

Smoking cessation drug not linked to an increased risk of self harm or depression

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There is no strong evidence that the popular smoking cessation drug varenicline increases the risk of self harm or depression compared to other cessation products, according to new research published on BMJ.com today.

Varenicline is a recently introduced smoking cessation product of proven effectiveness, but there have been concerns that it may increase the risk of [suicidal behaviour](#) and suicide. Despite warnings about the possible increased risks issued by regulatory authorities worldwide, varenicline continues to be used widely.

To provide more evidence, a team of researchers from the University of Bristol and the UK's Medicines and Healthcare products Regulatory Agency (MHRA) compared the risk of self harm among people taking varenicline with the risk of self harm associated with other smoking cessation products bupropion and nicotine replacement therapy (patch, inhaler, gum, tablet or lozenge).

Using data from the General Practice Research Database, 80,660 men and women aged between 18 and 95 years were identified who were prescribed a new course of smoking cessation product between September 2006 and May 2008.

Participants were prescribed either nicotine replacement products for (n=63, 265), varenicline (n=10,973), or bupropion (n=6,422).

All electronic patient records over the period of the prescription and for three months after the date of the last prescription were examined for incidences of fatal and non-fatal self-harm, suicidal thoughts and depression.

After controlling for confounding factors, there was no clear evidence of an increased risk of self harm, [suicidal thoughts](#) or depression associated with either varenicline or bupropion.

The authors caution that although they found no strong evidence of an increased risk of self harm linked to varenicline, "the limited power of the study means we cannot rule out either a halving or a twofold increased risk."

They go on to call for more investigation of varenicline's effect on [suicide risk](#) in other databases and secondary analysis of all adverse event reporting in clinical trials.

They conclude by cautioning that any risks must be balanced against the long term health benefits of stopping smoking and the effectiveness of varenicline as a [smoking cessation](#) product.

Source: British Medical Journal ([news](#) : [web](#))

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