

T. Hanioka<sup>1\*</sup>, M. Ojima<sup>2</sup>, H. Tanaka<sup>3</sup>,  
M. Naito<sup>4</sup>, N. Hamajima<sup>4</sup>,  
and R. Matsuse<sup>5</sup>

<sup>1</sup>Department of Preventive and Public Health Dentistry, Fukuoka Dental College, 2-15-1 Tamura, Sawara-ku, Fukuoka 814-0193, Japan; <sup>2</sup>Department of Preventive Dentistry, Graduate School of Dentistry, Osaka University, Suita, Osaka, Japan; <sup>3</sup>Division of Epidemiology and Prevention, Aichi Cancer Center Research Institute, Nagoya, Aichi, Japan; <sup>4</sup>Department of Preventive Medicine/Biostatistics and Medical Decision Making, Nagoya University Graduate School of Medicine, Nagoya, Aichi, Japan; and <sup>5</sup>Department of Research and Development, Kyoto Medical Science Laboratory, Inc., Kyoto, Japan; \*corresponding author, haniokat@college.fdcnet.ac.jp

*J Dent Res* 89(1):66-70, 2010

## ABSTRACT

Smoking exerts detrimental effects on dental treatment and oral health. Our goal was to evaluate effectiveness in terms of the abstinence rate in smoking-cessation intervention delivered by dental professionals. Individuals who were willing to quit smoking were randomly assigned to either an intervention or a non-intervention group. Intensive intervention was provided, consisting of 5 counseling sessions, including an additional nicotine replacement regimen. Reported abstinence was verified by the salivary cotinine level. Thirty-three persons in the intervention and 23 in the non-intervention group started the trial. On an intent-to-treat basis, 3-, 6- and 12-month continuous abstinence rates in the intervention group were 51.5%, 39.4%, and 36.4%, respectively, while the rates in the non-intervention group were consistent at 13.0%. Adjusted odds ratios (95% confidence interval) by logistic stepwise regression analyses were 7.1 (1.8, 28.5), 8.9 (1.7, 47.2), and 6.4 (1.3, 30.7), respectively. Intensive smoking-cessation intervention in the dental setting was therefore effective.

**KEY WORDS:** smoking cessation, dentist, dental hygienist, randomized control trial.

DOI: 10.1177/0022034509350867

Received December 7, 2007; Last revision June 23, 2009;  
Accepted July 22, 2009

# Intensive Smoking-cessation Intervention in the Dental Setting

## INTRODUCTION

The causal association of smoking with oral diseases has been established—for example, oral cancer and periodontal disease (US Department of Health and Human Services, 2004). Smoking is also associated with various forms of oral symptoms. Premature tooth loss is associated with smoking (Krall *et al.*, 1997; Hanioka *et al.*, 2007a), and smoking impairs the effects of dental treatments. Smoking also decreases the effects of periodontal treatment (Preber and Bergström, 1990; Kaldahl *et al.*, 1996; Grossi *et al.*, 1997). Root canal treatment (Krall *et al.*, 2006), wound healing after tooth extraction (Larsen, 1992), and dental implant failure (Chuang *et al.*, 2002) have also been shown to be affected by smoking. Smoking cessation decreases the risk of tooth loss (Dietrich *et al.*, 2007) and dental implant failure (Lambert *et al.*, 2000) and increases the speed of recovery after periodontal treatment (Preshaw *et al.*, 2005). Smoking cessation is therefore an important measure for the prevention of oral diseases and symptoms and may help to ensure that the effects of dental treatment are sustained.

Various dental organizations around the world have recommended the cessation of tobacco use. A chart of mucosal lesions was disseminated for the early detection of oral cancer (Mecklenburg *et al.*, 1994). A smoking cessation manual for dental teams was developed by the US Government (Mecklenburg *et al.*, 1991) and another by the British Dental Association (Beaglehole and Watt, 2004). At a global level, an advocacy guide for oral health professionals included smoking cessation practice (FDI/WHO, 2005). Since clinical trials with physician and dentist involvement were conducted for a comprehensive tobacco control strategy (Cohen *et al.*, 1994), the effectiveness of smoking-cessation intervention in the dental setting has been highlighted; however, standardizing the evaluation is difficult due to the variety of intervention regimens (Carr and Ebbert, 2007).

In Japan, the smoking rates for male and female adults were 39.9% and 10.0%, respectively, in 2006. The rate in men is high in developed countries and that of young females is increasing. Smoking cessation guidelines were first introduced in cooperation with 7 medical and 2 dental academies in 2005 and included the role of dental professionals; however, little information is available on smoking-cessation practices in Japan. In 2006 in Japan, smoking-cessation treatment by physicians was approved by governmental health insurance *via* the recognition of “nicotine dependence” as a disease. The protocol for intensive intervention includes the diagnosis of nicotine dependence, counseling about smoking behavior modification, and prescription of the nicotine patch. An intensive smoking-cessation intervention conducted by dental hygienists has been successful (Binnie *et al.*, 2007). In the dental setting, smoking-cessation intervention may be implemented to ensure effective treatment against dental diseases. The aim of this feasibility study was to evaluate the potential effectiveness of an intensive smoking-cessation intervention delivered by dental professionals, with the outcome measured in terms of abstinence rates.

## METHODS

Two local dental associations, one in Hiroshima prefecture and one in Nagasaki city, agreed to the recruitment of dental clinics. Dentists and dental hygienists in 30 dental clinics participated in a 3-hour training course of intensive smoking-cessation intervention. The course, which consisted of a counseling lecture and an additional pharmaceutical regimen and role-playing exercises, was organized to achieve the goals of the experimental protocol. The detailed protocol for the intervention is described below. This study was approved by the ethics committee of Fukuoka Dental College.

Adults were screened by means of a questionnaire that asked about their willingness to stop smoking within 1 mo. Those who were pregnant, breast-feeding, or had a history of at least one of the following diseases were excluded: angina pectoris, myocardial infarction, arrhythmia, another heart disease, cerebral hemorrhage, subarachnoid hemorrhage, and another cerebral disease.

Patients in each clinic were assigned to intervention and non-intervention groups. Because free nicotine transdermal patches were provided to the intervention group, with no similar benefit to the non-intervention group, non-intervention group participants may have been disappointed to find that they were not being offered this benefit. Disappointment could have led to selective dropout or unwanted changes in behavior. We therefore used a modified random consent design (Kaper *et al.*, 2005); participants were blinded to the existence of the counterpart experimental group.

Participants were given brief verbal information about the study and were asked about their interest in taking part. Those who agreed to participate were assigned to the intervention or non-intervention group according to an assignment card in an envelope provided *a priori* to the clinics. After randomization, those assigned to the intervention group were told in more detail that the study examined the effectiveness of intensive smoking-cessation intervention, and those in the non-intervention group were told about the salivary test. Participants in both groups then gave written informed consent to participate. A brief intervention protocol had been recommended previously (Tomar, 2001; Gordon *et al.*, 2005).

The protocol in the intervention group consisted of 5 visits. At the first visit, participants were counseled to set a quit date, including two major regimens to prevent relapse, consisting of behavioral and pharmaceutical approaches. Self-help material and nicotine patches (Nicotinel® TTS®, Novartis Pharma K.K., Tokyo, Japan), which consisted of 3 dosage levels, were provided for the first 6 wks with information regarding nicotine gum (Nicorette®, Johnson & Johnson K.K., Consumer Company, Tokyo, Japan), which participants could purchase in a drug store. The pharmaceutical approach could reduce withdrawal symptoms. Counseling during the first visit could be performed in 2 consecutive visits, because informed consent was obtained during the visit for ordinal dental treatment, and counseling during the first visit often required a longer time than in other visits. Following the first visit, approximately 2, 4, 8 wks, and 3 mos after the quit date, smoking-cessation counseling was further conducted in a similar but concise manner to assist participants in overcoming withdrawal symptoms and preventing relapse.

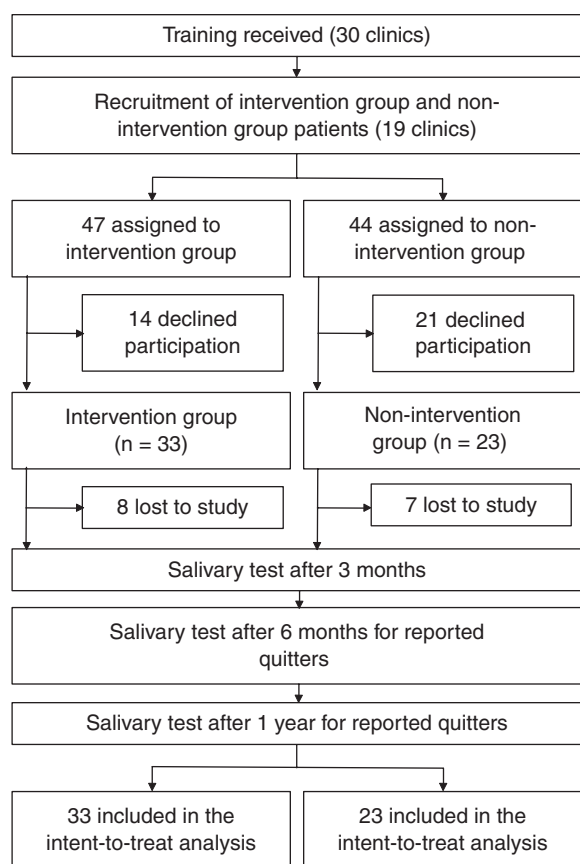
Daily use of cigarettes and duration of smoking data were collected from the questionnaire. Nicotine dependence was estimated by means of the Tobacco Dependence Screener (TDS), which consists of 10 questions (Kawakami *et al.*, 1999). Smokers with a TDS score of more than 5 were estimated as being nicotine-dependent. For each participant, the times at the start and end of intervention by a dentist and dental hygienist were recorded. To verify smoking cessation, we used saliva to determine the level of cotinine, which is a metabolite of nicotine. Saliva was collected about 3 mos after the first visit from participants in both groups. After 6 and 12 months' follow-up, saliva was collected from individuals who reported smoking cessation. Each participant chewed a cotton plug (Salivette, Sarstedt Ltd., Nümbrecht, Germany) for 1–2 min to ensure that it was fully saturated with saliva. The cotton plug was stored in a sampling tube and mailed to a laboratory. At the laboratory, samples were centrifuged to harvest saliva and plated for a competitive enzyme-linked immunosorbent assay with a solution of rabbit polyclonal anti-goat IgG (Dako, Glostrup, Denmark). A cut-off of 20 ng/mL was used to verify reported abstinence (Etzet, 1990). Participants were counted as smokers if they were lost to follow-up and failed to provide a saliva sample for the intent-to-treat analysis.

Differences in averages between groups were assessed *via* the two-tailed *t* test. Differences in distribution between groups were evaluated with the  $\chi^2$  test. Effectiveness of smoking cessation intervention was evaluated by comparison of the 3-, 6-, and 12-month continuous abstinence rates between the intervention and non-intervention groups. The continuous abstinence rate was defined, for intent-to-treat analysis, as the number of individuals who continuously stopped smoking during the observation period divided by those who participated in the study. Adjusted odds ratio (OR) and 95% confidence interval (CI) for continuous abstinence in the intervention group relative to the non-intervention group were calculated by logistic regression analysis with backward stepwise selection to eliminate non-significant factors (*p* value > 0.10) from among sex, age, daily use of cigarettes, and the TDS score. Statistical analyses were conducted with SPSS software (SPSS Japan Inc., Tokyo). The significance level was set at 5%.

## RESULTS

Among the facilities participating in the training course, 19 clinics (63.3%) began the trial. Of the 47 and 44 participants assigned to the intervention and non-intervention groups, respectively, 33 and 23 individuals, respectively, consented to participate (Fig.). During the intervention period, 15 persons were lost to study among the 56 participants. In the intervention group, two persons did not use nicotine patches. One participant reported using nicotine gum after patches, but had ceased by the 6-month period. No adverse event regarding smoking cessation was reported.

There were no significant differences between the groups with respect to sex, age, cigarettes smoked daily, and smoking yrs (Table 1). The TDS score was lower in the non-intervention group than in the intervention group, but the differences were not significant.



**Figure.** Training of intensive smoking-cessation intervention and flow of participants and salivary tests for chemical validation of abstinence in intervention and non-intervention groups.

**Table 1.** Comparison of Characteristics of Smokers between Intervention and Non-intervention Groups

Characteristics	Intervention Group (n = 33)	Non-intervention Group (n = 23)	p
Number of participants			
Males	26	14	
Females	7	9	NS <sup>a</sup>
Age (yrs)	48.0 (43.4, 52.6) <sup>b</sup>	46.7 (41.2, 52.3)	NS
Cigarettes smoked daily	24.3 (19.5, 29.0)	20.6 (14.9, 26.3)	NS
Yrs smoked	26.7 (22.2, 31.2)	24.1 (18.7, 29.5)	NS
TDS score <sup>c</sup>	7.3 (6.5, 8.1)	6.0 (5.1, 6.9)	NS

<sup>a</sup> Not significant between intervention and non-intervention groups.

<sup>b</sup> 95% confidence interval.

<sup>c</sup> Tobacco dependence screener (TDS) consists of 10 questions. Smoker with a TDS score of more than 5 could be assessed as a nicotine-dependent smoker.

The total intervention time *per* intervention group participant was 116.2 min on average (Table 2). The mean number of interventions *per* person was 4.6, and 63.6% of participants completed the intervention. The number of interventions received was similar

**Table 2.** Characteristics of Intervention Practices in Intervention Group (N = 33)

Intervention	Dentists	Dental Hygienists	Total
Mean time <i>per</i> participant (min) <sup>a</sup>	73.7 (53.9–93.5) <sup>b</sup>	42.3 (27.9–56.8)	116.2 (86.8–145.6)
Mean number <i>per</i> participant	4.4 (3.8–5.0)	4.3 (3.7–4.9)	4.6 (4.0–5.1)

<sup>a</sup> One record was not available, because it was incomplete.

<sup>b</sup> 95% confidence interval.

between dentists and dental hygienists; however, the contact time with dentists was 1.7 times longer than with dental hygienists. Many participants (63.6%) completed the maximum visits (5 or 6 visits).

The effectiveness of intervention was evaluated in 33 participants in the intervention group and 23 participants in the non-intervention group according to the continuous abstinence rate on an intent-to-treat basis (Table 3). In the 3-month period, 75.8% and 69.6% were evaluated for smoking status in the intervention and non-intervention groups, respectively, and abstinence rates were 51.5% and 13.0%, respectively. Abstinence rates in the non-intervention group in the follow-up assessments at 6 and 12 mos were consistent with those at 3 mos, while the rates decreased to 39.4% at 6 mos and 36.4% at 1 yr in the intervention group. Adjusted OR (95% CI) for continuous abstinence in intervention relative to non-intervention groups at 3, 6, and 12 mos were 7.1 (1.8, 28.5), 8.9 (1.7, 47.2), and 6.4 (1.3, 30.7), respectively.

## DISCUSSION

The present study demonstrated that intensive smoking-cessation intervention is effective in the dental setting in terms of the long-term abstinence rate, which was verified chemically. In the present study, participants were limited to smokers who were willing to quit within 1 mo. A brief intervention in individuals who were not willing to quit within 1 mo was about 3 times as effective in their attempt to quit (Hanioka *et al.*, 2007b); therefore, the dental clinic could be an independent facility where smokers are motivated and helped to quit effectively.

A national survey was conducted for the first time to verify the effectiveness of smoking-cessation treatment in the medical setting in 279 facilities (response rate, 61.2%) in Japan at the time of the present study, and the reported 6- and 12-month continuous abstinence rates for 2546 smokers were 40.8% and 32.6%, respectively. These numbers were similar to those for the intervention group in the present study. The number of participants who completed the maximum visits was lower in the medical setting (30.0%) than in the present study (63.6%). About 75% of participants were examined in the 3-month period in both the intervention and non-intervention groups. Most participants completed the maximum intervention. Good compliance in the dental setting may be due to the necessity of continuing dental treatment.

Dental professionals trained in smoking-cessation intervention may have influenced smoking behavior in the non-intervention group, since they might have intervened unconsciously. This type of bias, if any, and possible bias due to a lower TDS score in the non-intervention group than in the intervention group, may

**Table 3.** Abstinence Ratios in Intervention and Non-intervention Groups, and Adjusted Odds Ratios (OR) by Logistic Stepwise Regression Analysis

Period	Assessment	Intervention Group	Non-intervention Group	p
Registration		33 (100%)	23 (100%)	
3 mos	Days <sup>a</sup>	107.7 (100.3, 115.1) <sup>b</sup>	103.1 (93.9, 112.4)	NS
	Examined	25 (75.8%)	16 (69.6%)	NS
	Quit <sup>c</sup>	17 (51.5%)	3 (13.0%)	0.004
	Crude OR	7.1 (1.8, 28.5) <sup>c</sup>		0.006
	Adjusted OR <sup>d</sup>	7.1 (1.8, 28.5)		0.006
6 mos	Days	196.5 (181.8, 211.1)	204.3 (176.3, 232.3)	NS
	Quit	13 (39.4%)	3 (13.0%)	0.039
	Crude OR	4.3 (1.1, 17.6)		0.040
	Adjusted OR <sup>e</sup>	8.9 (1.7, 47.2)		0.010
	Days	433.2 (402.2, 464.2)	453.3 (388.8, 517.9)	NS
1 yr <sup>f</sup>	Quit	12 (36.4%)	3 (13.0%)	NS
	Crude OR	3.8 (0.9, 15.5)		NS
	Adjusted OR <sup>e</sup>	6.4 (1.3, 30.7)		0.021

<sup>a</sup> Based on the first day of intervention. Since setting a quit day within 1 wk after the first visit was recommended in the intervention group, the period may be approximately 7 days shorter than in the Table.

<sup>b</sup> 95% confidence interval.

<sup>c</sup> Reported abstinence was verified according to a salivary cotinine level of less than 20 ng/mL at 3, 6, and 12 mos. Salivary tests at 6 and 12 mos were performed for those who reportedly quit.

<sup>d</sup> No variables were entered.

<sup>e</sup> Age and daily use of cigarettes were entered.

<sup>f</sup> Assessment was delayed for approximately 2 mos due to the extension of financial support.

underestimate the effectiveness of the current intervention. The adjustments for age and daily cigarette use between groups contributed to the increases of crude odds ratio. We used random consent to minimize the overestimation of effectiveness due to participation bias, although this method has inspired debate and controversy regarding ethical issues (Homer, 2002). This method was appropriately used in a study which examined effectiveness with respect to behavior change (Kaper *et al.*, 2005). We avoided a parallel design in which participants were assigned to intervention and non-intervention clinics, since a participation bias may occur between groups.

Study designs to assess the efficacy of a smoking-cessation program in the dental setting have varied greatly (Warnakulasuriya, 2002; Carr and Ebbert, 2007), including the abstinence rate in on-treatment *vs.* intent-to-treat bases, intervention in the general population *vs.* dental patients, lack *vs.* existence of a control group, brief *vs.* intensive intervention regimen, short- *vs.* long-term observation periods, use of reported abstinence *vs.* chemical verification, and intervention by a single professional *vs.* a team approach. The team approach has been recommended, because differences in the intervention approach were identified between dental and physician settings (Cohen *et al.*, 1994). The strength of the present study was the use of more confirmative evaluation of the intervention trial, with comparison of abstinence verified chemically with the control group on an intent-to-treat basis.

A few limitations to this study should be noted. First, the number of participants in the non-intervention group was about two-thirds of that in the intervention group. This imbalance may have been due to the greater benefit of free nicotine patches in the intervention than in the non-intervention group. We cannot expect an effect on abstinence in these individuals if they participated in the trial. Second, nicotine patches have

been available over the counter in Japan since May, 2008. The influence of their availability in drug stores on the effectiveness of intervention in the dental setting should be further clarified. Third, smoking-cessation counseling by dentists and dental hygienists requires a certain time commitment, and thus the efficacy of the practice should be considered. Approval for smoking-cessation practice in the health insurance system may improve efficacy in the dental setting. Further discussions are required regarding medical economics: how much and by which dental professional the intervention could save in dental expenditures by preventing dental diseases and improving dental-treatment effectiveness.

Another source for dental patients to receive intensive smoking-cessation intervention is referral services (Gordon *et al.*, 2007). In the present study, dental professionals were briefly trained in smoking-cessation intervention. Since dental professionals have the potential for behavioral and pharmaceutical approaches, dental visits are an opportunity for smokers to be effectively helped to quit smoking by trained professionals.

## ACKNOWLEDGMENTS

This study was supported by a Fukuoka Dental College Grant and by Grant-in-Aids for Cancer Research from the Japanese Ministry of Health, Labor and Welfare (13-3, 17-1).

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