence that the sleep patterns (i.e., suppressed SWS) which would lead to long-term chronic diseases like hypertension, heart disease, diabetes, and obesity were corrected by the CBT-I.

**RATIONAL DELIVERY OF CARE:**

**The Sleep Profile System is cost effective for the payer:**

• The cost for two-night pre- and post-treatment Sleep Profiler with online CBT-I delivery and monitoring is equivalent to six office CBT-I sessions.
• In patients with insomnia, the return on investment is three to six months as a result of reductions in direct and indirect costs.

**The Sleep Profile System is cost effective for the provider:**

• A two-night Sleep Profiler study generates reimbursement equivalent to reimbursement for two nights of an obstructive sleep apnea home sleep test (HST).
• The per-study cost for use of the device, disposables and the web-portal is less than 10% of the reimbursed amount.

**Reimbursement Model in the United States:**

• Billing code CTP 95827 – overnight EEG technical and professional can be combined with one of the following diagnostic (ICD-9) codes
  o 780.56 Dysfunctions associated with sleep stages or arousal from sleep
  o 327.42 Insomnia, not due to known physiological condition
  o 327.01 Insomnia due to medical condition classified elsewhere
  o 327.02 Insomnia due to mental disorder (e.g., depression, anxiety, PTSD)
• Utilization of CPT-95827 is appropriate for the diagnostic code (ICD-9/10)
  o Acquisition of overnight EEG to stage sleep has been used for over 20 years as an integral component of polysomnography because sleep staging is necessary to evaluate sleep disorders.
  o The Clinical Guidelines from the American Academy of Sleep Medicine recommend quantification of sleep and sleep stages when the initial diagnosis is uncertain, treatment fails, or when there is suspicion of comorbid disorders.

**Sleep Profiler is appropriately reimbursed between $450-$650:**

• Acquiring data in the home provides a more realistic representation of the patients true sleep patterns for patients with non-OSA sleep issues. Two nights of data were required to assess night-to-night fluctuations in sleep patterns.
• Staging sleep in 30-second epochs from an in-home overnight EEG recording requires similar time and technical expertise as staging sleep acquired in a laboratory setting.
• Staging sleep for a laboratory polysomnography study comprises 50% of the technical component involved in preparing the study for interpretation.
• Interpreting night-to-night fluctuations in sleep patterns requires five times the amount of work than analyzing signals acquired during a home sleep test (HST) to diagnose OSA.
REFERENCES (click on the name to access):