

No evidence that smoking drug linked to increased risk of suicide or traffic accidents

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There is no strong evidence that the popular smoking cessation drug varenicline is associated with increased risks of suicidal behaviours, criminal offending, transport accidents, traffic-related offences, and psychoses, finds a study in *The BMJ* this week.

The findings are based on over 69,000 individuals in Sweden who were prescribed varenicline between 2006 and 2009. Previous reports suggesting a link may not have taken full account of underlying risk factors, say the authors.

Varenicline is widely prescribed for the treatment of nicotine dependence, but reports that it may be linked with increased risks of <u>suicidal behaviour</u>, depression, psychoses and violence have led regulatory agencies in Europe and the US to issue warnings.

Varenicline use has also been restricted or prohibited for several transportation industry professions, including pilots, <u>air traffic</u> <u>controllers</u>, truck and bus drivers, and certain military personnel, due to reports of increased traffic accidents.

However, these increased risks are based on post-marketing surveillance and individual case reports, and are not consistent with observational studies and trials that have found no association between varenicline and depression, suicidality, or violence.

To address these inconsistencies, researchers at the Karolinska Institutet



in Sweden and the University of Oxford in the UK examined associations between varenicline and a range of adverse outcomes in 69,757 individuals aged 15 and over who were prescribed varenicline between 2006 and 2009.

They performed several analyses, adjusting for known <u>risk factors</u> such as age, sex and pre-existing psychiatric disorders, and also studied rates of adverse events in the same individual during periods of medication and non-medication, a novel approach in this area.

National registers were used to collate information on criminal convictions, psychiatric conditions, suicidal behaviour, <u>transport accidents</u> and traffic offences, and substance abuse.

The results show that varenicline was not associated with significant increases in suicidal behaviour, criminal offending, transport accidents, traffic offences, or psychoses.

However, a small increased risk of mood and anxiety conditions during periods of medication was found in individuals with pre-existing psychiatric disorders, which the authors say "requires confirmation using other study designs."

The authors suggest that their findings may be generalizable to other high income countries like the UK and USA due to similar prescribing patterns and rates of these outcomes.

Although this is an observational study so no definitive conclusions can be drawn, the authors state that their results "provide no evidence for a causal association between <u>varenicline</u> and criminal offending, transport accidents, traffic offences, or psychoses."

More information: Varenicline and the risk of psychiatric conditions,



suicidal behaviour, criminal offending, and transport accidents and offences: population based cohort study, *The BMJ*, www.bmj.com/cgi/doi/10.1136/bmj.h2388

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