



AMERICAN COLLEGE OF GASTROENTEROLOGY

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Acid Reflux, Functional Dyspepsia Have Significant Impact on Disordered Sleep

Esomeprazole Reverses Driving Impairment in GERD Induced Sleep Disorders; Baclofen Decreases Reflux, Improving Sleep Quality in Nighttime Heartburn Sufferers

San Antonio, Texas (October 18, 2010) – The impact of upper GI conditions, like gastroesophageal reflux disease (GERD) and functional dyspepsia, on sleep—and treatments aimed at providing relief to heartburn/acid reflux patients who suffer from disordered sleep—were explored in three new studies related to sleep dysfunction presented today at the American College of Gastroenterology’s (ACG) 75th Annual Scientific meeting in San Antonio, Texas.

Functional dyspepsia is a common, but poorly understood, upper GI condition affecting approximately 10 percent of U.S. adults. The condition is described as chronic abdominal pain and a sensation of fullness, pressure or discomfort in the upper abdomen. This sensation is associated with eating as symptoms usually worsen after meals.

While the prevalence of disordered sleep in patients with functional dyspepsia is unknown, a new study unveiled today found that disordered sleep is significantly more common in functional dyspepsia patients than in healthy controls.

Patients with functional dyspepsia were 3.25 times more likely to have disordered sleep compared to healthy controls, according to the study, **“Functional Dyspepsia: A Risk Factor for Disordered Sleep,”** which also found that women with functional dyspepsia were 2.3 times more likely to have disordered sleep than men with this same condition. While gender tended to be associated with disordered sleep, age, tobacco and alcohol use was not a factor. The study also found that mental and physical factors were related to disordered sleep in patients with functional dyspepsia.

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Routine exercise, for instance, appeared to decrease the likelihood of a patient suffering from sleep disorders. Functional dyspepsia patients also had higher scores for anxiety and

depression, according to the study, suggesting that depression may be a contributing factor to functional dyspepsia symptom generation.

“Fatigue changes the sensation for pain, said Brian Lacy, M.D., Ph.D., associate professor of medicine, Dartmouth Medical School who presented the results of the study. “The key finding here is that disordered sleep may affect nerve function in upper GI tract which could lead to worsening dyspepsia, creating a vicious cycle leading to more pain and more insomnia,” said Dr. Lacy. He added that, “future clinical trials for functional dyspepsia should include validated measures of sleep, as improvements in functional dyspepsia symptoms may be mirrored by improvements in sleep.”

Esomeprazole Reverses Driving Impairment in GERD Induced Sleep Disorders

GERD-induced sleep dysfunction has a previously unrecognized and significantly adverse affect on simulated driving performance, which improved with esomeprazole, according to the results of another study, ***“GERD-Induced Sleep Disorders and a Reversible Driving Impairment with Esomeprazole-A Prospective Pilot Study.”***

Dr. David A. Johnson, Chief of Gastroenterology and Professor of Medicine at Eastern Virginia Medical School in Norfolk, Va., presented the findings from this prospective-pilot study that evaluated 11 healthy patients with well-established GERD with nocturnal symptoms.

Testing was done in a validated commercial driving simulator that responds to driver inputs (steering, throttle, brake) and generates realistic roadway images. Driving performance (standard deviation of lane variation SDLP) was compared across six consecutive 10-minute driving periods while subjects were on and off the drug.

According to the study, SDLP increased over time ($p=0.0002$) and improved with esomeprazole. Patients on esomeprazole had an overall average 62.5 percent decrease in the number of sleep disordered nights vs. a 9.5 percent decrease without the drug. The Epworth Sleepiness Scale, used to determine the level of daytime sleepiness, decreased to 5.9 and 3.5 from 7.9 and 2.5 and GERD symptom score decreased from 2.10 to 0.33.

“The improved ESS score suggests that reduced sleepiness contributed to improved performance,” said Dr. Johnson. “We know that GERD impairs sleep quality and next day function as measured by quality of life and work productivity assessments. Furthermore, sleep dysfunction (such as sleep apnea) has been linked to impaired psychomotor function including worsening driving simulator performance.

Therefore, appropriate treatment for patients with GERD and nocturnal symptoms may have potentially new and life-saving implications.”

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Dr. Johnson also noted that further prospective blinded controlled trials are warranted to validate these findings.

Baclofen Decreases Reflux, Improving Sleep Quality for Nighttime Heartburn Sufferers

Nighttime heartburn sufferers also may get relief —and better sleep quality, from the muscle-relaxant and antispastic drug, baclofen, according to results of another new study unveiled today, ***“Baclofen Decreases Reflux and Improves Sleep Quality in Individuals with Nighttime Heartburn.”***

While baclofen has been shown to reduce episodes of GERD, this new study found that in addition to reducing the number of reflux events during sleep, baclofen significantly improved several measures of sleep in patients with documented GERD and sleep disturbances.

“About 70 percent of individuals who have GERD also suffer from nighttime heartburn, and 40 percent of those people say they experience disturbed sleep at night,” said study co-author Dr. William Orr, president and CEO of the Lynn Health Science Institute and a clinical professor of medicine at the University of Oklahoma Health Sciences Center. “They don’t feel good the next day and they don’t perform as well.”

Approved by the FDA in 1977, baclofen is typically used by neurologists to treat uncontrolled movements, such as shakes and tremors. The drug inhibits nerve activity within the part of the brain that controls the contraction and relaxation of skeletal muscles.

“In this study, we found that baclofen significantly reduces the amount of waking which occurs after the onset of sleep,” said Dr. Orr. “Baclofen addresses the physiological causes of reflux, by preventing the relaxation of the lower esophageal sphincter and preventing the stomach acid from entering the esophagus. Few drugs inhibit the occurrence of reflux and 40 to 50 percent of those taking PPIs don’t get satisfactory relief, especially at nighttime,”

Baclofen reduced the number of reflux events compared to a placebo (4 events vs. 1.3). Patients on baclofen also had more sleep time (434 minutes vs. 379 minutes) and greater sleep efficiency (91 percent vs. 79 percent), according to the study. “The results of this study suggest that baclofen could be a useful adjunct therapy to proton pump inhibitors in patients with nighttime heartburn and sleep disturbance,” said Dr. Orr.

About the American College of Gastroenterology

Founded in 1932, the American College of Gastroenterology (ACG) is an organization with an international membership of more than 11,000 individuals from 80 countries. The College is committed to serving the clinically oriented digestive disease specialist through its emphasis on scholarly practice, teaching and research. The mission of the College is to serve the evolving needs of physicians in the delivery of high quality, scientifically sound, humanistic, ethical, and cost-effective health care to gastroenterology patients. www.acg.gi.org View releases on other research breaking at the ACG meeting at www.acg.gi.org/media/press.asp

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