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Evolution of nicotine dependent smokers in a pharmacy with varenicline and active intervention of the pharmacist

Abstract

Background and objective: The objective of this study is the presentation of results obtained in the abstinence rate and relapse of the smoking practice after a 12-month pharmacotherapeutic follow-up in a pharmacy office.

Subjects and methods: Smokers assigned referred to the pharmacy for a pharmacotherapeutic follow-up with varenicline treatment. Abstinence and relapses were evaluated at 5, 12 and 52 weeks. The abstinence obtained was by self-declaration verifying it with coxymetry of 6 ppm or less.

Results: 78 patients (53.8% males), 43.92 (± 9.41) years and 27.36 (± 10.54) years of mean duration. 71.8% patients treated varenicline therapy and 28.2% were not treated with a drug. Of the 56 patients treated, completed 12 weeks of treatment 21.4%. 50% of subjects remained non-smoking at 12-week treatment and at the end of follow-up at 52 weeks only 33.9% remained abstinent.

Conclusion: There were high rates of relapse per year, which depended on adherence. Patients who had more adherence to treatment had better annual abstinence rates.

Keywords: varenicline, nicotine, pharmacotherapeutic follow-up, adherence to treatment, tobacco abstinence, deshabituation programme

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FJ Camacho,[1] FJ López,[2] A Cañizares,[3] P Zafrilla[4]

[1]Doctor of Pharmacy, Universidad San Antonio Murcia, Spain
[2]Department of Health Sciences. Universidad Católica de Murcia, Spain
[3]Community Pharmacy in Pharmacy office
[4]Vicedean of the Degree in Pharmacy, Universidad Católica San Antonio de Murcia, Spain

Correspondence: Francisco Javier Camacho Poyato, Doctor of Pharmacy, UCAM Cartagena, Calle Porto Alegre, 30310 Cartagena, Murcia, Spain, Email fjcamacho@ucam.edu

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Introduction

Smoking is the leading cause of avoidable death in developed countries. It is the most prevalent disease that affects humanity and is the first isolated cause of premature morbidity and mortality.[1] It is a chronic systemic disease, belonging to the group of addictions and cataloged by the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-DR) of the American Psychiatric Association. This category includes nicotine dependence and withdrawal syndrome caused by the absence of nicotine in the body.[2] Every smoker should have a therapeutic intervention to help him or her stop smoking.. The form and intensity of the treatment of each patient depends on several factors. The motivation as well as the degree of physical and psychological dependence, should be valued for the choice of the best treatment. The pharmacist is a figure easily accessible by the general population. Pharmacy offices have an advantage, they are easily accessible to all patients and specifically to smokers. The intervention of the pharmacist to help stop smoking is essential because of the advantages mentioned above.

The intervention of the smoking patient in the community pharmacy office requires commitment on the part of the pharmacists and adequate training to be able to individualize the intervention. Each smoker is a different case, due to the characteristics of their smoking habits, their social and family environment and their degree of motivation when faced with the possibility of quitting tobacco. And for that reason, we must act in a flexible way before each patient, in order to offer the best response and the best help at any time for him. It has been observed that the drug Varenicline (Champix®) is effective to give up smoking. Tobacco consumption is reduced due to the action on α4β2 receptors, decreasing the symptoms of the withdrawal syndrome and reducing the euphoric effects of nicotine. There are numerous studies comparing different first line treatments (bupropion, varenicline and TSN in different pharmaceutical forms).[3–8] Different authors have observed that they increase the rates of abstinence with longer varenicline treatments.[9] The aim of this article is to analyse adherence to a standard varenicline treatment for 12 weeks. Patient abstinence was tested at 3 months and 12 months.

Material and methods

This study has been designed and conducted in accordance with the standards of good clinical practice of the harmonized tripartite guide of the International Conference on Harmonization (ICH), and in accordance with art.38 of Royal Decree 1090/2015, and the Medicine Law 29/2006.

Type of study and design

This study is considered quasi-experimental and a pharmacotherapeutic follow-up is carried out in a pharmacy in Murcia (Spain), during 3 months, of patients who began treatment with varenicline and annual control. The study and intervention is carried out by a pharmacist who analyses, evaluates and intervenes, on a weekly basis, in the process of smoking cessation. Pharmacotherapy follow-up is performed weekly for the first three months and an annual review. The data will be collected in 3 times, when the patients are in pharmacological treatment with varenicline as in the annual control (Figure 1).

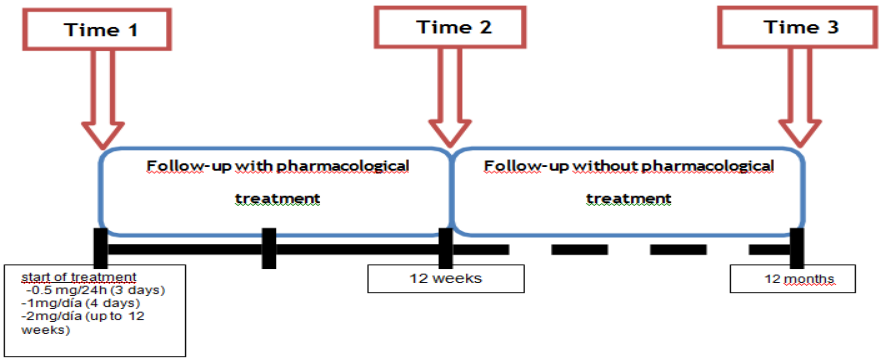

Figure 1 General outline of the study.

Population studied in clinical research

The sample was selected from patients who came to the pharmacy with a prescription for varenicline treatment. The first subjects were admitted in February 2013 and the last one was registered in December 2015. The end of the pharmacotherapy follow-up was in December 2016.

Study variables: adherence to treatment

Attendance at the pharmacy for weekly pharmacotherapeutic follow-up is useful for the researcher to check that the patient correctly complies with the prescribed treatment. Any dispensation of the current drug (Champix®), interruption, new treatment for smoking cessation, or abandonment of research is recorded by the investigator in the database. The study evaluates attendance at pharmacotherapeutic follow-up (yes/no) at the times previously established.

Tobacco abstinence

To control abstinence from tobacco in the study, the pharmacist records in the database the weekly abstinence of each patient. If the patient does not smoke, the number of days from the start of treatment to abstinence is recorded. For the study, abstinence to tobacco (yes/no) was evaluated in the times established previously.

Intervention plan

In accordance with the standards of good clinical practice and the ethical principles that have their origin in the Declaration of Helsinki, patients who are going to participate in the study were given verbal explanation of the study in which they were proposed to participate. When they understood the information, the patient signs the informed consent to be included in the study. The treatment involved in the study will be based on the patient's purchase of the drug Champix ® with a medical prescription, whose active ingredient is varenicline, dosage of 1mg/12h (the start of treatment according to the technical sheet of the drug). The patient himself bears the total cost of treatment.

Statistical analysis

Quantitative variables shall be described by statistical mean and standard deviation. Qualitative variables shall be analysed by the homogeneity test based on Chi-square distribution where the expected results make this possible and by Fisher's exact test if this is not possible. In the case of qualitative variables, we will make a study of relative risks. The evolution of these variables will be analyzed by parametric tests (T-Student or ANOVA), nonparametric tests (Wilcoxon or Friedman) or with the McNemmar test according to the characteristics of the variables under study. In the set of statistical tests the level of significance used will be alpha=0.05. The statistical analysis will be carried out with the computer software SPSS 21.0.

Results

General patient characteristics

The following table (Table 1) describes the general characteristics of the patient sample.

Table 1 General characteristics of the patients

sex	36 women (46,2 %) 42 men (53.8%)
age	43.92 (9.41) years

Evolution of the population sample during the investigation: Abandonment of the deshabituation programme

Of the total of 78 patients included in the program (n=78), 22 patients (28.2%) did not start varenicline treatment, so 56 patients smokers (72.8%) started treatment. Of the patients who start treatment, 12 patients (21.4%) complete a 12-week treatment. The following figure (Figure 2) shows the evolution of the patients throughout the smoking cessation programme.

Relationship between clinical parameters and adherence: Tobacco abstinence

To assess tobacco abstinence, 3 time values were determined: start of treatment; 12 weeks after completion of treatment and control time 12 months after completion of treatment. When comparing abstinence to tobacco of the 56 patients who were treated with varenicline, it is observed that when completing the treatment increases the success of abstinence at 12 weeks. Of the all patients treated, 28 patients (50%) were abstinent at 3 months and 19 patients (33.9%) were abstinent at one year, as shown in Table 2.

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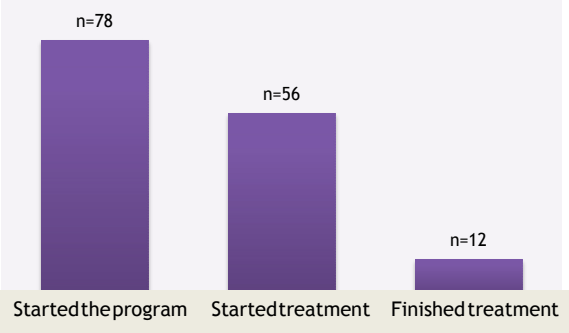

Figure 2 Evolution of the population in the tobacco cessation programme.

Table 2 Tobacco abstinence at 12 and 52 weeks

N (%)	N patients	% absolute
Abstinence at 12 weeks	28	50%
Abstinence at 52 weeks	19	33,9%
Total	n=56	100%

Discussion

In the population sample, not all smokers accepted into the smoking cessation service were given varenicline treatment. Of the patients who started varenicline, only a few were able to complete it. Although the total population may be low, the ratio between the city's total population and smokers going to the pharmacy is high. Godoy Mayoral et al.,[10] conducted a study similar to this one, in the specialized unit of tobacco cessation of the University Hospital Complex of Albacete, observed that of the 158 patients who started treatment (TSN, varenicline and bupropion), 67 (42.4%) completed it, following varenicline treatment 27.4%. Although, smoking abstinence rates in our study are promising, adherence data are much lower than in other studies.[10,11] In addition, there is the problem that patients have to pay the full cost of treatment. In spite of this problem, the pharmacist's job is to support the patients and follow their unhabituation closely in order to resolve the problems and achieve the objective. Frequently, in this type of studies the doses are modified, decreasing it even suppressing it, not following correctly the dosage nor the established dose.[12]

In a Cochrane review of therapeutic intervention to increase adherence to smoking cessation treatments, Hollands et al.,[13] observed that therapist intervention can improve adherence to smoking cessation treatment, and this objective can be complemented with correct information and by removing problems that may arise during follow-up. In this study, the meetings with the pharmacist were weekly, although sometimes the smoker was absent punctually. The first meetings with initial follow-up lasted approximately 45 minutes, and the subsequent interviews lasted approximately 15 minutes. This approach to patients makes them feel safe because they have a health professional to solve the problems that may arise. It is necessary to clarify that pharmacists are health professionals capable of solving problems related to varenicline and in this study there are many problems that appear of this type. To improve results, correct adherence to treatment is necessary. This correct adherence to treatment is important to obtain better abstinence data.[12,14,15]

Conclusion

The abstinence rate achieved at 12 months in smokers with varenicline treatment, financed by the patient himself, and with a weekly pharmacotherapeutic follow-up in the pharmacy office, carried out by the pharmacist is 33.9%. Self-financing is a factor to consider although weekly contact with the pharmacist achieves acceptable abstinence rates. Pharmacotherapy follow-up is important when giving health hygiene advice and correct drug administration to reduce adverse reactions and ensure adherence to treatment. The pharmacist is an unavoidable person in this type of uninhabitation because the pharmacy offices are a place of easy access to the population, with very qualified professionals, many of them specialists in smoking and they are able to solve the problems related to varenicline.

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None.

Conflicts of interest

Authors declare that there is no conflict of interest.

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