

Results of Smoking Cessation Therapy in a Specialist Unit

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OBJECTIVE: The aim of this study was to assess the results of smoking cessation therapy in a specialist unit by calculating the probability of continued abstinence at 6-month follow-up and analyzing differences according to the characteristics of the individuals.

PATIENTS AND METHODS: A prospective longitudinal study was undertaken in smokers who received multicomponent smoking-cessation therapy over a period of 3 months. Continued abstinence was assessed on the basis of self-report by participants and confirmed by measurement of exhaled carbon monoxide levels. Kaplan-Meier survival analysis was performed to assess the probability of continued abstinence. Log-rank tests were used to analyze differences in continued abstinence according to different qualitative variables.

RESULTS: The 1120 patients who participated in the study (56% men and 44% women) had a mean (SD) age of 44.1 (9.5) years. The mean score on the Fagerström test was 6.3 (2.1). Nicotine replacement therapy was provided in 70.8% of patients while 29.2% received bupropion. The probability of continued abstinence at 6 months was 62.2%. Individuals with a high dependence had a lower probability of continued abstinence at 6 months, as did those in whom treatment adherence was poor. No differences were observed in the probability of abstinence according to sex or type of pharmacological treatment.

CONCLUSIONS: Individuals with a high nicotine dependence can benefit from intensive smoking-cessation treatment in a specialist unit to achieve continued abstinence.

Resultados del tratamiento del tabaquismo en una unidad especializada

OBJETIVO: Valorar los resultados del tratamiento del tabaquismo en una unidad especializada, mediante el cálculo de la probabilidad de permanecer abstinentes a los 6 meses del seguimiento, y analizar las diferencias existentes según las características de los individuos.

PACIENTES Y MÉTODOS: Se ha realizado un estudio analítico prospectivo y longitudinal entre los fumadores que recibieron tratamiento multicomponente durante 3 meses. Se consideró la abstinencia continuada mediante la declaración de los propios participantes, confirmada con coximetría. Se realizó un análisis de supervivencia por el método de Kaplan-Meier. Se aplicaron contrastes de rangos logarítmicos para estudiar las diferencias en la abstinencia continuada de los pacientes para las distintas categorías de las variables cualitativas.

RESULTADOS: Se estudió a 1.120 pacientes (un 56% varones y el 44% mujeres), con una edad media (\pm desviación estándar de 44,1 \pm 9,5 años. La puntuación del test de Fagerström fue de 6,3 \pm 2,1 puntos. El 70,8% recibió tratamiento sustitutivo con nicotina y el 29,2% con bupropión. La probabilidad de mantenerse abstinentes a los 6 meses fue del 62,2%. Los individuos con alta dependencia presentaron menos probabilidad de permanecer abstinentes a los 6 meses, así como aquéllos con mal cumplimiento terapéutico. No se encontraron diferencias en la probabilidad de abstinencia según el sexo y el tratamiento farmacológico utilizado.

CONCLUSIONES: Los individuos con dependencia alta a la nicotina pueden beneficiarse del tratamiento intensivo en una unidad especializada de tabaquismo para conseguir la abstinencia mantenida.

Key words: Smoking. Smoking cessation. Smoking cessation units. Survival analysis. Continued abstinence.

Palabras clave: Tabaquismo. Deshabitación. Unidades especializadas de tabaquismo. Análisis de supervivencia. Abstinencia continuada.

Introduction

Smoking cessation therapy has been the subject of numerous recent studies,¹ but as a result of the wide variety of approaches used, the results have been highly variable.

Irrespective of the intervention used, the most important methodological factors are those that are associated with the evaluation of abstinence, both in terms of the temporal dimension and in objective validation. In terms of temporal assessment of abstinence, taking the day the patient stops smoking as a starting point, we can measure abstinence at specific time points or continuously over time.² According to some authors, the gold standard would be the continuous approach since it is more strict, although they recommend that it is only used in cases in which the treatments used are expected to be effective from the

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outset.³ Various biochemical markers have been used to measure abstinence, including nicotine, cotinine, thiocyanate, and carbon monoxide.⁴ Of those, measurement of carbon monoxide in exhaled breath is the simplest and least expensive procedure and has a sensitivity and specificity of 90%.⁵

Another important factor is the population in which the results are evaluated. Percentage abstinence can be assessed exclusively in terms of the population that completes treatment without considering those who do not attend, or alternatively, an intention-to-treat analysis can be employed. Intention-to-treat analysis, characteristic of clinical trials,⁶ measures success as the proportion of individuals who remain smoke free in relation to the initial population, and therefore, those who do not attend are considered nonabstinent or smokers.

A more reliable technique with which to assess the results in such situations is the use of survival analysis, which allows the probability of success to be calculated over the course of cessation treatment and generates information that is more consistent with the reality of the process.⁷

The aim of this study was to analyze the results of smoking cessation treatment in a specialist unit by calculating the probability of remaining smoke-free at 6-month follow-up and to analyze possible differences according to the characteristics of the individuals.

Patients and Methods

Population

A prospective longitudinal analytic study was performed. The study population included smokers treated in a specialist smoking cessation unit. The unit serves the general population aged over 18 years who attend on their own initiative or are referred from primary or specialist care.

Acute psychiatric disorders, pregnancy, and active drug dependency or previous dependency within the last 2 years were considered criteria for exclusion. Combined-modality therapy (pharmacological and cognitive-behavioral) was offered in a group setting following an initial individual assessment in which a specific history relating to smoking was taken. Pharmacological therapy consisted of nicotine replacement therapy (NRT) or bupropion over a period of 8 weeks. The decision to use one or the other was based on individual patient characteristics (history of anxiety or depression, presence of contraindications) and, ultimately, according to patient preference. Psychological treatment involved 9 structured group sessions over a period of 3 months. In all patients, continued abstinence (the patient did not smoke from the beginning of treatment) was assessed by self-report and confirmed by analysis of carbon monoxide in exhaled breath (≤ 10 parts per million [ppm]) using a Mini Smokerlyzer cooximeter (Bedfont Scientific Ltd, Rochester, United Kingdom)⁸; treatment was considered successful in those patients who met both criteria.

Study Variables

The following variables were analyzed: sex, modified Fagerström test score,⁹ pharmacological therapy used (bupropion or NRT), level of treatment adherence (good if the patient attended 4 or more sessions and poor if the patient attended

fewer than 4 sessions), and success at 1 week, 1 month, 3 months, and 6 months. A telephone interview was carried out at 6 months to assess the status of the patient (smoker or not) and an appointment was made for analysis of carbon monoxide in exhaled breath.

Statistical Analysis

A database was prepared in SPSS version 13.0 for Windows in order to analyze the data. Firstly, a descriptive study of the variables analyzed was performed, expressing quantitative variables as means (SD) and qualitative variables as proportions and absolute frequencies.

Kaplan-Meier survival analysis was used to assess the probability of continued abstinence over time. Finally, log-rank tests were used to analyze differences in continued abstinence according to the different qualitative variables (sex, pharmacological treatment, and level of adherence) and the different subgroups created by stratification according to physical dependence measured with the Fagerström test as mild, moderate, or severe.

Results

The study group comprised 1120 patients—627 men (56%) and 493 women (44%)—with a mean (SD) age of 44.1 (9.5) years. Physical dependence, measured with the modified Fagerström test, was 6.3 (2.1) points; in terms of the 2 items with the greatest weight in the test, 853 patients (76.3%) smoked within 30 minutes of waking up and 725 (64.9%) smoked more than 20 cigarettes per day, indicating a high level of dependence in the sample. Between 1 and 3 previous attempts to stop smoking had been made by 58.9% (660 patients), whereas 28.5% (319 patients) had never tried to give up. Patient characteristics are shown in the table. NRT was used in 70.8% of the

Patient Characteristics at the Beginning of Treatment (n=1120)*

Variables	
Sex	
Men	627 (56%)
Women	493 (44%)
Age, y	44.11 (9.47)
Education	
Elementary	315 (28.1%)
Intermediate	487 (43.5%)
Advanced	318 (28.4%)
Marital status	
Single	245 (21.9%)
Married	782 (69.8%)
Others (widow/widower, separated, or divorced)	93 (8.3%)
Employment status	
Working	906 (80.9%)
Not working	214 (19.1%)
Fagerström test, overall score	6.3 (2.1)
Previous attempts	
None	319 (28.5%)
1-3	660 (58.9%)
>3	141 (12.6%)

*Data are shown as number of patients (%) or means (SD).

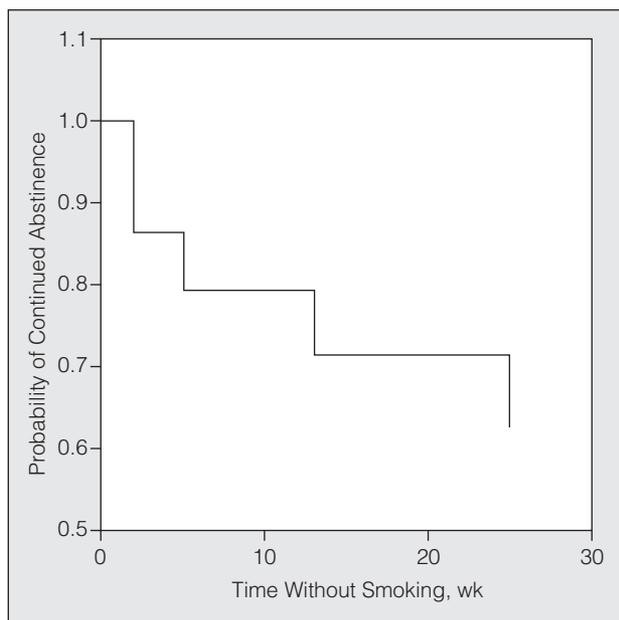


Figure 1. Survival analysis for overall continued abstinence.

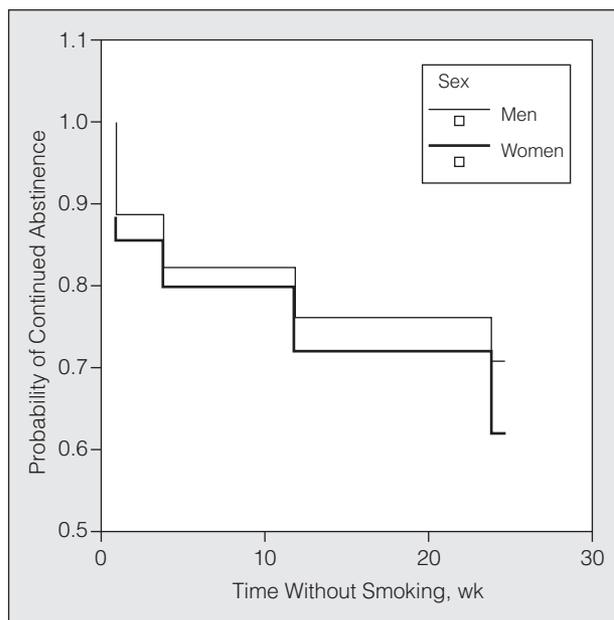


Figure 2. Continued abstinence according to sex.

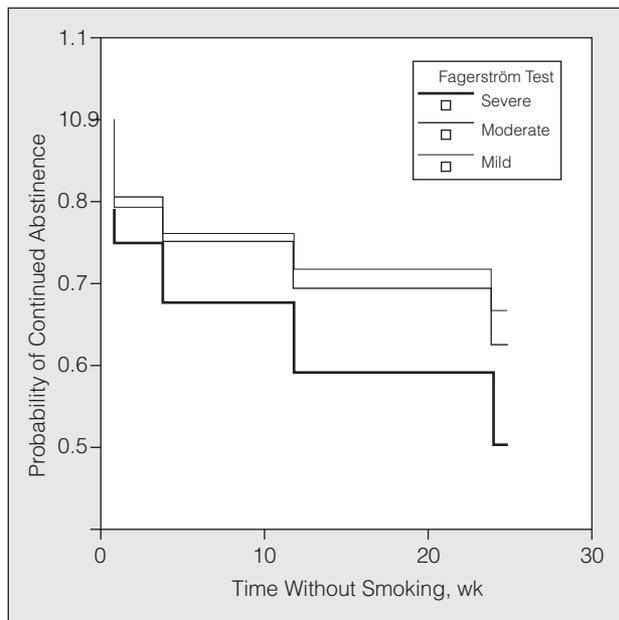


Figure 3. Continued abstinence according to physical dependence.

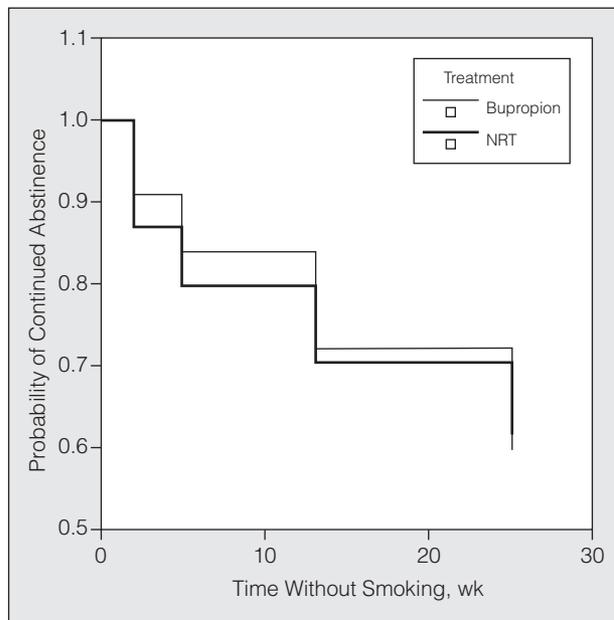


Figure 4. Continued abstinence according to pharmacological treatment used. NRT indicates nicotine replacement therapy.

patients (n=789) and 29.2% (325 patients) received bupropion. Treatment was initiated in 88% of the sample (985 patients), and of those, 82.7% (n=815) exhibited good adherence.

Survival analysis revealed that the probability of patients remaining abstinent was 86.3% at 1 week, 79.4% at 1 month, 71.5% at 3 months, and 62.2% at 6 months (Figure 1). The difference in the probability of continued abstinence according to sex was not statistically significant ($P=.054$), although, as shown in Figure 2, it was slightly higher in men than women at all cut points.

The survival curves according to the level of physical dependence showed that the patients with a severe dependence had a lower probability of remaining smoke free at all points (Figure 3), and those differences were statistically significant ($P=.0009$). No significant differences were observed in terms of the pharmacological treatment administered ($P=.37$), despite a slight improvement in continued abstinence in the group of patients treated with bupropion (Figure 4).

Finally, when survival analysis was performed in groups of patients with good and poor treatment adherence, the

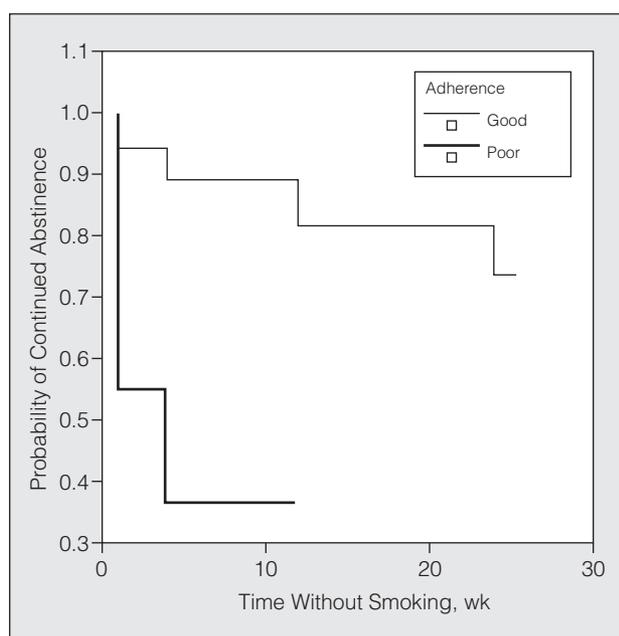


Figure 5. Continued abstinence according to adherence to group sessions.

importance of this variable as a determinant of success was confirmed in the group of patients studied. Figure 5 shows the divergent outcomes for the 2 groups over time; the log-rank test confirmed a highly statistically significant difference between the groups ($P < .0001$).

Discussion

In our study, the probability of remaining abstinent at 6 months was 62%, higher than the rate reported by other authors.¹⁰ These results can be explained in part by the type of intervention used and by methodological factors related to the analysis. Both bupropion and NRT are first-line treatments for tobacco dependence and, like psychotherapy, have demonstrated efficacy.¹¹⁻¹³ In terms of the use of individual or group psychotherapy, although there is no consensus on this point, group psychotherapy would appear to yield better results than individual interventions.^{10,14} It is also accepted that the more intensive the intervention the better the results. In our study, all of the smokers received pharmacological treatment along with psychological therapy in a group setting. This can be defined as an intensive intervention, partly explaining the results obtained.

In terms of the methods used to analyze the results, most researchers have employed estimates at specific time points to determine the effectiveness of treatment,¹⁵⁻¹⁷ applying intention-to-treat criteria. However, smoking is not a static process over time,¹⁸ and it would therefore seem more appropriate to evaluate the results using dynamic techniques such as survival analysis, which are extensively applied in other areas of medicine.^{19,20} In fact, in a recent study, the probability of abstinence at 1-year follow-up was 42.8%,²¹ and although data were not provided for 6-month follow-up, it is reasonable to suggest that the results of that study were similar to ours. Since in the case

of smoking cessation intention-to-treat analysis considers all patients who do not attend as relapses, it is not surprising that the results are worse. It has been reported that patient attendance is reduced over time even if those patients remain smoke free,²² suggesting that intention-to-treat analysis is not appropriate for assessing a process such as addiction, since failure to attend does not necessarily indicate that a patient has started smoking again. In survival analysis, individuals who do not attend follow-up visits are discarded (referred to as "censored data"), but it is assumed that the outcome (success or failure) will be similar to that of individuals who continue in the program, meaning that survival analysis, by reflecting temporal change and yielding information on probability, more accurately reflects the true situation. In addition, survival analysis only considers those patients who initiate treatment and not all patients who are recruited, since the analysis is based on treatment, not intention to treat.⁶ There are other advantages to the calculation of probabilities by survival analysis. As indicated by Hughes et al,²³ these techniques based on conditioned probability not only allow estimation of abstinence at a given moment in time, but rather, if the reference curve is known, allow comparison of studies with different periods of follow-up. Thus, if the probability of continued abstinence at 6 months in patients who were abstinent at 6 weeks is known to be 50%, a study reporting 40% abstinence at 6 weeks would be equivalent to 20% abstinence at 6 months.²³

The literature is extremely heterogeneous both in terms of the criteria used to assess abstinence and in the objective measures of abstinence, even though recommendations have been published on the reporting of results.^{3,5} In our study, continued abstinence and objective confirmation by analysis of carbon monoxide in exhaled breath were used to define success; this represents the strictest criterion compared with studies that assess abstinence at given time points (7 days without smoking prior to a given date) or use patient self-report as a measure of abstinence. In terms of self-report, there is generally little difference between the rate of self-reported success and objectively confirmed success, although there is a greater risk of disagreement between the 2 measures in patients with a high level of dependence.²⁴

In terms of relapse, as shown by the survival curve (Figure 1), the greatest reduction was in the first week, with a lower percentage at later points. This course is similar to the one described in individuals who give up smoking without treatment, although in this case the rates of abstinence do not exceed 5%.²⁵ As reported previously by other authors, the higher frequency of relapse in the first weeks justifies more intensive interventions at the beginning of the process of smoking cessation.²⁶

Analysis of the variables affecting the probability of continued abstinence reveals that there is a lower likelihood of success in individuals with a high level of dependence and those who do not attend treatment sessions. As shown in Figure 5, patients in whom treatment adherence is good have greater success, a finding that highlights the importance of intensive treatment. In smokers with a moderate or high level of dependence, the use of pharmacological treatment (NRT or bupropion) during

the first few weeks, although effective,^{27,28} is inadequate, and benefits are seen with the use of the behavioral techniques as part of the treatment offered in a specialist unit.²⁹ We did not observe differences according to the treatment used (bupropion or NRT), which was chosen according to patient characteristics rather than random allocation, since the study was undertaken in a normal clinical setting. Also, no sex differences were observed; however, analysis of the survival curves (Figure 2) showed that men had higher probabilities of continued abstinence than women at all points analyzed. The role of sex in smoking cessation is currently a topic of debate. However, there is widespread consensus regarding the need for prospective studies that consider gender, given the high rate of smoking in women.³⁰

There have been few studies in Spain on the use of smoking cessation treatment in specialist units. However, our results support the importance of using intensive treatments for smoking cessation in individuals with a moderate or high dependence who want to give up.

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