

Varenicline – a New Treatment for Smoking Cessation

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Most people trying to quit smoking fail without any medical help. The rate of success is only 3-5% per year. Nowadays, pharmacological treatments are available in the USA and in the European Union: nicotine replacement therapy (NRT), sustained-release (SR) bupropion and, most recently, varenicline.

The last product showed greater efficacy in several studies, but the present one was the first randomized clinical trial comparing varenicline with transdermal nicotine. It was an open-label trial, conducted in 24 centres in Belgium, France, The Netherlands, UK and USA. The participants smoked at least 15 cigarettes per day, without any skin or psychological disorder or drug or alcohol dependence within the previous 12 months, were not pregnant or breastfeeding, had no clinically significant renal or hepatic impairment and no use of any form of NRT in the previous 6 months.

376 subjects were randomized to 1 mg varenicline twice daily for 12 weeks and 370 subjects to 21 mg/day reducing to 7 mg/day transdermal NRT for 10 weeks. There was a

follow-up period until week 52, without treatment. The primary outcome was the self reported continuous abstinence rate (CAR) for the last 4 weeks of treatment, which was biochemically confirmed (exhaled carbon monoxide = 10ppm). Secondary efficacy end points included CAR for the last 4 weeks of treatment and also at week 24 and 52. In addition, there were scales and questionnaires used in order to assess the urge to smoke, depression, anxiety, poor concentration, increased appetite and insomnia (The Minnesota Nicotine Withdrawal Scale- MNWS), respectively the smoking satisfaction, psychological reward, enjoyment of respiratory tract sensations and craving reduction (the modified Cigarette Evaluation Questionnaire- mCEQ).

The results were in favor of varenicline treatment: the CAR for the last 4 weeks of treatment was significantly greater for varenicline (55.9%) than NRT (43.2%; OR 1.70, 95% CI 1.26 to 2.28, $p < 0.001$). The week 52 CAR (NRT, weeks 8–52; varenicline, weeks 9–52) was 26.1% for varenicline and 20.3% for NRT (OR 1.40, 95% CI 0.99 to 1.99, $p = 0.056$). Varenicline significantly reduced craving

($p < 0.001$), withdrawal symptoms ($p < 0.001$) and smoking satisfaction ($p < 0.001$) compared with NRT. The most frequent adverse event was nausea (varenicline, 37.2%; NRT, 9.7%).

In conclusion, this trial showed varenicline had significantly greater abstinence rate than transdermal NRT, with a higher reduction of craving and withdrawal rate and a safe profile.



Comment on the paper:

Aubin HJ, Bobak A, Britton et al – Varenicline versus transdermal nicotine patch for smoking cessation: results from a randomized open-label trial. *Thorax* 2008; 63:717-724