The Development and Assessment of Modified Fagerstrom Test for Nicotine Dependence Scale among Malaysian Single Electronic Cigarette Users

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Background: The Fagerstrom test for nicotine dependence (FTND) is the most widely used scale for assessing nicotine dependence on conventional tobacco cigarettes (TCGs). But the FTND does not evaluate the subject’s nicotine dependence to electronic cigarette (EC). Objective: The aim of this study was to develop and assess an equivalent modified FTND scale that measures the nicotine dependency via EC. Materials and Methods: The investigator developed the equivalent modified FTND scale that scores identical to the original scale, that is, 0–10. The developed scale piloted among 15 EC single users, that is, use only EC verified by carbon monoxide (CO) level of <8 ppm. The assessment of the scale was done among 69 EC single users and observed for 1 year to determine their nicotine status. Results: The modified scale revealed an acceptable Cronbach α value of 0.725. Further test–retest reliability of the scale showed a satisfactory Spearman’s rank correlation coefficient value of 0.730 (P > 0.05). A 1-year observation showed that of 69 single users, 11 single users completely stopped nicotine intake, 24 remained as EC single users, 15 shifted to dual-use, and 19 relapsed to TCG. Surprisingly, the EC users who completely stopped nicotine intake after 1 year had a low average nicotine dependence value of 3 that was measured by the modified FTND scale at the baseline. Conclusion: The modified FTND scale precisely identifies the physical dependence to nicotine via EC. Therefore, as per this study results the modified FTND scale can be applied in any EC-related studies to assess nicotine dependency via EC.

Keywords: Dependence, electronic cigarette, nicotine, scale, tobacco cigarette

INTRODUCTION

With the introduction of nicotine electronic cigarette (EC) products in the market, it has become necessary to determine the physical nicotine dependency on ECs for consumer’s safety reasons and public awareness.[1] EC popularity has increased rapidly over the past decade and their dependency potential is still unknown.[2] There are various scales with proven effectiveness in measuring dependency to nicotine for tobacco cigarettes (TCGs). However, there are limited scales that assess the nicotine dependency that administered through EC.[3] The most commonly used scale for assessing nicotine dependence on traditional TCGs is the Fagerstrom test for nicotine dependence (FTND).[4] The FTND scores ranged from 0 to 10. The scale consists of six questions with scores at every answer, which is related to the smoker’s level of nicotine dependence. A score of 1–3 was categorized as low nicotine dependence, a score of 4–6 as medium nicotine dependence, and a score of 7–10 as high nicotine dependence.[4]
Another short scale that estimates the nicotine dependency on TCGs is the Heaviness of Smoking Index (HSI).

This scale uses the two questions from the FTND scale the first question “time to first smoking in the morning” and the second query is “the number of cigarettes per day.” It is a 6-point scale that calculates the number of cigarettes smoked per day, that is, 1–10, 11–20, 21–30, 31–60, and 61+ min. Nicotine dependence is then categorized based on score: low (0–1), medium (2–4), and high (5–6). HSI is used as a measure for assessing nicotine dependence in nonclinical populations. But the strength of the measuring dependency in a general population may be questioned. However, the HSI scale is used both in clinical and nonclinical population surveys to assess nicotine dependency on TCG. Another is a 68-item longer scale that theoretically measures tobacco dependence by the Wisconsin Inventory of Smoking Dependence Motives (WISDM-68). The WISDM-68 is a multi-subscale that shows the psychometric characteristics and elucidates diverse nicotine dependence factors and mechanisms. But neither the full score nor most of the subscales are as predictive of nicotine cessation results such as short-term FTND scale.

Alternatively, the scale, namely Hooked on Nicotine Checklist (HONC), was developed principally to evaluate the progress of nicotine addiction in young smokers. The HONC is a 10-item scale used to determine the onset and strength of tobacco dependence. The scale has good psychometric properties, but many adult smokers’ range comes under maximum score and the average smoker trying nicotine replacement therapy scores 8/10 and so it is less sensitive among a diverse population.

**Problem Statement**

Literature studies revealed the absence of scale that measures the nicotine dependency via EC. The various aforementioned scales measured the nicotine dependence to TCG but do not point out the subject’s dependency to nicotine by the use of EC. Thus, there is a necessity to assess nicotine dependency via various EC products for consumer’s safety reasons and public awareness. Therefore, the researcher has developed a new scale by modifying FTND that assesses the nicotine dependency, which was administered through the various EC products.

**Materials and Methods**

**Scale development**

The modified FTND scale has scores such as the original scale, that is, from 0 to 10 with equivalent six questions. The modified scale categorized the vapers identically to the original FTND scale, that is, the score 1–3 labeled as low nicotine dependence, a score of 4–6 indicated as medium nicotine dependence and a score of 7–10 was categorized as highly nicotine dependence via EC. But the modified scale has few variations as compared to the original FTND scale. The principal changes are replacing the word TCG with an EC. Another modification during the scale development process that pointed out by almost all reviewers was the frequency of EC use. Because unlike a TCG that is generally smoked as a whole and then discarded. But the EC can be used the same for many times at a different vaping session. Hence, based on reviewers’ comments the investigator replaces the questions “how many tobacco cigarettes a day did you smoke” by the query “how many times a day do you vape.” The investigator adopted one-time of vape session consists of an average puff up to 15.

**Validity and reliability of the scale**

The developed scale was sent to five experts in associated disciplines to evaluate the face and content validity. The reviewer individually ranked each item of the scale by using a 4-point grading system, that is, 1 = not relevant, 2 = somewhat relevant, 3 = relevant, and 4 = highly relevant. The Item Content Validity Index (I-CVI) was applied to assess the validity of each item. The items on the scale with CVIs ranging from 0.91 to 1.00 had retained. The calculated average I-CVI scale value was 0.95 and a content validity ratio (CVR) of 0.99 respectively. The face validity of the scale was also assessed in terms of feasibility, readability, clarity, and uniformity of the language. The face validity was determined on a 1–4 scale which was denoted as 4 = strongly agree, 3 = agree, 2 = disagree, and 1 strongly disagree. All experts were graded 3 or 4 on the scale and indicated that the questionnaire is feasible and appeared understandable to the desired population. The items and scoring guide of the modified developed scale are shown in Table 1.

**Pilot test and reliability of the scale**

The developed modified scale was then piloted on 15 EC single users, that is, who use only EC verified by exhaled carbon monoxide (CO) of <8 ppm. The internal consistency of the scale was determined by using Cronbach α which revealed a satisfactory value of 0.725. Moreover, the consistency of the scale was further accomplished by test–retest followed up among all 15 users of the pilot study after 2 weeks. The results of the test–retest reliability after 2-week intervals of the scale showed an acceptable Spearman’s rank correlation coefficient value of 0.730 with a value of $P > 0.05$. The
correlation coefficient value indicated that there was no significant variation at two different interval periods and the scale is stable over time. Finally, the approved piloted scale was tested among 69 EC single users and observed for 1 year to assess their nicotine status.

**Assessment of the developed scale**

At baseline, the recruitment was supported by distributing flyer related to the study at EC sales points, vaping stations surrounding at the Kuantan and Pekan districts, province Pahang, Malaysia. The study participants have contacted the researcher and clarified any queries related to the study before the enrolment process. The information sheet and consent forms were given to the committed participants. The participants who met the eligibility criteria were selected for the enrolment process. The sociodemographic details, smoking packs per years, and EC history were reported. Then participant’s physical dependence to EC was evaluated by newly modified MFTND. At week 52, all the subjects were verified through the biochemical validation by measuring the CO test irrespective of any smoking status. At week 52, for the self-reported complete nicotine abstinence subjects, additionally validated through the saliva NicAlert strip to evaluate their complete nicotine-free status. At week 52, subjects without biochemical validation were documented as nicotine users for analysis purposes. Intention-to-treat (ITT) analysis was applied to evaluate the final outcomes of the study. That means those users who lost to follow-up were categorized as nicotine users. Also, participants who withdrew from the study were omitted for analysis.

**Ethical committee approval**

The study was approved by the research ethics committee (IREC) of Kulliyyah of Medicine, International Islamic University of Malaysia (IIUM) Kuantan on October 9, 2014, with IREC registration number 302. The study was also registered in the National Medical Research Registration with NMRR number: 15-180-24825.

**RESULTS**

After a 1-year observation period, the investigator measured nicotine status of the participants. Among 69 EC single users, 11 EC single users completely stopped nicotine intake, another 24 remained as EC single users, 15 shifted to dual use, that is, using both EC and TCGs, and 19 relapsed to TCG validated by CO level and saliva cotinine tests, respectively. Those EC single users who were completely stopped nicotine cessation after the 1-year period had nicotine dependence value between 1 and 3 measured by modified FTND scale at the baseline. Figure 1 shows participants’ nicotine dependence status measured by modified FTND scale at baseline and their nicotine status at week 52.

**DISCUSSION**

The newly developed scale was first of its kind which assesses the physical dependence to nicotine, which was administered through EC. The study showed that the EC users who evaluated as low nicotine dependence, that is, on 1–3 by modified FTND at baseline, have been completely stopped the nicotine intake. The participant’s nicotine status at week 52 was

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**Table 1: Fagerstrom test for nicotine dependence equivalent modified scale**

| Nicotine dependence characteristics                                      | Score          |
|-------------------------------------------------------------------------|----------------|
| 1. How soon after waking do you vape your electronic cigarette.         | Within 5min = 3|
|                                                                          |                |
| 2. Do you find difficulty to refrain from vaping in places where it is   |                |
| forbidden such as mosque, church, library?                              | Yes = 1        |
|                                                                          | NO = 0         |
| 3. Which vaping would you hate to give up?                              | The first in the Morning = 1|
|                                                                          | Any other = 0  |
| 4. How many times a day do you vape?                                    | 10 or less = 0 |
|                                                                          | 11–20 = 1      |
|                                                                          | 21–30 = 2      |
|                                                                          | 31 or above = 3|
| 5. Do you vape more frequently in the morning?                          | Yes = 1        |
|                                                                          | NO = 0         |
| 6. Do you vape even if you are sick in bed most of the day?             | Yes = 1        |
|                                                                          | NO = 0         |
| Total                                                                   |                |

Score: 1–3 = low dependence, 4–6 = moderate dependence, 7–10 = high dependence
validated by measuring CO test and saliva cotinine level (NicAlert). The study results suggested that the EC users who totally quit nicotine have less nicotine dependency which was assessed by the modified FTND scale. The reason for the complete abstinence of nicotine among these EC single users may be due to less nicotine dependency induced by EC use. The study result is similar to Farsalinos et al.\textsuperscript{[12]} which found that EC users showed a low nicotine dependency than prior to cigarette smoking. Moreover, most of the studies suggest that EC usage delivers the lower nicotine as compared to TCG, which is also a distinct possibility that may lead to less nicotine addiction among some EC users.\textsuperscript{[13,14]}

The literature studies also revealed that nicotine users who desire to quit completely nicotine intake required high confidence. In addition, there are various environmental factors such as help from family, friends, colleagues, media health campaign, and advice from the health-care professionals can trigger the smokers’ level of confidence in the direction of complete nicotine abstinence.\textsuperscript{[15]} The previous smoking surveys also revealed that the media health campaigns and advice from the health-care professionals are also important factors that motivate the smokers for smoking cessation.\textsuperscript{[16]}

The reasons for this study participants who did not quit complete nicotine intake and remained on nicotine use may possibly be due to their high nicotine dependency score measured by the modified FTND scale. Previous studies exposed that there are various reasons that reinforce vapers to remain on nicotine such as to fulfill their craving for smoking, high dependence on nicotine, and fear of weight gain problem. The previous studies also indicated that personal stressful events, social pressure, and euphoric effects induced by nicotine create more dependency on nicotine.\textsuperscript{[17]}

In this study populations, the suggested causes who shifted to dual-use and relapsed to TCG possibly may be due to the smoking-related withdrawal symptoms such as a craving for smoking, increase appetite, and adverse effects such as dry mouth and coughing by EC use. Tobacco experts agreed that EC is not totally hazard free but less harmful than tobacco smoking.\textsuperscript{[3]}

The other possible causes that lead to TCG relapsed and shifted to dual-use may be associated with the selection of very low strength of nicotine in the e-liquids and inadequate supply of nicotine via EC.\textsuperscript{[19]} The study was conducted among small vapers population in just two locations. Therefore, the scale needs to verify on a large sample size before applying in any EC-related studies. Further, factor analysis, construct, and concurrent validities are the limitations of this study.

**CONCLUSION**

The modified developed FTND scale precisely identifies the physical dependence to nicotine, which administered via EC. Therefore, as per this study results the modified FTND scale can be applied in any EC-related studies to determine the dependency to nicotine via various EC products. However, the scale needs to be validated further in various EC products with a large sample size.

**Data availability statement**

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

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**Conflicts of interest**

There are no conflicts of interest.

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