

Chantix study finds little evidence to support suicidal, criminal warnings

June 3 2015, by Steven Reinberg, Healthday Reporter



But quit-smoking drug may be linked to other adverse effects.

(HealthDay)—The quit-smoking drug Chantix (varenicline) doesn't increase the risk of suicidal behavior, mental illness, criminal acts or traffic accidents, European researchers say.

A study of more than 69,000 Swedes who used the smoking aid found no evidence for these worries, some of which led the U.S. Food and Drug Administration to place its strongest warning on the [drug](#)'s label in 2009.

"Some of the concerns about the safety of Chantix are not supported by evidence," said lead researcher Dr. Seena Fazel, a senior research fellow in the psychiatry department at the University of Oxford in England. And some concerns may have been overstated, he added.

However, among participants with a history of psychiatric problems, the study found a small increased risk of mood changes and anxiety.

And several U.S. health experts said they're reluctant to prescribe Chantix because of unwanted side effects, such as nightmares.

Chantix, approved by the FDA in 2006, is a twice-a-day pill intended to ease nicotine withdrawal. It works by blocking the effects of nicotine on the brain.

Fazel said the FDA and similar agencies issued warnings based on individual patient reports of suicidal feelings and depression, not on clinical trials that can spot these problems in wider populations.

For example, because of concerns about higher risk for [traffic accidents](#), use of Chantix is restricted or prohibited for pilots, [air traffic controllers](#), truck and bus drivers, and certain military personnel, Fazel said. "Our study questions that," he said.

For the study, published June 2 in *BMJ*, researchers collected data on 69,757 people in Sweden who were prescribed Chantix between 2006 and 2009. When the investigators looked for psychiatric or criminal behaviors linked to the drug, they found it was not associated with significant increases in [suicidal behavior](#), criminal acts, car accidents, traffic offenses or psychosis.

The study was observational in nature, however, not one that looks at cause and effect.

While patients and their doctors may be relieved by the study findings, the drug is still associated with unwanted side effects, two American experts said.

"In our program, patients who use Chantix do not report suicidal thoughts or attempts, criminal activity, or traffic accidents and offenses," said Patricia Folan, director of the Center for Tobacco Control at North Shore-LIJ Health System in Great Neck, N.Y.

"Some, however, were unable to tolerate the nausea or vivid dreams that accompanied the medication," Folan noted.

This study may encourage more doctors to prescribe Chantix, Folan said. But doctors should closely monitor patients and educate them about potential adverse reactions to the drug, she added.

Dr. Len Horovitz, a pulmonary specialist at Lenox Hill Hospital in New York City, doesn't prescribe Chantix. "In the handful of times I prescribed Chantix, patients reported bad dreams and nightmares, so I stopped using it," he said.

These dreams were so bad that patients could not tolerate them, he added.

Horovitz said he prefers [nicotine replacement therapy](#) to help people quit, not antidepressants or drugs such as Chantix that affect the brain.

The FDA has also warned that the Pfizer drug can increase the risk of heart problems and reduce tolerance to alcohol. In rare cases, the drug also has been linked to seizures.

More information: For more on quitting smoking, visit the [American Lung Association](#).

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Citation: Chantix study finds little evidence to support suicidal, criminal warnings (2015, June 3)
retrieved 26 April 2024 from

<https://medicalxpress.com/news/2015-06-chantix-evidence-suicidal-criminal.html>

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