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ORIGINAL INVESTIGATION

Can a Computer-Based Prescription of Free Medication Increase Smoking Cessation Rates Efficiently?

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Abstract

OBJECTIVES: In 2011, in the context of a research project, bupropion and varenicline were distributed to smoking cessation clinics by the Ministry of Health of Turkey to be prescribed free of charge by a computer-based system. In the present study, we compared smoking cessation rates between patients who were prescribed free medications during the period of the project and those who had to pay for their medication.

MATERIAL AND METHODS: Six hundred four patients who applied during the project period were given either bupropion or varenicline, which were prescribed using an algorithm-based computer system. Three hundred sixteen patients who applied after that period were prescribed medicines deemed appropriate by the attending physician but had to pay for the medication on their own. Follow-up visits were arranged for one year. Carbon monoxide (CO) levels in the expired air were used as indicators of cessation.

RESULTS: A total of 537 patients began treatment, of which 438 (81.6%) applied during the first period (group 1) and 99 (18.4%) applied during the second period (group 2). The mean age and concomitant disease presence were higher in the second-period patients ($p< 0.05$). Advanced age, comorbidities, pathological findings in spirometry, and chest X-ray were also higher in those who paid for the cost of their treatment ($p= 0.009$, 0.001, 0.006, 0.001, respectively). Smoking cessation rates were found to be 14.8% and 27.3% after six months ($p= 0.008$) and 10.7% and 18.2% after one year ($p= 0.059$), respectively, for group 1 and group 2. Age, dependence score, cigarettes smoked (as pack-years), and percentage of patients who paid for the treatment were found to be significantly higher ($p< 0.001$, 0.021, 0.018, 0.001, respectively) for those who quit smoking at the end of six months. For the patients who quit smoking at the end of one year, age was found to be significantly higher ($p= 0.008$), and the number of males was higher, although the difference was not statistically significant ($p= 0.05$). When logistic regression analysis was applied, age, dependence score, and paid treatment were found to be independent variables ($p= 0.002$, 0.008, 0.012, respectively) for those who quit smoking at the end of six months. Only age was found to be an independent variable for those who quit smoking at the end of one year ($p= 0.029$).

CONCLUSION: More smokers could receive treatment by the distribution of free drugs. However, quitting rates at the end of six months were higher when patients had to pay for their treatment. On the other hand, quitting rates at the end of one year were not affected by whether the treatment was paid for or free of charge. The most important factor increasing quitting rates at the end of six months and one year was found to be advanced age.

KEY WORDS: Smoking cessation, smoking cessation policies, treatment efficiency

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INTRODUCTION

Tobacco dependence is a chronic and recurrent disorder that is the foremost preventable cause of death worldwide. In the whole world, 70% of all smokers want to completely quit smoking. Each year, 40% of them try to quit, but only 3-5% can successfully sustain cessation for a long term on their own [1,2]. However, success rates of 15% to 30% can be achieved by administering treatments recommended by guidelines [3,4]. The most effective method for smoking cessation is a multidisciplinary approach encompassing psychological, behavioral, and pharmacological therapies [1-6].

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Nicotine replacement therapy (NRT), bupropion, and varenicline combined with behavioral therapies are the first-line pharmacological treatments recommended in smoking cessation centers [3-7]. In clinical trials, long-term cessation rates in smokers with smoking-related disorders were reported to be 15-29%, 27-29%, and 43-48% for nicotine therapy, bupropion, and varenicline, respectively [5]. In addition to pharmacological treatments, intensive face-to-face or group interviews providing psychological support and phone call follow-ups increase smoking cessation rates [3-6].

Treating tobacco dependence is very important economically in that it can reduce the cost of treatment of chronic diseases and complications such as heart disease, pulmonary disease, cancer, and delayed wound healing. Without supportive systems and policies, individual clinicians may not be able to assess and treat tobacco dependence sufficiently. Just as clinicians must assume responsibility for the treatment of tobacco dependence, so also must health care administrators, insurers, and purchasers for crafting policies and providing resources that result in consistent and effective tobacco dependence treatment [3-5,8]. The updated guidelines [4] suggest that sufficient resources should be allocated for clinician reimbursement and systems support to ensure the delivery of efficacious tobacco use treatments.

A global adult tobacco survey conducted in 2008 showed that smoking rates in Turkey were 31.2% (47.9% in men and 15.2% in women) [9]. The Action Plan for National Tobacco Control Program was put into effect over the last five years in Turkey [10,11]. Smoking prohibition by law and increases in cigarette costs helped decrease smoking rates by 10.7% [9]. In this regard, cessation counseling and supportive interventions were paid by social security institutions as a component of this program [10,11]. However, the costs of pharmacological treatments are not yet included in the reimbursement programs of either Social Security Institution or private health insurance companies. In January 2011, according to a Council of Minister's decision, the Ministry of Health of Turkey purchased 350.000 boxes of bupropion and varenicline (150.000 of bupropion and 200.000 of varenicline) in the context of a research project. These medications were distributed to smoking cessation clinics to be prescribed free of charge by an online computer system [12].
With this study, we aimed to assess the effects of a computer-based free-of-charge provision of smoking cessation medications on smoking cessation rates.

MATERIALS AND METHODS

The study was planned according to the World Medical Association Declaration of Helsinki (2008). It is a retrospective cohort study.

Nine hundred twenty patients who applied to our smoking cessation clinic between April 2011 and June 2012 were included in this study. Six hundred four of these patients applied during the prescription of free pharmacological treatments between April 2011 and December 2011 (first nine-month period), while 316 applied between January 2012 and June 2012 (second six-month period) when they had to meet the cost of this treatment on their own.

On first interview, all patients were asked about their comorbidities and tobacco use statuses. The Fagerstrom test for Nicotine Dependence was used to assess their dependence scores [13]. Physical examinations and pulmonary function tests were performed (Sensor Medics Vmax22, CareFusion, San Diego, California,USA). The carbon monoxide (CO) level in expired air was measured (piCO Smokerlyzer, Bedfont Scientific Ltd, Harrietsham Maidstone Kent, England), and chest X-rays were taken. Interviews with patients, the interpretation of pulmonary function tests, and the measurement of CO levels in expired air were conducted by the same physician.

For group 1, comorbidities and tobacco use statuses of all patients were entered in to the hospital patient registration system and also to an online patient registration system regulated by the Ministry of Health. In total, 350.000 boxes of varenicline and bupropion were purchased on the context of the project by the Ministry of Health, and these were provided to smoking cessation clinics, including ours. These medications could be prescribed for a patient only when the aforementioned computer system deemed it appropriate. This computer system decided whether to prescribe varenicline or bupropion taking into account the patient's age, gender, smoking status, Fagerstrom score, comorbidities, and contraindications to either medication [12]. The system had no rules for selection of any of the two drugs in the case of absence of any absolute contraindication for bupropion. Smokers with a history of depression received none of them, and in those cases, the attending physician prescribed NRT. The provision was only free of charge if the patients were prescribed medications decided by the computer system. NRT was not included in the project, and if prescribed by the attending physician the cost had to be paid for by the patient.

The information on the group 2 patients was only entered in to the hospital patient registration system. This group was prescribed medications deemed appropriate by the attending physician after a face-to-face interview and they paid the cost on their own because the free medication provision period was over and the costs of the smoking cessation medications were not included in the reimbursement programs. The physician prescribed bupropion, varenicline, or NRT after taking all the medical characteristics into consideration, informing the patient about the drug side-effects, and asking for the patient's oral or transdermal drug choice. All patients were given an appointment to attend an interactive seminar in which epidemiology and the harmful effects of smoking; tobacco dependence, and the treatment options for cessation and the benefits of smoking cessation were discussed with the aid of visual slides. The seminars lasted 45 min and were performed twice weekly for groups of 8 to 10. After attending the seminar, group 1 patients were given the medications assigned by the computer system free of charge after their

informed consents were taken. Group 2 patients were given their prescriptions by the attending physician and they had to buy those medications from pharmacies. One hundred sixty-seven patients who could not receive any drugs by the system and 217 patients who learned that they could not receive free drugs in the second period refused to buy the medication or start the pharmacological therapy. All those who started the treatment in the first period were assigned to group 1, and those who started treatment in the second period were assigned to group 2. All patients were given control appointments once a month for the first three months, then once every two months for the following four months, and once every three months for the rest of the one year follow-up period. During the control visits, the patients were questioned about their smoking status and medication side-effects. CO levels in the expired air were measured. Patients with a CO level between 0 and 5 parts per million (ppm) were accepted as non-smokers, while those with ≥ 6 ppm were considered still to be smokers [14,15]. Patients who did not attend the control visits were considered as non-quitters. The data were entered into the hospital registration system. Analyses were performed after all patients were followed-up for one year.

Statistical Analysis

Data from the standardized medical reports were transferred to the Statistical Package for the Social Sciences (SPSS Inc, 17.0, Chicago Illinois, USA) program by the lead researcher. The data were analyzed for the frequency distributions. Comparisons were made for each period and for each group of patients who had therapy. The chi-square test was used in the analysis of the categorical variables. The Kolmogorov–Smirnov test was used to test normality of the numerical variables. For normally distributed variables, an independent samples t-test was performed. Logistic regression analysis was used for the confounding factors. The statistical significance level was taken as a p value < 0.05.

RESULTS

Between April 2011 and June 2012, a total of 920 patients applied to the smoking cessation clinic. The average age of all patients was 42.9 ± 11.5, of which 548 (59.6%) were males and 372 (40.4%) were females. The average amount of smoking was 28.2 ± 18.8 pack-years (mean package of cigarettes smoked per day times years of smoking), the mean Fagerstrom Nicotine Dependence Test score was 6.1 ± 2.3, and the average CO level in the expired air was 14.2 ± 8.5 ppm. For 32.8% of the patients, pathological findings consistent with small airway obstruction in 13.2%, obstructive disease in 18%, and restrictive disease in 3.4% were found in pulmonary function tests. In chest X-rays, 52.5% of the patients had pathological findings (increased aeration, increased bronchovascular markings, milimetric nodules, opacity, etc.). In 259 (28.2%) patients, comorbid diseases (COPD, asthma, cardiovascular disease, cancer, depression, cerebrovascular disease, diabetes, etc.) were present.

Out of all patients, 604 (65.7%) applied during the prescription of free pharmacological treatments by the online system (first period), and 316 (34.3%) applied when they were prescribed medication by the attending physician and had to meet the cost of this treatment on their own (second period). Mean age (42.3 years vs 44.0; p= 0.033), mean CO level in the expired air (13.4 ppm vs 15.3; p= 0.001), and the presence of concomitant disease (22.8% vs 38.6%; p= 0.001) were higher in the second period patients.

A total of 537 patients began treatment, of whom 438 (81.6%) applied during the first period (group 1), and 99

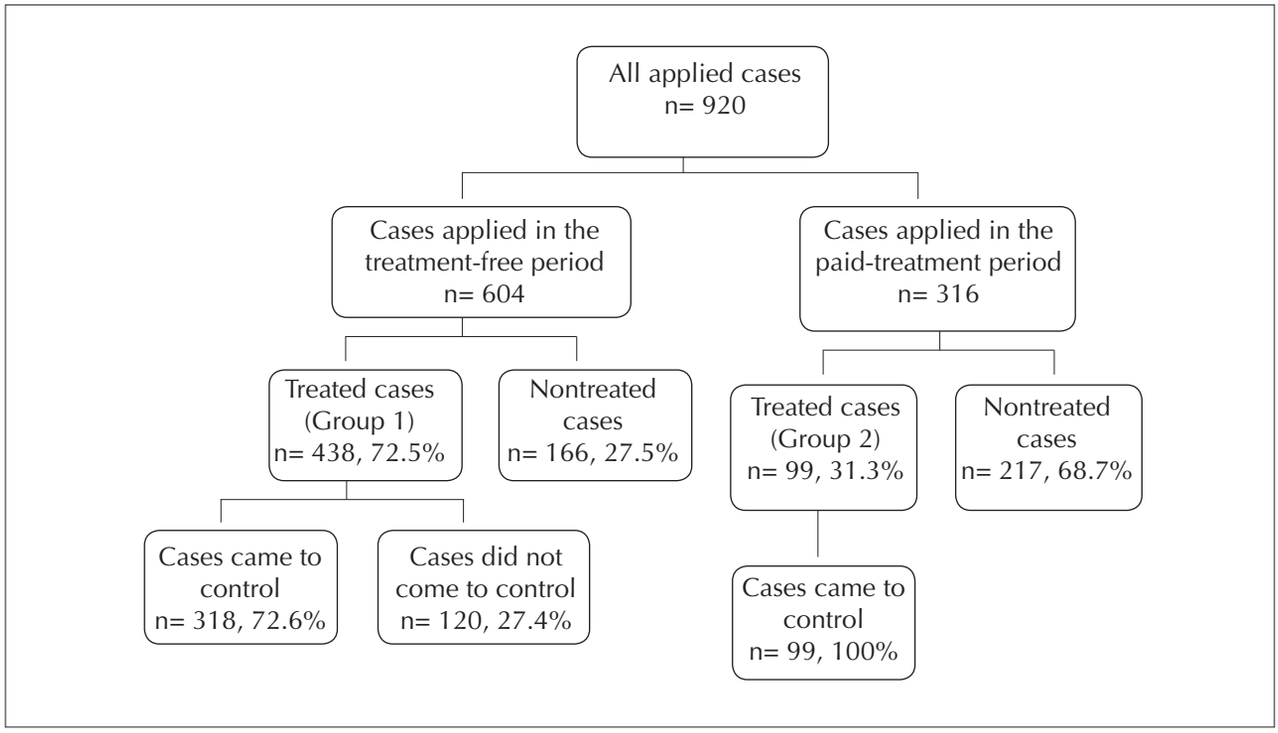

Figure 1. Distribution of smokers.

(18.4%) during the second period (group 2). Of all the treated patients, 417 (77.6%) attended control visits at least once. Three hundred eighteen (72.6%) of the group 1 patients and all group 2 patients attended the first control visit (Figure 1).

Of group 1 patients, 297 (67.9%) used varenicline, 140 (31.9%) used bupropion, and 1 (0.2%) used nicotine patches plus bupropion. Of group 2 patients, 32 (32.3%) used varenicline, 32 (32.3%) used bupropion, 28 (28.2%) used nicotine patches, 3 (3.1%) used nicotine patches plus bupropion, and 4 (4.1%) used nicotine patches plus nicotine gum. Considering the medications, the success rates after one year in the two groups were 13% and 12.5% for varenicline, 5.8% and 22.8% for bupropion, respectively, and 14.7% for NRT in the second period.

When the characteristics of the patients treated in the two groups were compared, in group 1, the patients were younger (43.0 ± 10.8 vs. 46.8 ± 13.4, p= 0.009). The presence of concomitant disease (26% vs. 45.5%, p= 0.001), the incidence of pathological findings in pulmonary function test (PFT) (23.5% vs. 42.4%, p= 0.001), and the presence of pathological findings in chest X-rays (39.8% vs. 56.5%, p= 0.006) were also higher in group 2. More patients used varenicline (67.9% vs. 32.2%, p< 0.001), and no patients used nicotine patch (0% vs. 32.3%, p< 0.001) in group 1. There were no differences between the two groups in terms of gender, average duration of smoking, Fagerstrom score, and bupropion usage (p> 0.05) (Table 1).

During the control visits, a total of 60 patients (11.5%) reported drug side-effects (tachycardia in 0.2%, sleep problems in 1.5%, depression in 0.7%, blood pressure related problems in 0.3%, headache in 0.5%, nausea in 2.9%, vertigo in 1.9%, and allergic reactions in 1.5%). The incidence of side-effects were not different in the two groups (10.7% vs. 15.2%, p= 0.214) (Table 1).

Smoking cessation rates for one month (43.5% vs. 75.8%, p< 0.001), for three months (25.4% vs. 42.4%, p= 0.002), and for six months (14.8% vs. 27.3%, p= 0.008) were higher in group 2. There was no difference statistically between the two groups after one year (10.7% vs. 18.2%, p= 0.059) (Table 2).

When the characteristics of six-month and one-year quitters/non-quitters were compared, age was greater for patients who quit at the end of six months and one year (p< 0.001, p= 0.003, respectively). The percentage of men was higher for those who quit smoking at one year. The difference was close enough to be statistically significant (p= 0.050). For those who quit at six months, the Fagerstrom score, cigarettes smoked (as pack-years), presence of pathological findings in chest X-rays, and the percentage of patients who paid were found to be significantly higher (p= 0.021, 0.018, 0.013, 0.012, respectively) (Table 3).

When logistic regression analyses were made, advanced age, higher Fagerstrom score, and paying for the cost of the treatment were found to be independent variables (p= 0.002, 0.008, 0.037, respectively) for those who quit smoking at six months. Only age was found to be an independent variable for those who quit smoking at the end of one year (p= 0.029).

DISCUSSION

The high smoking rates (31.2%) [9] in Turkey raise the need for free quitting drugs in national tobacco control programs. The current study compares the cessation success rates in a period when patients could receive free drugs distributed by the Ministry of Health and a second period when patients

Table 1. Characteristics of the treated patients

	All patients n= 537	Group 1 (free) patients n= 438	Group 2 (paid) patients n= 99	p
Mean age (years)	43.7±11.4	43.0±10.8	46.8 ± 13.4	**0.009**
Gender				
Male, %	56.6	55.4	61.6	0.322
Female, %	43.4	44.6	38.4	
Mean Fagerstrom score	6.2 ± 2.3	6.1 ± 2.3	6.3 ± 2.4	0.533
Mean smoking duration (pack-years)	28.0 ± 17.7	27.4 ± 17.6	30.9 ± 17.8	0.097
Concomitant disease, %	29.6	26	45.5	**0.001**
Pathological findings in chest X-ray, %	42.8	39.8	56.5	**0.006**
Pathological findings in PFT, %	27	23.5	42.4	**0.001**
Bupropion, %	32.2	32.1	32.3	0.487
Varenicline, %	61.3	67.9	32.3	**< 0.001**
NRT, %	32	0	32.3	**< 0.001**
NRT+Bupropion, %	4	0.2	3.1	**< 0.009**
Medicine side-effects, %	11.5	10.7	15.2	0.214

NRT: nicotine replacement therapy; PFT: pulmonary function test.

Table 2. Smoking cessation rates observed in treated patients

	All patients n= 537	Group 1 (free) patients n= 438	Group 2 (paid) patients n= 99	p
For one month, n (%)	287 (53.5)	190 (43.5)	75 (75.8)	**< 0.001**
For three months, n (%)	153 (28.4)	111 (25.4)	42 (42.4)	**0.002**
For six months, n (%)	92 (17.8)	65 (14.8)	27 (27.3)	**0.008**
For one year, n (%)	65 (12.2)	47 (10.7)	18 (18.2)	0.059

Table 3. Characteristics of the patients who had quit/had not quit smoking after six months and after one year

	Quitters 6 months 1 year		Non-quitters 6 months 1 year		p	
	n= 90	n= 61	n= 447	n= 476	6 months 1 year	
Mean age (years)	48.9 ± 11.4	47.8 ± 11.1	42.6 ± 11.1	43.2 ± 11.4	**< 0.001**	**0.003**
Gender						
Male, %	67.7	68.8	55	55.6	0.079	**0.050**
Female, %	32.3	31.2	45	44.4		
Fagerstrom score	5.5 ± 2.5	5.8 ± 2.2	6.3 ± 2.3	6.2 ± 2.3	**0.021**	0.334
Smoking pack-years	32.3 ± 17.8	31.3 ± 15.1	27.2 ± 17.6	27.6 ± 18.0	**0.018**	0.166
Comorbidities, %	36.6	31.1	28.6	29.8	0.129	0.833
Pathological findings in PFT, %	39	38.1	31.3	31.8	0.173	0.351
Pathological findings in chest X-ray, %	64.2	55.3	49.3	51.6	**0.013**	0.606
Cases who paid for the cost on their own %	27.7	24.5	16.5	17.6	**0.012**	0.188
Bupropion, %	32.2	26.2	32.4	33.1	0.968	0.274
Varenicline, %	62.2	68.8	60.6	59.8	0.777	0.176
NRT, %	8	8.1	6	6.3	0.318	0.573

NRT: nicotine replacement therapy; PFT: pulmonary function test.

had to pay for the drugs themselves. This study is the only study on this subject and is of great importance for predicting economic policies on tobacco control in Turkey.

To summarize our findings, more patients could access smoking cessation therapies when treatment costs were covered by the government (438 of 604 patients during the first period vs 99 of 316 patients during the second period); however, contrary to what was expected, the cessation rates were not found to be higher in the group 1. One-, three, and six-month success rates were statistically higher for patients who paid for their own drugs. One-year success rates were higher but not statistically different in the group 2. Independent variables that affect six month quitting rates were advanced age, higher dependence score, and the patient paying the cost of treatment. The sole factor that affects quitting rates at one year was found to be advanced age. The mode of payment (paid vs. free of charge) and drugs used were not found to affect quitting rates at one year.

Considering the fact that there are few drug alternatives, the idea of the prescribing smoking cessation medications by a computer that would run on an algorithm taking into account medication contraindications and patient comorbidities might sound intriguing. Taking into account the large number of smokers, it would require a substantial amount of manpower to be able to treat all smokers efficiently. The provision of smoking cessation medications free of charge would also greatly increase applications to smoking cessation clinics, as was shown in our study too.

The American Public Health Association on Tobacco Control consensus reports prepared in 2000 [3] and 2008 [4] indicated that when tobacco dependence treatments were covered by social security institutions and private health insurance companies, the success rates of smoking cessation increased. Over time, the widespread implementation of this approach provides a 2–3.5% decrease in the prevalence of smoking [16]. It was also shown that the support of employers, environmental incentives, and pursued politics are also important factors to reach more smokers [17,18].

Although the provision of free services to all smokers may be attractive, it is possible that they attract less motivated smokers than services for which co-payments are required, thus diluting their effectiveness. In the study by Curry et al. [19],

although they showed that the rates of smoking cessation were lower in patients for whom treatment costs were completely met by employers, more patients could quit smoking because more smokers were able to access free treatment. Similarly, in our study, more patients could be treated in the free period and more patients could quit smoking, but smoking cessation rates after one year were found to be very low, in fact lower than that in the second period (10.5% vs. 18.2%).

With smoking cessation treatments, only a small portion of smokers can sustain long-term abstinence; however, they prevent many smoking-related diseases. For such diseases, they are accepted as gold standard treatments in terms of cost effectiveness [20-23]. Moreover, more premature births can be prevented by the treatment of smoker pregnant women for cessation. Medicaid, which is a health insurance system in the USA, covers at least one type of treatment modality for smoking cessation in 37 states (In some states, only costs for smoking cessation for pregnant women are covered, while in others, all costs for every type of treatment for smoking cessation are covered for every patient) [24-27]. Because it was shown by studies that when tobacco dependence treatments were totally covered by insurance, success rates were much higher than when they were only partially covered and patients had to pay for a percentage of the treatment [28]. It was also found that cessation rates would dramatically decrease (especially for low-income populations) when patients had to pay even for a small percentage of the treatment; therefore, it was concluded that all costs should be covered by the insurance system [24-28].

In Turkey, over the last five years, only behavioral and supportive therapies have been covered by the insurance system, but not pharmacological therapies [11]. When our clinic was provided with the medications to be prescribed by the computer system, this project was already announced to the public [12]. Because of that, we think that those who applied to our clinic during the first period were less motivated than those who applied during the second period. While all those who began pharmacological therapy in the second period attended follow-up visits, only 72% of the patients who began pharmacological therapy in the first period attended follow-up visits. In the first period, patients who could not receive any free medications by the system neither bought the drugs nor attended the control visits. However, 31% of the patients in the group 2 paid for the drugs themselves, and all these patients attended follow-up visits. This can be explained by the fact that the patients in the latter group were more motivated. In addition, the higher percentage of advanced age, the presence of concomitant diseases, and the presence of respiratory problems in group 2 might indicate the higher decisiveness in this group.

In our study, contrary to the aforementioned studies, cessation rates for one, three, and six months were significantly higher in group 2 patients who had to pay for the treatment costs. Even if we conclude that those in group 2 were more determined, taking into account the presence of concomitant diseases in this group, the results are still surprising. We think that this discrepancy was caused by the attending physician being restrained by the computer system's decisions when prescribing medications for group 1 patients. All of the patients in group 1 were treated with bupropion or varenicline, even if the physician wanted to use NRT instead in some of the patients, because NRT was not free of charge these patients did not want to pay for it. More than two-thirds of patients who applied after the end of the project declined any treatment and/or follow-up visits when they learned that they would have to pay for their treatment. Only 31% of those patients could be treated. This finding again underscores the importance of the coverage of smoking cessation treatments by the insurance system.

The main limitations of this study are as follows: this is a single-center study; therefore, the results might not reflect the entire population. Due to the retrospective design of the study, some data loss could have occurred. Patients who had not attended follow-ups were considered as non-quitters. Patients in group 1 were younger, and this might have affected the success rates as well.

In conclusion, though more smokers could receive treatment, free drug distribution did not increase long-term smoking cessation rates as expected. We thought that the introduction of a computer-based system that restricts the physicians' decision making would reduce the success rate of treatments for smoking cessation in our clinic. The fact that the presence of advanced age and comorbidities were higher among those who paid for the drugs and the advanced age among one-year quitters implies that the aforementioned medications must be free, at least for this group of patients. On the other hand, many more people could reach medical care for smoking cessation, which shows that with an insurance system that would cover the treatment costs for smoking cessation, smoking-related diseases and deaths would be prevented for more people, which would also reduce the impact of smoking-related disease treatments on the economy. The fact that this project's success rates were lower than expected indicates that the method of the project should be questioned and the cost of the drugs should be covered by the insurance system after they are prescribed by the attending physician. More studies on wider case groups are needed to draw more convincing conclusions.

Ethics Committee Approval: Ethics committee approval was not received for this study because the procedure of this study has included routin practises of smoking cessation outpatient clinic.

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - B.S.; Design - B.S., B.Ç.; Supervision - B.Ç.; Resources - B.S., E.T.P., N.K.; Materials - B.Ç.; Data Collection and/or Processing - A.F., B.S., S.S.C., G.A.G.; Analysis and/or Interpretation - B.S., A.F., S.S.C.; Literature Search - B.S., N.K., E.T.P., E.S.; Writing Manuscript - B.S., A.F., E.S.; Critical Review - B.Ç.; Other - G.A.G., E.S.

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