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Podcast of the Journal of Clinical Sleep Medicine

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Welcome to the regular podcast of the *Journal of Clinical Sleep Medicine*. I am Dr. Stuart Quan, Editor of the *Journal*. These podcasts are a regular feature of each issue of the *Journal* and can be downloaded at the *Journal*'s website. Each podcast features summaries of important articles published in the current issue of the *Journal*, as well as occasional interviews with authors of these papers.

The lead article in this issue is entitled, "High Prevalence of Restless Legs Syndrome Among Patients with Fibromyalgia: A Controlled Cross-Sectional Study." The authors are Drs. Viola-Saltzman, Watson, Bogart, Goldberg, and Buchwald from Loyola University Medical Center in Maywood, IL, the University of Washington in Seattle, and Group Health Center for Health Studies in Seattle, WA. Restless legs syndrome is a relatively common condition with prevalence estimates of approximately 10%-15% in the general population. Fibromyalgia is also a chronic condition, which is characterized by pain in multiple locations as well as fatigue and insomnia complaints. In this study, fibromyalgia patients were identified through an academic clinic devoted to chronic pain and fatigue or through local advertising. Control participants were recruited through advertising. Those individuals with restless legs syndrome were identified using a modified version of the John Hopkins telephone diagnostic interview. 172 participants with fibromyalgia were recruited, in whom the mean age was 50 years and 93% were women. The control group consisted of 63 individuals, with a mean age of 41 years, and 56% were women. The authors found that the age and gender adjusted prevalence of restless legs syndrome in the fibromyalgia group was 33%, in comparison to 3.1% in the control group. In a fully adjusted model, which controlled for age, gender, ethnicity, martial status, employment, education and income, the odds of having restless legs syndrome in the fibromyalgia group was 11.2 times that of control participants. In addition, those in the fibromyalgia group were more likely to have higher scores on the Pittsburgh Sleep Quality Index, Insomnia Severity Index and the Epworth Sleepiness Scale. Furthermore, those individuals with fibromyalgia and restless legs syndrome had higher scores on the Pittsburgh Sleep Quality Index than those individuals with fibromyalgia without restless legs syndrome. The authors concluded that there was a high prevalence of restless legs syndrome in fibromyalgia patients and that in those individuals with restless legs and fibromyalgia, their sleep was more impaired than those without restless legs.

The next paper to be highlighted in this podcast is entitled, "Impaired Quality of Sleep In Ménière's Disease Patients," by Drs. Nakayama, Suzuki, Inagaki, Takemura, Watanabe, Tanigawa, Okamoto, Hattori, Brodie, and Murakami from Nagoya City University, Nagoya, Japan, Aichi Medical University, Aichi, Japan, Aichi Prefectoral College of Nursing and Health, Aichi, Japan, Hatori Otolaryngology Clinic, Nagoya, Japan, and the University of California - Davis, Davis, CA. Ménière's disease is characterized by progressive hearing loss, tinnitus and attacks of vertigo. A number of studies have indicated that there is significant emotional distress associated with Ménière's disease. Because emotional distress is associated with sleep disturbances, the authors hypothesized that individuals with Ménière's disease would have problems with insomnia and poor quality sleep. The authors recruited 35 patients with active unilateral Ménière's disease. In addition, 35 normal, healthy subjects were recruited as controls. All participants underwent full-night, in-laboratory polysomnography. Interestingly, the authors found that total sleep time in those with Ménière's disease was significantly higher than controls, as was the amount of Stage II sleep. In contrast, Delta sleep was shorter but REM sleep was not different. Of note is that the arousal index was higher in individuals with Ménière's disease, in comparison to controls. However, there was no significant difference in the periodic limb movement index. The authors concluded that Ménière's disease patients may suffer from poor sleep quality, as manifested by a higher arousal index. The poor sleep quality may lead to additional emotional distress and further sleep disturbance, resulting in a positive feedback loop.

Finally, in this issue of the *Journal*, are two studies describing the tolerability, efficacy and side effects from the use of armodafinil in patients with excessive sleepiness associated with obstructive sleep apnea, shift-work disorder or narcolepsy. Both of these report results from a 12-month, open-label extension studies that occurred after patients had been enrolled in randomized, clinical trials that were assessing the usefulness of armodafinil in obstructive sleep apnea, shift-work sleep disorder or narcolepsy. The first study is entitled, "Tolerability and Efficacy of Armodafinil in Naïve Patients with Excessive Sleepiness Associated with Obstructive Sleep Apnea, Shift-Work Disorder or Narcolepsy: A 12-Month, Open-Label, Flexible-Dose Study with an Extension Period" by Drs. Schwartz, Khan, McCall, Weintraub, and Tiller from the University of Oklahoma in Oklahoma City, OK, Northwest Clinical Research Center, Bellevue, WA, Wake Forest University School of Medicine, Winston-Salem, NC, Michigan Head-Pain & Neurologic Institute, Ann Arbor, MI, and Cephalon, Inc., Frazer, PA. This study enrolled 328 subjects in the open-label ex-

tension period. The second study is entitled, "The Long-Term Tolerability and Efficacy of Armodafinil in Patients with Excessive Sleepiness Associated with Treated Obstructive Sleep Apnea, Shift-Work Disorder or Narcolepsy: An Open-Label Extension Study," by Drs. Black, Hall, Tiller, Yang, and Harsh from Actelion Pharmaceuticals, Allschwil Switzerland, Stanford University, Stanford, CA, Vince & Associates Clinical Research, Overland Park, KS, Cephalon, Inc., Frazer, PA, and the University of Southern Mississippi, Hattisburg, MS. This study enrolled 1,108 patients in a 12-month extension trial. For both of these studies, the 12-month extension demonstrated that armodafinil was effective in treating excessive daytime sleepiness and generally well tolerated. In the first study, major adverse events were headache in 17%, insomnia in 14% and upper-respiratory tract infection in 10%. In the second study, major adverse events were headache in 25%, nasal pharyngitis in 17%, insomnia in 14% and upper-respiratory tract infection in 10%. Of note in the second study was that modest increases were noted in blood pressure and pulse rate. The magnitude of these changes were 3.6mm of mercury systolic pressure, 2.3mm diastolic pressure and 6.7 beats/minute in pulse. In general, the results of these studies demonstrate that armodafinil may be used on a long-term basis to treat individuals with excessive daytime sleepiness related to obstructive sleep apnea, shift-work disorder or narcolepsy, but a number of patients will have some side effects and that blood pressure and pulse rate may increase. With respect to the latter, it remains to be seen whether these increases in blood pressure and pulse will impact cardiovascular morbidity and mortality.

In addition to the above-highlighted articles, I also wish to call your attention to a perspective written by Drs. Lorenzi-Fillho and Drager from the University of Sao Paulo Medical School in Sao Paulo, Brazil, entitled, "Sleep Apnea: Why Should We Look for Cardiac Biomarkers?" This perspective provides rationale for why identification of relevant cardiac biomarkers may be important in the management of individuals with obstructive sleep apnea. Such research to identify a cardiac biomarker is currently underway. The Heart Biomarker Evaluation in Apnea Treatment (HeartBEAT) trial, sponsored by the National Heart, Lung & Blood Institute, is one such clinical trial that is in progress.

This concludes the regular podcast of the *Journal of Clinical Sleep Medicine*. The listener is encouraged to read the contents of the *Journal* for additional information regarding each of the articles summarized in this podcast, as well as other papers published in this issue of the *Journal*.