conceivable that future PA guidelines based on objective measures could possibly recommend a lower minimal dose of PA, one that is below the current guidelines.

Considering recent studies suggesting the health benefits of low doses of PA, the Japanese PA guidelines promoting, "Let's start with +10 min/day of activity," is a proper and more attainable public health message, as described by Murakami et al., which encourages and motivates more people to start increasing PA. Exercise is the best medicine with the least side effects to prevent and treat most chronic diseases for overall physical, mental, and social well-being.

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REPLY: "Add 10 Min for Your Health"

The New Japanese Recommendation for Physical Activity Based on Dose-Response Analysis

A journey of one thousand miles starts with your single step.
—Lao-tzu, Chinese philosopher, 600 BC (1)

We would like to thank Dr. Murakami and colleagues for their interest in our paper (2). We applaud the National Institute of Health and Nutrition of Japan for promoting exercise with an innovative approach, particularly for motivating the inactive couch potatoes. The benefits of exercising <30 min a day have not been promoted in the exercise guidelines of most countries. By firing the first salvo, the Japanese have called attention to a miracle medicine that requires minimal effort. With the conviction that "some is good, but more is better," the "+10 min" concept is a smart way to set the theme. The emphasis is not just a 10-min exercise by itself but stresses the "+" sign with an incremental effort on top of one's overall activity. As long as you have not met the recommended level, adding an additional 10 min of exercise is critical (Table 1).

With limited time to spend, most of us want to do only what is absolutely necessary. The search for the minimum amount to harvest health benefits has become increasingly popular. In the committee report of the "2008 Physical Activity Guidelines for Americans" (3), a meta-analysis of 12 cohort studies found positive benefits, not just at 150 min or more of exercise a week, but also with 90 min or less a week of exercise, including 60 min a week, or "+10," as part of the extrapolated conclusion. Nevertheless, the committee report fell short of identifying a specific minimal level for lack of evidence.

There are some limitations for "+10" (Table 1). First and foremost, its health benefits have not been documented. If the critical threshold is attainable only at 15 min of exercise per day, as proven by Wen et al. (4) in the *Lancet*, 10-min exercise may miss the 3-year life extension benefits expected. Second, while "+10" is a great motivator to initiate exercise, it lacks the magic of sustaining power. After all, it is persistent daily exercise that counts. As "+ 10" is simple to attain for a number of days, it may be too simple and boring to do daily for years. Third, socialization is an important way to make exercise fun and sustainable, but "+10" will be mostly done alone. Asking people to come may take longer than 10 min. Fourth, while "+10" is easy to get started, much of the first 10 min is spent warming up, without enough time for aerobic health effects to sink in, nor for exercisers to enjoy feeling the "high" from the release of endorphins.

As no public health guidelines issued by any government have incorporated the minimum threshold so far, such as 15 min of walking, the Japanese are lucky to hear the good news of "short walks work wonders" and to take advantage of it ahead of others. Whether "+15" is better than "+10" or whether it is scientifically proven is really academic, as it is

TABLE 1 The Strengths and Limitations for the Japanese "+10 for Your Health" Guideline

Strengths	Limitations
1. Great motivator to initiate for the inactive	1. Not easy to sustain, as it tends to be overlooked as a daily routine
2. In line with increasing evidence of minimum amount of exercise, such as 15-min walking or 5-min running	2. Significant health benefits from 10 min of walking has not been scientifically documented; "+15" may be better than "+10"
3. Easy to start and to accomplish	3. May be too short to have aerobic effects—most of the 10 min may be spent just in warming up
4. Most welcome by the elderly and disabled for this proposal	4. Younger adults gain less benefits and have less enjoyment
5. Easy to squeeze into one's schedule	5. Not enough time for socialization
6. Any exercise of 10 min duration counts	6. Confusion with nonexercise activity

a no-brainer to expect a miracle, once one starts to move "+10" regularly. As Chinese philosopher Lao-tzu said, "A journey of a thousand miles starts with your single step," (1) a 10-min dedicated brisk walk is worth every bit of the 1,000 steps it requires. Proof of these benefits will be experienced by the Japanese, who grabbed the low lying fruit of 10 min of exercise and declined to wait for the full 30-min prize, as if they knew "a bird in hand is worth two in the bush".

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Is the Long-Term Outcome of PCI or CABG in Insulin-Treated Diabetic Patients Really Worse Than Non-Insulin-Treated Ones?

In a recent issue of the *Journal,* Dangas et al. (1), after analyzing 1,850 subjects from the FREEDOM (Comparison of Two Treatments for Multivessel Coronary Artery Disease in Individuals With Diabetes) trial, found that in patients with diabetes and multivessel coronary artery disease, the rate of major adverse cardiovascular events (death, myocardial infarction, or stroke) is higher in patients treated with insulin than it is in those not treated with insulin. Their work is excellent, and the results deserved to be considered given the large number of patients with diabetes and multivessel coronary artery disease who are being treated with insulin. However, the investigators overlooked several issues that might influence the results that we shall discuss in the following text.

First, the patients were simply categorized into insulin-treated diabetes mellitus (ITDM) and non-ITDM according to their baseline use of insulin (either alone or in combination with other oral antidiabetic medication). However, the investigators ignored the duration of insulin treatment and the dose of insulin. Also, the kinds of oral antidiabetic medications were unreported both in the ITDM and non-ITDM groups.

Second, the hemoglobin A_{1c} was significantly higher in ITDM patients at baseline, which indicated that ITDM patients were undertreated in the study. But, why did this situation occur? Possibly because of one of the following: poor self-monitoring of blood glucose; worsening medical condition; insufficient insulin dose; or more severe insulin resistance. Moreover, the quality of blood glucose control was not reported either. From the original paper, we could not assess the following queries: How many patients discontinued insulin treatment? How often did the hypoglycemia happen? What would the hemoglobin A_{1c} be within the 5-year follow-up?

Furthermore, the prevalence of peripheral neuropathy was considerably low in the study compared with prior studies (1,2). There were only 5.2% peripheral neuropathy in non-ITDM patients, and 14.3% in ITDM patients. How do the investigators explain this?

Ultimately, this was a post-hoc analysis based on the FREEDOM trial. Though a multivariable Cox

Predictors of Lapse and Relapse to Smoking in Successful Quitters in a Varenicline Post Hoc Analysis in Japanese Smokers

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ABSTRACT

Background: The efficacy of the smoking-cessation agent varenicline has been reported in Asian smokers; however, few studies have investigated factors that contribute to lapse and relapse.

Objective: This post hoc analysis aimed to identify predictors of smoking lapse and relapse.

Methods: This was a post-hoc analysis based on a double-blind, placebo-controlled, randomized, parallel-group study in which Japanese smokers (aged 20–75 years) who smoked ≥10 cigarettes/day and were motivated to quit were randomized to receive varenicline (0.25 mg twice daily [BID], 0.5 mg BID, 1 mg BID) or placebo for 12 weeks followed by a 40-week non-treatment follow-up. For inclusion in this analysis, participants must have been nicotine dependent (Tobacco Dependence Screener score ≥5) and must have successfully quit smoking continuously for 4 weeks (weeks 9–12). Lapse was defined by answering yes to ≥1 question in the Nicotine Use Inventory. Relapse was defined by participants having smoked for ≥7 days during follow-up measured by the Nicotine Use Inventory.

Results: Of the 619 randomized individuals, 515 had a Tobacco Dependence Screener score of ≥5, and 277 quit smoking continuously from weeks 9 to 12. Approximately 75% were male, with a mean (SD) BMI of 23.0 (3.0) kg/m^2. Maximum length of continuous abstinence (CA) during treatment and age (both $P < 0.0001$) were significant predictors of lapse. Maximum CA ($P < 0.0001$), age ($P = 0.0002$), Minnesota Nicotine Withdrawal Scale (MNWS) score for urge to smoke ($P = 0.0019$), and having made ≥1 serious quit attempt ($P = 0.0063$) were significant predictors of relapse. For participants with a maximum CA of 4 to 6 weeks versus those with a maximum CA of 10 to 11 weeks, the ORs for lapse and relapse were 4.649 (95% CI, 2.071–10.434) and 3.337 (95% CI, 1.538–7.239), respectively. In participants aged 21–34 years versus those aged 47–72 years, the ORs for lapse and relapse were 3.453 (95% CI 1.851, 6.441) and 3.442 (95% CI 1.795, 6.597), respectively. Participants with a MNWS urge to smoke score of 2 to 4 versus 0 had an OR for relapse of 3.175 (95% CI, 1.166–8.644). Participants having made ≥1 versus no serious quit attempts had an OR for relapse of 2.108 (95% CI, 1.168–3.805).

Conclusion: Shorter maximum CA and younger age at quit attempt were associated with increased risk of lapse and relapse. Higher MNWS urge to smoke score and having made ≥1 serious quit attempt were associated with increased relapse risk. ClinicalTrials.gov identifier: NCT00139750. (*Clin Ther.* 2014;36:918–927) © 2014 The Authors. Published by Elsevier HS Journals, Inc.

Key words: Japan, lapse, relapse, smoking cessation, varenicline.

INTRODUCTION

Varenicline tartrate is a selective $\alpha_4\beta_2$-nicotinic acetylcholine receptor partial agonist that is approved

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worldwide as a smoking cessation aid at a dose of 1 mg BID for 12 weeks starting with a 1-week up-titration.[1] The efficacy of varenicline as a smoking cessation aid has been reported in a number of studies. Results from 2 double-blind, randomized, placebo-controlled studies conducted in the United States[2,3] have reported that smoking cessation success with varenicline is significantly better compared with other smoking cessation aids (eg, bupropion sustained-release tablets) or placebo. A Cochrane meta-analysis of 12,223 participants in 15 studies, 8100 of whom used varenicline, revealed that individuals who had received varenicline were 2.3 times more likely to quit at 6 months compared with those who had received placebo.[4]

A number of clinical studies have reported the efficacy of varenicline in Asian smokers.[5–8] Equivalence of efficacy and tolerability between Japanese and US smokers has been described in a study of 618 Japanese smokers.[5] This study reported a complete abstinence rate at weeks 9 to 12 of 65.4% for varenicline, which compared well with the 44% rate reported in the US studies.[2,3]

Although the efficacy of pharmacologic and behavioral treatment for smoking cessation is well established, these methods are not always used in quit attempts. It has been reported that 80% of smokers who attempt to quit without assistance relapse within the first month of abstinence, and only 3% to 5% continue to be abstinent at 6 months.[9,10] Results from the US Centers for Disease Control and Prevention 2010 National Health Interview Survey revealed that although 52.4% of smokers had made a quit attempt in the past year, only 6.2% had successfully quit within the same time frame.[11] Results of a Cochrane review concluded that there is insufficient evidence to support a role of behavioral therapy or extended treatment with bupropion in preventing relapse to smoking. However, the report suggested that extended treatment with varenicline may prevent relapse.[12] Furthermore, the results of a study investigating the use of 12 weeks of maintenance therapy in smokers who achieved abstinence for at least 7 consecutive days at the end of standard varenicline treatment confirmed that individuals who received maintenance treatment had significantly greater continuous abstinence during weeks 13 to 24 (70.5% vs 49.6%; odds ratio [OR], 2.48; 95% CI, 1.95–3.16; $P < 0.001$) and weeks 13 to 52 (43.6% vs 36.9%; OR, 1.34; 95% CI, 1.06–1.69; $P = 0.02$) compared with those who received placebo.[13]

The focus of health care professionals in treating tobacco dependence is now directed at reducing the number of patients who relapse after initially successfully quitting smoking. However, to date few studies have investigated the factors that contribute to relapse, and comparison of factors in Japanese smokers versus those from other countries has not been conducted. In a post hoc analysis of 626 smokers from 2 varenicline studies conducted in the United States, predictors of relapse from week 13 (end of treatment) to week 52 (1-year follow-up) were assessed for treatment-responding participants who achieved the primary efficacy end point of 4-week continuous abstinence during weeks 9 to 12. The results revealed that those who did not initiate continuous abstinence until the final 4 weeks of the treatment period were almost 5 times more likely to relapse (OR, 4.92; 95% CI, 2.77–8.97; $P < 0.001$) compared with those who initiated continuous abstinence at the end of week 1.[14] Another study conducted to assess whether smokers who achieved abstinence later in the original course of treatment would benefit from receiving an extended course of varenicline[15] confirmed that the 12-month quit success rates decreased with increasing delay in initial quitting, with quit rates of 54.9% for those quitting at week 1 of open-label treatment and 5.7% for those quitting at week 11.

This post hoc analysis was conducted to identify predictors of smoking lapse or relapse during the nontreatment follow-up period based on a double-blind, placebo-controlled, randomized, parallel-group study (ClinicalTrials.gov identifier: NCT00139750),[5] which was initially conducted to assess the efficacy and tolerability of varenicline in Japanese smokers.

Currently, it is not clear whether research conducted on smoking cessation with Western individuals also applies to Japanese individuals. Although there are no significant differences in the metabolism and efficacy of varenicline in Japanese and Western individuals,[8] relapse in Japanese smokers may be influenced by other factors. In Japan, unlike in many westernized countries, smoke-free environments are not mandated with penalties by law in indoor public places, in workplaces, or on public transport, and there are no legal restrictions on advertising. Tobacco is also relatively less expensive in Japan compared with many Western countries. In addition, there may be differences in the metabolism of nicotine, the severity of nicotine dependence, and other problems related to smoking cessation, depending on race.

This investigation was conducted to identify factors that could contribute to smoking relapse in Japanese individuals. It focused on identifying predictors and characteristics of smoking relapse, such as the use of a smoking cessation aid and a longer period of support during follow-up, which may help provide an effective strategy to prevent future relapse.

PATIENTS AND METHODS

Study Design

This was a post hoc analysis based on a double-blind, placebo-controlled, randomized, parallel-group study, which has been previously reported.[5] A total of 619 Japanese smokers aged 20 to 75 years, who smoked at least 10 cigarettes per day and were motivated to quit smoking (indicated in the informed consent form), were randomized to receive varenicline or placebo. The number of days of cigarette smoking since the previous contact was checked at each visit or at each telephone contact during the nontreatment follow-up period or at the early termination visit if individuals discontinued the study early during the follow-up phase.

Objectives and Definitions

The primary objective of this analysis was to identify predictors of smoking lapse and relapse during the nontreatment follow-up period among individuals who reported being continuously abstinent during the last 4 weeks of the treatment period. The secondary objective was to investigate the time from week 13 to smoking relapse for individuals who reported being continuously abstinent during the last 4 weeks of the treatment period, stratified by levels of a predictor. Lapse was defined by having an exhaled carbon monoxide measurement of >10 ppm (at clinic visits) during the nontreatment period (ie, from week 13 through week 52) or answering yes to at least one of the questions about smoking in the Nicotine Use Inventory (NUI): "Has the subject smoked any cigarettes (even a puff) since the last contact?" or "Has the subject used any other tobacco products since the last contact?" Relapse was defined by an individual having smoked for ≥ 7 days during the nontreatment follow-up period as measured by the NUI. Time to lapse or relapse was defined as the time (in weeks) from the beginning of the nontreatment follow-up period (ie, week 13) to the first visit when the individual's lapse or relapse was observed. Those who didn't lapse or relapse were censored at week 52. For individuals who discontinued follow-up visits before lapsing, time to lapse or relapse was defined as the time from week 13 to the week corresponding to the first missing visit that occurred after the date of discontinuation.

Participants

Participants were Japanese smokers (aged 20–75 years) who had participated in an earlier smoking cessation study investigating varenicline[5]; had been diagnosed as being nicotine dependent with a score of ≥ 5 (range, 0–10) on the Tobacco Dependence Screener (TDS),[16] which defines the criteria used to determine which smokers are permitted access to the smoking cessation treatment service that is reimbursed by public health insurance in Japan; and had successfully quit smoking continuously for 4 weeks from weeks 9 to 12. Individuals were excluded if they had significant cardiovascular disease, uncontrolled hypertension, severe chronic obstructive pulmonary disease, or a history of cancer. Individuals who had quit smoking continuously for 4 weeks from weeks 9 to 12 of the smoking cessation study were included in the analysis for the primary and secondary objectives.

Predictors of Relapse

Potential predictors of relapse included age, sex, body mass index (BMI), age at onset of smoking, number of cigarettes smoked per day, longest abstinence in previous year, living with a smoker, frequent contact with a smoker, number of serious quit attempts before study entry, pack-years smoked, baseline Fagerström Test for Nicotine Dependence score, baseline serum cotinine level, baseline weekly alcohol consumption, all domains of the Minnesota Nicotine Withdrawal Scale (MNWS; negative affect, insomnia, urge to smoke, restlessness, and increased appetite) at week 12, maximum length of continuous abstinence (CA) during the treatment phase, and quit pattern, defined as whether an individual could initiate abstinence on or before the target quit date.

Statistical Analysis

Model building was based on a logistic regression model with forward selection, backward elimination, and stepwise selection used to select potential predictors of lapse and relapse.[17,18] A model validation based on data resampling using 70% of randomly selected data

was performed to assess the robustness of the model that resulted from the process described above.

Treatment group (0.25 mg BID, 0.5 mg BID, or 1 mg BID of varenicline or placebo) was also considered for inclusion in the initial set of predictors and in the reduced model. However, because the treatment group was not identified as a predictor during the model building phase and neither affected the estimates in the reduced models, treatment group was subsequently dropped from inclusion for further consideration as a predictor. All potential predictors were descriptively summarized by status: smoking relapse (lapser or non-lapser or relapser or nonrelapser). Odds ratios (ORs) and 2-sided 95% CIs were calculated for identified predictors. Time to lapse or time to relapse was assessed using Kaplan-Meier plots.[19] Statistical hypotheses were not tested because of the anticipated small sample sizes.

RESULTS

Participant Characteristics

The disposition of the participants used in this subgroup analysis is shown in Figure 1. A total of 619 individuals were enrolled and randomized to receive varenicline (0.25 mg BID, 0.5 mg BID, or 1 mg BID) or placebo, and 618 participants received either varenicline or placebo in the original clinical trial[5]; 577 (93.4%) completed treatment, and 510 (82.5%) completed the study. Most (approximately 75%) were male, with a mean (SD) BMI of 23.0 (3.0) kg/m^2. A total of 515 participants had a score of ≥ 5 on the TDS. In total, 277 participants quit smoking continuously for 4 weeks from weeks 9 to 12 of the study and were included in this subgroup analysis. Twelve participants discontinued the study in the nontreatment follow-up period (8 because of adverse events, 1 because of death [traffic incident unrelated to treatment], and 3 because of other reasons [no regular follow-up hospital visits]). These individuals were classified as lapsers or relapsers.

Predictors of Lapse or Relapse

A summary of potential predictors by lapse and relapse status is presented in Table I. Nonlapsers and nonrelapsers were generally older and had a longer maximum CA compared with lapsers and relapsers. Maximum CA and age were identified as predictors of both lapse and relapse. In addition, MNWS score for urge to smoke and having made ≥ 1 serious quit attempt were identified as predictors of relapse (Table II). When analyzed as categorical variables, shorter maximum CA and younger age at quit attempt were identified as being associated with increased risk of lapse and relapse (Table III). In addition, higher MNWS urge to smoke score was associated with

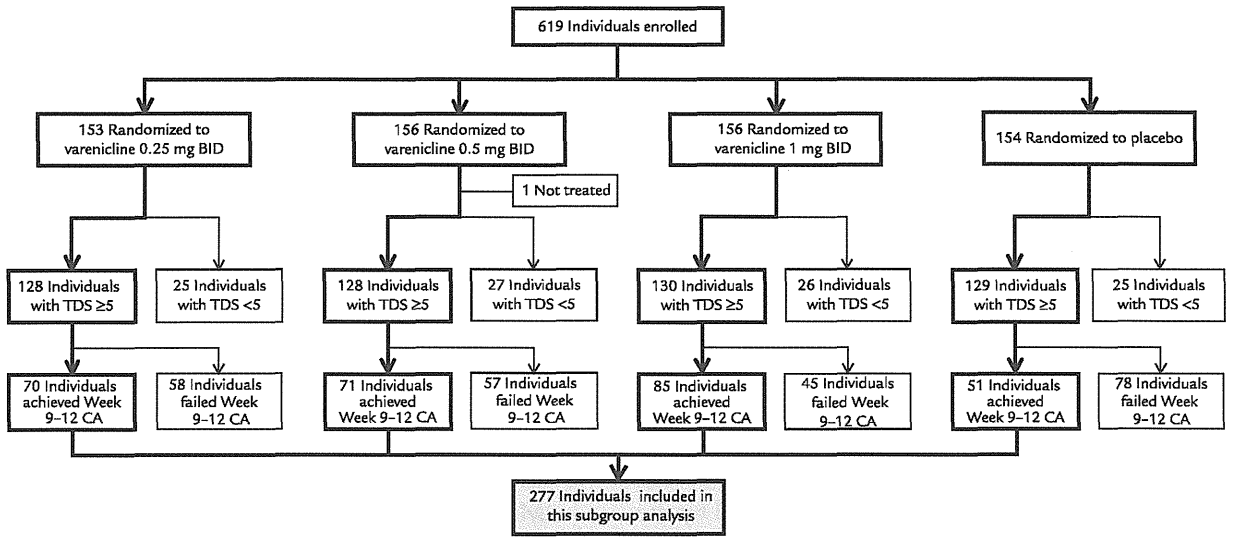

Figure 1. Disposition of the study participants included in the subgroup analysis. CA = continuous abstinence; TDS = Tobacco Dependence Screener.

Table I. Predictors of lapse and relapse: descriptive statistics by status

Potential Predictor	Lapse		Relapse	
	Lapsers (n = 130)	Nonlapsers (n = 147)	Relapsers (n = 113)	Nonrelapsers (n = 164)
Demographic characteristics				
Age, mean (SD), y	38.0 (12.2)	44.4 (12.0)	38.0 (12.3)	43.8 (12.0)
Male, No. (%)	95 (73.1)	114 (77.6)	82 (72.6)	127 (77.4)
Body mass index, mean (SD), kg/m^2	23.2 (3.0)	23.2 (3.0)	23.3 (3.0)	23.1 (3.0)
Smoking				
Age at onset of smoking, mean (SD), y	18.7 (3.1)	18.6 (2.4)	18.7 (2.8)	18.7 (2.8)
Length of smoking, mean (SD), y	18.9 (11.3)	25.3 (11.5)	18.9 (11.4)	24.6 (11.6)
Cigarettes per day in the past month, mean (SD)	22.8 (7.8)	23.3 (9.6)	22.9 (7.9)	23.2 (9.4)
Longest abstinence in previous year, No. (%)				
0 days	90 (69.2)	121 (82.3)	77 (68.1)	134 (81.7)
1–30 days	37 (28.5)	23 (15.6)	33 (29.2)	27 (16.5)
>30 days	3 (2.3)	3 (2.0)	3 (2.7)	3 (1.8)
Lives with a smoker, No. (%)	41 (31.5)	54 (36.7)	38 (33.6)	57 (34.8)
Frequent contact with smoker, No. (%)	120 (92.3)	131 (89.1)	104 (92.0)	147 (89.6)
Made ≥1 serious quit attempt, No. (%)	98 (75.4)	93 (63.3)	89 (78.8)	102 (62.2)
Pack-years, mean (SD)	23.0 (18.0)	30.6 (21.8)	23.1 (18.0)	29.8 (21.6)
FTND score, mean (SD)	5.2 (2.0)	5.3 (2.1)	5.3 (2.0)	5.3 (2.0)
Baseline cotinine, mean (SD), ng/mL	261.0 (160.9)	249.9 (155.9)	262.5 (157.7)	250.1 (158.6)
Baseline weekly alcohol intake, mean (SD), U	18.8 (31.3)	16.7 (25.9)	19.0 (31.8)	16.8 (26.0)
MNWS and length of abstinence during treatment phase				
MNWS,* mean (SD)				
Negative affect	0.1 (0.3)	0.1 (0.3)	0.2 (0.4)	0.1 (0.3)
Insomnia	0.4 (0.8)	0.3 (0.6)	0.4 (0.8)	0.3 (0.6)
Urge to smoke	0.5 (0.8)	0.4 (0.7)	0.6 (0.8)	0.4 (0.6)
Restlessness	0.1 (0.4)	0.1 (0.3)	0.1 (0.5)	0.1 (0.3)
Increased appetite	1.1 (1.2)	1.1 (1.3)	1.1 (1.3)	1.1 (1.3)
Quit pattern (immediate), No. (%)	51 (39.2)	85 (57.8)	42 (37.2)	94 (57.3)
Maximum CA,† mean (SD), wk	8.7 (2.5)	9.9 (1.7)	8.7 (2.5)	9.8 (1.8)

CA = continuous abstinence; FTND = Fagerström Test for Nicotine Dependence; MNWS = Minnesota Nicotine Withdrawal Scale.
*At week 12.
†Maximum CA during treatment phase.

increased risk of relapse (Table III). Table III details the ORs generated by analysis using predictors as categorical values. For participants with a maximum CA of 4 to 6 weeks versus those with a maximum CA of 10 to 11 weeks, the ORs for lapse and relapse were 4.649 (95% CI, 2.071–10.434) and 3.337 (95% CI, 1.538–7.239), respectively. In participants aged 21–34 years versus those aged 47–72 years, the ORs for lapse and relapse were 3.453 (95% CI 1.851, 6.441) and 3.442 (95% CI 1.795, 6.597), respectively. Similarly, those with a MNWS urge to smoke score of 2 to 4 had an OR for relapse of 3.175 (95% CI, 1.166–8.644) compared with those with a score of 0. Individuals having made ≥1 serious quit attempt versus no

Table II. Identified predictors of lapse and relapse using a logistic regression model.

Identified predictor*	Odds ratio (95% CI)	*P* value
Lapse		
Maximum CA	0.762 (0.673–0.863)	<0.0001
Age	0.958 (0.938–0.978)	<0.0001
Relapse		
Maximum CA	0.786 (0.696–0.887)	<0.0001
Age	0.959 (0.938–0.981)	0.0002
MNWS urge to smoke	1.798 (1.241–2.604)	0.0019
Made ≥1 serious quit attempt	2.278 (1.262–4.113)	0.0063

CA = continuous abstinence; MNWS = Minnesota Nicotine Withdrawal Scale.
*All predictors were continuous variables.

serious quit attempt had an OR for relapse of 2.108 (95% CI, 1.168–3.805). Figure 2 presents these results as Kaplan-Meier plots. The Kaplan-Meier plots reveal that individuals with high-risk predictors tend to relapse to smoking earlier compared with those with low-risk predictors.

DISCUSSION

This post hoc study was conducted to identify predictors of smoking lapse and relapse in a population of Japanese smokers treated with varenicline. It has been reported that any smoking after the target quit date is predictive of relapse.[20,21] The results of this

Table III. Identified predictors as categorical variables.

	Odds ratio (95% CI)	
Identified predictor	Lapsers	Relapsers
Maximum CA, wk		
4–6	4.649 (2.071–10.434)	3.337 (1.538–7.239)
7–9	2.342 (1.269–4.320)	2.474 (1.315–4.654)
10–11	—	—
Age, y		
21–34	3.453 (1.851–6.441)	3.442 (1.795–6.597)
35–46	1.553 (0.828–2.913)	1.845 (0.943–3.609)
47–72	—	—
MNWS urge to smoke score		
0	—	—
1	—	1.975 (1.097–3.556)
2–4	—	3.175 (1.166–8.644)
Made ≥1 serious quit attempt		
No	—	—
Yes	—	2.108 (1.168–3.805)

CA = continuous abstinence; MNWS = Minnesota Nicotine Withdrawal Scale.

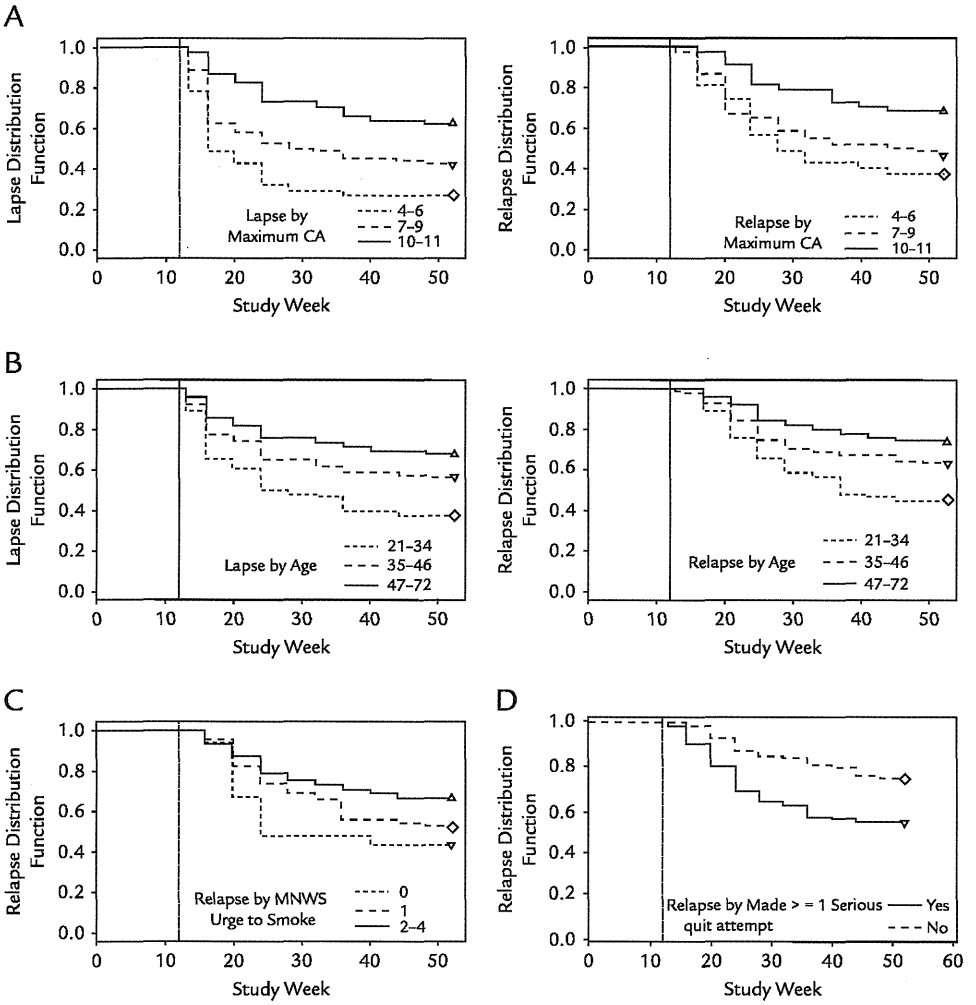

Figure 2. Kaplan-Meier plots by maximum continuous abstinence (CA) (A), age (B), Minnesota Nicotine Withdrawal Scale (MNWS) urge to smoke (C), and ≥1 serious quit attempt (D).

study revealed that when analyzed as categorical variables, shorter maximum CA and younger age at quit attempt were identified as being associated with increased risk of lapse and relapse. In addition, higher MNWS urge to smoke score was associated with an increased risk of relapse. The risk of lapse for smokers with a maximum CA of 4 to 6 weeks was 4.6 times higher than with a maximum CA of 10 to 11 weeks. These results are in agreement with those from a pooled analysis of 2 registration studies for varenicline, which revealed that maximum CA during the treatment phase of the study and the longest period of abstinence in the year before study entry were predictors of relapse.[14] Hajek et al[15] reported that the later in the 12-week treatment period with varenicline smokers obtained abstinence, the less likely they were to remain abstinent at 1 year.

Individuals whose maximum CA was 4 to 6 weeks started their CA nearer the end of the treatment phase than those whose maximum CA was 10 to 11 weeks. To prevent relapse, longer-term treatment after the initial quit date would be required. Tonstad et al[13] reported that the use of 12 weeks of maintenance therapy with varenicline in smokers who achieved abstinence for at least 7 consecutive days at the end of standard varenicline treatment was associated with significantly improved quit rates compared with placebo. Hajek et al[15] reported that extended treatment with varenicline prevented relapse in late quitters (OR, 1.7; 95% CI, 1.2–2.4; $P = 0.0015$) but

not in early quitters (OR, 1.1; 95% CI, 0.8–1.5; $P = 0.6995$). They also concluded that smokers should have the best chance of successfully quitting if they took varenicline for the full 12-week treatment period while they are abstinent because this would permit sufficient time for neuroadaptation. Another pooled analysis of the 2 varenicline registration studies in which smokers received varenicline, bupropion sustained release, or placebo[2,3] revealed a positive correlation between adherence to treatment and tobacco abstinence.[22] The authors reported that age, number of cigarettes smoked per day, and week 2 abstinence were significant predictors of adherence for all treatment groups. Our study also found that smokers aged 21 to 34 years were more likely to relapse compared with older smokers. These results are in agreement with a number of other studies reporting that older age is linked to a positive cessation outcome.[23–25]

To our knowledge, this is the first analysis to identify predictors of smoking lapse and relapse in Japanese smokers. This study investigated predictors not only for lapse to smoking but also for relapse. Maximum CA and age were identified as predictors of both lapse and relapse; however, MNWS urge to smoke score and having made ≥1 serious quit attempt were not identified as predictors of lapse.

Lapse was defined as a break in abstinence, whether or not it led to a full relapse. However, if the lapse occurred for >7 days during the follow-up period (ie, 280 days), the event was classified as a relapse. In this study, 113 of 130 patients (86.9%) who lapsed also relapsed. Therefore, it is not surprising to identify the same predictors of lapse and relapse. However, urge to smoke and ≥1 serious quit attempt were identified as predictors of relapse but not of lapse.

Several studies have examined the association between lapse and relapse and the urge to smoke. For example, West et al[26] found that smokers who had frequent urges to smoke were likely to relapse in the short term. Killen et al[27] found that postquit craving was significantly associated with abstinence at the 2-month follow-up and the intensity of craving was associated with the time to relapse. Swan et al[28] revealed that craving was a robust predictor of relapse and a higher level of craving was associated with a shorter time to relapse. Brown et al[29] reported that relapsers who had never sustained any previous quit attempt for >24 hours tended to feel a greater urge to smoke compared with those who had sustained a quit attempt lasting for ≥3 months.

The results of this study for the urge to smoke are consistent with previous studies. Reducing the urge to smoke at the beginning of smoking cessation is important to achieve long-term cessation. Recently, Foulds et al[30] reported the results of the effects of varenicline on nicotine withdrawal symptoms from a pooled analysis of 8 randomized, placebo-controlled clinical trials of varenicline. The urge to smoke was lower for varenicline than placebo.

The effect of the past quit attempt on lapse or relapse has found conflicting results in earlier studies. These different results may be related to the characteristics of the participants (ie, all current smokers or quit attempters only) and the definition of a past quit attempt used in the various analyses. For example, Hagimoto et al[31] found that one of the predictors of achieving abstinence successfully in a general Japanese population was never having tried to quit before. In both this study and the study by Hagimoto et al,[31] the study populations were limited to smokers who had made a quit attempt during the follow-up period (quit attempters). Hyland et al[32] investigated predictors of smoking cessation in quit attempters and all current smokers. They found that a past quit attempt was not a significant predictor in quit attempters, whereas it was negatively associated with smoking abstinence in all current smokers, including quit attempters. In contrast, Hymowitz et al[23] found that a past quit attempt was a positive predictor of quitting success, but this was in an analysis of current smokers (ie, using the different populations from the previous 2 studies and this study).

With regard to the inconsistent effects of a past quit attempt on the results from this study and those of Hagimoto et al[31] and Hyland et al,[32] it should be taken into consideration that the definition of a past quit attempt was different among the various studies. A past quit attempt during a lifetime was defined in the present study and in the study by Hagimoto et al,[31] whereas in the study by Hyland et al,[32] a past quit attempt was defined as being during the previous year.

Several other studies have also reported that a past quit attempt was positively associated with making a further quit attempt.[33–35] However, a past quit attempt was also negatively associated with making a further quit attempt in the study by Hyland et al.[32] They reported that short previous past attempts

(<1 week) were associated with reduced success, whereas longer attempts (≥6 months) were associated with increased success compared with no previous attempt. These short failure attempts close to the start of the study might have caused the smokers to lose their confidence, which reduced their likelihood of a further quit attempt. As Hagimoto et al[31] pointed out, high motivation and past quit attempts were considered to be expressions of the smokers' eagerness to quit smoking. A past quit attempt was also a marker of unknown attributes or circumstances, which made it hard to quit smoking because it indicated that the smokers did not succeed in quitting smoking despite their eagerness to stop.

The present study used a subgroup of patients (n = 277) from an earlier clinical trial.[5] As a result, the participants may have been subject to bias, and the sample size was small. Therefore, further studies will be required to confirm these results. Furthermore, the numbers of lapsers but not relapsers was very small (n = 17). Additional analyses might be able to identify more clearly the number of pure lapsers and the effect of the urge to smoke and past serious quit attempt on smoking relapse.

CONCLUSION

The results of this analysis suggest that shorter maximum CA and younger age at quit attempt were associated with increased risk of lapse and relapse. Higher MNWS urge to smoke score was also associated with an increased risk of relapse. A longer treatment duration with varenicline after the initial quit date could help prevent these relapses to smoking.

ACKNOWLEDGMENTS

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CONFLICTS OF INTEREST

Masayuki Ohkura, Carmen Arteaga, and Kiyomi Suwa are employees of and shareholders in Pfizer Inc. Masakazu Nakamura has a research contract with Pfizer Japan Inc (Tokyo, Japan) for clinical trial of varenicline and has received a Medical Education Grant from Pfizer Japan Inc for the Japan Stop-Smoking Training Outreach Project (J-STOP) as a member of the Japan Medical-Dental Association for Tobacco Control. Akira Oshima has research contracts with Pfizer Japan Inc (Tokyo, Japan) for clinical trials of varenicline and, as the president of the Japan Medical-Dental Association for Tobacco Control, has received grants from the Pfizer Foundation Global Health Partnership (New York, New York) during 2008 to 2010 and from Pfizer Japan Inc (Tokyo, Japan) during 2011 to 2012 to conduct J-STOP.

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4　喫煙

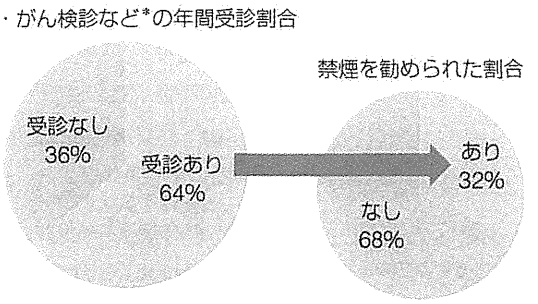
喫煙は高血圧と並んで日本人の死亡への寄与が大きいことが明らかになっています。能動喫煙と受動喫煙による超過死亡数は各々年間13万人，約7,000人で，予防できる最大の病気の原因です[1]。喫煙は高血圧，脂質異常，糖尿病と並んで，動脈硬化の独立したリスク因子です。また，糖代謝障害ならびに脂質代謝障害を引き起こし，糖尿病やメタボリックシンドロームの発症リスクを高めます[2]。さらに，循環器疾患や糖尿病，慢性腎臓病(Chronic Kidney Disease：CKD)の発症だけでなく，重症化を引き起こすこともわかっています[2,3]。

このようなエビデンスを踏まえて，2013年度からの第二期において喫煙の保健指導(禁煙支援)が強化されました。改訂版では，「血圧及び喫煙については，虚血性心疾患や脳血管疾患の発症リスクとして重視すべき項目であるため，健診当日を含め，面接での対応を強化することが求められる。特に喫煙者に対しては，禁煙支援および積極的な禁煙外来の利用を促すことが望ましい」と述べられています[4]。

メタボリックシンドロームに対する保健指導では，減量を目的とした食事や身体活動に重点がおかれることが一般的です。しかし，前述したようなエビデンスから，メタボリックシンドロームの有無に関わらず，すべての喫煙者に禁煙を働きかける必要があります。

わが国では健診やがん検診，人間ドックが広く実施されており，医療と並んで，多くの喫煙者に対して禁煙の働きかけが可能です。喫煙者が1年間に健診やがん検診，人間ドックを受診する割合は約6割に上りますが，その際に医療関係者から禁煙を勧められた割合は約3割に留まっています[5](図3-4)。

健診を含めて保健医療の場で禁煙のアドバイスを広く実施することは，わが国が批准しているWHOのたばこ規制枠組条約においても求められていま



*勤務先や市町村，医療機関などで受けた健康診断，がん検診，人間ドックを含む

中村正和ほか：発がんリスクの低減に資する効果的な禁煙推進のための環境整備と支援方策の開発ならびに普及のための制度化に関する研究，平成23年度総括・分担研究報告書，厚生労働科学研究費補助金 第3次対がん総合戦略研究事業，2012より作成

図3-4　喫煙者の健診・がん検診などの年間受診割合および禁煙を勧められた割合

す[6]。2013年に策定された健康日本21の第二次計画ならびにがん対策推進基本計画の見直しにおいて，成人喫煙率を19.5%(2010年の国民健康栄養調査結果)から2022年度までに12%に低下させるという目標が設定されました。この目標は，たばこをやめたいと考えている37.6%の喫煙者全員がたばこをやめることを想定しています。この目標を達成するためには，たばこ規制枠組条約に沿って，たばこ税・価格の大幅な引き上げの継続や受動喫煙防止のための法的規制の強化などの対策の実施に加えて，喫煙の本質がニコチン依存症という病気であることを踏まえ，保健医療の場での禁煙のアドバイスと禁煙治療の推進が必要です。

取り組みが強化された禁煙支援の内容

今回の禁煙支援の強化に合わせて，厚生労働省から『禁煙支援マニュアル(第二版)』[7]が発行されました。本マニュアルでは，「短時間支援」と「標準的支援」の2つの方法が示されています(**表3-9**，**図3-5**)。健診当日のように禁煙支援の時間が十分確保できない場合は短時間支援の方法，保健指導など健診後の保健指導のように時間がある程度確保できる場合は標準的支援を行います。

短時間支援：ABR方式

短時間支援の方法は3つのステップの頭文字をとってABR方式と呼ばれています。まずA(Ask)で，問診票を用いて喫煙状況を把握する。B(Brief

表 3-9　短時間支援と標準的支援の内容

回数	個別面接 1 回	個別面接 1 回，電話フォローアップ 4 回
時間	1～3 分	初回面接 10 分，フォローアップ 5 分
内容		Ask：喫煙状況の把握
		Brief advice：短時間の禁煙アドバイス (1)禁煙の重要性を高めるアドバイス (2)禁煙のための解決策の提案
	Refer：医療機関等の紹介(準備期のみ)	Cessation support：禁煙実行・継続の支援 (1)初回の個別面接(準備期のみ) ①禁煙開始日の設定 ②禁煙実行のための問題解決カウンセリング ③禁煙治療のための医療機関等の紹介 (2)電話によるフォローアップ(禁煙開始日設定者のみ) ①喫煙状況とその後の経過の確認(禁煙に対する賞賛と励まし) ②禁煙継続のための問題解決カウンセリング
支援の場	特定健診，がん検診などの各種健診	特定保健指導や事後指導などの各種保健事業

厚生労働省健康局：禁煙支援マニュアル(第二版)，p.49，2013 より一部改変

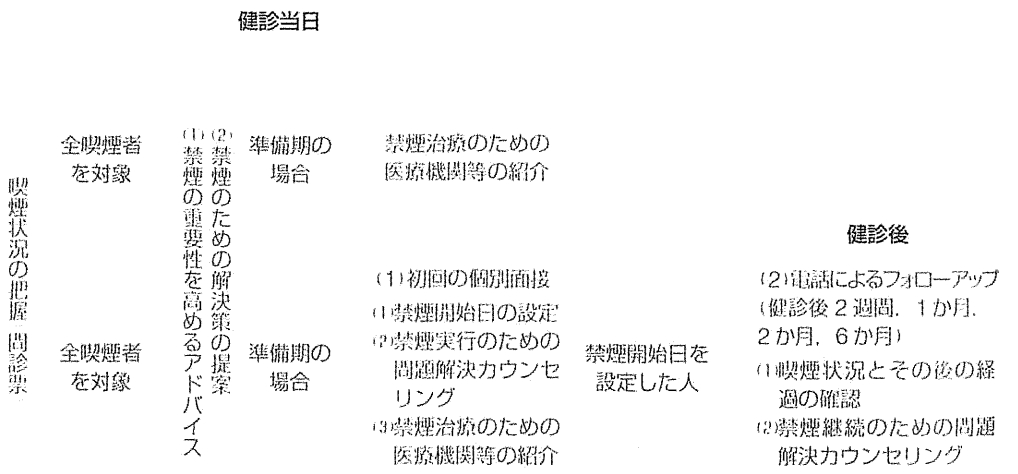


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図 3-5　短時間支援と標準的支援の流れ

advice)で，喫煙者全員を対象に①禁煙の重要性を高めるアドバイス，(2)禁煙のための解決策の提案，R(Refer)で，禁煙を希望する喫煙者を対象に，禁煙治療が健康保険で受けられる医療機関の紹介や一般用医薬品の禁煙補助薬の入手方法の説明を行います。

標準的支援：ABC 方式

標準的支援の方法は「ABC 方式」と呼ばれています。A(Ask)と B(Brief advice)は，短時間支援の ABR 方式と共通です。異なるのは，初回の個別支援内容の B(Brief advice)に加えて，1か月以内に禁煙を考えている準備期の喫煙者を対象に C(Cessation support)を実施するという点と，初回の禁煙支援の結果，禁煙開始日を設定した喫煙者を対象に健診後の電話フォローアップを実施するという点です。つまり，短時間支援に比べて支援内容が長期にわたり充実しています。

C(Cessation support)では初回の個別支援として，①禁煙開始日の設定，②禁煙実行のための問題解決カウンセリング，③禁煙治療のための医療機関等の紹介を行います。

フィードバック文例集を活用した禁煙支援

日本人の死亡への寄与が大きい喫煙と高血圧は，健診当日に把握可能であるため，健康への動機が高まる健診当日に短時間支援を実施することが効果的です。それが難しい場合は健診結果の通知や保健指導の機会を利用することになります。

短時間の禁煙アドバイスのねらいは

短時間の働きかけで喫煙者の禁煙の動機づけや自信を高めるのに重要なステップが B(Brief advice)です。このステップで「喫煙に関するフィードバック文例集」を活用します。

前述したように，B(Brief advice)は喫煙者全員を対象に，①禁煙の重要性を高めるアドバイス，②禁煙のための解決策の提案の2項目から成ります。これらをとりあげた理由は行動科学の理論的な基礎と方法にあります。英国ウェールズ大学のロルニックらは，行動を変える「重要性(importance)」と行動を変える「自信(confidence)」の2つの概念には相関関係があり，これらを高めることで，行動変容の実行を促すというアプローチを提唱しています[8]。

準備性に応じたアプローチ

一般に禁煙の準備性の低い喫煙者では禁煙の重要性を高めるアプローチ，準備性の高い喫煙者では自信を高めるアプローチが優先されます。そこで B(Brief advice)の②禁煙のための解決策の提案は，自信を高めることをねらいとした情報提供を行います。

表 3-10　禁煙の重要性を高めるための情報提供

血圧高値の場合
喫煙と高血圧は日本人が命を落とす二大原因であることがわかっています。喫煙と高血圧が重なると，いずれも該当しない人と比べて，脳卒中や心臓病で命を落とす危険が約 4 倍に高まります。この健診を機会に禁煙されることをお勧めします。

脂質異常の場合
喫煙すると，血液中の善玉(HDL)コレステロールが減少したり，中性脂肪や悪玉(LDL)コレステロールが増加することがわかっています。また，喫煙と脂質異常が重なると，動脈硬化がさらに進んで，脳梗塞や心筋梗塞にかかりやすくなります。この健診を機会に禁煙されることをお勧めします。

血糖高値の場合
喫煙すると，血糖値が上昇したり，糖尿病に約 1.4 倍かかりやすくなったりします。喫煙によって交感神経の緊張が高まって血糖値が上がり，膵臓から分泌されるインスリンというホルモンの効き具合が悪くなるためです。また，喫煙と糖尿病が重なると，喫煙しない場合と比べて，動脈硬化がさらに進んで，約 1.5〜3 倍，脳梗塞や心筋梗塞で命を落としやすくなります。さらに，腎臓の機能もより低下しやすいことが報告されています。この健診を機会に禁煙されることをお勧めします。

メタボリックシンドロームの場合
喫煙すると，血液中の善玉(HDL)コレステロールが減少したり，中性脂肪や血糖値が増加したりするため，メタボリックシンドロームになりやすいことがわかっています。また，喫煙とメタボリックシンドロームが重なると動脈硬化がさらに進んで，いずれも該当しない人と比べて，約 4〜5 倍，脳梗塞や心筋梗塞にかかりやすくなります。この健診を機会に禁煙されることをお勧めします。

上記いずれも該当しない場合
今回の健診では，血圧，脂質検査，血糖のいずれにおいても異常はありませんでした。しかし，喫煙を続けていると，肺がんなどのがん，脳梗塞や心筋梗塞，糖尿病，COPD(慢性閉塞性肺疾患)などの病気にかかりやすくなるため，現在のよい状態を維持できなくなってしまう可能性があります。この健診を機会に禁煙されることをお勧めします。

厚生労働省健康局：禁煙支援マニュアル(第二版)，79-80，2013 より作成

しかし，実践してわかることは，禁煙の準備性の低い喫煙者でも心の中では禁煙したいと考えていることが多く，禁煙のための解決策の提案に反応する場合が少なくありません。したがって，対象者の特性や反応を考慮しながら，2 つの内容をうまく組み合わせて情報提供するとよいでしょう。

どのように行うか

禁煙の重要性を高めるアドバイス

病歴や検査値の異常，自覚症状がある場合は，それらと喫煙との関係を結びつけて，喫煙の影響や禁煙の効果について説明します。その際にどのような内容を説明するかについては，特定健診・保健指導に関係した主な病態や検査異常別に情報提供の内容が文例集に示されています[4,7](表 3-10)。

病歴や検査値に問題がない喫煙者に対しては，異常がないことをほめたう

表 3-11　禁煙のための効果的な解決策の提案

直ちに(1 か月以内)に禁煙しようと考えている場合，または情報提供の結果，禁煙の動機が高まった場合

禁煙は自力でも可能ですが，禁煙外来や禁煙補助剤を利用すると，ニコチン切れの症状を抑えることができるので比較的楽に，しかも自力に比べて 3〜4 倍禁煙に成功しやすくなることがわかっています。健康保険の適用基準を満たしている場合，1 日 20 本のたばこ代に比べて 1/3〜1/2 の安い費用で医療機関での禁煙治療を受けることができます。

そうでない場合

現在禁煙しようと考えておられないようですが，今後禁煙の気持ちが高まったときのために，次のことを覚えておかれるとよいと思います。
禁煙は自力でも可能ですが，禁煙外来や禁煙補助剤を利用すると，比較的楽に，しかも自力に比べて 3〜4 倍禁煙しやすくなることです。健康保険の適用基準を満たしている場合，1 日 20 本のたばこ代に比べて 1 か月あたり 1/3〜1/2 の安い費用で医療機関での禁煙治療を受けることができます。

厚生労働省健康局：禁煙支援マニュアル(第二版)，p.80，2013 より作成

えで，禁煙が取り組むべき重要な健康課題であることを伝えると，より喫煙者の心に響くという印象があります。

また，禁煙の重要性を高めるアドバイスとして，健康面だけでなく生活面での喫煙のデメリット(喫煙によって小遣いや時間が奪われる，息が臭くなる，美容に悪いなど)について本人が興味をもっていることと結びつけて伝えることは，禁煙の重要性を高めるうえで有効です。

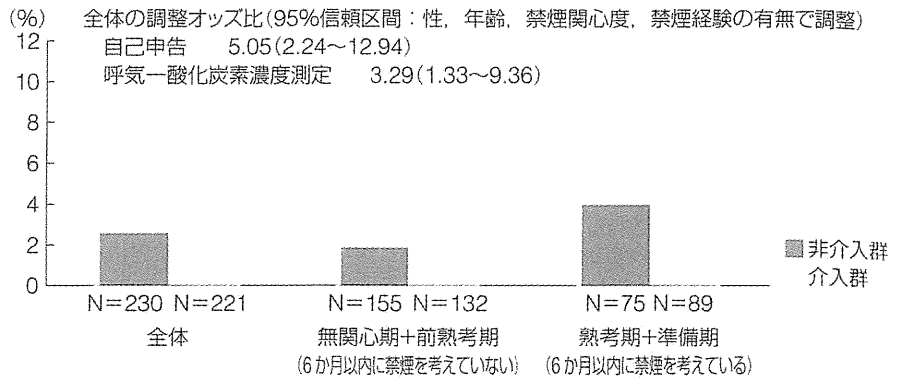
禁煙のための解決策の提案

禁煙のための解決策の提案については，禁煙治療や禁煙補助薬を利用すれば，「比較的楽に」「より確実に」「あまりお金もかけずに」禁煙できることを伝えます。喫煙者の多くは「禁煙は自分の力で解決しなくてはならない」「禁煙はつらく苦しいもの」と思い込んでいる傾向があります。その思い込みを変え，禁煙には費用負担の少ない効果的な解決策があることを知らせることが大切です[4,7](表 3-11)。

禁煙に関心のない人にいきなり禁煙方法について説明しても反発を受けるだけです。現在禁煙する気持ちがないことを受けとめたうえで，「今後の禁煙のために覚えておかれるといいですよ」と前置きをして，禁煙に関心のある人への情報提供と同じ内容を伝えます。そうすることによって抵抗感情があまり生じることなく素直に耳を傾けてくれるでしょう。

期待される効果

最近実施された健診当日の短時間支援法の効果に関する研究によると，診



研究方法：A市での総合健診(がん検診を含む)の場での介入研究，月ごとに割り付け
研究対象：介入群221人(応諾率91.7%)，対照群230人(応諾率90.9%)
研究時期：2011～2012年
介入内容：介入群…診察医師の禁煙の助言と保健指導実施者による1～2分間程度の禁煙支援
非介入群…アンケート調査のみ

大井田隆ほか：特定健康診査・特定保健指導における禁煙支援から始めるたばこ対策．日本公衆衛生協会．p.131，2013より一部改変

図3-6　健診の場での短時間の禁煙介入の効果
6か月後断面禁煙率(呼気一酸化炭素濃度測定)

察医師の禁煙の助言と保健指導者による1～2分程度の禁煙支援により，呼気一酸化炭素濃度の確認による6か月後の禁煙率が約3倍高まることが報告されています[7,9](図3-6)。

特定健診・保健指導の場で禁煙に取り組むことによる経済効果の推計結果によると，15年目には1,000人の集団で約700万円の黒字になるという試算結果が報告されています[7]。このシミュレーションでは，メタボリックシンドロームの有無に関わらず，特定健診の場で禁煙の働きかけをして，4人に1人が禁煙治療を受け，5割が禁煙に成功したと仮定しています。取り組みの費用として，禁煙治療の費用が必要となりますが，喫煙者の減少により，保健指導の費用の削減効果が期待できるだけでなく，中長期的には医療費の削減効果が期待できます。

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