



Evaluation and Comparison of the Effects of Three Different Medications on the Success of Smoking Cessation in Adults

KEYWORDS

varenicline; bupropion; nicotine replacement; smoking cessation

Seyhan Dulger

Bursa Sevket Yilmaz Training and Research Hospital, Department of Chest Disease

Mehmet Haksever

Bursa Sevket Yilmaz Training and Research Hospital, Department of Otorhinolaryngology, 16800 Yıldırım, Bursa, Turkey

Ercan Gündoğdu

Bursa Sevket Yilmaz Training and Research Hospital, Department of Otorhinolaryngology, 16800 Yıldırım, Bursa, Turkey

Davut Akduman

Bursa Sevket Yilmaz Training and Research Hospital, Department of Otorhinolaryngology, 16800 Yıldırım, Bursa, Turkey

Fevzi Solmaz

Bursa Sevket Yilmaz Training and Research Hospital, Department of Otorhinolaryngology, 16800 Yıldırım, Bursa, Turkey

ABSTRACT *Introduction: Although nearly half of smokers try to cease smoking every year, only 3% of them can achieve this goal by themselves. Presence of organized smoking cessation units where people considering to quit smoking can consult is a basic element of tobacco control work-up.*

Aim: In this study, patients whose initial visit to our center was in its first 6 months of service (February-July 2012) and have completed their 1 year of follow-up are evaluated retrospectively.

Materials and Method: 174 patients who had referred to our center between February and July 2012 and made at least one visit of follow-up were included and studied retrospectively.

Results: All patients underwent behavioral therapy. In addition to behavioral therapy, 94 patients (54.0%) were given varenicline tartrate, 63 (36.2%) were given nicotine replacement therapy (NRT), and 17 (9.8%) were given bupropion hydrochloride. 72 patients (41.3%) kept on being a non-smoker at the end of the first year (the success group) but 102 (58.7%) failed to do so (the failure group). No statistically significant difference was found between the success rates of the three medications

Conclusion: Both behavioral support and, unless contraindicated, pharmacological treatment should be applied to patients willing to quit smoking. For this purpose, number of smoking cessation centers should be increased.

Introduction

According to data obtained from the World Health Organization (WHO), smoking causes 6 million deaths per year and its annual economic burden is more than US \$ 500 000 worldwide. According to the estimations, approximately 1 billion people are going to die because of smoking in this century, unless preventive measures are applied.¹

Although nearly half of smokers try to cease smoking every year, only 3% of them can achieve this goal by themselves.^{2,3} All patients who want to cease smoking are advised to be medically treated except the presence of any medical contraindication or any condition where there is not enough evidence for efficacy such as pregnancy or adolescence.⁴ Beside the medical treatment, behavioral education and motivational support are also recommended.⁵

Presence of organized smoking cessation units where people considering to quit smoking can consult is a basic element of tobacco control work-up.⁶ In this context, Our Smoking Cessation Center has been in service in our hospital since February 9, 2012. In this study, patients whose initial visit to our center was in its first 6 months of service (February-July 2012) and have completed their 1 year of follow-up are evaluated retrospectively.

Materials and Methods

This study was designed respectively with 174 patients who referred to our Smoking Cessation Center between February and July 2012 and made at least two visits of follow-up. IRB was approved by the ethic committee. The cases were followed up until July 2013 by either their visits to our center or

by telephone conversations.

At their first visit, detailed medical history and physical examination findings of all cases were noted and evaluated. Fagerström Test for Nicotine Dependence⁷ (FTND) was applied. They were asked why they had started smoking, why they wanted to quit, and whether they had tried to quit before. Exhaled carbon monoxide (CO) measurements, routine blood tests, chest X-rays, spirometric measurements and electrocardiograms (ECG) were also assessed during that visits. Patients considered to have any psychiatric problem were referred to the psychiatrist and they were undergone psychotherapy or medical treatment if needed.

The decision of the treatment regime to be applied to each patient was made by the physician and the patient together, taking into account the physical examination, the FTND score, clinical test results, any present chronic illnesses of the patient, and if present, the recommendations and considerations of the psychiatrist about the patient. All patients underwent behavioral therapy. A target quit date (TQD) was arranged within 7-14 days after their first visit. A telephone conversation or second appointment was made with the patients on the TQD or within 2-3 days of time. Follow-up visits were arranged at the end of the 1st, 2nd, 3rd, and 6th months and at the end of the first year after the day of cessation. Patients were kept in contact by telephone in case of any failure to attend any appointment. They were asked whether they had smoked or not. Exhaled CO measurements were performed. They were congratulated for their success if they had not smoked. Motivation-increasing activities were done, such as giving them certificates of success at the 3rd and 6th

months of cessation. Patients who were failing or about to fail were given motivation and support. Treatment of choice for those patients was reconsidered and they were followed up at more frequent intervals. Any presence of side effects of the medications they had been taking was assessed.

For measurement of exhaled CO levels, piCO^{+TM} Smokerlyzer Breath CO monitor (Betfont Scientific LTD) was used. The unit of measurement was taken as "parts per million" (ppm). The patient was accepted as he/she had not smoked if the test result was under the level of 5 ppm. The ambient CO levels were not measured since all measurements were done in a closed, non-smoking room. For statistical purpose, Fisher's exact test was used for categorical variables and Student's t-test was used for continuous variables.

Results

During this retrospective period (February-July 2012) totally 359 cases visited our center. Nearly half of them were excluded from the study. (Table 1) Remaining 174 cases were taken in to study. The mean age of those 174 cases was 41.38 ± 10.9 years. 53 cases (30.4%) were females and 121 (69.6%) were males. (Table 2)

The mean amount of smoking measured as pack-year (The pack-year is a unit for measuring the amount a person has smoked over a long period of time. It was calculated by multiplying the number of packs of cigarettes smoked per day by the number of years the person has smoked) was 26.92 ± 19.43 . (Table 2)

The mean FTND score at the first visit was 6.17 ± 2.24 . 28 patients (10.4%) had a history of chronic illness, 19 of which had had a diagnosis of chronic obstructive pulmonary disease (COPD) before. The mean exhaled CO level was 14.91 ± 7.55 ppm. (Table 2)

All patients underwent behavioral therapy. In addition to behavioral therapy, 94 patients (54.0%) were given varenicline tartrate, 63 (36.2%) were given (NRT), and 17 (9.8%) were given bupropion hydrochloride. 72 patients (41.3%) kept on being a non-smoker at the end of the first year (Success group) but 102 (58.7%) failed to do so (Failure group). (Table 2)

Of the patients on varenicline tartrate treatment, 6 (6.3%) developed gastrointestinal side effects such as nausea and indigestion. 2 (2.1%) experienced insomnia and 1 (1.0%) developed weeping periods and signs of depression. In one patient on bupropion hydrochloride treatment (5.8%) allergic skin reactions were seen. No side effects were encountered in patients who underwent NRT.

The mean age of the success group was 41.07 ± 10.53 years, whereas it was 41.6 ± 11.19 years for the failure group (Table 2). ($p > 0.05$)

The success group composed of 20 female (27.7%) and 52 male (72.3%) patients, whereas the failure group had 33 female (32.3%) and 69 male (67.7%) patients (Table 2). ($p > 0.05$)

Patients in the success group had a mean smoking history of 25.99 ± 17.91 pack year and a mean FTND score of 5.97 ± 2.21 . For the failure group, these values were 27.53 ± 20.52 and 6.31 ± 2.26 , respectively (Table 2). ($p > 0.05$)

There was no statistically significant difference between the groups in terms of age, dependence level and smoking history.

43 (45.7%) of 94 patients given varenicline tartrate succeeded to cease smoking at the end of the 1st year, whereas 51 (54.3%) failed. 6 (35.2%) of 17 patients who had used bupropion hydrochloride quit smoking, but 11 (64.8) of them were still smoking at the end of the 1st year. The number of patients who ceased smoking with NRT was 23 (36.5%) and that

of the patients who could not was 40 (63.5%). No statistically significant difference was found between the success rates of the three medications (Table 2). ($p > 0.05$)

There was no statistically significant difference between the mean exhaled CO levels of the patients who succeeded to cease smoking (15.04 ± 6.77 ppm) and the patients who could not (14.82 ± 8.08 ppm) at first visit. ($p > 0.05$) On the other hand, when the exhaled CO levels were measured again at the end of the 1st year, the mean exhaled CO level of the success group (1.68 ± 0.68 ppm) was significantly lower than that of the failure group (13.51 ± 5.65 ppm) (Table 3). ($p < 0.05$)

9 (47.4%) of 19 patients with a prior diagnosis of COPD succeeded to quit smoking, whereas 10 (52.6%) of them failed. COPD as co-morbid disease did not alter success rates significantly (Table 4) ($p > 0.05$)

Discussion

Tobacco control is one of the most effective interventions in preventive medicine.⁸ Most of the smoker want and try to quit smoking but only 3-5% of unaided attempts reach 1-year success.^{9,10} Positive effect of pharmacological and behavioral therapy has been approved in smoking cessation. Various form of pharmaceutical including nicotine replacement therapy bupropion and varenicline can be preferred. Previous studies showed the superiority of these chemical compared to placebo on tobacco control as at least doubling the odds of remaining abstinent 6-12 months after quitting.¹¹⁻¹⁵

Before discussing our results, it should be focused on the cases that were excluded from our study. Two major reasons for exclusions were; first, the cases were willing to cease smoking but they could not be convinced to take chemicals (drugs) for this purpose. Second, the cases were willing to cease smoking, they could be convinced to take chemicals (drugs), but we lost our contact with them during follow-up. They neither came to second visit nor replied our telephones in called at two different times. We think, smoking dependence is not commonly accepted as a treatable disease in public. Interestingly, some of the cases rejecting the drug use were more afraid of the side effect of drugs than real effect of smoking. Regarding the smoking cessation patient-doctor confidence is still a great challenge. There are needs to inform the population about hazards of smoking and importance of smoking cessation centers on published and visual media.

Smokers should be clearly informed about the roles of doctor and treatment before deciding a therapy. Expectation of the cases either from doctor and treatment must be realized. Some of the smokers do not comprehend that they are going to quit smoking by the aid of treatment however they believe that doctor and drugs make and force them to quit smoking. Another group of patients see the doctors having a 'magic stick' and just by touching they will stop smoking spontaneously and suddenly. Smokers must clearly understand that medical treatment of the tobacco dependence sits on their volition and desire to quit smoking.

Another impediment for treatment of the smoking dependence is the cost of the treatment. In our country, charge for the treatment of smoking dependence is not still paid back by medicare or health insurance. Smokers have to buy their drugs (varenicline tartrate, nicotine patch, bupropion hydrochloride) with their own money. Although the average cost for three months treatment (US dollars 150-250 in our country) is nearly equal to that of cigarettes smoked at the same period, it is very hard to convince the smokers to spend their money for drugs.

In this study, we retrospectively reviewed the patients who had been seen in the first 6 months of our smoking cessation

center and followed up for 1 year. We found our overall success rate as 41.3% at the end of the 1st year. Jin-Kyoung et al¹⁶ reviewed 354 554 patients referring to smoking cessation centers in Korean Republic in 2009. They found the 6-month success rate as 40% and estimated the 1-year success rate to be 28.1%. In 2007 Cadden¹⁷ reported 30% success rate at 1 year, whereas Arguder et al¹⁸ reported a 3-month success rate of 36.5%. On the other hand, there are higher success rates reported, as much as 40% by Uzaslan et al¹⁹, 45.5% by Solak et al²⁰, and 41.2% by Salepçi et al²¹. Our overall success rate is similar or slightly higher than average of the literature. We think that factors such as patient selection, direct doctor-to-patient interaction, effective behavioral therapy and motivational support and readily availability of the doctor for the patient affect the success rates positively, as stated by Uzaslan et al¹⁹.

There was no statistically significant difference between the success and failure rates in terms of age and sex in our study. Arguder et al found that the average age of successful patients was higher than that of failed subjects¹⁸. Also in the studies by Raheison et al²² and Tilgren et al²³ successful patients were found to be older. This situation found in our study might be attributed to the fact that the consciousness level of the population about smoking hazards is continually increasing and people are willing more to quit smoking before the impacts of smoking become manifest. Although in some reports it was stated that men are more successful than women at cessation of smoking²⁴, a lot of studies including ours found no correlation of sex with smoking cessation success rates^{19,25}. In the same manner, there was no statistically significant difference between the groups by means of cigarette consumption measured as packs/year. Although there are studies stating that the Fagerström Dependency Score is correlated with cessation success^{26,27}, there are also studies reporting no significant difference between the groups for this item¹⁸, with which we agree in our study. In a randomized, controlled and high-volume study, it was reported that the duration (as years) as well as the daily amount of cigarette consumption is associated with cessation of smoking²². There was no statistically significant difference between the groups in terms of cigarette consumption in our study also. Arguder et al¹⁸ had the same results as ours.

While there are studies stating that patients with COPD are less successful than other patients²⁸, the success rate of our patients with COPD was not found to be different than that of our healthy smokers. This situation might be attributable to our small number of patients with COPD.

Using visual material in smoking cessation centers and taking CO measurements during the first and the following visits increases success rates.²⁹⁻³¹ Exhaled CO measurements of our patients were also performed during their first visits and follow-up appointments. Our aim was to increase the success rate as well as to confirm smoking status of the patients during follow-up. The patients were considered as still smoking if the follow-up measurement was above 5 ppm. There was no significant difference for initial CO measurement (i.e. the measurement at the 1st visit of the patient) between the success and failure groups. CO levels of the success group at the end of the 1st year were significantly lower than their initial levels of measurement. But there was no significant difference in the failure group between the initial level and the level at the end of the 1st year.

There are two basic approaches to cessation of smoking: behavioral support and medical treatment. Behavioral support aims to reinforce the patient about his/her goal of quitting smoking, to increase the motivation against the urge to smoke, and give the patient support while he/she is struggling with the outcomes of abstinence. Medical treatment is used to lower the intensity of withdrawal and to inhibit the urge to smoke. Three pharmacotherapies are used worldwide: nicotine replacement therapy, bupropion, and varenicline.

There are studies reporting that behavioral support and medical treatment can increase the efficacy of each other.³²

Cessation rates at the end of 1 year range 15-25% for patients treated with NRT.³⁴⁻³⁷ Success rates for bupropion and varenicline are 23.1%³⁰ and 26.1%²⁶, respectively.

All patients visiting our center received behavioral therapy, combined with one of the three pharmacological agents mentioned above. Success rates at the end of 1 year of treatment with varenicline, NRT and bupropion were found as 45%, 36.5% and 35.2%, respectively. We believe that our higher-than-literature success rates are due to the intensive work done to keep the patients highly motivated by the help of effective behavioral support. There was no statistically significant difference between the success rates of the three treatment modalities, although the success rate of varenicline plus behavioral therapy was slightly higher than that of NRT plus behavioral therapy and bupropion plus behavioral therapy. In the randomized multicenter study by Aubin et al³⁴, success rate was 2 times greater than placebo with NRT and bupropion, and 2.5-3 times greater than placebo with varenicline. Craving for smoking and symptoms of withdrawal were less in varenicline-treated patients compared to others. However, on evaluation of 1-year success rates there was no statistically significant difference between NRT and varenicline³⁴. In a more recent study, success with bupropion was found to be higher than placebo, but lower than varenicline³⁸. Our findings comply with the literature.

In the study by Smith et al³⁹ of varenicline-treated patients, 16.3% reported nausea, 6.1% reported headache, 4.1% reported vomiting, and 1% reported insomnia. Also in another study, nausea was found to be the most frequent side effect during the 12 weeks of treatment⁴⁰. In our study, nausea was the most frequently encountered complaint of varenicline-treated patients too. No side effects were encountered due to NRT, and one patient using bupropion developed allergic skin rash.

CONCLUSION

Our study demonstrates that success rate of quitting smoking increases from less than 3% to around 40% when the patients are supported and treated by specialists of smoking cessation during this difficult and challenging period of life. Both behavioral support and unless contraindicated pharmacological treatment should be applied to patients willing to quit smoking. For this purpose, number of smoking cessation centers should be increased.

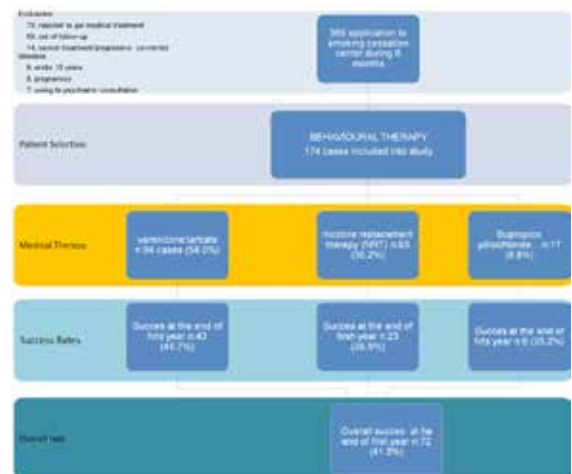


Table 1. Distributions of the all cases

Table 2: Distributions of the cases regarding age, sex, smoking habits and the types of treatment

	G _s (n,72)	G _F (n,102)	All cases (n,174)	P
Age (years)				
mean±SD	41.07 ±10.53	41.60 ±1.19	41.38±10.9	0.7530*
Gender (n%)				
Male	20/11.5	33/19.9	53/30.4	0.6163**
Female	52/29.9	69/39.7	121/69.6	
Smoking (packs per year)				
mean±SD	25.99±17.91	27.53±20.52	26.92 ±19.43	0.6080*
FTND				
mean±SD	5.97±2.21	6.31±2.26	6.17±2.24	0.3254*
Type of treat- ment (n%)				
Vareniklin	43/24.7	51/29.3	94/54.0	0.4585**
Bupropion	6/3.5	11/6.3	17/9.8	
NRT	23/13.2	40/23.0	63/36.2	
Total (n%)	72/41.4	102/58.6	174/100.0	

G_s: success Group, G_F: Failure Group, FTND: Fagerström Test for Nicotine Dependence NRT: Nicotine Replacement Therapy , * t test, **Fisher's Exact test p<0.05 is significant

Table 3: Exhaled CO level at first visit and at the end of first year in Success and Failure Group

Exhaled CO levels	Success group n,72	Failure group n,102	p
First visit (ppm)			
(mean±SD)	15.04±6.77	14.82±8.08	0.8504*
1 st year (ppm)			
(mean±SD)	1.68±0.68	13.51±5.65	<0.001*

CO: carbon monoxide, ppm: parts per million , *t test was used p<0.05 is significant

Table 4: The distribution of chronic obstructive pulmonary disease (COPD) as co-morbid disease for both groups

	Success group (n/%)	Failure group (n/%)	Total (n/%)	p
Yes	9/4.0	10/5.7	19/11.0	0.16438*
No	63/37.4	92/52.9	155/89.0	
Total	72/41.4	102/58.6	174/100.0	

COPD: chronic obstructive pulmonary disease , *Fisher's exact test was used, p<0.05 is significant

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