

Smoking cessation medications do not appear to increase risk of neuropsychiatric side effects, study finds

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Credit: Vera Kratochvil/public domain

The smoking cessation medications varenicline and bupropion do not appear to increase the incidence of serious neuropsychiatric side effects compared to placebo, according to a study published in *The Lancet* today.

The study is the largest trial to date looking at the safety and efficacy of three first line [smoking cessation](#) treatments - [varenicline](#), [bupropion](#) and nicotine patches - compared to placebo in smokers with and without psychiatric disorders, and finds that smokers who took varenicline achieved higher abstinence rates than smokers on bupropion, nicotine patches, or placebo.

The study involved more than 8000 people and was requested by the US Food and Drug Administration (FDA) following concerns about the neuropsychiatric safety of varenicline and bupropion.

"Given that an estimated 6 million people

worldwide die as a result of [tobacco smoking](#) every year, we need to be able to provide maximum support for people to [stop smoking](#). Our study shows that all three first-line [smoking cessation medications](#) are effective in helping people stop smoking, with varenicline being the most effective," says lead author Professor Robert M. Anthenelli, University of California, San Diego, USA.

Professor Anthenelli adds, "Clinical guidelines recommend that the most effective way to give up smoking is smoking cessation medication and counselling. However, smokers do not use these services enough, in part due to concerns that the medications may not be safe. The findings from this study, together with data from previous trials and large observational studies, make it highly unlikely that varenicline and bupropion increase the risk of moderate-to-severe neuropsychiatric side effects in smokers without psychiatric disorders."

Participants were adults aged 18-75 who smoked on average more than 10 cigarettes a day and were motivated to stop smoking (82% had made at least one attempt to quit). Half (4116) had a history of a past or current stable psychiatric condition including a mood, anxiety, psychotic, or borderline personality disorder, and about half of this group were taking psychotropic medication. The other participants (4028) did not have a psychiatric condition.

The trial was a double blind randomised trial and was designed to measure both the safety and efficacy of the two non-nicotine smoking cessation medications, varenicline and bupropion, relative to nicotine patches and placebo.

All participants were assessed to see whether they suffered any moderate-to-severe adverse neuropsychiatric events during and after treatment,

including agitation, aggression, panic, anxiety, depression and suicide ideation among others. Smoking cessation was verified by measuring levels of exhaled carbon monoxide (CO) at the end of treatment (9-12 weeks), and at follow up (9-24 weeks).

For smokers without a psychiatric disorder, there was no significant increase in the incidence of adverse neuropsychiatric events across the four treatment groups (1.3% varenicline; 2.2% bupropion; 2.5% nicotine patch; 2.4% placebo).

Overall, there were more adverse neuropsychiatric events reported in the group with psychiatric disorders, than in the group without. However, the researchers found there were similar rates across all treatment arms (6.5% varenicline; 6.7% bupropion; 5.2% nicotine patch; 4.9% placebo).

Varenicline was more effective in helping people stop smoking than bupropion, nicotine patches, or placebo. Bupropion was about as effective as nicotine patches, and both were more effective than placebo. Overall, at 9-24 weeks, 21.8% of people on varenicline were continuously abstinent (16.2% for bupropion; 15.7% [nicotine patches](#); 9.4% placebo). Smokers with a psychiatric disorder achieved slightly lower abstinence rates than smokers without a psychiatric disorder.

"Our study provides further evidence of the safety of these drugs in smokers with psychiatric disorders, who have some of the highest rates of smoking. We also show, for the first time, that the effectiveness of the medications is similar for smokers with or without psychiatric disorders. The small increased incidence of adverse neuropsychiatric effects in people with stable [psychiatric disorders](#) regardless of treatment needs to be balanced against the known significant health risks of smoking," explains Professor Anthenelli.

The authors warn that since the participants had a stable psychiatric disorder and were being treated, the findings might not apply to those with untreated or unstable psychiatric illness. The researchers also excluded people with current alcohol or substance abuse disorders and people who were at imminent risk of suicide. The study also did not look

at whether the strength of nicotine dependence, or the severity of psychiatric symptoms affected the findings. Finally, just over 20% of people dropped out of the study but this was seen across the board, whether or not participants had a psychiatric disorder and irrespective of whether they received one of the three treatments or placebo.

Writing in a linked Comment, Dr Laurie Zawertailo, University of Toronto, Toronto, Canada, discusses the impact on clinical practice. She says: "The findings from this study show that neuropsychiatric adverse events occurring during smoking cessation are independent of the medication used. This finding combined with previous findings showing no greater incidence of this type of adverse event associated with bupropion or varenicline, suggests that clinicians should be comfortable prescribing the smoking cessation medication they feel would be most effective for their patient and should not worry about a specific medication increasing the risk of neuropsychiatric side-effects. The findings also suggest that patients trying to quit smoking, irrespective of method, should be made aware of the small chance that severe changes in their mood and psychiatric well-being might occur. Furthermore, clinicians should monitor all of their patients, especially those with a current or past psychiatric illness, for these changes. This monitoring could be added to the behavioural counselling that clinicians should be providing to patients who are trying to quit smoking."

More information: *The Lancet*, [www.thelancet.com/journals/lan ...](http://www.thelancet.com/journals/lan...) (16)30272-0/abstract

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