TRIAL OF TRANSDERMAL NICOTINE PATCH IN SMOKING CESSATION

Sawang Saenghirunvattan

Pulmonary Unit, Department of Medicine, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok 10400, Thailand

Abstract. In order to evaluate the efficacy of the transdermal nicotine patch, 37 persons who wore the patches (group 2) were compared with 40 persons who attended an organized smoking cessation program (group 1). At 1 month, 8 persons of group 2 (21.62%) and 22 persons of group 1 (55%) were able to stop smoking. At 3 months, 8 persons of group 2 (21.62%) and 17 persons of group 1 (42.5%) were still abstinent. At 6 months, 7 persons of group 2 (18.9%) and 14 persons of group 1 (35%) were able to quit smoking. Counselling and follow-up support are needed to maintain abstinence.

INTRODUCTION

About 40 million adult Americans have quit smoking. People who quit smoking live longer than those who continue to smoke. Quitting smoking decreases the risk of lung cancer, oropharyngeal and esophageal cancers, heart disease, stroke, chronic obstructive lung disease and other respiratory illnesses. However, cigarette smoking remains a difficult habit to break. Many smokers must try several times before they actually manage to quit. Although most people who discontinue smoking do so without the use of professional help, many smokers are unable to stop on their own seeking professional help. We compared the use of the transdermal nicotine patch with a non-medicinal anti-smoking program.

MATERIALS AND METHODS

Between April 1992 and December 1992, 77 patients came to attend our clinic and were screened for eligibility. To be eligible, subjects had to be current daily cigarette smokers, aged 18-70 years, in good health, motivated to stop smoking and willing to adhere to the trial protocol which included attendance at regular follow-ups. Exclusion criteria were a history of cardiovascular disease, hypertension, diabetes, significant allergies; current use of psychotropic medication, use of nicotine gum in the past year, current abuse of alcohol or other drugs and pregnancy.

As a control non-medicinal group (group 1) 40 patients were enrolled in an organized program which included physical rehabilitation in a whirlpool for an hour every evening, group therapy, psychotherapy and meeting with chest specialists and ex-smokers for discussion and explanation of lung and heart diseases caused by smoking. Methods of smoking cessation without using nicotine replacement were discussed. The program consisted of 5 consecutive evenings. Individual follow-ups were scheduled for 1, 3, 6 months after the start of treatment.

The trial group (group 2) consisted of 37 subjects. They agreed to use nicotine replacement as an aid to smoking cessation for the relief of nicotine withdrawal symptoms. A 10-20 cm diameter transdermal nocotine patch (Nocotinell) was applied to each smoker for 24 hours for a 4-week period. Members of this group were followed at the same periods as the control group.

Statistical analysis

Student's *t*-test was used to compare the characteristics between group 1 and 2. $p < 0.05$ was considered statistically significant.

RESULTS

Attendance

Control and trial subjects were well matched on demographic and smoking characteristics. The average age of the group 1 was 39.2 ± 10.8 years and of group 2 40.5 ± 9.6 years ($p > 0.05$).

Quit smoking rates (Table 1)

The immediate quit smoking rate for group 1 was higher than for group 2 (55% vs 21.62%, $p < 0.05$). At 3-months follow-up, the quit rate for the control group was lower, 42.5%, while it remained stable in the trial group at 21.62%. Among the trial group, we observed that those subjects with strong motivation could stop smoking at a higher rates (50%) than those with poor motivation (11.11%) and this remained unchanged for the first three months of observation. At 6 months, the quit rate for the group 1 was 35% and for the group 2 was 18.9%.

Tobacco withdrawal symptoms

Subjects on the transdermal nicotine patch experienced significantly less withdrawal symptoms during the first week of treatment than did the control group. After one week, the severity of withdrawal symptoms lessened and the difference between the two groups was no longer significant.

Weight gain

One subject on transdermal nicotine patches gained 10 kg body weight after successfully discontinuing smoking at the 6-months follow-up visit.

Side effects

Among 37 subjects using transdermal nicotine patches, side effects were reported in 3 persons. One reported itching of the skin at the patch site, another had headache when smoking a cigarette, and one felt dizziness.

DISCUSSION

Our five-day organized non-medicinal program for smoking cessation yielded a success rate of 55%, 42.5% and 35% at 1-month, 3-months and 6-months follow-up, which equals the rate reported previously (Loryon *et al,* 1993). A high success rate depends on the smokers, namely their motivation, level of counselling, physicians' advice and an intensive course of psychotherapy, group therapy and physical rehabilitation for 5 consecutive days. At first, we tried to combine the program with a trial of transdermal nicotine patches. We had hoped to obtain higher quit smoking rates. Actually, when the patients entered the organized program, they usually quit smoking from the first day and denied any means of nicotine replacement. We nevertheless recruited 37 patients who were willing to use the transdermal nicotine patches from the first visit. Subjects who were referred to the program because of pressure from relatives or spouses failed to stop smoking (success rate was 11.1% at 1-month and 7.4% at 6-month follow-up). Those who had strong motivation had a high success rate of 50% at 1-month and 6-month follow-up. Our study emphasizes the importance of a comprehensive behavioral smoking cessation program and also reveals that the transdermal nicotine patch may be useful as an aid for relief of nicotine withdrawal symptoms. Long term follow-up and

Table 1

Quit rates among smokers participating in an organized control program and those using transdermal nicotine patches.

	Quit smoking rates		
	1 month	3 months	6 months
1. Organized control program (n=40)	55%	42.5%	35%
2. Transdermal nicotine patch (n=37)	21.6%	21.6%	18.9%
2.1 Strong motivation (n=10)	50%	50%	50%
2.2 Poor motivation (n=27)	11.1%	11.1%	7.4%

counselling are still important to maintain abstinence.

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