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**What Factors Influence Non-Adherence to the Smoking Cessation Program?**

**Short title:** Non-Adherence to Smoking Cessation Programs

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## **Abstract**

**OBJECTIVES:** To improve our knowledge and understand how to deal with non-adherence to the support programs and to determine the rate and possible factors related to non-adherence in subjects who attended our smoking cessation clinic.

**MATERIAL AND METHODS:** This was a case-control study that included 550 subjects who applied to our smoking cessation clinic between June 1, 2011 and December 31, 2011. After a 1-year follow-up period, subjects were divided into two groups: adherent (controls) and non-adherent (cases).

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Sociodemographic and clinical parameters and smoking habits were evaluated. A p value <0.05 was considered significant.

**RESULTS:** Of the 550 subjects, the number of cases (non-adherent) was 135 (24.6%), and the number of controls (adherent) was 415 (75.4%). Age to begin smoking was significantly young in subjects with non-adherence to the program ( $p=0.026$ ). The rate of receiving pharmacotherapy was significantly high in subjects with adherence ( $p<0.0001$ ). No difference was found between the groups according to varenicline, bupropion, nicotine gum, or combined therapy use, whereas nicotine patch use alone significantly increased the rate of non-adherence ( $p=0.022$ ). Multivariable logistic regression analysis showed that the age to begin smoking ( $p=0.045$ , odds ratio (OR): 1.05, 95% confidence interval (CI): 0.86-0.99) and pharmacotherapy ( $p<0.0001$ , OR: 5.00, 95% CI: 2.80-8.94) were independent variables that affected adherence to the program.

**CONCLUSION:** Care should be taken in the follow-up period when providing no pharmacotherapy and with subjects who started smoking at a young age.

**KEYWORDS:** Drug therapy, nicotine patch, patient non-adherence, smoking, smoking cessation

## INTRODUCTION

Smoking is the leading cause of preventable deaths of nearly 6 million people worldwide each year. Addiction to tobacco products represents a global public health problem. According to the World Health Organization (WHO), an estimated one-third of the adult population worldwide consists of smokers. If the present smoking pattern persists, it is expected that in 2020, approximately 10 million people will die worldwide each year. Reducing tobacco use and tobacco-related deaths are a first priority for WHO [1].

In Turkey, smoking is responsible for 25% of deaths annually. The National Strategy for Tobacco Control was launched in 2007. Although the prevalence of smoking decreased considerably from 31.2% in 2008 to 27.1% in 2012, it is still too high [2,3]. For these reasons, smoking cessation support programs have been employed by physicians in primary care units and hospitals country-wide for years [4].

Although it is supposed that patient compliance is a factor that determines the success of smoking cessation programs, knowledge is limited for dealing with non-adherence of participants [5]. One of the reasons of scarce knowledge is non-adherence that is often treated as missing data and excluded from most studies. However, findings show that a significant number of participants did not attend their scheduled follow-up sessions [6-8]. Predictors of non-adherence were found to be of low socioeconomic status and to have insufficient knowledge about health risks [9]. A study from Turkey reported that the mean age, smoking pack-years, and Fagerstrom Nicotine Dependence scores (FNDS) were lower in non-adherent participants than in participants who remained in the follow-up [8]. In addition, there was a positive correlation between adherence to treatment and tobacco abstinence [10].

We have noticed that there were many non-adherent subjects in our clinic. To understand what factors affect subjects' compliance may provide a chance to improve our smoking cessation program.

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In the present study, the primary outcome was to evaluate the rate of non-adherence, and the secondary outcome was to determine the factors that are associated with non-adherence to the program.

## **MATERIALS AND METHODS**

### **Study Design**

This was a case-control study conducted in the Smoking Cessation Clinic of a tertiary care hospital.

### **Study Population**

Subjects who participated in the smoking cessation program from July 1, 2011 to December 31, 2011 were included in the study.

### **Inclusion and Follow-up**

In accordance with the National Tobacco Control Program in Turkey [4], subjects included in the study followed the standardized follow-up protocol, and attendance was free of charge. The smoking cessation program was based on a cognitive-behavioral approach and pharmacotherapy. The program was implemented by a chest physician who specializes in smoking cessation. According to the degree of nicotine dependence and/or presence of contraindications for medication, the decision to provide pharmacotherapy was decided by the physician. In the first meeting, the danger of smoking, benefits of quitting, and the importance of making the decision to quit were explained to all subjects who participated voluntarily in the program. In addition, a quit date was assigned for each subject in this meeting. To improve motivation, meetings were recommended once within the first 15 days following the quit date, once every month for the proceeding next 3 months, and once every 3 months in the following 9 months. Cognitive-behavioral therapy and psychological support were provided every interview. For the first interview, subjects were called for a face-to-face meeting, and those unable to attend the support meeting were phoned by a polyclinic nurse. After the initial meeting, subsequent support contacts were made either through face-to-face or by phone. At the end of the 1-year period, subjects who did not participate in any support meetings after the initial meeting and with unknown smoking status were defined as non-adherent to the smoking cessation program (*cases*). On the other hand, subjects whose smoking status was known (quit smoking or resumed smoking) and who had at least two support contacts were classified as adherent to the program (*controls*). Using previously collected data, cases and controls were compared retrospectively according to various parameters to assess the factors that may influence non-adherence to smoking cessation support programs.

### **Data**

Sociodemographic characteristics including age, gender, educational level, and occupation were recorded. Occupations were categorized as blue collars, white collars, housewives, and others (e.g., student, retired, police, and soldier). Questions regarding smoking history (age to begin smoking, number of smoking years, daily cigarette count, presence of the thought or idea of quitting in the past, prior attempts to quit, and longest abstinence duration in the past) were asked. The FNDS, Beck Depression Scale (BDS), presence of household smoking, presence of respiratory symptoms and concomitant diseases, alcohol intake (alcohol consumption is defined as having up to one drink per

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day), pulmonary function test (PFT), whether they received pharmacological treatment in addition to psychological support to quit, and type of the pharmacotherapy were determined.

### Statistical Analysis

Descriptive statistics are described as frequencies, percentages, mean values, and standard deviations. The chi-square test was performed for between-group comparisons of categorical variables. The t-test and Mann-Whitney U test were used for comparison of continuous variables between the groups. Multiple backward stepwise logistic regression analyses were performed to detect any associations between variables and to express their mathematical model. A p value <0.05 was considered statistically significant. All statistical analyses were made using the IBM Statistical Package for the Social Sciences version 20 software package (IBM SPSS Statistics Corp.; Armonk, NY, USA).

### Ethics

The study was approved by the local Ethics Committee of the Dr. Lütfi Kırdar Kartal Education and Research Hospital and was conducted in accordance with the ethical principles of the Declaration of Helsinki. Informed consent was not required since this was a retrospective study.

### RESULTS

A total of 550 (289 male and 261 female) subjects who participated in the smoking cessation program within our institution were included in the study. The mean age of the subjects was 41.5±10.8 years. At the end of the 1-year follow-up period, the number of cases (non-adherent) was 135 (24.6%), and the number of controls (adherent) was 415 (75.4%).

When we compared the groups according to age, gender, smoking history, alcohol consumption, educational level, and occupation, there were no differences observed (Tables 1 and 2). In subjects who were non-adherent to the program, the age to begin smoking was found to be significantly young ( $p=0.026$ ). In both groups, half of the subjects had at least one smoker in their home. The presence of pulmonary symptoms and the mean values of PFT parameters were not different between the two groups. In addition, there was no difference in FNDS and BDS between the two groups. A total of 472 (85.8%) subjects received pharmacotherapy, and adherence to the program was found to be significantly higher in those subjects who received pharmacotherapy (91.3% vs. 69.6%,  $p<0.0001$ ). However, there was no difference with the use of varenicline, bupropion, nicotine gum, or combined therapy (bupropion+nicotine patch, varenicline+nicotine patch, and nicotine patch+nicotine gum). Adherence to the program was significantly low with nicotine patch use alone ( $p=0.022$ ) (Table 3).

Multivariable logistic regression analyses showed that the age to begin smoking ( $p=0.045$ , odds ratio (OR): 1.05, 95% confidence interval (CI): 0.86-0.99) and the provision of pharmacotherapy ( $p<0.0001$ , OR: 5.00, 95% CI: 2.80-8.94) were independent variables that affected adherence to the program. Although no statistical significance was achieved, the duration of smoking was close to being a significant factor ( $p=0.055$ , OR: 1.03, 95% CI: 0.95-1.00) (Table 4).

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## DISCUSSION

We observed that the ratio of subjects with unknown smoking status due to non-adherence to the smoking cessation support program was remarkably high. The aim of the present study was to evaluate the reasons for this non-adherence. We found that a younger age to begin smoking and the absence of pharmacotherapy were significant factors affecting non-adherence to the program.

Adherence is traditionally defined as “the extent to which a person’s behavior corresponds with agreed recommendations from a health care provider” [11]. In the present study, non-adherence was defined as having attended less than two meetings in the 1-year follow-up period and an unknown smoking status. While the ratio of adherence to smoking cessation support programs varies between 47% and 70% in the literature [12-14], we established that almost 25% of the subjects did not complete the program. In Turkey, according to another study, in a total of 1324 participants, 40.8% did not attend the program after the first visit [8]. We believe that this is a significant challenge for smoking cessation programs. One study reported that low adherence to a therapeutic program was found to be associated with the maintenance of tobacco use at 6 and 12 months [13], whereas another study stated that fully adherent users of technology-based behavioral change interventions were over four times more likely to quit smoking [15]. Another study reported that the number of treatment sessions and performance of treatment tasks were related to prolonged abstinence [16].

Results of studies on gender differences in smoking cessation are controversial. In some studies, male gender was associated with a high risk of relapse or non-adherence [17,18], whereas other studies reported that there was an inverse or no relationship between gender and smoking cessation [8,13,19-21]. There is a great deal of research about the sociodemographic characteristics and the success of quitting, but data regarding sociodemographic parameters and smoking cessation program adherence are scarce. In one randomized placebo-controlled study, lower adherence to treatment (both pharmacological and behavioral) was associated with higher daily smoking, greater withdrawal symptoms, and receiving placebo instead of an active nicotine patch [14]. In another study, the age of first use of cigarettes, years of addiction, living with other smokers, educational level, number of quit smoking attempts, and alcohol consumption had no influence on smoking cessation [13]. A study including 281 female subjects reported that greater nicotine dependence and lower educational levels predicted dropout from treatment or continued smoking versus quitting [22]. Conversely, another study concluded that the FNDS of the dropout group was lower than that of the follow-up group [8]. Treatment completion rates were found to be similar in both light and heavy ( $\geq 20$  cigarettes per/day) smokers [23]. There was no any association with the subjects’ demographic data, educational level, occupation, daily cigarette count, total duration of smoking, FNDS, previous quitting attempts, and living with a smoker with adherence to the smoking cessation program. We think that different study populations and research protocols may explain these conflicting findings. Although a relationship between alcohol intake and smoking relapse has been observed in many studies [16,24-27], we found no association with adherence to the program and alcohol use in our study.

Audrain-McGovern et al. [28] evaluated the predictors of participation in a smoking cessation program among young adult smokers (between 18 and 30 years old) and concluded that the mean age of participants is significantly higher than that of non-participants. Correspondingly, Bahadır et

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al. [8] reported that the mean age of the discontinued group is lower than that of the follow-up group. We found no association between the mean age of the subjects and adherence to the program. The age to begin smoking has also been reported as a determining factor for relapse [29,30]. Among female prisoners enrolled in a smoking cessation trial, older age of smoking initiation and higher baseline smoking predicted counseling adherence [31]. The likelihood of smoking cessation was greater in smokers who had started cigarette smoking after the age of 13 years than in those who had started earlier [32]. Although some researchers reported that the age of first use of cigarettes was associated with quitting smoking [33], Lopez-Torrecillas et al. [16] concluded that the age to begin smoking is not related to relapse. In the present study, we found that the age to begin smoking was significantly young in subjects with non-adherence. These discrepancies about age and smoking cessation may be due to the fact that smokers are a heterogeneous group. We also consider that early initiation of cigarette smoking may be associated with a greater potential for compliance problems, including heavy daily consumption, longer duration of smoking, and nicotine dependence.

In our smoking cessation clinic, we provide a combined cognitive-behavioral and pharmacological treatment, which we currently believe to be the best option to quit smoking [16]. In the present study, the specific treatment designated for each subject and the decision to provide pharmacotherapy was made by the physician according to the nicotine dependence of the subject and the presence of contraindications for drug therapy. We found that 85.8% of the subjects received pharmacotherapy, and they were five times more likely to adhere to the smoking cessation program. Nicotine replacement therapy (NRT) is reported as a cost-effective strategy that is associated with treatment success [25,34]. Interestingly, we found that the ratio of non-adherence to treatment was significantly high when only the nicotine patch was used alone. Bahadir et al. [8] also observed that NRT is more common in the discontinued group than in the follow-up group. Although this finding appears controversial, it may be due to the relatively low adverse effects of nicotine patches and higher tolerability [35]. Systemic therapy with varenicline and bupropion may be more uncomfortable than NRT because of adverse effects, such as nausea, abnormal dreaming, depression, tremor, headache, or anxiety. For this reason, subjects using varenicline or bupropion may need to see the physician and attend to their control visits regularly.

One of the limitations of the present study was that this was a single-center, tertiary care hospital study that could have resulted in our findings not being representative of a generalized population. Further limitations include unequal numbers of subjects with different types of pharmacotherapy and a small number of subjects with nicotine gum or combined therapy use as associated with the study design. On the other hand, to the best of our knowledge, there is currently limited information regarding the effect of the factors we have assessed in the present study on adherence to smoking cessation programs. An understanding of these factors may lead to better adherence interventions and improve the success of attempted smoking cessations.

In conclusion, variables regarding the subjects and/or support programs may affect the rate of adherence to smoking cessation programs. Providing pharmacotherapy to subjects without contraindications to medication use (with approval from the physician) and being more careful in the follow-up period with the subject's age to begin smoking was young may improve adherence to smoking cessation support programs.

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**Ethics Committee Approval:** Ethics committee approval was received for this study from the ethics committee of Dr. Lütfi Kırdar Kartal Education and Research Hospital (14.10.2014-89513307/1009/346).

**Informed Consent:** Due to the retrospective design of the study, informed consent was not taken.

**Peer-review:** Externally peer-reviewed.

**Author Contributions:** Concept - N.D.K. ; Design –N.D.K ; Supervision – N.D.K., Ü.A.A ; Resources – N.D.K., Ü.A.A ; Materials – N.D.K. ; Data Collection and/or Processing – N.D.K, Ü.A.A ; Analysis and/or Interpretation – N.D.K., Ü.A.A. , ; Literature Search – N.D.K., Ü.A.A. ; Writing Manuscript – N.D.K. ; Critical Review – N.D.K., Ü.A.A. ; Other – N.D.K., Ü.A.A.

**Conflict of Interest:** The authors have no conflicts of interest to declare.

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**Table 1:** Group comparisons according to categorical variables

<b>Variables</b>	<b>Adherent (Controls) n=415 (n, %)</b>	<b>Non-adherent (Cases) n=135 (n, %)</b>	<b>p*</b>
Gender			
Male	221 (53.3)	68 (50.4)	0.62
Female	68 (46.7)	67 (49.6)	
Cigarette count (daily)			
Max 10	45 (10.9)	15 (11.4)	0.99
11-20	181 (44.2)	57 (43.1)	
21-30	132 (32.2)	43 (32.6)	
>30	52 (12.7)	17 (12.9)	
Presence of household smoking	209 (50.4)	72 (53.3)	0.48
Presence of alcohol intake	105 (25.3)	27 (20.0)	0.25

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Presence of the thought of quitting in the past	353 (85.0)	109 (80.7)	0.47
Longest abstinence duration in the past			
<1 month	186 (60.8)	59 (63.4)	
1-6 months	84 (27.5)	25 (26.9)	
7-12 months	19 (6.2)	2 (2.2)	0.54
>12 months	17 (5.5)	7 (7.5)	
Education level			
Primary school	104 (25.7)	35 (27.6)	
Secondary school	48 (11.9)	20 (15.7)	0.32
High school	133 (32.9)	37 (29.1)	
University	119 (29.5)	35 (27.6)	
Occupations			
Housewives	84 (21.0)	33 (25.2)	
White collars	81 (20.2)	14 (10.7)	
Blue collars	35 (8.8)	10 (7.6)	0.08
Others	200 (50.0)	74 (56.5)	
Presence of concomitant diseases	185 (44.6)	67 (49.6)	0.32
Presence of symptoms	187 (45.1)	71 (52.6)	0.31
Dyspnea	142 (36.9)	53 (39.2)	0.35
Cough	119 (30.9)	43 (31.9)	0.16
Sputum	124 (32.2)	39 (28.9)	0.59

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Normal pulmonary functions test	272 (65.5)	79 (58.5)	0.48
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\*Chi-square test

**Table 2:** Group comparisons according to continuous variables

Variables	Adherent (Controls) (n=415) Mean (SD)	Non-adherent (Cases) (n=135) Mean (SD)	p*
Age, y	41.9 (10.7)	40.1 (10.9)	0.08
Age to begin smoking, y	18.4 (5.1)	17.3 (4.7)	<b>0.026</b>
Duration of smoking, y	23.6 (10.7)	22.7 (11.5)	0.97
Cigarette pack/years	29.4 (18.1)	28.1 (18.5)	0.49
Number of prior quitting attempts	2.9 (3.2)	3.7 (3.8)	0.09
FNDS	5.7 (2.4)	5.5 (2.5)	0.45
BDS	11.6 (8.4)	12.6 (8.2)	0.21
FVC, L	3.4 (1.0)	3.5 (1.1)	0.35
FVC, % predicted	85.9 (15.5)	87.4 (16.5)	0.45
FEV <sub>1</sub> , L	2.9 (0.9)	3.0 (0.9)	0.45
FEV <sub>1</sub> , % predicted	87.5 (16.8)	88.0 (18.6)	0.76
FEV <sub>1</sub> /FVC	85.3 (8.7)	84.5 (9.4)	0.39

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\*T-test, Mann-Whitney U Test

Abbreviations: BDS: Beck depression score, FEV1: Forced expiratory volume in 1.second, FNDS: Fagerstrom nicotine dependence score, FVC: Forced vital capacity, L: Liter, SD: Standard deviation, y: years.

**Table 3:** Group comparisons according to the treatment-related variables

Variables	Adherent (Controls) n=415 (n, %)	Non-adherent (Cases) n=135 (n, %)	p*
Pharmacotherapy			
Yes	378 (91.3)	94 (69.6)	<b>&lt;0.0001</b>
No	36 (8.7)	41 (30.4)	
Varenicline use			
Yes	169 (44.8)	35 (37.2)	0.20
No	208 (55.2)	59 (69.8)	
Bupropion use			
Yes	112 (29.7)	26 (27.7)	0.80
No	265 (70.3)	68 (72.3)	
Nicotine patch use			
Yes	69 (18.3)	28 (29.8)	<b>0.022</b>
No	308 (81.7)	66 (70.2)	
Nicotine gum use			
Yes	13 (3.4)	1 (1.1)	0.32

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No	364 (96.6)	93 (98.9)	
Bupropion+Nicotine patch use			
Yes	10 (2.7)	4 (4.3)	0.49
No	367 (97.3)	90 (23.9)	
Varenicline+Nicotine patch use			
Yes	9 (2.3)	1 (1.1)	0.69
No	368 (97.6)	93 (98.9)	
Nicotine patch+Nicotine gum use			
Yes	8 (2.1)	1 (1.1)	1.00
No	376 (99.7)	93 (98.9)	

\*Chi-square test

**Table 4:** multivariable logistic regression analyses

Variables, step 9*	p	OR	95% CI
Age to begin smoking, y	0.045	1.05	0.89-0.99
Duration of smoking, y	0.055	1.03	0.95-1.00
Pharmacotherapy	<b>&lt;0.0001</b>	5.00	2.80-8.94

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\*Variables entered on step 1: Age, gender, age to begin smoking (years), duration of smoking (years), number of quitting attempts in the past, cigarette count (daily), Fagerstrom nicotine dependence score, Beck depression score, respiratory symptoms (yes/no), comorbidity (yes/no), alcohol intake (yes/no).

OR: Odds ratio, CI: Confidence interval.

UNCORRECTED

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