

Relapse Rate and Factors Related to Relapse in a 1-Year Follow-Up of Subjects Participating in a Smoking Cessation Program

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BACKGROUND: The most important and difficult task when it comes to reducing tobacco-related morbidity and mortality is to convince smokers to quit and to maintain their abstinence. This study aimed to determine the smoking relapse rate and factors related to relapse in subjects who participated in a smoking cessation program and completed a 1-y follow-up in our center. **METHODS:** The study included 550 subjects who applied to a smoking cessation clinic from June 1, 2011 to December 31, 2011 and completed the 1-y follow-up. **RESULTS:** After 1 y, 282 (51.4%) subjects had relapsed, 132 (24%) had quit smoking, and 135 (24.6%) could not be contacted. The mean age \pm SD was 41.5 ± 10.8 y, and 52.5% were male. There was no difference between non-relapsed and relapsed subjects with regard to age, sex, average smoking duration and daily number of cigarettes, reason to quit, education level, presence of symptoms and concomitant diseases, Fagerström nicotine dependence score, Beck depression score, and frequency of pharmacotherapy administration. In the relapsed group, the age began smoking was younger ($P = .05$), and the longest prior duration of abstinence was shorter ($P = .04$). The average number of support contacts was found to be significantly higher in the non-relapsed subjects ($P < .001$). Logistic regression analysis revealed alcohol intake to be a factor influencing relapse (odds ratio: 2.11, 95% CI: 1.13–3.93, $P = .02$), as was the number of support contacts (odds ratio: 2.06, 95% CI: 1.59–2.65, $P < .001$). The presence of drug adverse effects was close to being significant (odds ratio: 1.96, 95% CI: 0.93–4.10, $P = .07$). **CONCLUSION:** The relapse rate in a 1-y period was 51.4%. Similar to previous studies, alcohol intake presented a relapse risk. In subjects receiving drug treatment, planning support meetings more frequently and paying attention to adverse effects may increase the success of smoking cessation. *Key words:* smoking; smoking cessation; alcohol dependence; varenicline; bupropion; nicotine replacement products; drug-related adverse reactions. [Respir Care 2015;60(12):1796–1803. © 2015 Daedalus Enterprises]

Introduction

Despite increased awareness of the risks of smoking, it continues to present a serious public health problem and constitutes one of the most frequent, preventable cause of

morbidity and mortality.¹⁻³ According to World Health Organization estimates, one-third of the world's popula-

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This study was presented as an oral presentation at the 35th Annual Congress of TÜSAD Solunum 2013, held October 2–6, 2013, in Çeşme-İzmir, Turkey.

The authors have disclosed no conflicts of interest.

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DOI: 10.4187/respcare.03883

tion over the age of 15 smokes, corresponding to approximately 1.1 billion people worldwide, including 16 million people in Turkey. Without intervention, this number is estimated to rise to 1.7 billion worldwide by the year 2025.⁴ The biggest difficulty in reducing tobacco-related morbidity and mortality is convincing smokers to quit and maintain their abstinence.⁵ Epidemiological data show that 70% of smokers want to quit, and 46% of these have made a prior attempt to quit, abstaining for at least 1 d.^{6,7}

People who want to quit smoking need a facilitative support approach to achieve abstinence. This may include non-pharmacologic and pharmacologic support programs and sometimes both. Even with pharmacologic and supportive therapy, quitting smoking is difficult for most smokers, and a considerable number of attempts result in relapses.⁸⁻¹⁰

In Turkey, the number of applications to smoking cessation clinics by individuals who want to quit increases every day. This is due to social awareness, prohibition of smoking in closed environments, associated diseases, and economic reasons. This motivation to quit can be supported by various medical and behavioral therapies.^{7,11} Determining the risk factors associated with unsuccessful attempts to quit may help in providing a more conscious and effective support treatment. We aimed to determine the relapse rate after 1 y and the factors affecting relapse in subjects who applied to a Smoking Cessation Clinic in our hospital.

Methods

Study Design

This was a case-control study. The control group comprised subjects who did not relapse. This study was approved by the local ethics committee.

Setting

This study was carried out in the Smoking Cessation Clinic of the Istanbul Süreyyapaşa Chest Diseases and Thoracic Surgery Education and Research Hospital. Istanbul is the most populous and leading commercial city in Turkey. It has a population of 14 million and has the most immigrants of any Turkish city.

Subject Selection and Subject Characteristics

Within the scope of the Smoking Cessation Program, the personal and social drawbacks of smoking were explained to all subjects as a group in their first meeting. The significance of making the decision to quit was highlighted, and subjects who made the decision were given cognitive and behavioral education on quitting. A quit date was

QUICK LOOK

Current knowledge

Despite increased awareness of smoking risks, this behavior continues to present a serious public health problem, constituting one of the most frequent preventable causes of morbidity and mortality. The most important difficulty for reduction of tobacco-related morbidity and mortality is to convince smokers to quit and maintain their abstinence. Epidemiological data have shown that 70% of smokers want to quit, and 46% have attempted to quit in the past, abstaining for at least 1 day. Even with pharmacotherapy and supportive therapy, quitting smoking is difficult for most smokers, and a considerable number of attempts result in relapses.

What this paper contributes to our knowledge

The relapse rate following smoking cessation in a 1-y period was 51%. Alcohol intake presented a risk for relapse. In patients who receive drug treatment, planning controls more frequently and attention to adverse effects may increase the success rates in smoking cessation treatment.

designated for each subject. Psychological support and motivating meetings were recommended once within the first 15 d following the quit date, once every month for the next 3 months, and once every 3 months for the following 9 months. Subjects were initially called for a face-to-face meeting. Subjects who did not attend the support meeting were phoned by a polyclinic nurse. The first meeting was carried out face-to-face, and subsequent support contacts were made either face-to-face or by telephone contact. Face-to-face and telephone contacts were available for each subject. Subject follow-up in the Smoking Cessation Polyclinic was carried out by a pulmonary disease specialist doctor in our hospital; psychiatric consultation was given as required, and subjects were followed up together in selected cases.

A total of 550 subjects who participated in the smoking cessation program from June 1 to December 31, 2011 and who completed a 1-year follow-up were included in the study. The demographic characteristics of the subjects, Fagerström nicotine dependence scores, Beck depression scores, presence of respiratory symptoms, pulmonary function test results, concomitant diseases, age began smoking, number of smoking years, daily cigarette count, smoking behavior in their environment (family, friends, and workplace), conditions that increase smoking desire (after meals, tea, coffee, alcohol intake, friend circle, workplace, etc), presence of regular alcohol consumption (alcohol consumption is defined as having up to 1 drink/d), reason for

quitting (health, family, financial), prior attempts to quit (and, if any, how long they lasted), whether they received pharmacologic treatment in addition to psychological support for quitting, type of pharmacotherapy, presence of adverse effects and their type, number of support contacts during the 1-year follow-up period, and time of relapse in relapsed subjects were obtained from subject records and entered into the database.

At the end of the 1-y period, the subjects who quit smoking were grouped into the non-relapsed group, whereas those who started to smoke again at any time during the year were grouped in the relapsed group. Those subjects who did not attend any support visits and who were not contactable on 2 different occasions were grouped in the unknown smoking status group. Since there was no carbon monoxide measurement facility in our hospital, the subject's smoking status was self-reported.

Statistics

The dependent variable or outcome was a relapse. The independent variables (risk factors) were: age, sex, age began smoking, smoking years, daily smoking count, education level, motivation to quit in the past and the longest period of abstinence, reason to quit, exposure to environmental tobacco smoke, alcohol intake, Fagerström nicotine dependence score, Beck depression score, respiratory symptoms, pulmonary function test parameters, pharmacotherapy, presence of adverse effects, and number of support interviews.

Measures subject to statistical analysis in the study were defined as the mean, SD, frequency, and percentage values. The chi-square and Fisher's exact probability tests were used to compare frequency and percentages between the groups.

For a comparison of normally distributed continuous variables between the 2 groups (relapsing and non-relapsing), the *t* test was used. When the distribution of variables was not normal, The Mann-Whitney *U* test was used for comparison. Multiple backward stepwise logistic regression analyses were performed to detect any associations between variables and to express their mathematical model. A *P* value of .05 was considered significant. Statistical analyses were carried out using SPSS 17.5 (SPSS, Chicago, Illinois).

Results

The age of the 550 subjects included in the study varied between 15 and 76 y (mean: 41.5 ± 10.8 y); 289 (52.5%) were male, and 261 (47.5%) were female. After 1 y, the number of relapsed subjects was 282 (51.4%), the number of non-relapsed subjects was 132 (24%), and

Table 1. Comparison of Relapsed and Non-Relapsed Subjects According to Quantitative Variables

Variables	Relapsed (<i>n</i> = 291)	Non-Relapsed (<i>n</i> = 132)	<i>P</i>
Age, y	41.7 (11.3)	42.4 (9.3)	.52
Age began smoking, y	18.0 (4.8)	19.1 (5.5)	.05
Duration of smoking, y	24.5 (15.5)	23.3 (9.5)	.44
Cigarette pack-years	23.8 (11.2)	23.4 (9.5)	.67
FNDS	5.7 (2.5)	5.6 (2.4)	.96
BDS	11.3 (8.1)	11.9 (8.8)	.43
FVC, L	3.4 (1.0)	3.3 (1.0)	.52
FVC, % predicted	85.7 (15.8)	86.3 (15.0)	.69
FEV ₁ , L	2.9 (0.9)	2.8 (0.9)	.49
FEV ₁ , % predicted	87.2 (17.5)	88.3 (15.3)	.53
FEV ₁ /FVC	0.85 (.088)	0.858 (.085)	.36
No. of support contacts	1.8 (0.9)	2.5 (1.3)	<.001

Data are shown as mean (SD).
Mann-W = Mann-Whitney *U* test
FNDS = Fagerström nicotine dependence score
BDS = Beck depression score

the number of cases with unknown smoking status was 135 (24.6%).

When the relapsed group was compared with the non-relapsed group according to quantitative variables, the age began smoking (*P* = .05) and number of support contacts (*P* < .001) were found to be significantly higher in the non-relapsed group (Table 1). The number of support contacts after the quit date varied between 0 and 5 (median: 2.0 ± 1.3). In the relapsed and non-relapsed groups, the average number of face-to-face meetings was 0.9 ± 0.7 and 1.2 ± 0.9, respectively (*P* < .001). The average number of telephone interviews was 0.8 ± 0.7 in the relapsed group and 1.3 ± 0.9 in the non-relapsed group (*P* = .02). There was a significant difference between the 2 groups with respect to alcohol intake (*P* < .001) and the duration of abstinence in the past (*P* = .04) (Table 2). There was no association between the presence of comorbidities and relapse state (the distribution of comorbidities is shown in Fig. 1).

Pharmacotherapy along with supportive treatment was administered in 470 (85.4%) cases. The most frequently used agent for medical treatment was varenicline (*n* = 206, 43.7%), but there was no difference between drugs in terms of treatment success (Table 3). Although subjects with depression received all types of pharmacotherapy, the rate of varenicline use was lower than in the general group (*n* = 18, 18.9%).

Drug-related adverse effects were observed in a total of 61 (13%) subjects. The most common adverse effects were nausea (22.9%), sleep disorders (13.1%), skin reactions (11.4%), depression (9.8%), and gastrointestinal intoler-

Table 2. Comparison of Relapsed and Non-Relapsed Group According to Categorical Variables

Variables	Relapsed, n (%)	Non-relapsed, n (%)	P
Sex			
Male	159 (56.4)	62 (47.0)	.07
Female	123 (43.6)	70 (53.0)	
Cigarette count, daily			
≤10	32 (11.5)	13 (9.9)	.27
11–20	118 (42.4)	63 (48.1)	
21–30	97 (34.9)	35 (26.7)	
>30	31 (11.2)	20 (15.3)	
Environmental exposure			
Home	42 (15.4)	19 (15.1)	.89
Work	34 (12.5)	13 (10.3)	
Friends	57 (21.0)	25 (19.8)	
All	139 (51.1)	69 (54.8)	
Alcohol intake			
Yes	87 (31.3)	18 (14.0)	<.001
No	191 (68.7)	111 (86.0)	
Quitting attempts			
Yes	242 (87.4)	111 (86.0)	.71
No	35 (12.6)	18 (14.0)	
Duration of abstinence			
<1 mo	139 (65.9)	47 (49.0)	.04
1–6 mo	50 (23.7)	34 (35.4)	
7–12 mo	12 (5.7)	7 (7.3)	
>12 mo	10 (4.7)	8 (8.3)	
Education level			
None	5 (1.8)	1 (0.8)	.88
Primary school	70 (25.2)	33 (25.2)	
Secondary school	34 (12.2)	14 (10.7)	
High school	91 (32.7)	42 (32.1)	
University	78 (28.1)	41 (31.2)	
Comorbidity			
Yes	122 (43.3)	57 (43.2)	.98
No	160 (56.7)	75 (56.8)	
Respiratory symptoms			
Yes	128 (46.0)	60 (45.8)	.96
No	150 (54.0)	71 (54.2)	
Pharmacotherapy			
Yes	258 (91.5)	119 (90.2)	.66
No	24 (8.5)	13 (9.8)	

ance (8.2%). The adverse effects observed and drugs administered are shown in Table 4.

Relapses occurred mostly in the first month (48.9%) and during the first 6 months (37.8%). According to the duration of pharmacotherapy, relapse rates were found to be higher around days 15–29 and days 60–90 of treatment (Fig. 2).

Variables (as shown in Table 5) (ie, alcohol intake and number of support contacts) were analyzed by multiple backward stepwise logistic regression and were found to have an important affect on relapse ($P = .02$ and $P < .001$,

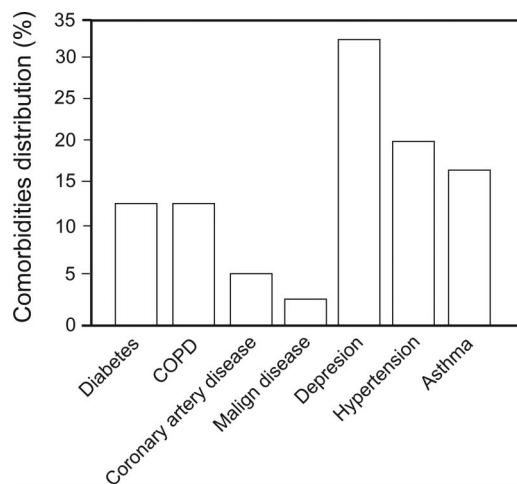


Fig. 1. Distribution of comorbidities: diabetes mellitus ($n = 35$, $P = .68$), COPD ($n = 36$, $P = .33$), coronary artery disease ($n = 14$, $P = .09$), malign disease ($n = 10$, $P = .94$), depression ($n = 95$, $P = .54$), hypertension ($n = 57$, $P = .58$), and asthma ($n = 45$, $P = .14$).

respectively). The presence of adverse effects was found to be close to significant ($P = .07$).

Discussion

It is well known that 70% of smokers have a desire to quit, but < 10% can achieve abstinence for an extended period.⁷ In our study, we found no difference between the age, sex, educational status, daily cigarette count, environmental exposure to tobacco smoke, and nicotine dependence level of those subjects who returned to smoking at the end of 1 y and those subjects who did not relapse. There are studies reporting diverse results on this subject. In 1 study that looked at demographic and smoking-related factors, being older, married, and male, having a lesser number of daily cigarettes, not being exposed to tobacco smoke at home, having a lower nicotine dependence level, having a longer prior abstinence period, and having a lower alcohol intake were found to be associated with a greater success of quitting.⁵ In another study, alcohol intake and environmental exposure to tobacco smoke were determined to be risk factors for relapse, whereas age, sex, and education level were found not to be associated with relapse.¹² A further study involving 103 smokers found a difference in smoking behavior between the sexes and found that the relapse rate was higher in males at the end of 1 year.¹³ On the contrary, other studies have found male sex to be a protective factor against relapse.^{14,15} Japuntich et al¹⁶ emphasized the significance of sex and the nicotine dependence level. In addition, several studies have noted the presence of another smoking person in the household environment as a factor affecting relapse.^{12,17-19}

RELAPSE FACTORS IN A SMOKING CESSATION PROGRAM

Table 3. Success Rates and Association With Relapse According to Type of Pharmacotherapy administered

Agents (<i>n</i> = 470)	<i>n</i> (%)	Relapsed, <i>n</i>	Non-Relapsed, <i>n</i>	Treatment Success, %	<i>P</i>
Varenicline	206 (43.7)	112	94	45.6	.24
Bupropione	137 (29.0)	67	70	51.1	.79
Nicotine patches	100 (21.2)	48	52	52.0	.06
Nicotine gum	12 (2.5)	10	2	16.7	.16
Bupropion + nicotine patches	12 (2.6)	7	5	41.7	.52
Bupropion + nicotine gum	2 (0.4)	1	1	50.0	.12
Varenicline + nicotine patches	1 (0.2)	0	1	100.0	.25

Table 4. Adverse Effects Related to Drugs and Their Frequencies

Type of side effect (<i>n</i> = 61)	Type of Drug			
	Varenicline, <i>n</i>	Bupropion, <i>n</i>	Nicotine patches, <i>n</i>	Nicotine gum, <i>n</i>
Nausea	13	0	0	1
Sleep disorder	5	2	1	0
Abnormal dreaming	4	0	0	0
Skin reaction	0	0	7	0
Depression	4	2	0	0
Gastrointestinal intolerance	3	2	0	2
Skin rash	2	2	0	0
Anxiety	3	0	0	0
Headache	2	1	0	0
Tremor	0	2	0	0
Dryness at mouth	1	1	0	0
Hallucinations	1	0	0	0

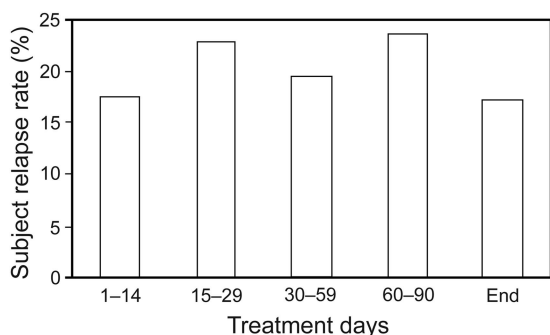


Fig. 2. Relapse rates according to the duration of pharmacotherapy.

Most adult smokers start smoking in their youth. Adolescents carry a greater risk for starting smoking and developing dependence, and the starting age for smoking is reported to be a determining factor for relapse.^{20,21} Studies carried out in Turkey indicate that the age began smoking varies between 13 and 20.^{3,17,22-25} In our study, the age began smoking was significantly younger in the relapsed group compared with the non-relapsed group.

Among those subjects who attend smoking cessation programs, a certain percentage of these have attempted to quit several times in the past.^{26,27} The presence and num-

Table 5. Multiple Backward Stepwise Logistic Regression Showing Variables With a Significant Effect on Relapse

Variables, step 10*	<i>P</i>	OR	95% CI
Alcohol intake	.02	2.11	1.13-3.93
Number of controls	<.001	2.06	1.59-2.65

* Variable(s) entered on step 1: alcohol intake (yes/no), environmental exposure (home/work/friends/all), reason to quit (health/family/financial), educational status (none/primary school/secondary school/high school/university), respiratory symptoms (yes/no), Beck depression score, number of controls, pharmacotherapy (yes/no), side effects (yes/no).
OR = odds ratio

ber of prior failed attempts is reported to be a significant adverse factor for subsequent attempts to quit.²⁶ Our results supported this; the longest period of prior abstinence was significantly lower in the relapsed group.

Many studies indicate an association between alcohol intake and relapse.^{2,5,12,17} In our study, there was a significantly higher alcohol intake in the relapsed subjects (31% vs 14%).

Another study showed that subjects who relapsed subsequent to quitting smoking after hospitalization for acute coronary syndrome had a higher level and intensity of depression.²⁸ Similarly, in cancer subjects who quit smoking after surgical treatment, relapse was found to be asso-

ciated with depression.²⁹ In contrast, a study involving 677 subjects showed that, although a history of depression was found to be a determining factor for relapse in the short term, it was not significant in the long term.³⁰ In our center, the Beck depression scale is used on each subject attending the smoking cessation program, and those with a high score and those who have a history of depression are referred to a psychiatric specialist, and the follow-up and treatment of these subjects are planned together. In our study, 95 (17.3%) subjects were diagnosed with depression, and, of these, there was no difference in the mean Beck depression scores between the relapsed and non-relapsed group. However, the information obtained with the Beck depression scale is subjective, and the number of subjects with depression in the whole group was small. Thus, it will be important to investigate the effect of depression on quitting smoking in a further study with a greater number of subjects suffering depression.

In our subject group, relapses were most remarkable within the first month (48.9%) and then during the first 6 months (37.8%). Similarly, other studies note relapses mostly during the first 6 months.^{18,31}

Most smokers assume that all that is necessary to quit is the decision to do it, but this is reported to be a misconception.³² In addition to behavioral and motivational support, pharmacologic treatment is also recommended in selected subjects. In our study, subjects received behavioral and psychological supportive treatment, and 85.4% received pharmacotherapy, including varenicline, bupropion, nicotine replacement treatment, or a combination of these. Several studies report that prolonged treatment with varenicline may prevent relapse.^{5,29} Prolonged nicotine replacement treatment has shown promising but controversial results,⁵ as there are more relapses with short-term nicotine replacement treatment compared with treatment regimens including bupropion and varenicline.³³ Interestingly, we found no difference in relapse rates between subjects who received pharmacologic treatment and those who did not. There was also no association between the type of pharmacotherapy and success of treatment, although the success rate with a nicotine patch alone was 52% (yielding a *P* value close to significant). This finding may be due to the relatively low adverse effects of nicotine patches and their higher tolerability.

There was a 13% incidence of adverse effects in those cases who received pharmacotherapy in our study. The presence of adverse effects was noteworthy, as the *P* value was close to significant after regression analysis, and it may be a factor affecting the success of pharmacotherapy indirectly. The reported adverse effects of varenicline, the most frequently prescribed agent used in our subjects, include the increased risk for cardiovascular accident development,³⁴ nausea,³⁵⁻³⁸ abnormal dreaming, sleeplessness,^{36,38} headache,^{37,38} depression, and possible serious

psychiatric conditions.^{39,40} The most frequent adverse effect we observed with varenicline was nausea. In addition, disrupted sleep, abnormal dreaming, depression, anxiety, gastrointestinal intolerance, skin rash, headache, hallucinations, and dryness of the mouth were also noted. Bupropion causes nausea, sleeplessness, anxiety, dryness of the mouth, and increased risk of seizures by decreasing the epileptic threshold.³⁴ We noted adverse effects related to bupropion in 12 subjects, and these included depression, gastrointestinal intolerance, skin rashes, sleeplessness, tremors, headache, and dryness of the mouth. Adverse effects of nicotine replacement treatment are rare and mostly include skin reactions, irritation, and burning sensations in the mouth and throat.^{34,40} Skin reactions were seen in 7 of our subjects following nicotine patch use. Adverse effects of nicotine gum are reported to be gastrointestinal intolerance and nausea, and these were observed in only 3 of our subjects. Consistent with the literature, the most commonly observed adverse effects in our subject group were nausea, sleep disorders, abnormal dreaming, skin reactions, depression, and gastrointestinal adverse effects.

Since sleep disorders and midnight awakenings are also symptoms of nicotine withdrawal, they were investigated in a Greek study⁴¹ and were found to be independent variables associated with relapse. Also, the use of bupropion and smoking the first cigarette of the day 30 min after getting up has been shown to increase quitting success.⁴¹ Since our study was not a prospective one, we could only analyze the variables that had been recorded, and nicotine withdrawal symptoms could not be analyzed in our study. As it is observed, sleep disorders should be examined from both perspectives. Pharmacotherapy did not have a significant effect on success in our study. Although the study design of Boutou et al⁴¹ was prospective, in our opinion, it would be improper to draw a conclusion from the long-term results, since the follow-up time was only 6 months.

We showed that the average number of support meetings in 1 y in subjects who were followed up in the polyclinic after quitting was significantly higher in the non-relapsed versus the relapsed subjects. The chance of intervening in the event of adverse effects is more likely in those subjects who attend support visits more regularly, and this factor may have affected this result.

There are some limitations to our study. The primary limitation is the subjective, self-reported evaluation of the subject's smoking status due to the lack of ability to measure carbon monoxide in exhaled breath in our hospital. Also, there was a high number of subjects who could not be contacted during follow-up and whose smoking status was unknown, as the study was not planned as a prospective design. In our polyclinic, the first interview with the subject is face-to-face, and subsequent communications are preferably face-to-face, but if not, they are via telephone contact. Each subject was assigned support meet-

ings both face-to-face and via telephone contact, and the total number of communications was reported as the number of support meetings. Different ways of conducting these support contacts may have an influence on success rates.

In addition, analysis of nicotine withdrawal symptoms, such as weight gain, which could influence relapse, could not be performed, since data analysis was retrospective, and this information was not available. A prospective study including different parameters that may affect relapse is necessary to take account the many variables that may influence a relapse during this complicated time.

There is also the question as to what extent our results can be generalized. Certainly, the behavior of smokers is expected to differ around the world and even within Turkey. At this point, it should be noted that Istanbul is the most cosmopolitan city in Turkey, and our hospital is one of the most important reference centers for pulmonary diseases in the country. On the other hand, our results are remarkable in that they emphasize the close follow-up of a specific subject group in whom the success rate is not high, despite various treatment methods that are commonly administered today.

Conclusions

The relapse rate at the end of 1 y was 51.4% in our smoking cessation center. In accordance with previous studies, alcohol intake presents a risk for relapse. The relapse rate did not differ in those subjects receiving pharmacotherapy; however, the presence of adverse effects from these agents was thought to be notable for relapse. Planning more frequent support contacts for subjects receiving medical treatment and paying attention to the development of adverse effects may increase success rates in smoking cessation programs.

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