Jikeikai Med J 2020 ; 67 : 19-28

Sequential Changes in Patient Enablement Instrument during a Smoking Cessation Program and its Effect on Smoking Abstinence

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ABSTRACT

Objectives : This study aimed to described the sequential changes in the Patient Enablement Instrument (PEI) scores during a smoking cessation program and to clarify the effect of PEI scores on short- and long-term smoking abstinence.

Methods : This prospective cohort study included 110 patients from one hospital and nine clinics from November 1, 2015, to February 28, 2018. The main predictor is PEI scores at 1st consultation (PEI1) and final evaluation (last-PEI). The primary outcome is smoking abstinence at 4 and 24 weeks.

Results : Among 110 patients (38 females, 72 males ; mean age ± standard deviation : 53.2±16.6 years), 75 (75/110 ; 68.2%) and 49 (49/97 ; 50.5%) individuals achieved 4 and 24 weeks' abstinence. Those who achieved 4 weeks' abstinence had higher PEI1 scores than those who did not (5.52±3.06 vs. 4.00±2.97). Those who achieved 24 weeks' abstinence had higher PEI1 and last-PEI scores than those who did not (PEI1 : 5.85±3.14 vs. 4.12±2.94 ; last-PEI : 7.45±3.73 vs. 5.19±3.23). PEI scores indicated the statistically significant increase during the program. After adjusting for covariates by logistic regression analyses, PEI1 and last-PEI scores had a significant effect on 24 weeks' abstinence.

Conclusions : Patient enablement increased over time during a standardized smoking cessation program, and PEI1 and last-PEI scores were significant predictors for 24 weeks of smoking abstinence.

(Jikeikai Med J 2020 ; 67 : 19-28)

Key words : Patient Enablement Instrument, self-efficacy, short- and long-term smoking abstinence, smoking cessation

INTRODUCTION

Smoking is a principal risk factor for many noncommunicable diseases, such as cancer, cardiovascular disease, and chronic obstructive lung disease.[1,2] In addition, although preventable, smoking remains the greatest cause of death for Japanese as a single factor.[3] As primary health care bears the responsibility for the primary prevention and control of noncommunicable disease, smokers are one of the most important targets to reduce the mortality and morbidity associated with cigarette smoking. However, nicotine dependence is often a barrier for primary care physicians when

Received : June 27, 2020 / Accepted : November 11, 2020
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treating such targets.

To achieve smoking cessation for individuals with nicotine dependence, pharmacological therapy is an effective tool.[4,5] In addition, behavioral therapy, such as motivational interviewing, is also useful for smoking cessation.[6] In 2006, Japan's national health insurance system started to cover the costs of a standardized smoking cessation program, which involves a combination of behavioral and drug therapy.[7] Similar to the results from a previous meta-analysis,[8] in this smoking cessation program, short-term smoking abstinence was associated with self-efficacy (range : 0%-100%) before the first consultation with a physician[9]. In addition to short-term smoking abstinence, self-efficacy has also been reported to be important for the prediction of long-term smoking abstinence.[10]

The Patient Enablement Instrument (PEI) is a tool developed to evaluate the quality of consultations for primary care physicians.[11,12] The PEI evaluates self-efficacy as a result of consultation as opposed to patient satisfaction.[13] However, it does not measure the degree of self-efficacy unitarily. According to a previous study in Japan that evaluated its validity and reliability,[14] the PEI consists of two factors : "coping with illness and health maintenance" and "confidence in oneself and independence". To evaluate the quality of consultations in the smoking cessation program, examining patient enablement, which consists of coping and independence, using the PEI appears to be more valid compared with only self-efficacy (range : 0%-100%). However, to our knowledge, no study has evaluated the quality of consultations in the Japanese standardized smoking cessation program using the PEI. In particular, a description of sequential changes in PEI scores could substantially improve the quality of the program.

Therefore, this study aimed to clarify both the sequential changes in PEI scores over time during a smoking cessation program in a primary care setting, and the effect of PEI scores on short- and long-term smoking abstinence.

Methods

Study group and setting

Participants in this prospective cohort study were consecutively recruited from among those who had participated in a smoking cessation program started between November 1, 2015 and February 28, 2018 at nine clinics, five of which were family-medicine teaching clinics, and one (Ouji Coop Hospital) a family-medicine teaching hospital located in a residential area of Tokyo. Among all these participants, 110 provided informed consent to participate in the present study.

The exclusion criteria were : 1) individuals under the age of 20 years, and/or 2) individuals who did not agree to participate in this research.

In Japan, nicotine addiction is treated at clinics and hospitals through a standardized smoking cessation program that has been covered by national health insurance since 2006. The targets of this program were individuals with a score or ≥5 on the Tobacco Dependence Screener[15] and a Brinkman index of ≥200, those who wished to stop smoking immediately, and those who agreed and provided written informed consent to take part in this treatment program. This smoking cessation program consists of behavioral and pharmacological therapy with varenicline or a nicotine patch. Individuals visited a clinic or hospital at 2, 4, 8, and 12 weeks after the start of the program. The pharmacological therapy protocol was as follows :

12 weeks of varenicline : varenicline 0.5 mg once daily for 3 days, followed by 0.5 mg twice daily for 4 days, followed by 1 mg twice daily for 11 weeks.

A transdermal nicotine patch for 8 weeks : 52.5 mg for 4 weeks, 35 mg for 2 weeks, and 17.5 mg for 2 weeks, according to the manual of Japanese anti-smoking therapy for the program.[16]

Measurement variables and evaluation process

Outcome measure

In this study, 4 weeks of smoking abstinence was defined as self-reported smoking abstinence at 4 weeks with confirmation by carbon monoxide (CO) concentration in expired air at the last consultation.

In the case that varenicline was selected for drug therapy, the first week, when participants often smoked, was included into the smoking cessation period described above.

In addition, 24 weeks of smoking abstinence was defined as self-reported continued smoking abstinence six months after the start of the program, which was confirmed through follow-up by a telephone call or clinical visit for a different reason after 4 weeks of smoking abstinence at the program.

Source of information on variables to be measured and data collection process

We extracted the following characteristics of patients from medical records at the first consultation : age, sex, presence of tobacco-related disease (all cancers, all cardiovascular diseases, all respiratory system diseases, or all digestive system diseases),[17] presence of psychiatric disease, smoking cessation drug (varenicline or nicotine patch), self-efficacy (range : 0%-100%) in smoking cessation, and exhaled CO concentration. Before the first consultation, the participants were asked to complete the Fagerström Test For Nicotine Dependence (FTND). They were also asked about their educational background using a self-report questionnaire.

Patient Enablement Instrument (PEI)

The PEI was developed to evaluate the quality of consultations by primary care physicians.[11] The concept of patient enablement involves the patient's understanding of their illness and his/her recognition that a patient has the ability to deal with the illness.[12, 13] Kurosawa et al. developed the Japanese version of the PEI and confirmed its validity and reliability for Japanese patients.[14] The PEI consists of six items (scoring range : 0-2 points), with a total possible score of 0-12 points. The higher the PEI score, the higher the patient enablement.[11-14] In this study, we modified the introductory statement of the PEI from "As a result of your visit to the doctor today, do you feel you are…" to "As a result of the treatment you have been receiving for smoking cessation, do you feel you are …" in Japanese. In accordance with this change, we evaluated the accumulated effect of the program at each consultation. This modification followed that used by Haughney et al.[18] We obtained permission to modify and use this statement from the author and the publisher (Springer Nature). The original version of PEI[13] was translated and modified by permission of Oxford University Press. The original version of Japanese PEI[14] was modified for this study with permission from Tohoku University Medical Press. All participants were asked to complete the PEI immediately after each consultation.

Fagerström Test For Nicotine Dependence (FTND)

The FTND, which is a revised version of the Fagerström Tolerance Questionnaire, was used to evaluate nicotine dependence. A score of 0-2 points is mild, 3-6 points is moderate, ≥7 points is defined as severe nicotine dependence.[19, 20]

Analysis and statistical methods

The participant's characteristics were presented by descriptive statistics. PEI1 represents the PEI score at the first visit, PEI2 : second visit (2weeks), PEI3 : third visit (4 weeks), PEI4 : fourth visit (8 weeks), and PEI5 : fifth visit (12 weeks). In addition, the PEI score at the last visit during the program is expressed as last-PEI. PEI1 and last-PEI were compared between those who did and did not achieve 24 weeks of smoking abstinence using the t-test, in the case that the data followed a normal distribution, or the Wilcoxon rank-sum test, in the case that the normality of the distribution was rejected by the Shapiro-Wilk test. Similarly, PEI1 scores were compared between those who did and did not achieve 4 weeks of smoking abstinence.

Logistic regression analyses were performed to identify the effect of PEI scores (PEI1 or last-PEI) on smoking abstinence (at 4 and 24 weeks) after adjusting for age, sex (male=1, female=0), years of education, FTND score, drug type (varenicline=1 or nicotine patch=0), tobacco-related disease (present=1, not present=0), and psychiatric disease (present=1, not present=0). Self-efficacy was considered to be included as a covariate in logistic regression models as it was reported to be correlated with future smoking.[8] In contrast to roughly evaluated self-efficacy (range : 0%-100%), the PEI consists of two factors : "coping with illness and health maintenance" and "confidence in oneself and independence". As PEI scores were assumed to be somewhat correlated with self-efficacy, we eventually excluded the variable of self-efficacy (range : 0%-100%) from the covariates in the logistic regression to clarify the effect of PEI scores on smoking abstinence.

To test whether PEI scores differed overall among the number of consultations, a mixed-effects random-intercept linear regression model was employed with patients as the random effect after adjusting for age, sex, years of education, FTND score, drug type, tobacco-related disease, and psychiatric disease. The variable, "number of consultation" was dealt with as an indicator variable, in which the reference level was "1". In the case that the overall time effect was statistically significant, predictive margins were compared between each pair of the number of consultations with adjustment for multiple comparisons using Scheffe's

method.

To describe the effect size of PEI scores and self-efficacy regarding 24 weeks of smoking abstinence, Cohen's d[21] was used with 95% confidence intervals (95% CIs) calculated using the bootstrap method. In this study, we referred to the standardized difference between those who did and did not achieve smoking abstinence, in which a negative d value indicated that those who achieved smoking abstinence had higher scores than those who did not. Stata 12 and Stata 15 were used for the statistical analyses.[22, 23]

Sample size

To calculate the sample size, we assumed the following : a mean PEI1 score of 7 among those who achieved 24 weeks of smoking abstinence, a mean PEI1 score of 5 among those who did not achieve 24 weeks of smoking abstinence ; a common variance of 3 (12[maximum PEI value] - 0[minimum PEI value] / 4), an α value of 0.05, a power of 0.8, and a ratio equal to 1 for the number of those who achieved smoking abstinence / the number of those who did not. Based on these calculations, each 36 participants would be needed.

For the logistic regression analyses, 160 participants would be needed in the case of eight explanatory variables and a ratio equal to 1 for those who achieved smoking abstinence / those who did not, as the smallest number of individuals with or without smoking abstinence must be at least 10 times the number of explanatory variables used in the model.[24] However, this sample size calculation was only used as a guide.

Ethical considerations

This study followed the Declaration of Helsinki and Ethical Guidelines for Medical and Health Research Involving Human Subjects. Announcements of this study were posted on boards at the participating facilities. All potential participants were informed verbally and in writing of the purpose and contents of the study. It was stated on the questionnaire that responding to the survey was considered as consent to participate in the study. The Tokyo Hokuto Health Co-operative Ethics Committee (No. 81) and Jikei University School of Medicine Ethical Committee (No. 29-283, 8899) approved the study protocols.

Patient and public involvement

This research was done without patient involvement. Patients were not invited to comment on the study design and were not consulted to develop patient relevant outcomes or interpret the results. Patients were not invited to contribute to the writing or editing of this document for readability or accuracy.

RESULTS

A total of 110 patients provided informed consent to participate in the study. During the 12-week program, 75 individuals (75/110 ; 68.2%) achieved 4 weeks of smoking abstinence. Of 97 individuals evaluated by telephone or a visit to clinic for a different reason six months after the start of the program, 49 individuals (49/97 ; 50.5%) achieved 24 weeks of smoking abstinence (Fig. 1).

Ninety eight individuals were evaluated in terms of PEI scores at the first consultations (PEI1) and were ascertained regarding 4 weeks abstinence until the end of program. Of these individuals, three who had missing values for the logistic analyses and one who had not used the smoking cessation drug were excluded from the analysis. Therefore, 94 individuals were targeted for the analysis of smoking abstinence at 4 weeks. In addition, 83 individuals who did not have missing values used in the logistic analyses were ascertained regarding 24 weeks of smoking abstinence. These 83 individuals were targeted for 24 weeks abstinence.

Participants' characteristics

The characteristics of the patients in these three groups. Among all participants, 79 (79/110 ; 71.8%) used varenicline and 30 (30/110 ; 27.3%) used a nicotine patch. Three participants changed the drug from varenicline to a nicotine patch because of nausea and vomiting ; these individuals were included in the varenicline group for analysis (Table 1).

Mixed-effects random-intercept linear regression model : PEI scores over time

The results of the mixed-effects model to test whether PEI scores differed overall among the number of consultations. A statistically significant effect of time on PEI score was observed ($\chi 2=33.9$, degrees of freedom$=4$, $p<0.01$)

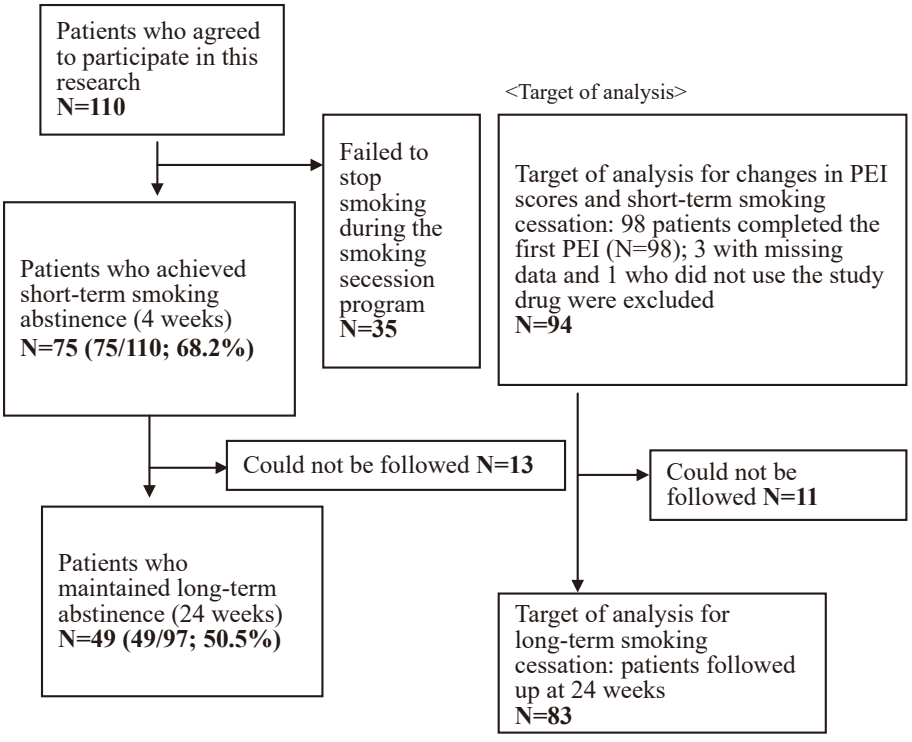

Fig. 1. Flowchart showing the follow-up process of the participants

(Table 2).

Predictive margins of time for PEI scores with 95% CIs

As Figure 2. demonstrated, the PEI scores increased over time by using the estimates of the predictive margins of time for PEI scores with 95% CIs. (Fig. 2).

The results of Scheffe's multiple comparison tests showed PEI scores differed significantly between PEI1 and PEI score at the third consultation (PEI3), PEI1 and PEI score at the fourth consultation (PEI4), and PEI1 and PEI score at the fifth consultation (PEI5).

The PEI1 scores for participants who achieved 4 weeks of smoking abstinence (mean ± standard deviation : 5.52±3.06) were significantly higher than those for the participants who did not (4.00±2.97 ; t-test, p=0.03). In addition, PEI1 (5.85±3.14) and last-PEI scores (7.45±3.73) for participants who achieved 24 weeks of smoking abstinence were significantly higher than those for participants who did not (PEI1 : 4.12±2.94, p=0.01, t-test ; last-PEI : 5.19±3.23, p=0.004, t-test).

Regarding smoking abstinence at 24 weeks, Cohen's d was −0.57 (95% CI : −1.01 to −0.13) for PEI1 and -0.65 (95% CI : −1.11 to −0.19) for last-PEI scores. By contrast, Cohen's d for self-efficacy (0%-100%) before PEI1 was −0.37 (95% CI : −0.84 to 0.11), which was not statistically significant.

Logistic regression analysis to identify the effect of PEI scores on smoking abstinence

The results of the logistic regression analyses. In contrast to the results of the univariate analysis, PEI1 scores were not significantly associated with smoking abstinence at 4 weeks after adjusting for covariates. By contrast, PEI1 scores had a significant effect on smoking abstinence at 24 weeks after adjusting for covariates (odds ratio [OR]=1.19, 95% CI : 1.01 to 1.42). Similarly, a logistic regression adjusting for covariates revealed that last-PEI scores were significantly associated with smoking abstinence at 24 weeks (OR=1.17, 95% CI : 1.01 to 1.37) (Table 3).

Discussion

The results of this study indicated a statistically significant sequential change in PEI scores over time during a standardized smoking cessation program in Japan. A comparison among the consultations revealed significant differ-

Table 1. Participants' characteristics

Sex, *N* (%)	All patients	PEI1 evaluated without missing data	Patients followed up at 24 weeks
Total	110	94	83
Male	72 (65.5%)	62 (66.0%)	52 (62.7%)
Female	38 (34.6%)	32 (34.0%)	31 (37.4%)
Age (years), *N* (%)			
20-39	30 (27.3%)	27 (28.8%)	22 (26.5%)
40-59	35 (31.8%)	30 (31.9%)	27 (32.6%)
≥ 60	45 (40.9%)	37 (39.4%)	34 (41.0%)
FTND, *N* (%) Mean ± SD			
Light FTND 0-2	9 (8.3%)	7 (7.5%)	6 (7.2%)
Moderate FTND 3-6	61 (56.0%)	55 (58.5%)	49 (59.0%)
Severe FTND ≥ 7	39 (35.8%)	32 (34.0%)	28 (33.7%)
Drug			
Varenicline	79 (72.5%)	69 (73.4%)	60 (72.3%)
Nicotine patch	30 (27.5%)	25 (26.6%)	23 (27.7%)
No drug	1 (0.9%)	0	0
Self-efficacy (range : 0%-100%) before treatment, Mean ± SD	56.7 ± 27.1	57.3 ± 27.0	56.4 ± 27.8
Tobacco-related disease	30 (27.3%)	22 (23.4%)	20 (24.1%)
Psychiatric disease	20 (18.2%)	16 (17.0%)	15 (18.1%)
Years of education, Mean ± SD (*N* = 103)	12.9 ± 2.4	13.1 ± 2.4	12.9 ± 2.3
Less than high school	15 (16.3%)	11 (11.7%)	10 (12.1%)
High school	47 (42.7%)	45 (47.9%)	42 (50.6%)
Junior college	15 (13.6%)	13 (13.8%)	11 (13.3%)
More than or equal to college	26 (23.6%)	25 (26.6%)	20 (24.1%)
Data missing			

FTND, Fagerström Test for Nicotine Dependence ; PEI1, Patient Enablement Instrument score at first consultation

ences between PEI1 and PEI3, PEI1 and PEI4, and PEI1 and PEI5. Moreover, in the logistic regression analyses, PEI1 and last-PEI scores were significantly correlated with smoking abstinence at 24 weeks. By contrast, after adjusting for covariates, PEI1 was not associated with smoking abstinence at 4 weeks.

Changes over time in PEI scores have been reported in regard to asthma.[25] However, to our knowledge, this is the first study to investigate sequential changes in PEI scores over time during a smoking cessation program in Japan. In this study, PEI1 differed significantly from PEI3, PEI4, and PEI5 based on Scheffe's multiple comparison test. Therefore, we observed a statistically significant increase in PEI scores. In particular, These results suggest that the participants acquired potential enablement to cope with smoking cessation through the program. This finding is compatible with a previous report in a higher number of visits was associated with a higher smoking abstinence.[26] In addition, since the PEI was developed as a tool to assess the quality of primary care physician consultations, this study evaluated not only patient enablement, but also the quality of the standardized smoking cessation program in Japan. Although caution is needed in regard to the possibility of the Hawthorne effect,[27] this affect alone might not be able to explain the increase in PEI scores over time during the program. Therefore, the results suggest that the program had at least some effect on enablement.

Furthermore, smoking abstinence at 24 weeks was associated with PEI1 as well as last-PEI scores. A previous meta-analysis reported that self-efficacy "after smoking cessation" had a strong negative association with future smoking (effect size : Cohen's $d = -0.47$)[8] ; by contrast, self-efficacy "before cessation" had a modest negative association with future smoking (effect size : Cohen's $d = -0.21$). Regarding the association between smoking abstinence at 24 weeks and last-PEI scores corresponding to "after smoking cessation", our results appear to be compatible with those of a previous meta-analysis (Cohen's $d =$

Table 2. Mixed-effects random-intercept linear regression model : Patient Enablement Instrument scores over time

Variables	Coefficient	Standard error	*p*-value	95% confidence interval
Number of consultations				
1	reference			
2	0.96	0.33	0.004	0.31 to 1.61
3	1.38	0.37	0.000	0.66 to 2.09
4	1.76	0.40	0.000	0.97 to 2.55
5	2.13	0.43	0.000	1.29 to 2.98
Age	0.06	0.02	0.003	0.02 to 0.09
Sex	−0.27	0.57	0.634	−1.39 to 0.85
Years of education	0.10	0.12	0.388	−0.13 to 0.34
Drug type	0.52	0.65	0.419	0.75 to 1.80
Psychiatric disease	0.76	0.76	0.317	−0.73 to 2.26
Tobacco-related disease	−1.36	0.69	0.048	−2.70 to −0.01
FTND score	−0.07	0.15	0.620	−0.36 to 0.21
Constant term	1.08	2.31	0.640	−3.45 to 5.62

FTND, Fagerström Test for Nicotine Dependence
A mixed-effects random-intercept linear regression model was employed with patient as a random effect after adjusting for age, sex (male = 1, female = 0), years of education, FTND score, drug type (varenicline = 1, nicotine patch = 0), tobacco-related disease (present = 1, not present = 0), and mental disease (present = 1, not present = 0). The variable, "number of consultation" was dealt with as an indicator variable, in which the reference level was "1."

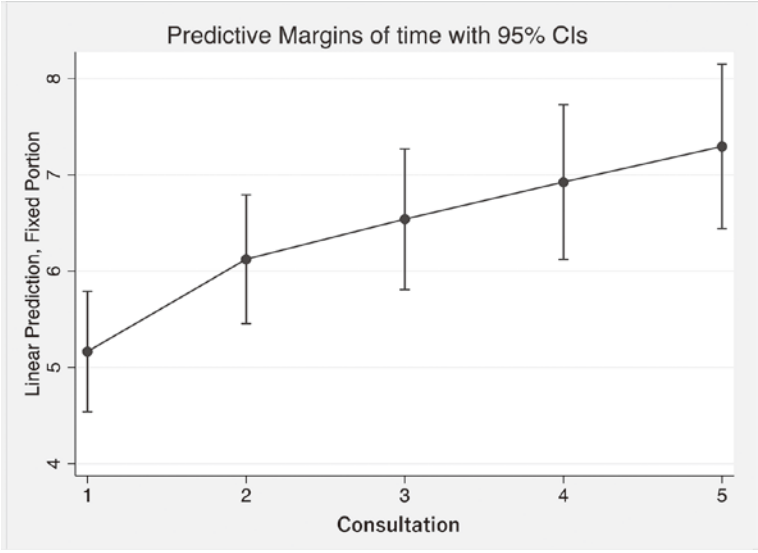

Fig. 2. Predictive margins of time for Patient Enablement Instrument scores with 95% confidence intervals

−0.65, 95% CI : −1.11 to −0.19), despite the wide 95% CI. In contrast to that previous meta-analysis, PEI1 scores corresponding to "before cessation" had almost the same ability to predict smoking abstinence at 24 weeks as last-PEI scores (Cohen's d= −0.57, 95% CI : −1.01 to −0.13 ; OR per 1 point of the PEI score, PEI1 : 1.19, last-PEI : 1.17). Moreover, in our study, Cohen's d for self-efficacy before the first consultation was −0.37 (95% CI : −0.84 to 0.11), which was not statistically significant. This suggests that patient enablement before smoking cessation may be more capable than self-efficacy of predicting long-term smoking abstinence. Another possibility is that the first consultation increased enablement, and thus predicted long-term abstinence more accurately.

Table 3. Logistic regression analysis to identify the effect of Patient Enablement Instrument scores on smoking abstinence

Variables	Odds ratio	Standard error	*p*-value	95% confidence interval
Patient Enablement Instrument at first consultation (PEI1) Response variable : 4 weeks of smoking abstinence				
PEI1	1.15	0.10	0.10	0.97 to 1.37
Age	1.04	0.02	0.03	1.01 to 1.08
Sex	1.05	0.57	0.92	0.37 to 3.03
Years of education	1.09	0.12	0.46	0.88 to 1.35
Drug type	2.34	1.31	0.13	0.78 to 7.03
Psychiatric disease	1.68	1.20	0.47	0.41 to 6.79
Tobacco-related disease	1.05	0.72	0.94	0.27 to 4.02
FTND score	0.94	0.13	0.66	0.73 to 1.22
Constant term	0.03	0.06	0.09	0.0005 to 1.76
PEI1 Response variable : 24 weeks of smoking abstinence				
PEI1	1.19	0.10	0.04	1.01 to 1.42
Age	1.04	0.02	0.03	1.003 to 1.08
Sex	0.97	0.51	0.96	0.34 to 2.73
Years of education	1.15	0.13	0.24	0.91 to 1.44
Drug type	1.65	1.00	0.41	0.50 to 5.43
Psychiatric disease	0.98	0.68	0.97	0.25 to 3.79
Tobacco-related disease	0.98	0.62	0.97	0.28 to 3.37
FTND score	0.90	0.13	0.44	0.68 to 1.18
Constant term	0.01	0.02	0.04	0.0001 to 0.88
Patient Enablement Instrument score at final consultation (Last-PEI) Response variable : 24 weeks of smoking abstinence				
Last-PEI	1.17	0.09	0.04	1.01 to 1.37
Age	1.04	0.02	0.046	1.0007 to 1.08
Sex	0.71	0.38	0.52	0.25 to 2.02
Years of education	1.14	0.13	0.27	0.91 to 1.43
Drug type	1.25	0.74	0.70	0.39 to 3.97
Psychiatric disease	0.58	0.42	0.45	0.14 to 2.39
Tobacco-related disease	1.10	0.69	0.88	0.32 to 3.78
FTND score	0.96	0.13	0.79	0.73 to 1.27
Constant term	0.01	0.03	0.049	0.0002 to 0.99

FTND, Fagerström Test for Nicotine Dependence
Scale of variables : age (years), sex (male = 1, female = 0), drug type (varenicline = 1, nicotine patch = 0), tobacco-related diseases (present = 1, not present = 0), mental disease (present = 1, not present = 0).

In contrast to smoking abstinence at 24 weeks, PEI1 scores were not associated with smoking abstinence at 4 weeks based on the results of logistic regression analysis after adjusting for covariates, even though a statistically significant correlation was found in the univariate analysis. It is therefore assumed that the effect of patient enablement was relatively lower than that of nicotine dependency since patients still had physical nicotine dependence at 12 weeks after the start of program.[28] Conversely, enablement appeared to be more likely to have an effect on long-term smoking abstinence (24 weeks).

Strengths and limitations

To our knowledge, this was the first study to describe sequential changes in patient enablement as evaluated by PEI scores during a standardized smoking cessation program in Japan. PEI scores may better suited than self-efficacy (range : 0%–100%) to predict future smoking cessa-

tion.

This study did have some limitations. First, as mentioned above, the small sample size may help explain the lack of statistical significance for some results. The sample size calculated to necessary was sufficient for the univariate analyses, but not for the logistic regression analyses. Nevertheless, even in the logistic analyses, PEI scores had a significant effect on long-term (24 weeks) smoking abstinence. Second, not all participants could be followed up at 24 weeks after the start of the program. Finally, the generalizability of the results may be limited because the facilities participating in this study were located in urban residential areas of Tokyo.

Conclusions

The findings of this study indicate that patient enablement as evaluated by PEI scores changed and increased over time during a Japanese standardized smoking cessation program. Moreover, PEI1 and last-PEI scores were significant predictors for smoking abstinence at 24 weeks, and could be superior to self-efficacy. The evaluation of patient enablement by PEI might lead to higher smoking abstinent rate. To confirm the results of this study, future research with larger sample sizes in a greater variety of locations is needed.

Conflict of Interest

MM received lecture fees and lecture travel fees from the Centre for Family Medicine Development of the Japanese Health and Welfare Co-operative Federation. MM is an adviser for the Centre for Family Medicine Development practice-based research network, MM is a Program Director of the Jikei Clinical Research Program for Primary-care. MM's son-in-law works at IQVIA Services Japan K.K., which is a contract research organization and a contract sales organization. SM and YS were trainees of the Jikei Clinical Research Program for Primary-care. SM works at a clinic and hospital participating in this study. YS works at a clinic participating in this study. There are no potential competing interests relevant to this work to declare other than the above description. This research was supported by The Jikei University Research Fund for Graduate Students.

Authors' contributions

SM designed the study and participated in the implementation, data analysis, interpretation of the results, and writing of the manuscript. MM designed the study, analyzed the data, interpreted the results, and drafted the manuscript. YS interpreted the data and critically reviewed the manuscript. All authors had full access to the data and take responsibility for their integrity as well as the accuracy of the analysis. All authors read and approved the final manuscript to be submitted.

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