Effectiveness of Smoking-Cessation Intervention in All of the Smokers at a Worksite in Japan

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Abstract: In Japan, the prevalence of smoking among males and females was 56.1% and 14.2%, respectively, in 1997. Male smoking prevalence was exceedingly high as compared to those in other industrialized countries. We conducted a randomized controlled intervention study on smoking cessation for all smokers in a worksite regardless of their willingness to quit smoking. All of the male smokers in a radiator manufacturing factory (n=263) were randomly allocated to an intervention group (n=132) or a control group (n=131). Subjects in the intervention group received individual counseling by a doctor, and those who signed a Smoking Cessation Declaration underwent a five-month intervention. Subjects in the control group received equivalent delayed intervention for four months. The cessation rate after the original intervention was 12.9% (17/132) and 3.1% (4/131) in the intervention and control groups, respectively (p=0.003). Among those who once succeeded in quitting, 48.6% (18/37) maintained cessation at the long-term survey. Overall, the cessation rate was 8.4% (22/263) and the prevalence of smoking among males significantly decreased from 62.9 to 56.7% (p=0.038). As a conclusion, intervention in all smokers at a worksite regardless of their willingness to quit is effective and impacts the overall smoking rate.

Key words: Health education, Intervention study, Occupational setting, Randomized controlled trial, Smoking cessation, Worksite

Introduction

Tobacco use is an important cause of premature mortality and disability worldwide1, and a serious problem particularly in developing countries, whose smoking prevalence has been increasing3. Smoking is expected to kill 10 million people annually worldwide by 2030, and over 70% of these deaths will be in the developing world3. China has followed a similar pattern of male cigarette smoking to that in the United States, with a delay of about 40 years3,4. The same problem holds true to Japan; the prevalences of smoking were 56.1% in men and 14.5% in women in 19975. Accordingly, the lung cancer mortality rate has been increasing and this is now the leading cause of death among malignant neoplasms in Japanese males, outweighing stomach cancer5, while in the US, the lung cancer mortality rate is beginning to decrease in accordance with a decrease in the prevalence of smoking6. In such a situation, an integrated strategy to reduce the prevalence of smoking is urgently necessary. There have been several reports on smoking intervention from Japan7,8, but they have chiefly been on a voluntary basis with a limited sample size. We should focus not only on smokers willing to quit smoking, but all the smokers regardless of their willingness to quit.

In order to determine the effectiveness of intervention in all smokers regardless of their willingness to quit smoking, we conducted a randomized controlled intervention trial in an occupational setting.
Subjects and Methods

Study population

We performed this intervention study in a radiator manufacturing factory that employed 542 (423 male and 119 female) workers in 1997. All the survey and intervention procedures were examined and approved by the Shiga University of Medical Science Ethics Review Board. We conducted a self-administered questionnaire survey along with a written informed consent, with a response rate of 100%. The questionnaire consisted of questions regarding their smoking status (current smoker/ex-smoker/non-smoker, number of cigarettes per day), history (years smoked, previous attempts at quitting, etc.), degree of nicotine addiction (Fagerstrom Tolerance Questionnaire or FTQ), willingness to quit (not at all/in the future/before long/currently trying to quit smoking), and how they feel about their smoking environment in the worksite. Through this baseline survey, 267 smokers (263 male and 4 female) were identified. We conducted the same procedure of intervention to all smokers, but female smokers were excluded from the analysis due to the small number of smokers. We randomly allocated the male smokers into an intervention group (n=132) and a control group (n=131) using a random number-generating software.

Smoking cessation intervention

The intervention group underwent five months of intervention beginning in January, 1997. First, we approached all of the smokers in the intervention group regardless of their willingness to quit. Each smoker was asked to visit the nurse’s office to attend a face-to-face counseling session with a doctor during working hours. The doctor discussed the harmful effects of tobacco and the benefits of cessation, and encouraged each smoker to quit. Smokers underwent a measurement of carbon monoxide (CO) concentration in expiratory air with a Smokerlyzer during the counseling. If a smoker expressed that he would try to quit, he was advised to decide when he would start smoking cessation and signed a Smoking Cessation Declaration along with when to start in order to express his determination. The doctor additionally explained situations where he might want to re-start smoking, and how to deal with such situations. Active intervention continued for five months from when the subject signed the Declaration. For those who did not sign the Declaration, we surveyed their smoking status without active intervention.

The five-month program included periodic visits to work stations by the doctor and an occupational nurse for encouragement and leaflet distribution, and group discussions. We also conducted A Smoking Cessation Marathon program beginning in the fourth months of the intervention. Participants were encouraged to try to abstain from smoking for 42 days in order to seize an opportunity of complete cessation. This was conducted for the purpose of giving re-smokers chances to challenge quitting again, exploring new challengers, and letting those who had quit maintain smoking cessation. During the five-month intervention, we used the materials (counseling material, pamphlets and follow-up leaflets) in Individual Health Education Manual on Smoking Cessation which was originally developed by a Ministry of Health and Welfare Study Group on Health Education Material Development for Preventing Lifestyle Related Diseases in 1997. We additionally distributed a stamp sheet to each of the Smoking Cessation Marathon participant to let him confirm daily cessation.

After five months, we conducted the same self-administered questionnaire survey in all of the workers to identify those who succeeded in smoking cessation (response rate: 94.1%). The smoking status of nonrespondents was confirmed individually by the occupational nurse. Successful smoking cessation was defined as self-reporting of quitting for more than one month and an expiratory CO concentration of less than 9 ppm. Those who succeeded in smoking cessation in both groups were asked to visit the nurse’s office to undergo an expiratory CO concentration.

Delayed intervention

For the purpose of offering each smoker an opportunity to consider smoking cessation, we made an equivalent intervention in the control group for four months after the initial five-month intervention was completed. During this delayed intervention period, the original intervention group was left without any active intervention.

Observation of long-term effects

To observe the long-term sustained cessation rate (more than 12 months in the intervention group and 8 months in the control group) and to determine the impact of our intervention on the smoking rate in the entire baseline population, we confirmed the smoking status of all of the subjects at an annual health check-up in June 1998. Each subject underwent an expiratory CO concentration measurement to confirm one’s smoking status. Those who had continued smoking cessation since our intervention additionally underwent a urine test of nicotine metabolites which remain longer than lung CO (NicCheck).
Statistical analysis

We used tests on the equality of proportion, Fisher’s exact tests for categorical variables, and t-tests or analysis of variance (ANOVA) for continuous variables.

As to the willingness to quit smoking, we divided the respondents into a negative group (not at all/in the future) and a positive group (before long/currently trying to quit smoking). Non-respondents are categorized into negative group.

As to the evaluation of nicotine dependence, we classified the FTQ score into low (score 0–3), medium (score 4–6) and high (score 7–) nicotine dependence. Non-respondents and incomplete respondents to the FTQ questions were excluded from the FTQ analysis.

In order to compare those who succeeded in smoking cessation and who did not after the delayed intervention, we combined the two groups and divided them into succeed and non-succeed groups. Those who were lost to follow-up were included in non-succeed group.

Those who initially answered to be non-smokers but identified themselves as originally habitual smokers (n=3) were categorized as current smokers, though we did not conduct any intervention approach for them.

We assumed that those who were lost to follow-up (retired, moved to some other branch, or left the company for some reason) did not change their initial smoking habit. If a subject was originally a habitual smoker and quit once during the intervention period before leaving the factory, we considered that he restarted habitual smoking after he left. However, in calculating a smoking prevalence, we included only those who remained there in order to show the actual smoking rate of those in the same setting at each step.

Results

Baseline survey

The smoking prevalence was 62.9% and 3.4% among males and females, respectively. As described above, we excluded female smokers from our analysis due to the small number of subjects (n=4). The mean age of ex-smokers was significantly higher than those of other categories (p=0.003) (Table 1).

Comparison between the intervention and control groups

The two groups showed no significant difference with regard to the number of subjects, mean age, beginning age of habitual smoking, number of cigarettes consumed per day, FTQ score, and proportion of those who had any previous experience with smoking cessation (Table 2).

Intervention

Each subject was first asked to attend an individual counseling session. Among the 132 intervention subjects, 125 (94.7%) received the counseling, and 63 (47.7%) signed a Smoking Cessation Declaration. The counseling took significantly longer time for those who signed the Declaration (16.0 ± 4.1 minutes) than those who did not (13.0 ± 5.4 minutes) (p=0.0005). Among those who signed the Declaration, 71.4% (n=45) and 28.6% (n=18) endured to abstain from smoking for one day and one week, respectively.

As for the Smoking Cessation Marathon, 19 subjects (4 subjects who had quit during our intervention, 14 re-smokers, and 1 new challenger) participated in the program.

Intervention results

The cessation rate at the five-month survey was 12.9% and 3.1% in the intervention and control groups, respectively (p=0.003), confirmed by the questionnaire (response rate:

| Table 1. Smoking status and age distribution of the male workers at baseline survey, a worksite in Shiga, Japan, 1997 |
|---------------------------------|------|------|------|------|
|                                | Smoker (n (%) | Ex-smoker (n) | Never-smoker (n) | Total (n) |
| Mean age* (SD+)*               | 33.3 (9.6)    | 38.2 (9.2)    | 34.1 (9.8)       | 34.2 (9.7) |
| Age distribution               | n    | n    | n    | n   |
| Age 18–24                      | 43   | 1    | 16   | 60  |
| 25–34                          | 115  | 22   | 45   | 182 |
| 35–44                          | 64   | 19   | 21   | 104 |
| 45–54                          | 32   | 14   | 16   | 62  |
| 55–60                          | 9    | 3    | 3    | 15  |

*p=0.003 in analysis of variance.  *Standard deviation.
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93.4%) and the expiratory CO measurement of less than 9 ppm (Table 3). All the non-respondents were individually clarified of their smoking status by the occupational nurse.

The cessation rates of the Smoking Marathon participants were 42.1% among all the 19 participants including those who had already quit (8/19), and 26.7% among those who smoked at the beginning of the Smoking Marathon program (4/15).

At the five month survey, the proportion of those who reduced the number of cigarette consumption (including those who quit) was significantly larger in the intervention group than the control group (p=0.016) (Table 3). Those with lower FTQ score showed higher cessation rate in both groups, but in the medium FTQ score group the cessation rate showed higher tendency in the intervention group (p=0.055) (Table 3). As for the willingness to quit smoking, the proportion of those who expressed negative willingness significantly decreased in the intervention group, while the distribution didn’t show a significant change in the control group (Table 3).

Delayed intervention

As to the delayed intervention for the original control group (n=131), there were 123 smokers left after excluding those...
who were lost to follow-up (n=4) and the subjects who had already quit smoking (n=4). After undergoing the four-month intervention equivalent to the original intervention, 16 subjects (13.0%) succeeded in smoking cessation at the end of the delayed intervention (Fig. 1).

Comparison of successful and unsuccessful subjects

A comparison of subjects in both groups who succeeded to those who did not succeed at quitting revealed that smokers were more likely to abstain from smoking if the number of cigarettes consumed per day was smaller and if the beginning age of habitual smoking was higher (Table 4). The proportion of those who signed the Smoking Cessation Declaration was significantly higher in the success group. Among those who had no intention of cessation at baseline (n=60) and signed the Declaration at the counseling session (n=19), the quit rate was 15.8% (n=3) (not shown in tables). As for age, there was no significant relationship between the age group and the smoking cessation rate through our intervention (not shown in tables). As for willingness to quit, there was a linear tendency between the willingness to quit and the cessation rate; 6.9% of those who had no intention to quit smoking succeeded in quitting, and the cessation rate significantly increased as the willingness became favorable toward cessation (p=0.002) (Table 5).

Observation of long-term effects

At the survey 18 months after the beginning of this study and eight months after completing the intervention in both groups, the overall cessation rate was 8.4%. In Figure 1, the numbers in ovals show the number of those who newly quit smoking or continued cessation at each survey. The cessation rate at the 18th month survey among those who had once succeeded in quitting smoking affected by our
intervention (those who quit during the original intervention period in both groups and during the delayed intervention period in the control group) (n=37) was 48.6% (n=18). The prevalence of smoking among males changed from 62.9% to 56.7% and the reduction was significant in one-sided test (p=0.038).

In the comparison between those who continued and discontinued smoking cessation after once quit through our intervention, there was no significant difference in age, age of beginning habitual smoking, number of cigarettes per day, FTQ score, previous quit attempts, deep inhaling of smoke, and signing the Declaration.

**Discussion**

We clarified the effectiveness of smoking cessation intervention in all smokers at a worksite regardless of their willingness to quit through a randomized controlled trial. The smoking cessation rate was 12.9% in the intervention group at five months, and 8.4% of the subjects quit smoking in the long term. Among those who once quit smoking, 48.6% sustained cessation. Considering the study design, which aimed at all of the smokers instead of only volunteers, our result strongly suggests that approaching all of the smokers in an occupational setting is effective, considering that 13% is thought to be a reasonable benchmark for assessing the effectiveness of smoking cessation programs for voluntary participants15. As an overall effect, the prevalence of smoking among males significantly decreased from 62.9% to 56.7%, which is a considerable decrease, given that the natural trend is a decrease of 5% in the past 10 years16.

As to nicotine dependence, those with lower FTQ score showed higher cessation rate in both groups. However, in the medium nicotine dependence group, which accounts for more than 40% of the smoking subjects, the cessation rate showed higher tendency in the intervention group. This suggests that intervention is especially effective for those who are less nicotine-dependent.
with medium nicotine dependence who may experience hardship in smoking cessation.

The results also showed that the intervention reduced the proportion of those with negative willingness toward smoking cessation; even if the subjects failed to quit smoking, they may potentially succeed in cessation in the next opportunity. Majority of smokers think that they can quit smoking by themselves; 68% of the male smokers answered that they do not need any support for smoking cessation according to a survey conducted in the same region. However, our results showed that professional support is actually effective. Intervention can either lead a smoker to successful cessation or improved willingness toward smoking cessation. It also provides a smoking cessation opportunity for those subjects who have never thought of quitting smoking; 6.9% of those who had no intention of quitting succeeded, which is a large decrease than the natural trend.

It has been reported that those who have tried to quit smoking previously are more likely to succeed in cessation in voluntary basis studies. This indicates that by approaching all smokers, we can either help a subject quit initially or help him in future cessation attempts. Although our results showed no difference in succeeding cessation between those who had previous quit attempts and who did not, this may be due to our study design which was not a voluntary basis; our subjects included smokers with little willingness toward cessation who have failed to quit in the past. We could still succeeded in reducing the proportion of those with negative willingness toward smoking cessation.

The results also suggest that continuous support should be necessary even after a person succeeded in short term smoking cessation; nicotine dependence did not affect re-smoking in the long-term once subjects succeeded in cessation. The reason why occupational settings are desirable is that the main target of the primary prevention is the healthy working population. In a clinical setting, doctors can have more opportunity to reach the working male subjects. The extent to which risk-reduction interventions are effective may depend on adherence of the subjects. In occupational settings, workers can readily reach occupational doctors or nurses within the worksite. For companies, smoking cessation is a sound economic investment according to a simulation analysis based on US data.

There are several limitations in our study. First, 51 of the male workers (12.1%) were lost to follow-up during the 18-month study period due to national economic conditions. To be conservative in our analysis, we assumed that all of those who were lost to follow-up did not change their original smoking habit; even if a subject succeeded in smoking cessation, we considered them to be a smoker after he left the factory. Second, smoking cessation assessment by CO measurement may not be sufficient, because the half-value period of CO varies with the level of the individual’s physical activity, and smokers may sometimes be classified as non-smokers if measured after several hours from the last cigarette smoking. The reason why we introduced the urine test of nicotine metabolites which remain about 20 hours in the long-term survey is to avoid misclassifying those who smoke only one or two cigarettes a day as a long-term result of our intervention.

In conclusion, we showed the effectiveness of smoking-cessation intervention in all smokers at a worksite. The results suggested that approaching all of the smokers impacts the overall smoking rate and encouraged intervention in all smokers regardless of their expressed willingness to quit.

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