



ORIGINAL ARTICLE

Effectiveness and safety of varenicline and nicotine replacement therapy among mental health patients: A retrospective cohort study

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KEYWORDS

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Abstract

Objective: To analyse the effectiveness and safety of two smoking cessation medications (varenicline and nicotine patches) in patients with controlled psychiatric disorders in daily practice in a Smoking Cessation Service.

Methods: This is a retrospective cohort study. It was carried on at a smoking cessation clinic in Madrid and used a convenience sampling strategy. We reviewed medical records of patients diagnosed with psychiatric disorders who attended a Smoking Cessation Service. All patients received similar treatment programme: a combination of pharmacological treatment (varenicline or nicotine replacement therapy) and intensive cognitive-behavioural therapy.

Results: The group included 349 patients (38.4% men). Mean age (SD) 49.6 (10.5) years. 28.3 (12.8) cigarettes per day. 156 subjects achieved 9–24 weeks continuous abstinence (44.7%), in 39% of those who used nicotine patches and in 53.7% of those who used varenicline. OR: 1.64 (95% CI: 1.03–2.61; $p=0.036$). Success rates were higher in men; OR 1.85 (95% CI: 1.12–3.04; $p=0.016$). High levels of CO and high daily cigarette use were associated with poorer success rates (OR: 0.98, 95% CI: 0.96–0.99, $p=0.007$; and OR: 0.98, 95% CI: 0.96–1.00, $p=0.045$), respectively. Nausea and pruritus were the most common adverse events. No cases of suicidal ideation or behaviour were found.

Conclusions: Varenicline and nicotine patches could be safe and effective smoking cessation treatments for patients with psychiatric disorders in daily clinical practice.

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Introduction

Tobacco use is very common among patients with psychiatric disorders. One study found that tobacco use was two to four times higher in a group of patients with psychiatric disorders than in the general population.¹ More than 40% of patients with schizophrenia, depression, bipolar disorder, panic disorder or post-traumatic stress are smokers, with tobacco use by schizophrenic and depressed patients in particular peaking at almost 80%.¹⁻³ Furthermore, morbidity and mortality rates caused by smoking-related diseases are particularly high among individuals with psychiatric disorders.⁴

Several studies have concluded that smoking cessation treatments are less effective in patients with psychiatric disorders than in smokers from the general population. Abstinence rates for smokers with schizophrenia range from 13% to 26% when using nicotine patches^{5,6} and increase to 28% when treated with a combination of patches plus bupropion.⁷ Eagles' study analysed the safety and efficacy of different smoking cessation treatments in two patient cohorts⁸; psychiatric-cohort and non-psychiatric cohort. The results revealed that the various treatments were more effective, although not significantly, in the non-psychiatric cohort than in the psychiatric cohort.⁸ 18.5% of healthy subjects treated with nicotine patches achieved sustained abstinence at six-months follow-up, compared to just 13% of patients in psychiatric cohort. Similarly, 18.8% and 22.5% of healthy subjects treated with bupropion and varenicline, respectively, achieved sustained abstinence at six month follow-up, vs just 13.7% and 18.3% of patients in the psychiatric cohort.⁸ It is worth mentioning that this study found varenicline to be the most effective of all active treatments, and more effective than placebo, at both three and six months follow-up.⁸

Another important aspect to consider when treating tobacco use in patients with psychiatric disorders is the safety of the various smoking cessation drugs. The results of Eagles' study in this regard are conclusive.⁸ Patients with controlled psychiatric disorders treated with either varenicline, nicotine patches or bupropion did not experience a greater number or more intense neuropsychiatric adverse effects than subjects treated with placebo.⁸

Eagles' findings in terms of the safety and efficacy of smoking cessation treatments in smokers with psychiatric disorders had been suggested in previous meta-analyses and reviews^{10,11} and were confirmed by a recent meta-analysis.⁹

However, relatively few studies have analysed the effectiveness and safety of the various smoking cessation drugs in daily clinical practice in patients with controlled psychiatric disorders. Furthermore, very little is known about the effectiveness of the different drugs in patients with different psychiatric disorders.

On the other hand, psychiatric patients are a group of smokers who attend frequently Smoking Cessation Services. The majority of Smoking Cessation Services are run by lung physicians, so lung physicians should know how to develop effective Smoking Cessation Strategies in this specific group of patients. In this paper, we present the experience of a Smoking Cessation Service run by lung physicians.

The aim of this study was to analyse the effectiveness and safety of two smoking cessation medications (varenicline

and nicotine patches) in patients with controlled psychiatric disorders in daily practice in a Smoking Cessation Service.

Methodology

This is a retrospective cohort study. The medical records of all patients diagnosed with psychiatric disorders who attended our Smoking Cessation Service (Community based clinic that receives patients refer by primary care health-care professionals) with the intention of quitting smoking between January 2009 and January 2016 were reviewed. The subjects suffered from a range of psychiatric disorders: bipolar disorder, schizophrenia, depression, obsessive-compulsive disorder, borderline personality disorder and generalised anxiety disorder. They were admitted to receive treatment as long as they had not experienced psychiatric symptom exacerbation in the previous six months, were receiving stable treatment and had been recommended for smoking cessation treatment by a psychiatric specialist.

All patients received a very similar treatment programme, comprising a combination of pharmacological treatment and cognitive-behavioural therapy. Cognitive-behavioural therapy was administered over 10 individual sessions: one baseline visit and nine follow-up visits. The cognitive-behavioural therapy consists of the following activities: self-monitoring, identifying high-risk situations, coping strategies, and intra-treatment support. All the subjects received the same therapy.

The patients' medical records and smoking history were taken at the baseline visit. Patients received behavioural therapy and non-tailored self-help materials, and selected a day to quit. Pharmacological treatment was prescribed and patients were instructed on its correct use. The baseline visit lasted approximately 40-45 min.

During the follow-up visits, patients received additional cognitive-behavioural therapy to prevent relapses and to manage high-risk situations. The onset of adverse effects was monitored, regardless of the treatment administered, and patients were asked about any neuropsychiatric adverse effects. Sustained abstinence was measured between weeks 9 and 24 and was defined as no tobacco consumption of any kind between weeks 9 and 24. Patients' verbal declaration of abstinence was verified by measuring CO levels <4 ppm in exhaled air (we chose this cut off point in order to increase accuracy). Follow-up visits were conducted during weeks 1, 2, 4, 6, 8, 10, 12, 18 and 24 after the day of quitting. Each follow-up visit lasted between 20 and 25 min.

Pharmacological treatment consisted of nicotine patches or varenicline. 24-h nicotine patches at a dose of 21 mg/day were administered for 6 weeks, followed by 14 mg/day for 4 weeks and then 7 mg/day for 2 weeks. Patients were advised to use 4-mg nicotine gum sporadically to curb cravings. Subjects were instructed how to use the gum correctly. Varenicline was administered at 0.5 mg/day for the first three days, 0.5 mg/12 h for the next four days and 1 mg/12 h from day 8 onwards until treatment completion at 12 weeks. We did not use bupropion because bupropion can have several interactions with psychiatric medications.

The study was conducted according to the principles of the Declaration of Helsinki (last revision Washington 2002).

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