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Correlates of support for a nicotine-reduction policy in smokers with 6-week exposure to very low nicotine cigarettes

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Abstract

Background—The US Food and Drug Administration recently issued an advanced notice of proposed rulemaking for reducing the nicotine content in cigarettes to a minimally addictive level. Very little is known about whether use of very low nicotine content (VLNC) cigarettes affects support for a nicotine reduction policy.

Objective—This study examined the effects of using VLNC versus usual brand (UB) cigarettes on support for a nicotine reduction policy and determined whether participant characteristics and responses to VLNC cigarettes were associated with policy support.

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Contributors

All authors fulfill all three ICMJE criteria for authorship on this manuscript.

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Methods—Participants from a cigarette trial who were assigned to either 0.4 mg nicotine/g tobacco research cigarettes or their UB for 6 weeks were asked about their support for the policy. χ^2 tests were used to compare support for the policy between cigarette conditions and logistic regression analyses were conducted to assess covariates associated with policy support.

Findings—Policy support did not differ by condition. After 6 weeks of using VLNC cigarettes, 50% of participants supported the policy, 26% opposed and 24% responded 'Don't Know'. Support was higher among those adherent to smoking only VLNC cigarettes (65%) compared with those who were non-adherent (44%). Older participants and those interested in quitting had increased odds of support. Cigarette satisfaction, perceived harm and perceived nicotine content were not significantly associated with support.

Conclusions—Smoking VLNC cigarettes did not affect support for a nicotine reduction policy. Understanding predictors of policy support and opposition will help public health officials to maximise the public health acceptance and impact of this policy (ClinicalTrials.gov Identifier: NCT01681875 Post-Results).

INTRODUCTION

The Food and Drug Administration (FDA) recently announced a new tobacco control framework that includes a nicotine reduction policy for cigarettes.¹ By mandating that all cigarettes sold in the USA have minimally addictive nicotine levels,² fewer adolescents may transition to becoming adult smokers and current smokers may be more successful at quitting.³ A policy simulation found that if a nicotine reduction policy were implemented by 2020, an estimated 5 million smokers would quit within the first year and nearly 2.8 million tobacco-related deaths would be averted by 2060.⁴

Survey research in the USA indicates that 47%–79% of respondents support this policy and 20%–28% oppose it.^{5–9} Women, racial minorities, people with lower educational attainment and smokers interested in quitting were more likely to support this policy.^{6–8} However, respondents likely had minimal or no exposure to very low nicotine content (VLNC) cigarettes. Only one study has assessed support for a nicotine reduction policy among people who have used VLNC cigarettes; this was a qualitative study of smokers in New Zealand who tried up to 15 VLNC cigarettes within a 1-week period.¹⁰ Among the 16 participants who had tried the cigarettes, product dissatisfaction, particularly dislike of the cigarette taste, emerged as a primary theme underlying policy opposition. US smokers who have had brief exposure to VLNC cigarettes have also reported low VLNC satisfaction.^{11–13} Furthermore, in a recent study,¹⁴ 78% of participants randomised to use VLNC cigarettes for 6 weeks had some level of biochemically verified non-adherence with VLNC cigarettes during the trial,¹⁵ and non-adherence was associated with low cigarette satisfaction. If smokers in the USA find extended use of VLNC cigarettes to be unsatisfying, then they may be less supportive of a nicotine reduction policy. On the other hand, it is possible that smokers may be supportive of a policy that would reduce the addictiveness of cigarettes even if the cigarettes are not satisfying.

The aims of the current study were to examine the effects of 6 weeks of use of VLNC cigarettes among US smokers on support for a nicotine reduction policy and to determine if

participant characteristics and responses to VLNC cigarettes were associated with support. Based on prior research,⁷¹⁰ we hypothesised that (1) participants who had used VLNC cigarettes would report lower support for this policy compared with those who had used their usual brand (UB); (2) participants who rated the VLNC cigarettes as less satisfying, were less adherent with VLNC cigarettes, or perceived them as low/very low in nicotine would have lower odds of support and (3) women, racial minorities, individuals with lower educational attainment, those interested in quitting and those perceiving the cigarettes as more harmful would have increased odds of support.

METHODS

Study design

Data were collected during a double-blind, randomised trial that included a baseline UB smoking phase followed by randomisation to 6 weeks of use of UB cigarettes or one of six spectrum research cigarette conditions varying in nicotine content, which were mentholated or non-mentholated according to preference. Participants received free study cigarettes at weekly sessions. Additional details are available in the primary manuscript.¹⁴ For the current study, analyses included only those assigned to the UB and VLNC conditions (0.4 mg nicotine/g tobacco with 9 or 13 mg tar, combined as there were no differences in smoking outcomes between tar conditions). We selected the 0.4 mg nicotine/g tobacco cigarettes for the analyses because this level aligns with the FDA's advanced notice of proposed rule-making for implementing a low nicotine product standard for cigarettes.¹⁶

Assessments

At baseline and week 6, we measured support for a nicotine reduction policy with the question⁵ 'Would you support or oppose a law that reduced the amount of nicotine in cigarettes, to make cigarettes less addictive?' with the following response options: Support, Oppose, or Don't Know.

At baseline and week 6, we measured cigarette satisfaction using the modified Cigarette Evaluation Scale¹⁷ (mCES). Participants responded on 7-point Likert Scales ('not at all' to 'extremely'). Only the satisfaction subscale is included in the present analyses.

Urine samples collected at week 6 were analysed for total nicotine equivalents (TNEs), and VLNC adherence was defined as TNE <6.41 nmol/mL.¹⁸

At baseline and week 6, we measured perceived risks of developing seven tobacco-related diseases using the Perceived Health Risk Scale¹⁹ (PHRS). Participants responded on 10-point Likert Scales ('very low risk' to 'very high risk'). Since disease ratings were highly correlated, we averaged across diseases to create an overall PHRS score.

At week 6, we asked participants in the VLNC cigarette condition 'What level of nicotine do you think was in your study cigarette?' with the following response options: very low, low, moderate, high, or very high in nicotine.

Statistical analyses

We used χ^2 tests for independence to measure differences in support response counts between the VLNC and UB conditions and between adherent and non-adherent participants in the combined VLNC condition. We used logistic regression analyses to measure associations between policy support and gender, race, educational attainment, cigarette flavour, age, Fagerström Test for Nicotine Dependence²⁰ scores, mCES satisfaction subscale scores, PHRS scores, intention to quit smoking in the next 6 months and perceived nicotine content of the VLNC cigarettes. For the regression analyses, we first dichotomized policy support as Support versus Oppose and excluded Don't Know responses and then compared Support versus Oppose and Don't Know combined to evaluate the robustness of our findings. Tests were considered significant at $\alpha=0.05$, two-tailed. Analyses were conducted using R statistical software V.3.3.0.²¹

RESULTS

At baseline (n=360), 59% of participants supported a nicotine reduction policy, 18% opposed and 23% responded Don't Know. At week 6, 50% of participants in the VLNC condition supported the policy, 26% opposed and 24% responded Don't Know, whereas 55% the UB condition supported the policy, 20% opposed and 25% responded Don't Know. Responses at week 6 did not differ by condition (χ^2 (2, n=333)=1.74 p=0.42). Among those in the VLNC condition who had supported the policy at baseline, 69% continued to support the policy, 15% opposed and 16% indicated Don't Know at week 6. Among those in the UB condition who had supported the policy at baseline, 78% continued to support the policy, 6% opposed and 16% responded Don't Know at week 6. Support at week 6 was lower among non-adherent VLNC smokers (71 out of 163; 44%) compared with adherent smokers (37 out of 57; 65%) (χ^2 (1, n=220)= 6.87, p=0.01).

In the adjusted logistic regression analysis assessing predictors of support at week 6 (table 1), older participants (OR=1.24, 95% CI 1.10 to 1.41) and those interested in quitting in the next 6 months (OR=5.05, 95% CI 2.64 to 9.67) had increased odds of support. No other covariates were significantly associated with support. This did not change when we analysed Support versus Oppose and Don't Know.

DISCUSSION

To our knowledge, this is the first US study to report on support for a nicotine reduction policy among smokers who had used VLNC cigarettes. Policy support did not differ between the VLNC and UB conditions and over two-thirds of participants in the VLNC condition who supported the policy at baseline continued to support it after 6 weeks of exposure to VLNC cigarettes. Consistent with US surveys, older smokers and those interested in quitting reported greater policy support.⁷⁹ Cigarette satisfaction was not a significant predictor of support, but support was lower among participants who were not exclusively adherent with VLNC cigarettes, which may be considered a behavioural measure of dissatisfaction.

Understanding predictors of support among smokers who have used VLNC cigarettes may help public health officials prepare for policy implementation. For example, health communication campaigns targeting people who are likely to support the policy (eg, smokers interested in quitting) as well as those who may oppose or are uncertain about the policy (eg, younger smokers) will be essential for maximising its public health impact. In US surveys, support for a nicotine reduction policy was greater when questions explained the possible benefits of the policy.⁶ Therefore, emphasising the policy's potential public health benefits may increase support among undecided smokers.

In this study, 15% of participants in the VLNC condition switched from supporting the policy at baseline to opposing it at week 6. While the sample size was too small to analyse correlates of loss in policy support, such information would help public health officials prepare for any negative consequences of policy implementation. Some tobacco control experts have expressed concerns that low support for this policy could lead to consumer black markets for conventional cigarettes or product tampering to increase nicotine levels.^{22–25} Qualitative research would be informative to determine how to minimise such practices.

This study has several limitations. First, exclusive use of VLNC cigarettes during the trial was low and non-adherence was associated with lower levels of support.¹⁵ Furthermore, it is possible that participants might have been less supportive if higher-nicotine cigarettes had not been readily available, as would be the case if all cigarettes sold in the USA had minimal levels of nicotine. Future research should explore how the availability of alternative sources of nicotine, in combination with VLNC cigarettes, may affect policy support. Second, the VLNC sample was relatively small (n=240) and not nationally representative, so results may not be representative of all smokers. Third, participants had self-selected into a VLNC cigarette trial and therefore may have greater baseline support for the policy compared with the general population. Fourth, we excluded participants who tested positive for illicit drugs or reported heavy drinking patterns, which may reduce the generalisability of our findings. Fifth, we assessed policy support using a single question, but multiitem questionnaires are generally considered to be more valid.²⁶ Further, because our study was conducted prior to the FDA's announcement of a nicotine reduction strategy, our question did not match the phrasing used in the FDA's announcement.

Specifically, we asked about support for a law that would reduce the amount of nicotine in cigarettes to make cigarettes less addictive, but our question did not specify that nicotine would be reduced 'to a minimally addictive level' as proposed by the FDA.²⁷ It is possible that support for the policy might have been lower if our question had used the phrase 'a minimally addictive level' or specified the degree to which nicotine would be reduced. Thus, more precise wording in future studies is necessary for accurately capturing support for and opposition to the FDA's current proposed nicotine reduction strategy. Finally, participants were blind to the nicotine content of the VLNC cigarettes. Future studies should explore how explicit knowledge of the nicotine content in cigarettes and how the availability of alternative nicotine sources may affect policy support.

Despite these limitations, this study contributes important information to the VLNC cigarette literature. A nicotine reduction policy is the cornerstone of the FDA's comprehensive tobacco control initiative, with the goal of moving current tobacco users away from the most dangerous products (eg, cigarettes) to cessation or cleaner forms of nicotine (eg, non-combusted products).^{127–30} Understanding policy support and opposition among smokers who have used VLNC cigarettes may help public health officials to maximise the public health benefits and anticipate potential challenges as the FDA moves forward with nicotine regulation for cigarettes.

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What this paper adds

- Although past US surveys have indicated support for a nicotine reduction policy, respondents likely had minimal or no experience with very low nicotine content (VLNC) cigarettes.
- Minimal research has been conducted on whether using VLNC cigarettes affects smokers' support for a nicotine reduction policy.
- In this study, support for a nicotine reduction policy did not differ between smokers randomly assigned to smoke VLNC cigarettes (50%) or usual brand cigarettes (56%) for 6 weeks; however, support was higher among those adherent to smoking only VLNC cigarettes (65%) compared with those who were non-adherent to smoking only VLNC cigarettes (44%).
- Among participants assigned to VLNC cigarettes, 69% who supported the policy at baseline continued to support it at Week 6.

Table 1

Covariates associated with support for a nicotine reduction policy at week 6 (Support vs Oppose)

Covariate	Reference group	Week 6		
		unadjusted model		Adjusted model
		Or (95% CI)	P values	OR (95% CI) P values
Female	Male	1.4 (0.82 to 2.40)	0.22	1.68 (0.91 to 3.08) 0.10
White	Non-white	0.9 (0.53 to 1.54)	0.71	1.23 (0.61 to 2.49) 0.56
<12 Years of education	>12 Years	1.33 (0.77 to 2.3)	0.31	1.55 (0.83 to 2.90) 0.17
Menthol flavour preference	Non-menthol	0.99 (0.58 to 1.68)	0.97	1.01 (0.51 to 2.01) 0.973
Age (5 years difference)		1.19 (1.07 to 1.33)	<0.01	1.24 (1.1 to 1.41) <0.01
Fagerstrom Test for Nicotine Dependence score at week 6		1.01 (0.90 to 1.13)	0.90	0.96 (0.84 to 1.10) 0.578
Quit in 6 months—yes at week 6	No	3.97 (2.22 to 7.10)	<0.001	5.05 (2.64 to 9.67) <0.001
Cigarette Evaluation Scale satisfaction score for study cigarettes at week 6		1.03 (0.89 to 1.18)	0.71	1.01 (0.82 to 1.24) 0.93
Perceived Health Risk Scale score for study cigarettes at week 6		1.02 (0.93 to 1.11)	0.67	0.97 (0.88 to 1.08) 0.628
Perceived nicotine content: low/very low	Moderate/High/ Very high	0.81 (0.4 to 1.63)	0.55	1.37 (0.59 to 3.15) 0.46
Perceived nicotine content: usual brand	Moderate/High/Very high	1.27 (0.59 to 2.73)	0.54	1.97 (0.75 to 5.19) 0.17

The unadjusted and adjusted logistic regression analyses comparing Support versus Oppose for the nicotine reduction policy question assessed at week 6. The adjusted model includes all variables listed in the table.