

Obesity raises death risk tied to sleeping pills

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Obesity appears to significantly increase the risk of death tied to sleeping pills, nearly doubling the rate of mortality even among those prescribed 18 or fewer pills in a year, researchers reported Friday.

"Obesity emerged as a marker of increased vulnerability," said Robert Langer, M.D., M.P.H., at the annual American Heart Association's Epidemiology and Prevention | Nutrition, Physical Activity and Metabolism 2012 Scientific Sessions in San Diego.

"The associations between <u>sleeping pills</u> and increased mortality were present, and relatively stronger, even in people aged 18 to 54," said Dr. Langer, a <u>family physician</u> and <u>epidemiologist</u> with the Jackson Hole Center for <u>Preventive Medicine</u> in Jackson, Wyo.

"Obese patients appear particularly vulnerable, perhaps through interaction with sleep apnea," said study co-author Daniel Kripke, M.D., a psychiatrist with Scripps Clinic's Viterbi Family Sleep Center in San Diego.

He noted that sleeping pills were previously associated with more and longer pauses in breathing in people with <u>sleep apnea</u>.

Among obese patients, use of sleeping pills was associated with about one extra death per year for every 100 people who were prescribed the medications, Dr. Langer said.

Additionally, men who took sleeping pills were about twice as likely to



die as women who received the medications, after accounting for other factors, he said.

Friday's findings were the latest to emerge from a Scripps Clinic-led study of almost 40,000 patients, which was initially published in late February in the open-access online journal *BMJ Open*.

The research was the first to show that eight of the most commonly used hypnotic drugs were associated with increased hazards of mortality and cancer, including the popularly prescribed medications <u>zolpidem</u> (known by the brand name Ambien) and temazepam (also known as Restoril), Dr. Kripke said.

Those drugs had been thought to be safer than older hypnotics because of their shorter duration of action but were found to have associations with excess deaths no different from the older drugs they have largely replaced.

In order to eliminate the possibility that other factors led to the results, study participants who were prescribed sleeping pills were matched with control patients of similar ages, gender and health who did not receive hypnotics.

The newest findings were delivered by Dr. Langer during an oral session at the <u>American Heart Association</u> conference that focused on drug safety.

For obese patients in the study who had an average body mass index of 38.8, the risk of death was 8.1 times higher on average among those who were prescribed the smallest number of pills (18 or fewer annually) when compared with similar study participants who did not take the medications. The mortality rate was 9.3 times higher on average among obese patients receiving the largest number of pills (132 or more



annually).

Death was 4.6 times more likely on average among all patients who received any amount of sleeping pills.

The study cast a shadow over a growing segment of the pharmaceutical industry that expanded by 23 percent in the United States from 2006 to 2010 and generated about \$2 billion in annual sales.

Using data stored in an electronic medical record that has been in place for more than a decade, the researchers obtained information on almost 40,000 patients cared for by a large integrated health system in the northeastern United States.

The research included 10,531 sleeping pill users who were prescribed the medications for an average of 2.5 years and 23,674 control participants who were not prescribed the drugs. Information came from outpatient clinic visits conducted between Jan. 1, 2002, and Sept. 30, 2006.

"It is important to note that our results are based on observational data, so even though we did everything we could to ensure their validity, it's still possible that other factors explain the associations," said co-author Lawrence E. Kline, D.O., who is medical director of the Viterbi Family Sleep Center. "We hope our work will spur additional research in this area using information from other populations."

Funding for the study came from the Scripps Health Foundation and other philanthropic sources.

The research should prompt physicians to consider alternatives to hypnotic medications, Dr. Kline said.



Clinicians at the Viterbi Family Sleep Center focus on cognitive therapy that teaches patients to better understand the nature of sleep. For example, some people suffering from insomnia might require less than the eight hours of sleep commonly recommended for each night.

Patients also can benefit from practicing good sleeping habits and relaxation, as well as taking advantage of the body's natural clock, which is driven by the rising and setting of the sun, Dr. Kline said. "Understanding how to use the circadian rhythm is a very powerful tool that doesn't require a prescription," he said.

When insomnia results from emotional problems such as depression, doctors should treat the psychological disorder rather than prescribe sleeping pills that could prove to be harmful, Dr. Kripke said.

More information: View the paper here: http://bmjopen.bmj.com/content/2/1/e000850.full

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