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Smoking Cessation with Nicotine Replacement Therapy among Health Care Workers: Randomized Double-blind Study

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Aim. To assess the smoking prevalence and efficacy of nicotine replacement therapy on the quitting rate after 3 weeks of therapy and after 1- and 5-year follow-up among health care workers with a smoking habit in Split, Croatia.

Methods. Among 311 hospital health professionals included in the study, there were 112 (36%) smokers; 44 (39%) of them were physicians and 68 (61%) nurses. In a randomized double-blind study, 112 smokers were divided in 2 groups, applying daily either a transdermal nicotine system (TNS) or placebo patch over 3 weeks. Abstinence was evaluated via questionnaire and on the basis of carbon monoxide concentration measured in the exhaled breath.

Results. The abstinence rates after the 3-week intervention period were 39% in the TNS group and almost 20% in the control group (chi-square test, $p=0.038$). After one year, these rates declined to 23% and 16%, respectively ($p=0.476$), and converged to 18% and 14% ($p=0.797$), respectively, at 5-year follow-up.

Conclusions. Short-term TNS treatment is effective in smoking cessation, although the effects steadily wane over time and the relapse rate is high. Continuous, structured, and composite efforts are needed for the maintenance of the non-smoking behavior.

Key words: *double-blind method; health personnel; nicotine; smoking; smoking cessation; tobacco use disorder*

Tobacco use, notably cigarette smoking, is the leading cause of an array of preventable diseases. It is estimated that some 30-40% of world adult population smoke and the situation is particularly alarming in adolescents (1). Health professionals are not much better in this respect, although the opposite would be expected: it is estimated that over 30% of the Croatian physicians are current smokers (1). Similar situation can be found in other countries (2). Among hospital health care workers in Italy, 23.7% male physicians, 27.5% female physicians, and 36.1% nurses smoke (2). Some 40% of the Italian general practitioners and about 45% of their Spanish colleagues also smoke (2). Health care professionals are important opinion leaders in the community and their behavior more than their words has a significant impact on the life style of their patients. It is therefore discouraging to learn that so many doctors and nurses still smoke. Nevertheless, recent data from Croatia (3) are quite encouraging: only 13% of the Croatian Medical Association members are current and 28% former smokers, and 59% have never smoked.

Particularly important is the notion that smoking cessation is associated with unequivocal benefits, and that these gains begin to accrue rapidly. Thus, within 20 minutes of the last cigarette, the acute effects of nicotine begin to wear off, and heart rate, blood pressure, and body temperature return to normal. Respiratory function improves within 3 days, and breathing becomes easier. An improvement in circulatory function occurs within 3 months, and lung capacity may increase as much as 30% (4). Within 1-2 years, the excess risk of coronary events in former smokers declines by about 50% as compared with people who continue to smoke, and begins to approach that of never-smokers, as recently shown in the large, multinational INTER-HEART study (5).

Nicotine is a highly addictive substance, and smoking cessation is a challenging undertaking for individuals of all ages. In general, the approach to smoking cessation follows the "4 A model" (6):

Ask about tobacco use at every patient contact,

Advise all smokers to quit,

Assist quitting attempts (self-help materials, couseling, nicotine replacement therapy, and other drug interventions), and

Arrange for appropriate follow-up.

Although cessation rates based on physician's advice alone are quite low, failure to advise patients to quit still represents an important missed opportunity, which can be extremely cost-effective and valuable for the patients who decide to quit (7). Selected subgroups, such as patients with a recent myocardial infarction, are often highly motivated to stop smoking and for them direct counseling may be particularly helpful. Well-organized and adequately structured weekly non-smoking schools (7-9), conceptualized in the 1970s, and functioning in Croatia since 1988 in Zagreb and since 1995 in Split, achieve reassuring results in urban populations (20-30% quitting rates after 6 months).

Among several pharmacologic options enhancing these behavioral interventions, just a few are generally accepted. The most important are the various modes of nicotine replacement therapy, such as nicotine patches (transdermal nicotine delivery systems), nicotine gums, nicotine nasal sprays or nicotine inhalers, and non-nicotine interventions, particularly with bupropion. Based on the data pooled from randomized clinical trials, the net efficacy of various smoking cessation strategies over several months is encouraging (8,9). For example, in comparison with placebo, the quit rates increase 2.6-fold with nicotine patches after 6 months, 2.2-fold with nasal sprays, 2.1-fold with inhalers, and about 1.6-fold with bupropion (8,9). In most studies, the cessation rates in the control arm ranged from 5% to 20%.

Nicotine replacement therapy is currently the most studied and most widely used pharmacological approach to smoking cessation (9). The substance attenuates the withdrawal symptoms and there is no exposure to tar and carbon monoxide, which heavily contribute to the morbidity and mortality risk. Starting on any nicotine replacement therapy, patients must stop smoking immediately, be highly motivated, and supported by their healthcare providers. There are rare risks of nicotine toxicity with concomitant smoking or an overdose of nicotine replacement therapy (manifested by nausea, abdominal pain, vomiting, diarrhea, flushing, diaphoresis, dizziness, confusion, and/or palpitations), or of a withdrawal syndrome with nicotine underdose (similar signs and symptoms on top of craving, restlessness, irritability, sleep disturbances, impaired concentration, and/or increased appetite with weight gain) (9). The possibility of precipitating an acute coronary event by initiating nicotine replacement therapy in persons with a pre-existing condition may cause some concern. Recent studies have indicated that such therapy is generally safe (10,11). Nevertheless, it should not be started around the time of an acute myocardial infarction, coronary artery surgical procedures, or coronary angioplasty.

Transdermal nicotine systems, or nicotine patches, are the most popular formulations of nicotine replacement therapy. The patches are generally applied over 24 h and then substituted, delivering either 20-25 mg of nicotine per 24 h (30 cm^2 of active area), 13-15 mg/24 h (20 cm^2), or 7-8 mg/24 h (10 cm^2). The higher dosage is mostly recommended for the first 4 weeks of nicotine replacement therapy, followed by 2 weeks of each lower dose preparation (6,8-10). We have recently shown that a short-term transdermal nicotine system treatment of 3 weeks is as effective as a longer one (6 weeks): the dosage in the present trial was designed accordingly (12).

In addition to the assessment of the smoking status in a segment of Croatian health professionals, the aim of this study was to evaluate the efficacy of nicotine replacement therapy in the form of transdermal nicotine system in a subset of smoking medical workers, and determine the stability of an initially achieved abstinence rate over time (13-15).

Parcipants and Methods

We polled 320 health professionals in one of the Split University Hospital facilities, and 311 (97.2% response rate) returned the questionnaires about their smoking habits. There were 207 (66.6%) women and 104 (33.4%) men among the respondents, of which 119 (38.3%) were physicians (91 or 76.5% men, and 28 or 23.5% women), and 192 (61.7%) nurses (178 or 92.7% women, 14 or 7.3% men).

Out of 311 respondents, 112 (36.0%) were current smokers, ie, lighting at least one cigarette per day. Out of those 112 smokers, 44 were physicians (39.3%) and 68 were nurses (60.7%). There were no remarkable differences between the various subsets of these individuals: 38 out of 104 (36.5%) men and 74 out of 207 (35.7%) women among health workers were smokers; or 44 out of 119 (37.0%) physicians and 65 out of 192 (33.9%) nurses. The most frequent answers to a modified Fagerström questionnaire (13) indicated their degree of nicotine dependence (Table 1).

Subsequently, 112 respondents were individually approached; all of them have fulfilled the inclusion criteria for this trial (age over 18 years, smoking for at least 12 months, and decision to quit) and none the exclusion criteria (pregnant or lactating women, other drug dependence, major psychiatric disorders, and skin pathology interfering with patch placement). We explained them the study details, potential benefits, and possible transdermal nicotine system side-effects, such as skin irritation or

Table 1. Nicotine dependence features of smokers (n = 112) among health care professionals included in the study

Feature*	Percent of participants
Strong desire to quit	67.5
Already tried to quit	51.8
Friends are smoking	91.1
Fagerström score 6 points (slight dependence)	74.1
Fagerström score 6 points (strong dependence)	25.9
Average nicotine content per cigarette 0.6-1.1 mg	81.3
Always inhaling the smoke	74.1
Smoking mostly in the afternoon	50.9
First morning lighting within 30 min of awakening	5.7
Morning cigarette is the most missing	50.9
Smoking 16-25 cigarettes per day	48.2
No abstinence problems in prohibited areas	75.9
Not smoking while ill	88.4

*According to medical history or Fagerström score (13).

Table 2. Demographic and smoking characteristics of transdermal nicotine system (TNS) and placebo group

Feature	Group	
	TNS	placebo
No. of participants	56	56
Women/men ratio	37/19	37/19
Age in years (mean ± SD)	34.4 ± 4.7	33.8 ± 4.4
Cigarettes/24 h (mean ± SD)	24.1 ± 5.8	22.5 ± 5.7
Nicotine content per cigarette (mean ± SD)	0.8 ± 0.2	0.7 ± 0.2
Smoking years (mean ± SD)	16.4 ± 4.7	16.5 ± 4.1
Attempts at quitting (mean ± SD)	2.3 ± 2.2	2.3 ± 1.6
Level of dependence (mean ± SD)*	6.8 ± 1.5	6.9 ± 1.1

*According to Fagerström questionnaire (13).

insomnia. To our surprise, all smokers volunteered to take part in this randomized double-blind trial, which was approved by the hospital's Ethical Committee. The differences between the study groups in their main characteristics were minimal and statistically not significant (Table 2).

At the beginning of the study, each participant signed an informed consent form, filled out the questionnaire on smoking habits, and blew in a device measuring carbon monoxide content in the exhaled air (Ecolyser Model EC 50-DMP, Bedford Technical Instruments, Kent, UK). After that, each examinee received a presealed envelope, labeled after random numbering, which contained either 8 transdermal nicotine system patches or matching placebo stickers. Each active, self-adhesive, five-layer patch delivered nicotine at a rate of about 0.7 mg per cm^2 per 24 h. There were 3 different patch sizes (30, 20, and 10 cm^2). The placebo patches were of the same size and appearance; all study formulations were prepared by Novartis (at that time Ciba-Geigy, Basle, Switzerland). According to the presumed level of dependence, "heavy" smokers (20 cigarettes per day) received large, 30 cm^2 patches; "medium" smokers (10-19 cigarettes per day) received medium, 20 cm^2 patches, and the "light" smokers (10 cigarettes per day) received small, 10 cm^2 patches. The patients were instructed to apply a single patch each morning to non-hairy, clean, and dry skin on the trunk or upper arm; remove it the next morning; and apply a new one. To avoid skin irritation, it was recommended that the same skin site should not be used for at least 7 days. The follow-up visits were set after 7, 14, and 21 days, on the same weekdays. The subjects were expected to return one spare patch at each visit, and receive another envelope with the same code number. After this initial phase of the study, the patients were seen again after 12 months and after 5 years (Fig. 1). At each visit, general well-being, untoward effects, and smoking status were recorded. Abstinence was assessed in two ways: analyzing the answers to the questionnaire (quitters: 1 Fagerström point and 3 cigarettes per week; and non quitters 1 Fagerström point, 3 cigarettes per week) and measuring carbon monoxide content in the exhaled breath (quitters: 11 ppm CO, and non-quitters: 11 ppm CO).

The results were tabulated and statistically evaluated by use of two-tailed t-test with the Bonferroni adjustment, 2x2 chi-square test with the Yates' correction, and the Mann-Whitney U test for nonparametric distributions (e.g., cigarette consumption); $p < 0.05$ was considered statistically significant. Because of the intention-to-treat design, all the drop-outs were assumed to be failures (smokers) and evaluated accordingly.

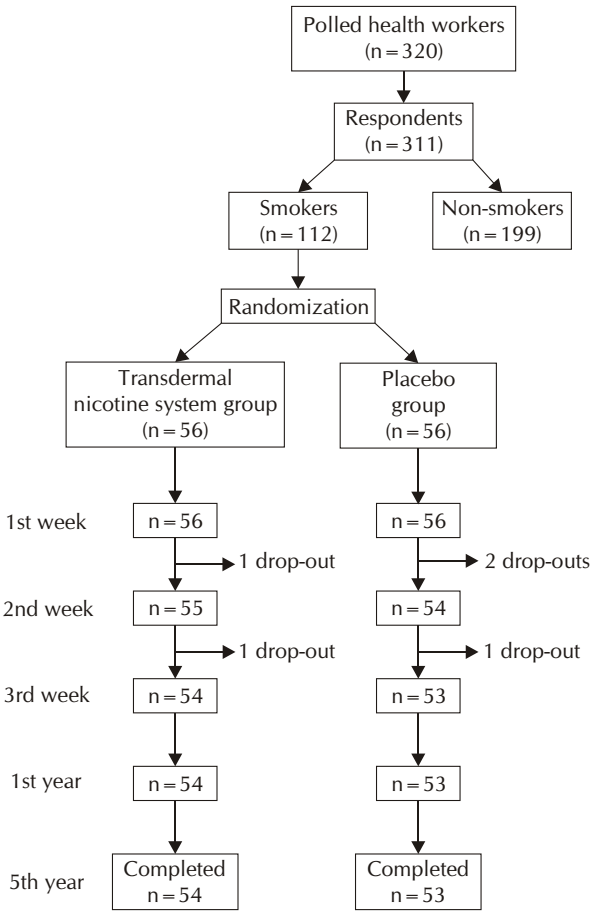

Figure 1. Participant flow through the study.

Results

The smoking prevalence among health professionals at the beginning of this study (spring 1997) was 36%, similar for both physicians (37.0%) and nurses (33.9%).

From 112 participants in the trial, there were only 5 drop-outs (4.5%), all due to non-compliance: 2 in the transdermal nicotine system and 3 in the placebo arm (Fig. 1). These individuals were considered non-quitters. The observed and/or reported side-effects were minimal: transient redness with itching at the patch site in 4 transdermal nicotine system and 1 placebo subject, and sleeping disturbances in 5 transdermal nicotine system and 2 placebo subjects.

The number of cigarettes smoked per day and the carbon monoxide levels in the exhaled breath were recorded at the beginning of this investigation, during the 3-week intervention, and during the follow-up (Table 3). The starting differences between the groups were not significant. A radical decrease in both the number of cigarettes and carbon monoxide content in the exhaled air was observed immediately (ie, after the first week) and was maintained at approximately the same level to the end of the intervention period (3 weeks). At that time the amount of consumed cigarettes, compared with baseline, decreased by 74.7% in the transdermal nicotine system, and by 50.7% in the control group, whereas the CO content in the exhaled air diminished by 61.3% in the transdermal nicotine system, and by 37.4% in the control group. At

Table 3. Daily cigarette consumption and CO concentration in exhaled breath in transdermal nicotine system (TNS) and placebo group

	Cigarettes per day (mean ± SD)			CO (ppm; mean ± SD)		
Trial point	TNS	placebo	p*	TNS	placebo	p*
At entry	24.1 ± 5.8	22.5 ± 5.7	0.160	34.1 ± 3.2	32.6 ± 4.1	0.070
After 1 week	5.1 ± 6.3	9.9 ± 8.2	< 0.001	12.1 ± 7.4	18.2 ± 9.9	0.002
After 2 weeks	5.7 ± 6.3	10.9 ± 7.9	< 0.001	13.2 ± 8.0	20.0 ± 9.6	< 0.001
After 3 weeks	6.1 ± 6.2	11.1 ± 8.0	< 0.001	13.8 ± 8.1	20.4 ± 9.3	< 0.001
After 12 months	9.8 ± 7.3	14.5 ± 10.2	0.006	18.5 ± 8.7	26.1 ± 11.2	< 0.001
After 5 years	10.5 ± 7.1	14.7 ± 10.4	0.015	19.7 ± 8.9	28.3 ± 12.0	< 0.001

*Mann-Whitney U-test.

Table 4. Smoking abstinence rates among transdermal nicotine system (TNS, n = 56) and placebo (n = 56) group

	TNS group		Placebo group		
Time period	No.	% (95% CI)*	No.	% (95% CI)*	p†
1 week	28	50.0 (36.3-63.7)	14	25.0 (14.4-38.4)	0.011
2 weeks	25	44.6 (31.3-58.5)	12	21.4 (11.6-34.3)	0.016
3 weeks	22	39.3 (26.5-53.3)	11	19.6 (10.2-32.4)	0.038
12 months	13	23.2 (13.0-36.4)	9	16.1 (7.6-28.3)	0.476
5 years	10	17.8 (8.9-30.4)	8	14.3 (6.4-26.2)	0.797

*CI – confidence interval.
†Chi-square test.

the end of the study, 5 years after the intervention, the reported number of consumed cigarettes was still significantly lower in both groups (a decrease vs baseline by 56.4% in the transdermal nicotine system and by 34.7% in the control group); the same was true for the carbon monoxide concentration (a decrease by 42.2% in the transdermal nicotine system and by 13.2% in the placebo group). The initial quitting rate among the subjects treated with transdermal nicotine system was quite high, 50%, or exactly two-fold greater than that in the placebo arm (Table 4). Over the next two weeks, a small decline was observed in both groups. At the end of the transdermal nicotine system/placebo intervention, the abstinence rate in the nicotine replacement arm was again two-fold greater than that in the control group (39.3% vs 19.6%). The decline in the abstinence rate over the next few months may be inferred from the results at the end of the first year (23.2% vs 16.1% abstainers; p = 0.476). The same trend continued over the following years as well (Fig. 2): after 5 years, there were just 18 (16.1%) "permanent" quitters out of the initial 112 smokers, a little bit more of them among the transdermal nicotine system patients (17.8%) than among the controls (14.3%; p = 0.797). This absolute difference of just 3.5% was equally distributed across the subgroups: there were 8 abstainers among men (4 in each study group) and 10 among women (6 in the transdermal nicotine system and 4 in the control group); or 9 doctors and 9 nurses, 5 in the transdermal nicotine system and 4 in the placebo group each.

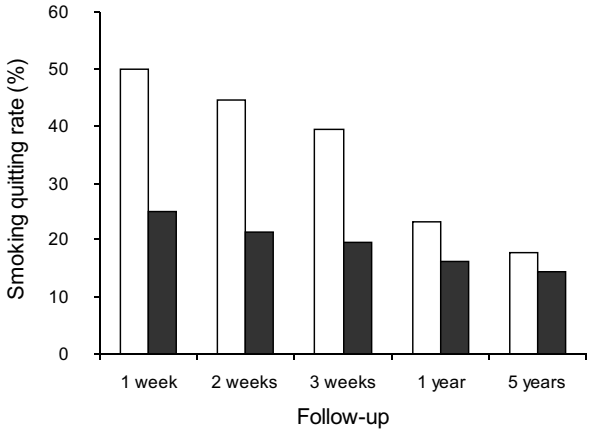

Figure 2. Quitting rates in our examinees during the follow-up, from the start of the study up to the 5th year. Open bars – transdermal nicotine system; closed bars – placebo group.

Discussion

The aim of this study was to see how effective and how lasting a particular intervention with nicotine replacement therapy was in the form of transdermal nicotine system among health professionals. Our results over the first three weeks of transdermal nicotine system active treatment were comparable with, if not better than those from a meta-analysis (16) or other recently published reports (17-20). For instance, meta-analysis of 17 transdermal nicotine system trials in over 5,000 smokers (16) showed an average quitting rate of 27% vs 13% among those receiving placebo immediately after the intervention, and of 22% vs 9%, respectively, after 6 months. Comparing four nicotine replacement therapies, ie, patch, gum, nasal spray, and inhaler, Hajek et al (20) reported abstinence rates of 21%, 24%, 20%, and 24% after a 12-week follow-up, respectively. Our abstinence rates of 40-50% within the first 3 weeks, and over 23% after 12 months are encouraging in this respect, indicating that health professionals are probably more motivated to stop smoking than the population at large. The remarkable decline in the abstinence rate over time, approaching some 18% after 5 years, and similar to that achieved with placebo (about 14%), indicates that pharmacotherapy alone leaves much to be desired in a smoking cessation program (21). Nevertheless, our abstinence criteria were stringent and our examinees in both groups had, at least declaratively, reduced their cigarette consumption 5 years from baseline by 56.4% (transdermal nicotine system) or 34.7% (placebo). This compared favorably with the exhaled carbon monoxide, which decreased by 42.2% in the transdermal nicotine system group or 13.2% in the placebo group. The possibility that some ex-smokers have switched from cigarettes to a permanent use of transdermal nicotine system or other nicotine replacement therapies, ie, substituting one dependence for another (which we have not observed in this study) is open and deserves further attention and investigation.

According to a study among 1,384 adolescents (22) from New Hampshire, USA, there were 19.9% smokers, and 28.6% of them described themselves as non-smokers after a 3-year follow-up. Smoking cessation in this report was highest in persons with definite intentions to quit in the future (average odds ratio 2.67) and in occasional smokers (average odds ratio 6.67). Conversely, controlled clinical trials have shown that nicotine replacement therapy and bupropion increase the cessation rates only in moderate to heavy smokers, lighting 15 or more cigarettes per day

(9-12,16-21). This difference is presumably caused by different therapeutic approaches to light smokers (mostly counseling and persuasion) vs heavy smokers (pharmacotherapy). California Tobacco Surveys polls in 1992, 1996, and 1999 showed that smoking cessation attempts in this period increased from 38.1% to 61.5% per year, and the use of nicotine replacement therapy among quitters increased from 9.3% to 14.0% (22). A total of 17.2% of quitters used nicotine replacement therapy, bupropion, or both as an aid in cessation in 1999. The median duration of aid use, 14 days, was less than generally recommended, and only about 20% of the users had adjuvant behavioral counseling. The optimal duration of nicotine substitution is not yet defined. In this study and an earlier one (12), we showed that a 3-week transdermal nicotine system course is as effective as a longer, 6-week one, with clear medical and economic implications. Even a 2-week use of nicotine replacement therapy increased the cessation success in moderate to heavy Californian smokers, but only before it became widely available over-the-counter (23). In our opinion this loss of effectiveness was not due to the change in prescription policy, but to further decrease in compliance because of additional weakening in doctor-patient relationship and in other behavioral supports to people striving to escape their tobacco dependence.

As our data show, the initial nicotine replacement therapy success rate, ie, doubling a smoker's chance of quitting, progressively declines over time. To avoid this loss, nicotine replacement should last not less than 3 weeks (12) and be accompanied and followed by repetitive behavioral interventions in the form of "booster shots", such as yearly anti-smoking schools, dedicated sessions, and anti-smoking or ex-smokers' clubs. The role of the health professionals in these endeavors, particularly if ex-smokers themselves, is invaluable. Unfortunately, physicians' practices fall short of the health objectives and practice guidelines (24). For instance, smoking counseling in 1991-1995 (analysis of 3,254 US physicians and 145,716 US adult patient visits) included less than 30% of such patients, currently amounting at 21%; nicotine replacement therapy prescription rate increased from the very low 0.4% of the smokers' visits in 1991 to 2.2% in 1993, decreasing again to 1.3% in 1995 (24). These missed opportunities for intervention should be corrected.

In conclusion, although initial nicotine replacement therapy success rates can be impressive, recidivism is high, emphasizing the importance of long-term follow-up and continued support to maintain long-term freedom from smoking. Patients are particularly vulnerable to resume smoking during periods of emotional stress, and additional support or medication may be required in these circumstances.

In short, nicotine replacement therapy is a useful adjunct to any smoking cessation program; it doubles the abstinence rates in comparison with controls over several weeks. A short, 3-week transdermal nicotine system intervention is as effective as a longer one, but cheaper and easier to implement. The quitting rate thereafter progressively decreases to some 15-20% after 5 years. Nicotine replacement therapy should therefore go hand in hand with behavioral measures, and the results should be reassessed at least yearly, repeating the procedure if necessary. Smoking habits among health professionals reflect and do not differ substantially from those in a community. It seems that doctors and nurses are more motivated to quit than their counterparts in general population, allowing more effective smoking cessation programs.

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