Archivos en Medicina Familiar Artículo Original Vol. 9 (1) 21-29 **2007**

Role of Intensive Counseling in Smoking Cessation. A Multicausal Prospective Study in the Primary Care Setting

Papel del Consejo Intensivo para la Cesación de Fumar. Estudio Prospectivo Multicausal en centros de Atención Primaria de Salud

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Recibido: 28-05-06 **Aceptado:** 12-12-06
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ABSTRACT

Background: Group counseling for tobacco dependence is based on behavior counseling with or without pharmacotherapy. **Objective**: To evaluate the success of three smoking cessation protocols in the primary care setup.**Design**: Prospective, nonrandomized natural experiment. Variables affecting successful outcome were evaluated by logistic analysis. **Intervention**: Eight sessions of behavioral therapy with or without nicotine replacement therapy and/or pharmacotherapy (bupropion SR) as per subject's choice. *Outcome Measures*: Self-report of smoking cessation with validation by level of carbon monoxide in exhaled air. **Results**: Most of the patients were under 50 years old and otherwise healthy. More than 85% had smoked more than 20 cigarettes a day. Smoking cessation rates were 71.6% immediately after the program, 52.8% at 6 months, and 43% at one year. Participation in more group sessions was a positive predictor of success, and high Fagerström score was a negative predictor. There was no significant difference in outcome among the three groups. **Conclusions**: Group counseling in the primary care setting is an effective aid for patients who seek to quit smoking. Compliance with counseling is an important factor for success. Nicotine replacement and pharmacotherapy, either alone or combined, do not significantly increase the smoking cessation rate. *Practice Implications*: We recommend that physicians evaluate the level of addiction to smoking of patients referred to smoking cessation programs

Key words: Smoking cessation, Behavioral therapy, Pharmacotherapy.

RESUMEN

Antecedentes: El grupo orientador contra la dependencia al tabaco se fundamenta en un asesoramiento conductual con o sin farmacoterapia. **Objetivo**: Evaluar el éxito de tres protocolos para el abandono del tabaquismo en un centro de atención primaria. **Diseño**: Estudio prospectivo no aleatorio. **Intervención**: Ocho sesiones de terapia con o sin sustitución de nicotina y/o fármacoterapia (Bupropion) a elección de los sujetos del estudio. *Mediciones externas*: Auto reporte del cese del tabaquismo con validez del nivel de monóxido de carbono exhalado. **Resultados**: La mayoría de los pacientes tuvieron una edad inferior a los 50 años, y aparentemente saludables. Una cifra superior al 85% fumó más de 20 cigarrillos al día. Los promedios de abandono del tabaquismo fueron: 71.6% inmediatamente al concluir el programa; 52.8% a los seis meses y el 43% al año. La participación en más grupos fue una predictor positivo de éxito; la más alta calificación en el test de Fagerstrom fue un predictor negativo. No hubo diferencia significativa en el resultado clínico entre los tres grupos. **Conclusiones:** El grupo orientador en la clínica de atención primaria es una ayuda efectiva para los pacientes que desean abandonar el tabaquismo. La condescendencia de los pacientes y el asesoramiento son un importante factor de éxito. La sustitución de nicotina y farmacoterapia ya sea sola o combinada no aumentó significativamente el abandono del tabaquismo. *Implicaciones clínicas*: Recomendamos que los médicos evalúen el nivel de adicción al tabaco de los pacientes remitidos al los programas de abandono del tabaquismo.

Palabras clave: Abandono del tabaquismo, Terapia conductual, Farmacoterapia.

Introduction

Tobacco dependence is a worldwide chronic disease which carries significant risks of morbidity with loss of quality of life and mortality [1]. It is the leading cause of preventable illness and death [2,3]. Although smoking cessation

is probably the most important step smokers can take to improve their health, many addicted patients cannot or will not quit [4].The main obstacles to doing so appear to be an underestimation by smokers of the complex physiological and psychological influence of nicotine and smoking addiction, and their belief that willpower alone is enough, which leads to inadequate utility of effective treatments [5].

It is well recognized in the medical community that the most appropriate treatment for tobacco dependence is a combination of behavioral counseling and pharmacotherapy. Success appears to be directly associated with the number of sessions/duration of counseling [6,7].Group therapy may be more feasible than individual therapy because it can be applied to an average of 15 people per session [3,6].

The effects of gender, age, underlying diseases, social support, level of nicotine dependence, and self-efficacy on the benefit of counseling remain unclear [8-10]. Some recent randomized clinical trials reported differing results for effectiveness of medication (bupropion SR) and nicotine replacement therapy (NRT) (patch, gum, inhaler) as first-line treatment of smoking addiction [11-13]. However, most of them focused on the role of pharmacotherapy at the expense of behavioral therapy [6]. Indeed, other reviews and guidelines claimed that the use of NRT and bupropion SR roughly doubled the success rate of counseling [3,14,15].

The main purpose of the present study was to evaluate the factors that influence smoking-cessation success in support groups combining behavioral counseling and pharmacotherapy in the primary care setting.

Methods

The study group consisted of all 90 patients who participated in seven smoking-cessation programs held in 2 primary care clinics by the same specialist between 2002 and 2003. Both men and women over 18 years old were eligible. Only those who attended at least 2 meetings were included in the analysis.

The patients were enrolled by asking the physicians and nurses to suggest the intervention to every smoking patient who visited the clinic. The cost per patient was less than the cost of one month of smoking one package of cigarettes a day.

Each program consisted of 2-hour meetings once a week for 8 weeks. At the first meeting, participants were interviewed by questionnaire for demographic data, medical status, and medical history; smoking status and addiction features were evaluated with the Fagerstrom Tolerance Scale [16], measurements of carbon dioxide in exhaled air, and a self-efficacy scale. A natural-experiment design applicable to primary clinic studies was used.

There was no randomization, and participants were free to choose their own form of pharmacotherapy (patch, gum, inhaler, bupropion SR, or none) after receiving a detailed explanation of each, in addition to information on the harms of smoking and the benefits of smoking cessation. Participants were advised to base their decision on the presence of any contraindications, personal history of pharmacotherapy use, and convenience. Between the second and third meetings, the participants were instructed to plan a “quitting day”, and between the third and eighth meetings, they were given strategies to prevent relapse and to change their attitudes and beliefs, for example: avoiding the “slippery slope” of having one cigarette after cessation, coping with a smoking environment, and coping with symptoms of withdrawal.

Smoking status was evaluated immediately after the program by interviews with the smoking-cessation specialist and primary care team. Self-reports of nonsmoking in the interview were validated against measurements of carbon dioxide in exhaled air. Failure was defined as a carbon dioxide value over 7 ppm. The interviews were repeated 6 months and one year later.

The data were analyzed by χ^2or Fisher exact tests. Comparisons of continuous data with a non-normal distribution were done with Student’s t-test. A two-tailed p value of 0.05 was used to define statistical significance for -

differences between groups and to calculate confidence intervals. All analyses were done with the SPSSWIN software, version 9.01b. Three logistic analysis models were used to evaluate the contribution of the study variables to the rate of persistent smoking at the end of the program and after 6 months and one year.

Results

Table I shows the composition and characteristics of the study population. Most of the participants (65.2%) were men less than 50 years old; most were healthy with no known underlying diseases. About 25% reported having more than two diseases, most commonly (almost 20%) some form of mental disease (anxiety, depression, bipolar disease), treated or untreated, and 30% had one of the three major diseases that have a direct association with smoking (cancer, cardiovascular disease or respiratory disease). Almost 50% were unmarried.

More than 85% of the study population had smoked more than 20 cigarettes per day and had a moderate to high score on the Fagerstrom Tolerance Scale. More than half reported living in a close smoking environment that could have had an effect on their behavior. On average, patients reported less than one meaningful previous attempt (at least 2 months) to quit smoking.

Comparison of the background data between patient who underwent group behavior therapy alone or with the addition of bupropion SR and/or NRT revealed a lower average age and lower rate of patients with mental disease in the combined therapy groups than the behavior-therapy-only group. In addition, more subjects who lived in a smoking environment opted for combined therapy (mainly NRT). Expectations of personal success prior to onset of the program were moderate to high.

Compliance with group therapy for the whole sample was about 75%. At the end of the 8-week program, 71.6% of the participants reported that they had stopped smoking (Table II). There was no significant difference in success rate between the treatment groups, indicating the lack of an additive effect of bupropion SR or NRT to behavioral therapy. At the end of the 6-month follow-up, 20% of the nonsmokers had relapsed, and after one year, another 9.6% had relapsed, for a final success rate of 43%.

Comparison of the self-reports of smoking cessation against the levels of carbon dioxide in exhaled air yielded an invalid report in only one subject (Table III). Four subjects who reported continued smoking had negative carbon dioxide levels; this finding was explained by a low number of cigarettes smoked. These individuals were considered treatment failures.

To evaluate the predictors of success or failure in quitting smoking, we performed a logistic analysis including demographic, addictive, and pharmacotherapy variables. The findings at the 3 time points are shown in Tables IV-VI.

At the end of the intervention, the model explained more than 50% of the variance (R^2 of total model = 0.515). The significant predictions on final stepwise analysis, after controlling for all the other variables of the model, were Fagerstrom Scale score (significant effect of p= 0.03 explaining 8.2% of the variance) and participation in sessions (p= 0.001 explaining about 30% of the variance). A lower Fagerstrom Scale score and a higher rate of participation predicted greater success. Having a mental disease had a significant negative effect (p= 0.01, 10%). The variables rejected due to lack of significance were age, gender, study group, workshop number, and smoking environment.

At 6 months after the intervention, the model explained more than 40% of the variance (R^2 of total model = 0.415). The significant predictors on final stepwise analysis, after controlling for all the other variables, were Fagerstrom Scale score (significant effect of $p < 0.01$ explaining 12.5% of the variance) and participation in sessions ($p = 0.01$ explaining about 12% of the variance). Having a mental disease had a significant negative effect ($p = 0.01$, 16%)

Table I

Background Data of Study Groups

Variable		Behavior Therapy+Bupro-pion+NRT	Behavior Therapy + NRT	Behavior Therapy+ Bupro-pion	Behavior Therapy Only	p Value
Sex						
Female	31 **(34.8)**	1 (12..5)	10 (31.3)	8 (32.0)	12 (50.0)	NS*
Male	**58** (65.2)	7 (87.5)	22 (68.8)	17 (68.0)	12 (50.0)	
Age (yr)						
0–50	43 **(48.3)**	6 **(75.0)**	20 **(62.5)**	7 **(28.0)**	10 **(41.7)**	0.024*
51+	46 **(51.7)**	2 **(25.0)**	12 **(37.5)**	18 **(72.0)**	14 **(58.3)**	
Family status						
Married	47 **(52.8)**	5 **(62.5)**	11 **(34.4)**	16 **(64.0)**	15 **(62.5)**	
Divor./widow	22 **(24.7)**	2 **(25.0)**	9 **(28.1)**	5 **(20.0)**	6 (25.0)	NS*
Single	20 **(22.5)**	1 **(12.5)**	12 **(37.5)**	4 **(16.0)**	3 **(12.5)**	
Cardiovascular disease						
Yes	10 (11.4)	1 (12.5)	2 (6.3)	2 (8.0)	5 (21.7)	NS*
No	78 (88.6)	7 (87.5)	30 (93.8)	23 (92.0)	18 (78.3)	
Respiratory disease						
Yes	15 (17.0)	1 (12.5)	6 (18.8)	3 (12.0)	5 (21.7)	NS*
No	73 (83.0)	7 (87.5)	26 (81.3)	22 (88.0)	18 (78.3)	
Cancer						
Yes	2 (2.3)	0 (0.0)	2 (6.3)	0 (0.0)	0 (0.0)	NS*
No	86 (97.7)	8 (100)	30 (93.8)	25 (100)	23 (100)	
Mental disease						
Yes	17 (19.5)	0 (0.0)	11 (35.5)	2 (8.0)	4 (17.4)	0.027*
No	70 (80.5)	8 (100)	20 (64.5)	23 (92.0)	19 (82.6)	
Other diseases						
Yes	24 (27.0)	3 (37.5)	11 (34.4)	4 (16.0)	6 (25.0)	NS*
No	65 (73.0)	5 (62.5)	21 (65.6)	21 (84.0)	18 (75.0)	

Note: Values are in (%) unless otherwise indicated
*$\chi 2$ test. † by ANOVA.
NRT= nicotine replacement therapy.

After one year, the model explained about 40% of the variance (R^2 of total model = 0.384), and the same variables proved significant on final stepwise analysis: Fagerstrom Scale score ($p < 0.05$ explaining 20.2% of the variance) and participation in sessions ($p < 0.01$ explaining about 10% of the variance). The variables rejected due to lack of significance were age, gender, study group, workshop number, mental disease, use of NRT and/or bupropion SR, and smoking environment.

Table I (Cont.)

Background Data of Study Group

Variable		Behavior Therapy+Bupropion+NRT	Behavior Therapy + NRT	Behavior Therapy+Bupropion	Behavior Therapy Only	p Value
No. of concomitant diseases						
0	45 (51.7)	5 (62.5)	13 (41.9)	17 (68.0)	10 (43.5)	
1	21 (24.1)	1 (12.5)	7 (22.6)	6 (24.0)	7 (30.4)	NS*
2	17 (19.5)	2 (25.0)	8 (25.8)	1 (4.0)	6 (26.1)	
3 or more	4 (4.6)	0 (0.0)	3 (9.7)	1 (4.0)	0 (0.0)	
No. cigarettes per day						
Less than 20	13 (14.8)	0 (0.0)	4 (12.5)	6 (24.0)	3 (13.0)	
20-39	54 (61.4)	7 (87.5)	19 (59.4)	15 (60.0)	13 (56.5)	NS*
40-59	18 (20.5)	0 (0.0)	7 (21.0)	4 (16.0)	7 (30.4)	
60+	3 (3.4)	1 (12.5)	2 (6.3)	0 (0.0)	0 (0.0)	
Packs/yr, mean	42.2	48.4	41.0	38.1	46.3	NS†
Fagerstrom scale (0-10), mean	6.1	6.6	6.7	5.3	6.2	NS†
Smoking environment						
Yes	52 (59.1)	5 (62.5)	25 (78.1)	10 (40.0)	12 (52.2)	0.029*
No	36 (40.9)	3 (35.5)	7 (21.9)	15 (60.0)	11 (47.8)	
No. of previous smoking cessations of ≥ 2 months						
Mean	0.76	0.88	0.50	1.2	0.59	NS†
No. of sessions attended (out of 8)						
Mean	6.22	7.00	6.25	6.60	5.54	NS†
Self-confidence about success (0-10)						
Mean	7.05	6.63	7.16	7.13	6.95	NS†

Success of Program by Study Groups

Table II

Continued Smoking		Behavior Therapy+Bupropion+NRT	Behavior Therapy + NRT	Behavior Therapy+ Bupropion	Behavior Therapy Only	p Value
At end of program						
Yes	25 (28.4)	1 (12.5)	12 (37.5)	3 (12.0)	9 (39.1)	NS*
No	63 (71.6)	7 (87.5)	20 (62.5)	22 (88.0)	14 (60.9)	
Six months after program						
Yes	42 (47.2)	3 (37.5)	19 (59.4)	7 (28.0)	13 (54.2)	NS*
No	47 (52.8)	5 (62.5)	13 (40.6)	18 (72.0)	11 (45.8)	
One year after program						
Yes	50 (56.8)	5 (62.5)	20 (62.5)	9 (37.5)	16 (66.7)	NS*
No	38 (43.2)	3 (37.5)	12 (37.5)	15 (62.5)	8 (33.3)	

* $\chi 2$ test NRT = nicotine replacement therapy.

Table III

Correlation between Smoking and Level of Carbon Monoxide (CO) in Exhaled Air at One year after Program

CO Level (ppm)	Yes	No	Total	p Value
1-6	4 (28.6)	54 (98.2)	58 (84.1)	NS
7+	10 (1.8)	1 (1.8)	11 (15.9)	p<0.0001*
Total	14 (100.0)	55 (100.0)	69 (100.0)	NS

*$\chi 2$ = **40.35**

Table IV

Logistic analysis: Variables Predicting Continued Smoking (yes=1, no=0) Immediately after Program (n=89)

Variable	B	P	R^{2*}
Workshop no.	0.251	0.886	-
Age group	0.499	0.480	-
Mental disease	2.202	0.014	0.1
Fagerstrom scale	0.459	0.030	0.082
Smoking environment	1.735	0.188	-
Participation in sessions	-0.800	0.001	0.298
Behavioral therapy only	0.211	0.976	-
Behavioral therapy + bupropion	0.006	0.940	-
Behavioral therapy + NRT	0.090	0.765	-
Behavioral therapy+bupropion+NRT	0.003	0.959	-
Variables not in the model	-	-	0.035

*R^2 of total model = 0.515

NRT = nicotine replacement therapy.

Table V

Logistic analysis: Variables Predicting Continued Smoking (yes=1, no=0) at Six Months after Program (n=89)

Variable	B	P	R^{2*}
Workshop no.	0.015	0.993	-
Age group	0.005	0.942	-
Mental disease	2.534	0.012	0.162
Fagerstrom scale	0.487	0.006	0.125
Smoking environment	0.175	0.676	-
Participation in sessions	-0.552	0.012	0.117
Behavioral therapy only	0.762	0.858	-
Behavioral therapy + bupropion	0.650	0.420	-
Behavioral therapy + NRT	0.427	0.513	-
Behavioral therapy+bupropion+NRT	0.001	0.980	-
Variables not in the model	-	-	0.011

*R^2 of total model = 0.41 NRT = nicotine replacement therapy.

Table VI

Logistic analysis: Variables Predicting Continued Smoking (yes=1, no=0) at One Year after Program (n=89)

Variable	B	P	R^{2*}
Workshop no.	2.218	0.188	-
Age group	0.517	0.472	-
Mental disease	1.366	0.242	-
Fagerstrom scale	0.363	0.019	0.202
Smoking environment	0.581	0.446	-
Participation in sessions	0.631	0.004	0.094
Behavioral therapy only	2.727	0.436	-
Behavioral therapy + bupropion	2.576	0.108	-
Behavioral therapy + NRT	0.211	0.646	-
Behavioral therapy+bupropion+NRT	0.297	0.586	-
Variables not in the model	-	-	0.088

*R^2 of total model = 0.384
NRT=nicotine replacement therapy.

Discussion

The main aims of this study were to determine the one-year rate of success for a behavioral therapy or combined behavioral-pharmacotherapy program for smokers and to evaluate the factors predicting success. We used a nonrandomized, natural-experiment design wherein subjects were able to choose the therapeutic approach.

The majority of participants were less than 50 years old and healthy. It is noteworthy that the primary care team was able to recruit healthy young people along with older and sicker patients, who are probably more aware of the health consequences of smoking through knowledge and experience. Healthy populations gain the maximal benefit from smoking cessation, especially those under age of 35 [17].

The succes rate of the program was 43% at one year, at the high range of findings reported for similar interventions in the primary care setting (16% to 43%) in different populations [18-20]. Studies in hospital patients are more sparse, with success rates for the most intensive group-based interventions ranging from 15% to 24% after one year [21-23]. The difference in results between community and hospital further emphasizes the importance of instituting counseling groups early, when patients are young and healthy and continuity of care is possible.

To determine the predictors of success, we selected variables that have been found to have a potential effect on smoking cessation, although the findings are still controversial. Both NRT and bupropion SR are considered first-line therapies for subjects who want to quit smoking [3,14,15]. Most of our knowledge on these treatments, however, is derived from placebo-controlled randomized clinical trials designed to examine the pharmacotherapy, and not the whole program of behavior therapy and pharmacotherapy [6]. Moreover, there was great diversity of behavior therapy in these trials, with only a few using group counseling [11-13]. At the same time, the Cochrane Review of group behavior therapy reported only limited data on the addition of NRT to behavior therapy, and it failed to mention bupropion SR at all [24].

The present study found that adding either NRT or bupropion SR or both had no significant effect on either the short-term or the one-year success rate of intensive behavior counseling by a dedicated primary care specialist, with team follow-up. Further support for the effectiveness of behavior counseling was provided by our regression analysis showing that the better the subject's participation in the group sessions, the greater his or her chances of quitting smoking, even for as long as one year. A dose-response abstinence rate has also been reported by others using number of counseling sessions or overall counseling time [3,6].

The level of nicotine dependence, as measured by the Fagerstrom Tolerance Scale [16], was the most significant negative factor for success at all time points: The higher level of nicotine dependence, the less likely the subject was to quit smoking.

The most common disease reported by patients was mental illness. Our analysis revealed that mental illness was also a negative factor for success, but only in the short term. The comorbidity of mental disease and smoking is well described in schizophrenia, depression, bipolar diseases, anxiety and even somatoform disorders [25]. Several theories on the difficulty of smoking cessation in this population have been proposed. Most authors presume that relapse is associated with the burden of the disease and/or the neuropharmacology or self-treatment [26]. We speculate that the subjects who attended our primary care counseling groups had less severe mental disease than those who participate in psychiatry-oriented smoking-cessation interventions.

The role of age and gender in smoking cessation remains unclear. Some authors believe that younger smokers lack the motivation to quit whereas others argue that older patients who have smoked all their lives pose a greater challenge [27]. Regarding gender, some studies implied that female smokers are less likely to quit than male smokers [28]. However, a recent review found that women participate more in counseling sessions than men and that this may be a source of bias [28].

Others suggested a more complex relationship, namely that the cessation rate is higher in women of childbearing age, lower in women than men in middle-age, and equalizes afterward [28]. In our study, most of the participants were men, with almost half under 50 years old. Neither age nor gender had a significant influence on the quitting rate.

Finally, to our surprise, there was no effect of either family background or smoking environment on outcome. A study reported that being married to a nonsmoker increased the likelihood of stopping [29]. It is possible that in our program, the social support generated by the group meetings and follow-up of the primary care team counter-balanced the negative influence of smoking environment.

Conclusion

Group counseling in primary care clinics is effective for smoking cessation. Good attendance is a positive predictor for success, and a high level of nicotine dependence is a negative predictor. NRT or bupropion SR or both apparently play no significant contributory role in this setting. These findings should prompt the establishment of additional programs of group counseling that focus on strategies to prevent relapse, change attitudes, and provide social support. Patients should be educated that compliance with the smoking cessation program is the most important factor for success.

Practice Implications

This study reinforces the policy of primary care practices to either perform and/or refer patients who smoke to smoking cessation program groups.

As a result of the present study, we recommend that physicians evaluate the level of addiction to smoking of patients referred to smoking cessation programs. In this way, the primary care physician will be able to evaluate the progress of the program which is more effective when the level of addiction is low. This is important because physicians are asked by their patients about the success rate of smoking cessation programs. I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

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