

Effect of telling patients their “spirometric-lung-age” on smoking cessation in Japanese smokers

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Background: Cigarette smoking remains a significant public health problem. However, current treatment programs have not yet succeeded in sufficiently reducing smoking rates. The study aimed to examine whether patients' recognition of “spirometric-lung-age (SLA)” estimated from spirometry data prompts smoking cessation.

Methods: From December 2010 to September 2011, participating smokers were prospectively enrolled into the standardized smoking cessation program (Visits 1–5 for 12 weeks) and assigned single-blindly to either SLA assessment or control groups. The SLA group was informed of the estimated age of their lungs from spirometry analysis and given an opportunity to recognize the difference from their actual chronological age, whereas the control group was not. The primary calculation of outcome was the smoking quit rate on Visit 5, whereas the secondary end-point was the proportion of patients who remained abstinent 1 year later.

Results: One hundred and twenty-six Japanese smokers (88 males) participated and were randomly assigned to the SLA group (n=52) or the control group (n=74). The smoking quit rate on Visit 5 was similar in the SLA assessment group and control group (59.6% vs. 41.9%; P=0.0700). However, the proportion of patients who remained abstinent 1 year later was similar in both groups (78.6% vs. 69.0%; P=0.5497). Multivariate logistic regression analysis after adjusting baseline characteristics demonstrated that telling patients their SLA, the use of varenicline, and age were significantly associated with smoking quit rate on Visit 5 whereas only age was associated with remaining abstinent 1 year later.

Conclusions: Telling patients their SLA can become a useful tool prompting smoking cessation among Japanese smokers although other factors such as pharmacotherapy and age also influence the cessation of smoking.

Keywords: Smoking cessation; spirometry; nicotine patch; varenicline

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Introduction

Cigarette smoking remains a significant public health problem internationally, despite some modulation by

tobacco control efforts in several countries. However, smoking rates have not yet declined sufficiently (1). In our country, the smoking rate in adults was 19.3% in 2014 (male 32.2%, female 8.2%) (2). The trend indicated a

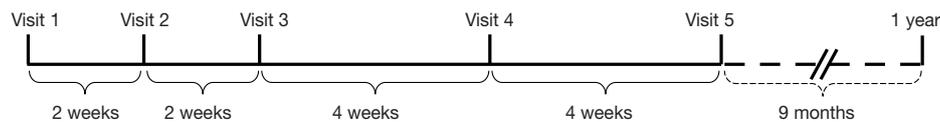


Figure 1 Standardized program for smoking cessation in Japan. The program is approved by the Ministry of Health, Labour and Welfare in Japan and utilized by smoking cessation clinic all over Japan. The medical costs of treatment for obeying this program (Visits 1 to 5, solid line) are accepted by medical health-insurance system. However, after Visit 5 (dotted line), no support contacts are included in the program, and none is covered by health-insurance. Smokers who failed to quit but want to be on the program again must wait for 1 year after Visit 1 to re-enter.

slow but consistent decline since 1997, but the smoking rate remains almost unchanged during the past 4 years (2). Tobacco control efforts, which comprise media campaigns, increased taxes on cigarettes, restricted smoking areas, plain packaging, and smoking cessation programs, etc., have been conducted by governments and society. For smoking cessation, several modalities of evidence-based treatments for tobacco-dependence (brief advice from health professionals, toll-free quit lines, pharmacotherapy such as nicotine replacement therapy and varenicline, etc.) are available in many countries (3). Additionally, numerous efforts are directed at increasing smoking quit rates. For example, one report described several motivational interventions to encourage smoking cessation that successfully raised the quit rate (4). Nurse-interviewing and telephone- or web-based programs have been demonstrated to efficiently raise subjects' efforts to stop smoking (5-7). However, the overall effects of these programs have often been inconsistent and the prevalence of smoking has not reduced sufficiently, even with these various efforts.

Spirometry can detect patients at a high risk of developing chronic obstructive pulmonary disease (COPD) among smokers in general practice. This lung function test leads to an early detection of airflow obstruction [forced expiratory volume in 1 second (FEV_1) <80% of predicted], which appears to develop approximately in a quarter of smokers with chronic cough (8). The early detection of ventilatory impairment in individuals who are at risk of developing COPD and education of patients about smoking-related lung damage is a positive means of influencing smokers to engage in cessation programs. Furthermore, if even subtle abnormalities in pulmonary function are proven by spirometry, that result may provide an educational opportunity for asymptomatic smokers. Unfortunately, though, the detection of abnormalities in pulmonary function has so far failed to raise smoking quit rates (9). One of the possible causes seems to be that

smokers are poorly educated in this subject, suggesting that familiar or understandable terms rather than scores showing defective pulmonary function may be required to motivate smokers to quit smoking.

The concept of "spirometric-lung-age (SLA)" (the age of an average person who has, for example, FEV_1 equal to a subject) was developed in 1985 as a way of making spirometry data easier to understand (10) and also as a potential psychological tool to show smokers the apparent ageing of their lungs (11). However, the effect of these motivational interventions may be influenced by multiple factors including the differences in racial backgrounds and cultural practices (12), smoking cessation programs, and so on. Thus, we evaluated the effect of telling patients their SLA on the smoking quit rate among Japanese smokers at our outpatient clinic.

Methods

The standardized smoking cessation program in Japan

As shown in *Figure 1*, we performed this treatment according to the standardized program for smoking cessation approved by the Ministry of Health, Labour and Welfare in Japan. This program consists of five visits (Visits 1 to 5) during 12 weeks for treatment with either a nicotine patch or varenicline as medicinal support for smoking cessation. The medical costs are covered by our health insurance system if the treatment adheres to this standardized program. However, no further treatments for smoking cessation are covered by this health insurance system for 1 year after Visit 1, irrespective of whether patients successfully quit smoking or not. This means that those who quit successfully have no contact support under the coverage of health insurance system after Visit 5. Additionally, smokers who failed to quit in the program have to wait for 1 year before re-entering the smoking cessation program covered by health insurance.

Intervention by telling SLA

On Visit 1 of the smoking cessation program, all participants were informed of smoking-related health problems and randomly assigned either to the SLA group or control group by odd-even allocation. That is, the participants who consulted the clinic on odd-numbered months were assigned to the control group, whereas those who visited on even-numbered months were placed in the SLA group. The SLA group received education about the natural history of smoking-related airflow obstruction (13) and the concept of SLA (14) before seeing the doctors, whereas the control group did not have that information. The SLA group underwent a standard measurement of pulmonary function [FEV₁, forced vital capacity (FVC), FEV₁/FVC] with a spirometer, Hi-Checker® (Takara Tsusho Co., LTD, Tokyo, Japan) and estimation of their SLA. SLA was calculated as follows: $[0.036 \times \text{height (cm)} - 1.178 - \text{FEV}_1 \text{ (L)}] / 0.028$ for males and $[0.022 \times \text{height (cm)} - 0.005 - \text{FEV}_1 \text{ (L)}] / 0.022$ for females according to a formula approved by the Clinical Pulmonary Functions Committee of the Japanese Respiratory Society. Accordingly, participants in the SLA group noticed the difference between their personal lung age and chronological age immediately after spirometry. If the SLA was more than the individual's chronological age, the participants were informed that smoking had damaged their lungs. An explanation followed that smoking cessation would slow down the rate of deterioration of their lung function back to a physiological age-related decline but that the smoking-related lung damage would not be repaired. On the other hand, if the SLA was equal to or less than the individual's chronological age, the participants were informed that their lungs currently seemed to be normal, but their risk of having other smoking-related health problems would remain. Participants in the control group were informed only that they would receive the standard treatment for smoking cessation, but they were not given any motivational intervention.

On Visit 1, all participants completed Prochaska's questionnaire about stages and processes of self-change from habitual smoking (15), which surveyed their intention to stop smoking to be classified from the "pre-contemplative" "contemplative" "preparation" to "action" phases. All participants were also given a questionnaire from the Tobacco Dependence Screener (TDS) (16) and were examined for their exhaled carbon monoxide (e-CO) levels (non-smoker, e-CO <3 ppm; Smorkelyzer®, Harada Corp., Osaka, Japan). Both Prochaska's questionnaire and

TDS were obtained by participants' self-rating. TDS is a standard questionnaire for participants who intend to stop smoking cigarettes in Japan (16-19). Either the nicotine patch or varenicline was prescribed as medication to support smoking cessation according to patients' preferences. All participants were carefully observed whether they used the medication properly and had adverse events from the medication on every visit to outpatient clinic. We also educated them about benefits from smoking cessation, encouraged to stop smoking or stay abstinent, and then tried to keep them motivated to stop smoking.

Outcome measures

The primary outcome is to establish the smoking quit rate on Visit 5 of the program. Termination of smoking was confirmed by measuring e-CO according to the standardized program. The secondary outcome is whether participants continue abstinence or not. Abstinence or recidivism was confirmed 1 year later by mailing questionnaires.

Ethical considerations

The present study was conducted prospectively and single-blindly at our outpatient clinic from December 2010 to September 2011. The study protocol was reviewed and approved by the institutional ethics committees of Juntendo University Hospital on December 12th, 2010 (approval number: 22-235). Written informed consent was obtained from all participants before inclusion in the study. The researchers will ensure that the study is conducted in compliance with principles of the Declaration of Helsinki and the International Conference on Harmonization guidelines for good clinical practice and applicable legislation.

Statistical analysis

Groups were compared with the unpaired *t*-test for continuous variables and by Fisher's exact test or Chi-square test for categorical variables. Multivariate logistic regression analysis was performed to identify factor that significantly associates with smoking quit rate on Visit 5 as well as the rate the quitters on Visit 5 remained abstinence 1 year later. Variables were selected on Visit 5 with a forward stepwise procedure. Variables of age (10-year regarded as 1 unit), gender, group (SLA/control), smoking (100-pack-year

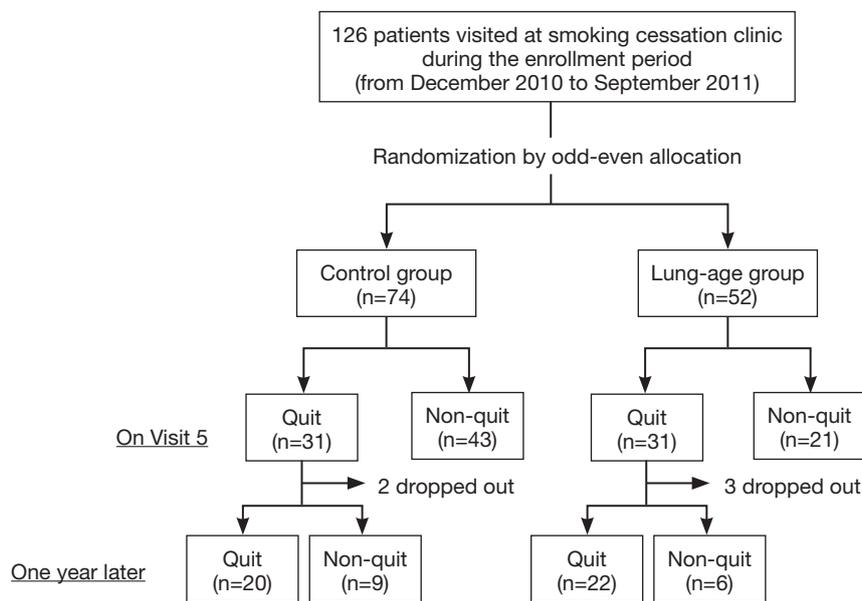


Figure 2 Study profile and participants flow.

regarded as 1 unit), TDS, treatment (varenicline/nicotine patch) and comorbidities (respiratory, cardiovascular, mental, others) were included in the model. For the analysis of 1 year later abstinence, the same variables as on Visit 5 were used in the model with 57 patients who quit smoking on Visit 5.

For all statistical analyses we used SPSS version 19.0. Data are presented as means \pm standard deviation (SD). Differences with P values <0.05 were considered statistically significant.

Results

Baseline characteristics

All subjects who visited at our smoking cessation clinic were asked to participate in this study. They decided to visit at our clinic by themselves, were referred to by general practitioners, or introduced to by other clinics in our university hospital. From December 2010 to September 2011, we prospectively recruited 126 subjects and all gave consent to participate in this study (Figure 2); they were assigned to either the control group (n=74) or the SLA group (n=52) by odd-even allocation on the month they visited at our clinic. A total of five participants in both groups were lost from the survey 1 year later since we could not contact them. The baseline characteristics of all participants appear in Table 1. Mean age at participation as an entire group was 51.9 ± 12.1 years old,

and 69.8% of participants were male. There was no significant difference in gender, age, smoking status, and pharmacotherapy between control and SLA groups. However, the differences were noted in comorbidities and intention to quit smoking: less frequency of comorbidities classified as others including dyslipidemia, diabetes mellitus, collagen vascular diseases and others, and higher intention to quit smoking in the SLA group.

Outcomes

The smoking quit rate on Visit 5 was similar between SLA and control groups (59.6% vs. 41.9%; $P=0.0700$) (Table 2). However, the proportion of patients who remained abstinent 1 year later became similar in both groups (78.6% vs. 69.0%; $P=0.5497$) (Table 2). Since the baseline characteristics of SLA and control groups showed the difference in some aspects, we performed multivariate logistic regression analysis to adjust the baseline differences and then to identify factors that significantly associated with smoking quit rates on Visit 5 and 1 year later (Table 3). We found that telling patients their SLA, the use of varenicline, and age were significantly associated with smoking quit rate on Visit 5. On the other hand, age was the factor only associating with stayed abstinent 1 year later.

We next analyzed whether there are differences in the clinical characteristics between quit and non-quit in the

Table 1 Baseline characteristics of participants

Variable	All (n=126)	Control group (n=74)	SLA group (n=52)	P value
Gender				0.8454 ^b
Male	88	51	37	
Female	38	23	15	
Age, years	51.9±12.1	51.5±12.8	52.4±11.3	0.6697 ^a
Comorbidities, n (%)				
Respiratory	26 (20.6)	16 (21.6)	10 (19.2)	0.8252 ^b
Cardiovascular	9 (7.1)	4 (5.4)	5 (9.6)	0.4865 ^b
Mental	22 (17.5)	10 (13.5)	12 (23.1)	0.2329 ^b
Others	42 (33.3)	36 (48.6)	6 (11.5)	<0.0001 ^b
Smoking status				
Pack, years	36.8±22.9	35.7±21.6	39.1±25.0	0.6760 ^a
TDS	8.1±1.7	8.1±1.8	8.0±1.7	0.1744 ^a
e-CO, ppm	13.9±8.9	14.5±9.1	12.9±8.3	0.8960 ^a
Intention to quit smoking				0.0019 ^c
Pre-c	32	25	7	
Cont	40	22	18	
Prep	21	6	15	
Act	16	12	4	
Treatment, n (%)				0.0992 ^b
Varenicline	93 (73.8)	59 (79.7)	34 (65.4)	
Nicotine patch	33 (26.2)	15 (20.3)	18 (34.6)	

Values are mean ± SD where data are continuous variables. Unpaired *t*-test^a was used for the analysis of continuous variables. Fisher's exact test^b or chi-square test^c for categorical variables. e-CO, exhaled carbon monoxide; TDS, tobacco dependence screener; SLA, spirometric-lung-age; Pre-c, pre-contemplative; Cont, contemplative; Prep, preparation; Act, action.

Table 2 Comparison of smoking quit rate between SLA group and control group

Variable	Quit	Non-quit	Odds ratio (95% CI)	P value
On Visit 5			2.04 (0.99–4.46)	0.0700
SLA group (n=52)	31 (59.6%)	21 (40.4%)		
Control group (n=74)	31 (41.9%)	43 (58.1%)		
One year later (stayed abstinent)*			1.64 (0.45–6.04)	0.5497
SLA group (n=28)	22 (78.6%)	6 (21.4%)		
Control group (n=29)	20 (69.0%)	9 (31.0%)		

*, indicates the number of participants who had stopped smoking on Visit 5 and stayed abstinent for the subsequent 9 months. As indicated in *Figure 2*, three patients from lung-age group and two from control group dropped out. The term “one year” means the period starting from Visit 1. Fisher's exact test was utilized. Odds ratio indicates the likelihood of quitting on Visit 5 or staying abstinent 1 year later as compared with control group. CI, confidence interval; SLA, spirometric-lung-age.

Table 3 Variables associated with smoking quit rate

Variables	Visit 5 (n=126)		One year later (stayed abstinent) (n=57)	
	Odds ratio (95% CI)	P value	Odds ratio (95% CI)	P value
SLA group/control group	2.55 (1.19–5.68)	0.0181	1.67 (0.46–6.50)	0.4373
Varenicline/nicotine patch	2.87 (1.20–7.32)	0.0217	1.24 (0.22–6.27)	0.7932
Age	1.50 (1.04–2.19)	0.0316	2.10 (1.14–4.24)	0.0239
Smoking (pack-year)	0.93 (0.84–1.02)	0.1225	0.99 (0.84–1.19)	0.8824

Logistic regression modeling analysis for smoking quit rate was performed. Variables were selected on Visit 5 with a forward stepwise procedure. Variables of age (10-year regarded as 1 unit), gender, group (SLA/control), smoking (100-pack-year regarded as 1 unit), TDS, treatment (Varenicline/nicotine patch) and comorbidities (respiratory, cardiovascular, mental, others) were included in the model. For the analysis of 1 year later abstinence, the same variables as on Visit 5 were used in the model with 57 patients who quit smoking on Visit 5. SLA, spirometric-lung-age; CI, confidence interval.

Table 4 Characteristics of participants in SLA group: comparison between participants who quit and who did not on Visit 5

Variable	Quit (n=31)	Non-quit (n=21)	P value
SLA, years	72.2±22.0	73.1±19.0	0.8728 ^a
Difference between SLA and chronological age, years	18.3±17.6	22.1±18.4	0.4544 ^a
FEV ₁ , L	2.46±0.80	2.31±0.66	0.4862 ^a
FEV ₁ /FVC, %	0.80±0.20	0.76±0.23	0.4998 ^a
Treatment, n (%)			0.1411 ^b
Varenicline	23 (74.2)	11 (52.4)	
Nicotine patch	8 (25.8)	10 (47.6)	

Values are mean ± SD where data are continuous variables. Unpaired *t*-test^a was used for the analysis of continuous variables. Fisher's exact test^b was used for categorical variables. SLA, spirometric-lung-age; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity.

lung-age group. No significant difference distinguished those who did stop smoking cigarettes from those who did not in SLA, difference between SLA and chronological age, FEV₁, FEV₁/FVC, or treatment status (*Table 4*). Multivariate logistic regression analysis failed to identify a statistical difference between quit and non-quit in SLA group (data not shown).

Discussion

The present study examined the effect of telling patients their SLA on smoking quit rate among smokers at our outpatient clinic. Our study demonstrated that three variables, telling patients their SLA, the use of varenicline, and age, were identified to be significantly associated with smoking quit rate on Visit 5, but only age remained significant for sustained abstinence 1 year later. These results suggest that

the motivational intervention of telling patients their SLA is effective and helpful for smokers to quit smoking for the short-term. The exact mechanism by which this intervention achieved its effect remains undetermined. Although the results of spirometry would provide an ideal educational opportunity for asymptomatic smokers to perceive the status of their lung health, that process failed to promote longer term smoking cessation (9), possibly because the lay public generally fails to understand the full meaning of spirometry in the context of long-term health and life span. In contrast, the term “SLA” estimated from spirometry data appears to be easier and more acceptable for smokers. Conceivably, the concept of SLA may effectively draw smokers' attention to their risk of developing lung diseases. Helping smokers to realize the current status of their lung health would, then, have prompted smoking cessation.

Parkes *et al.* (11) previously reported the efficacy of

telling patients their SLA on smoking quit rates among 561 smokers for 12 months. That study demonstrated that the smoking quit rate increased to 13.6% after telling patients their SLA *vs.* 6.4% in the control group. However, there is a striking difference in the baseline quit rate (control group, *i.e.*, without motivational intervention by telling SLA) between our outcome and that of Parkes *et al.* (11). In our program, the quit rate of the control group was 41.9% on Visit 5 and two-third of them stayed abstinent 1 year later. Although the number of participants was quite different between the two studies [126 in ours *vs.* 561 in Parkes *et al.* (11)], the results suggest the following interpretations. First, telling patients their SLA appears to induce smokers to quit smoking even when they differ in ethnicity, although ethnic disparities in daily cigarette smoking rates, nicotine dependence, cessation motivation, and knowledge of cessation methods and products have been reported (12). Rather, these disparities may influence the baseline quit rate as seen in the differing outcomes between the report of Parkes *et al.* (11) and the present study. Secondly, motivational intervention by telling SLA appears to be effective in raising the smoking quit rate irrespective of the program's length [1 year for Parkes *et al.* (11) *vs.* 12 weeks for the present study]. Further study is needed to test whether telling patients their SLA universally promotes smoking cessation regardless of ethnicity and cultural background.

In the present study, the effect of telling SLA on smoking quit rate was lost, considering the relapse rate at 1 year after successful quit on Visit 5: 21.4% (6/28) in the SLA group *vs.* 31.0% (9/29) in controls. Agboola *et al.* demonstrated a 55% relapse after abstinence from smoking at week 52 among varenicline users (20), whereas Ebbert *et al.* showed that abstinence rates from smoking among varenicline users were 32% during 15 through 24 weeks and 27% during 21 through 52 weeks (21). Compared to those reports, the relapse rates seemed to be lower in our study. Factors related to relapse after abstinence from smoking have been attributed to increased alcohol intake and lower numbers of support contacts (22). Unfortunately, we did not survey alcohol intake in our study population. Furthermore, any support contacts were not offered after Visit 5, because health insurance does not cover longer terms under the current smoking cessation program in Japan. Cochrane's review (4) reported that psychosocial interventions for smoking cessation in patients with coronary heart diseases are effective in promoting abstinence up to 1 year, provided the interventions are of sufficient duration. Accordingly, the great risk of relapse appears to reside

inherently in our government-approved program, which the result of our study illustrated. Interestingly, multivariate analysis demonstrated that age was significantly associated with not only the smoking quit rate on Visit 5 but also the rate of remaining abstinent 1 year later. Odds ratio were even higher for the rate of remaining abstinent 1 year later than for the smoking quit rate on Visit 5. The reason for this remains undetermined, but further study on socioeconomic factors may help resolve this issue.

We found the favorable influence of pharmacotherapy from varenicline on the smoking quit rate at Visit 5, but not on the rate of remaining abstinent 1 year later. Several studies demonstrated that both the nicotine patch and varenicline effectively encouraged smoking cessation; however, a higher quit rate was reported for varenicline users (23,24). Kotz *et al.* described results from their prospective study in which varenicline users had a 3.8 times higher quit rate than subjects who chose the nicotine patch (25). In addition, the relapse rate after abstinence from smoking was demonstrably smaller in varenicline users than nicotine patch users (26). Since this information is widely distributed, this knowledge about pharmacotherapy seems to be the reason why more participants chose varenicline than a nicotine patch in the present study. Despite of different ethnicities, cultural backgrounds, and health-care systems, the influence on pharmacotherapy-related smoking quit rates from varenicline may be consistent.

Some limitations should be addressed in the present study. First, the number of participants in this study was limited as compared with the preceding studies. Secondly, the disparity in the number of participants between control and SLA groups existed due to our method of randomization. Third, individual situations of participants who failed to quit smoking 1 year later were not investigated. Those statistics might have influenced the interpretation of results in our study. Further research should be addressed the comparative effectiveness in the long term.

Conclusions

In conclusion, motivational intervention by familiar or understandable terms, telling patients their SLA, may be a noticeable way to smoking cessation, leading to reduction in the effect of smoking on international public health problem. To make the most of this short-term effect of telling patients their SLA on convincing them to stop smoking, exploring interventions to promote permanent abstinence, such as, periodic support contacts covered by

health insurance, is a worthwhile endeavor.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The study protocol was reviewed and approved by the institutional ethics committees of Juntendo University Hospital on December 12th, 2010 (approval number: 22-235). Written informed consent was obtained from all participants before inclusion in the study.

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