



TITLE: Varenicline Versus Other Therapy for Patients with Psychiatric Disorders: Comparative Safety and Guidelines

DATE: 24 February 2011

RESEARCH QUESTIONS

1. What is the clinical evidence regarding the comparative safety and risks associated with the use of varenicline versus other therapy options for smoking cessation in patients with psychiatric illnesses?
2. What are the evidence-based guidelines regarding the use of varenicline for smoking cessation in patients with psychiatric illnesses?

KEY MESSAGE

From the limited literature search, we identified three non-randomized studies¹⁻³ that addressed the research question, and whose findings were mixed. Four guidelines were identified.⁴⁻⁷ No relevant health technology assessments, systematic reviews, randomized controlled trials or controlled clinical trials were identified that presented relevant evidence regarding the safety of varenicline in patients with mental illness.

METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2011, Issue 1), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Research question #1 is an update of "[Varenicline for smoking cessation in patients with psychiatric illness: a review of the risks](#)"; results were retrieved from April 23, 2010 to February 8, 2011 and no filters were applied to limit the retrieval by study type. For research question #2, methodological filters were applied to limit retrieval to guidelines from January 1, 2006 to February 8, 2011. The search was also limited to English language documents. Internet links were provided where available.

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The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.

RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, and evidence-based guidelines.

Three non-randomized studies were identified that provided information on safety and risks associated with the use of varenicline versus other therapy options for smoking cessation in patients with psychiatric illnesses. Four guidelines were identified that provide information regarding the use of varenicline for smoking cessation in patients with psychiatric illnesses. Other articles of potential interest are included in the appendix.

OVERALL SUMMARY OF FINDINGS

Findings from the studies included to address the first research question were mixed. In a retrospective chart review, the use of varenicline resulted in a 29% increase in mental health encounters for veterans with posttraumatic stress disorder.¹ A retrospective cohort study indicated that varenicline was effective as an antismoking agent and did not significantly increase serious psychological distress.² However, the abstract indicates only 23% of the sample was treated with varenicline, and findings for varenicline are grouped with combination therapy results; therefore, conclusions from this study should be interpreted carefully.² Finally, a comparative study found that smokers with a previous psychiatric diagnosis were more likely to report anxiety and depression than smokers with no such history, but intensity ratings did not differ after adjusting for multiple comparisons.³ This study warrants further examination due to limited information in the abstract. No relevant health technology assessments, systematic reviews, randomized controlled trials or controlled clinical trials were identified that presented relevant evidence regarding the safety of varenicline in patients with mental illness.

For patients who are prescribed varenicline and who have a history of psychiatric illness, the identified guidelines⁴⁻⁷ recommend the following:

- Clinicians should inquire as to their patients psychiatric history⁴
- Clinicians should closely monitor their patients for changes in mood and behavior⁴⁻⁷
- Patients with a history of depression should be monitored more closely for symptoms of depression following smoking cessation⁵

REFERENCES SUMMARIZED

Health technology assessments

No literature identified.

Systematic reviews and meta-analyses

No literature identified.

Randomized controlled trials

No literature identified.

Non-randomized studies

1. Steinberg MB, Bover MT, Richardson DL, Schmelzer AC, Williams JM, Foulds J. Abstinence and psychological distress in co-morbid smokers using various pharmacotherapies. *Drug Alcohol Depend.* 2011 Mar 1;114(1):77-81.
[PubMed: PM20951511](#)
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3. McClure JB, Swan GE, Catz SL, Jack L, Javitz H, McAfee T, et al. Smoking outcome by psychiatric history after behavioral and varenicline treatment. *J Subst Abuse Treat.* 2010 Jun;38(4):394-402.
[PubMed: PM20363092](#)

Guidelines and recommendations

4. Fiore MC, Jaén CR, Baker TB, Bailey WC, Benowitz NL, Curry SJ, et al. Treating tobacco use and dependence: 2008 update [Internet]. Rockville (MD): U.S. Department of Health and Human Services; 2008 May. Available from: http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf See pages 54, 113–116.
5. Bjornson W, White E. Bringing everyone along: resource guide for health professionals providing tobacco cessation services for people with mental illness and substance use disorders [Internet]. Portland (OR): Tobacco Cessation Leadership Network; 2008 Jan. Available from: http://www.tcln.org/pdfs/BEA_Resource_Guide-web.pdf See page 40.
6. Action on Smoking and Health. Varenicline - Guidance for health professionals on a new prescription-only stop smoking medication [Internet]. London: ASH; 2007 Jul. Available from: http://www.ash.org.uk/files/documents/ASH_447.pdf See pages 2, 7, 8.
7. Ministry of Health. New Zealand smoking cessation guidelines [Internet]. Wellington: Ministry of Health; 2007. Available from: [http://www.moh.govt.nz/moh.nsf/pagesmh/6663/\\$File/nz-smoking-cessation-guidelines-v2-aug07.pdf](http://www.moh.govt.nz/moh.nsf/pagesmh/6663/$File/nz-smoking-cessation-guidelines-v2-aug07.pdf) See pages 16, 26, 48.

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APPENDIX – FURTHER INFORMATION:

Review articles

8. Lorenz RA, Whitley HP, McCoy EK. Safety of varenicline in patients with mental illness. *Prim Psychiatry* [Internet]. 2010 Sep;17(9):60-6. Available from: http://mbldownloads.com/0910PP_Lorenz.pdf
9. Purvis TL, Nelson LA, Mambourg SE. Varenicline use in patients with mental illness: an update of the evidence. *Expert Opin Drug Saf.* 2010 May;9(3):471-82. [PubMed: PM20166836](#)
10. Tonstad S, Els C. Varenicline: smoking cessation in patients with medical and psychiatric comorbidity. *Clinical Medicine Insights: Therapeutics* [Internet]. 2010;2:681-95. Available from: <http://www.la-press.com/varenicline-smoking-cessation-in-patients-with-medical-and-psychiatric-article-a2191>

Additional references

11. Action on Smoking and Health (ASH) Scotland. Tobacco use and people with mental health problems [Internet]. Edinburgh: Action on Smoking and Health (ASH) Scotland; 2010 Nov. Available from: <http://www.ashscotland.org.uk/media/3787/Tobaccouseandpeoplewithmhproblems.pdf>
12. University of Colorado Denver, Department of Psychiatry, Behavioral Health and Wellness Program. Smoking cessation for persons with mental illnesses: a toolkit for mental health providers [Internet]. Aurora (CO): University of Colorado Denver; 2009 Jan. Available from: http://smokingcessationleadership.ucsf.edu/Downloads/catalogue/MHtoolkitJan_2009.pdf
13. Els C, Kunyk D. Management of tobacco addiction in patients with mental illness. *Smoking cessation rounds* [Internet]. 2008;2(2):1-6. Available from: <http://www.smokingcessationrounds.ca/crus/140-013%20English.pdf>