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Title: Efficacy of nicotineless non-pharmacologic alternative tool for smoking cessation program using varenicline

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Body: Background: Tobacco addiction is associated with not only nicotine dependence but also mental dependence based on the habitual smoking situation (e.g. drink alcohol, after meal). The efficacy of substitute nicotineless non-pharmacologic tool (e.g. nicotineless electronic cigarettes) in these situations for smoking cessation was unclear. Method: This prospective observational study aimed to investigate the efficacy of non-pharmacologic alternative tool in patients who were treated with a 12-week outpatients smoking cessation program using varenicline. We screened 180 patients who were treated with the program from March 2010 to February 2012. Tobacco addiction in this study was defined as a condition with both at least five points of the Tobacco Dependence Screener (TDS; Kawakami, et al., 1999) and at least 10 pack year. At the first medical examination, we instructed all the patients to use the nicotineless alternative tool when they urge to smoke. We assessed the success rate of smoking cessation at 12 weeks. Result: Of 136 patients were eligible (35 were lost, 9 dropped). The success rate was 77.8%. Eighty patients (58.9%) used alternative tool as we instructed. The success rate of the patients who used alternative tool was significantly higher than that of the patients who didn't use the tool ($p < 0.001$). In multivariable logistic regression analysis, the independent predictors of smoking cessation failure were untreatable side effect ($p = 0.05$) and disuse of alternative tool ($p = 0.01$). Conclusion: In outpatients smoking cessation program using varenicline, non-pharmacologic alternative tool was useful for patients who urge to smoke in the habitual smoking situations.