Original Article

Need for validation of Fagerstrom Test for Nicotine Dependence in Indian context: Implications for Nicotine Replacement Therapy

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ABSTRACT

Background: Variety of smokeable and chewable tobacco products with diverse nicotine content are used in India. Nicotine quantity in tobacco products has a direct bearing on developing tobacco dependence. The present work used this information to derive scores on the Fagerstrom test for nicotine dependence (FTND). It was used to determine the dosing of nicotine replacement treatment (NRT). **Materials and Methods:** Nicotine score quantitation was taken from the previous study. This data was applied to FTND to determine the relationship of nicotine content to the potential degree of dependence. **Results:** Application of nicotine quantitation to FTND in a hypothetical experiment significantly altered the scores from medium to high depending on the brand the used. **Conclusion:** Application of qunatitation of nicotine content in FTND score has implications for the assessment of tobacco dependence and NRT dose. The study implies validation of FTND using nicotine quantity in the consumed tobacco product as a scorable parameter in the FTND.

Key words: *Fagerstrom test for nicotine dependence, nicotine, nicotine replacement treatment, quantitation*

INTRODUCTION

Tobacco use is a major health threat in the Southeast Asian region and India has one of the largest numbers of tobacco users in the region accounting for an annual consumption of ~250 million kg tobacco.[1] Consequences of tobacco use in India are compounded by the prevalence of both smoking and smokeless tobacco products widespread across socioeconomic and ethnic groups both in urban and rural areas.[2]

It is the addictive nature of tobacco that maintains its use and though a majority of users would like to quit, only 2-3% spontaneously quit each year.[3] Addiction to cigarettes and tobacco products is attributed to the presence of nicotine.[4] Nicotine replacement treatments (NRTs) form the first line management of nicotine dependence in many countries. There are many nicotine delivery devices commercially available including nicotine gum, transdermal patches, vapor inhalers, nasal spray, lozenges, and sublingual

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tablets.[5] These treatments enhance tobacco cessation by delivering nicotine without exposure to other carcinogens found in the tobacco products. The use of these nicotine replacement products have led to varying degrees of success in long-term smoking cessation.[6] In India, a preliminary experience from the tobacco cessation centers in the country suggests improved cessation rates with the use of nicotine replacement therapy or bupropion combined with counseling.[7]

The prescription and dosage of NRT is directly related to the quantity of tobacco consumed and the nicotine content of these products. Further based on the pattern of smoking and the type of product (smoked/chewed), the nicotine ingestion is highly variable.[8] A cigarette typically contains ~8.4 mg of nicotine which upon smoking delivers ~1.6 mg of nicotine. Five milligram of nicotine per day is the threshold level to sustain addiction.[9] No such clear quantification exists for bidis or smokeless tobacco products such as gutkha, zarda, khaini, mishri, and kaddipudi, which are widely used in different parts of India.[2]

Nicotine content ranged from 5.7 to 13 mg/rod in cigarettes, 1.01 to 8.7 mg/rod in bidi, 1.7 to 11.8 mg/pack in gutkha, and 17.3 to 76.2 mg nicotine/pack in khaini. It was done using liquid-liquid extraction. 1% methanolic potassium hydroxide[1] was applied for extracting nicotine from products and quantification was done using high-performance thin-layer chromatography.[10] In the present, we applied the nicotine quantitation scores to Fagerstrom test for nicotine dependence (FTND) which may have important implications for NRT dosage.

MATERIALS AND METHODS

Since the nicotine content of the various products varied significantly, we investigated whether variations in the nicotine content of a particular tobacco product influenced the severity rating on the FTND [Table 1]. FTND-It is used to assess the use of smoking. It got the internal consistency of 0.61 and obtained score are related to biochemical indices of the heaviness of smoking.[11] The nicotine content of brands used in the current study are: Brand 1-5.7 mg/rod; brand 2-1.01 mg/rod; brand 3-8.8 mg/rod; brand 4-2.7 mg/rod; brand 5-1.3 mg/rod and brand 6-4.8 mg/rod.[10] For this, we analyzed the FTND of three hypothetical patients (named X, Y, and Z), one each in the cigarette smoker and bidi smoker categories. We also presumed that the three patients used different tobacco products in each of the categories. For unfussiness, scores of all questions in FTND except question 4 were presumed equal to one. The fourth question, which refers to the number of cigarettes/bidis consumed/day, was also maintained at 10 units [Table 1]. On question 5, we scored these patients in two groups as follows:

1. Based only on the number of units (rods or packets) without knowledge of nicotine content/based on self-report, that is, all patients in this group scored 0, thus giving a final FTND score of indicating medium nicotine dependence.
2. In the second group, where nicotine content was presumed to be known, we scored the patients based on the nicotine content in the respective products (corresponding to 10 units/product).

Thus, depending on the brand used, the nicotine intake varied, which in turn would alter the nicotine load on the patient. For example, patient X smoked 10 bidis of particular brand corresponding to an intake of 10.1 mg nicotine/day and score of '0' with total FTND score = 5 thereby classifying the patient as medium-dependence on nicotine. Patients Y and Z also smoked 10 units, but of brands 4 and 6 corresponding to an intake of 27 and 48 mg nicotine/day respectively, which in turn corresponded to 2.7 and 4.8 bidis of particular brand respectively. Taking the nicotine content into consideration, we would score patients Y and Z 2 and 3, respectively on question number 4, now placing them in the high dependence category.

RESULTS

Table 1 also indicates how a specific brand of cigarette or smokeless product with varying nicotine content can alter the dependence severity scoring on the Fagerstrom's questionnaire in comparison to scores obtained based on self-report.

DISCUSSION AND CONCLUSIONS

The study document that nicotine quantitation based rating score for the individual smoking brand has altered the nicotine dependence scores. It will also affect the tobacco cessation treatment outcome [Table 1]. The current used approach to determine the dosage for NRT is based on the empirical score of FTND.[12] The amount of nicotine in a particular product will have a direct bearing on the level of dependence with implications for NRT.[1,13] The validity of using the FTND to determine NRT dosing is highly questionable, as it does not take into consideration the nicotine content of tobacco products.[6] The FTND scores were found to have a relatively weaker correlation with other smoking questionnaires when the question related to the number of cigarettes smoked per day was omitted.[14] Among relatively light smokers, FTND measure found to be higher than the number of cigarettes smoked per day thereby emphasizing the need for

Table 1: Application of nicotine content in tobacco products in FS of nicotine dependence with implications for NRT in a hypothetical experiment

FTND criterion number	Question	Cigarette smoker (user X, Y, Z)	Bidi smoker (user X, Y, Z)	Cigarette smoker (user X, Y, Z)	Bidi smoker (user X, Y, Z)
		Based on verbal report		With information regarding nicotine content	
1	How soon after you wake up do you smoke your first cigarette	X, Y, Z=1		X, Y, Z=1	
2	Do you find it difficult to refrain from smoking in places where it is forbidden	X, Y, Z=1		X, Y, Z=1	
3	Which cigarette would you hate the most to give up	X, Y, Z=1		X, Y, Z=1	
4	How many cigarettes do you smoke per day? a. 10 or less (score=0) b. 11-20 (score=1) c. 21-30 (score=2) d. 31 or more (score=3)	Patient X=0 (10 cigarettes; brand number 1) Patient Y=0 (10 cigarettes; brand number 3) Patient Z=(10 cigarettes; brand number 5)	Patient X=1 (10 bidis; brand number 1) Patient Y=1 (10 bidis; brand number 4) Patient Z=(10 bidis; brand number 6)	Patient X: Brand number 1×10 rods at 5.7 mg/rod=57 mg nicotine/day=score of 0 Patient Y: Brand number 3×10 rods at 8.8 mg/rod =88 mg nicotine/day= 15.4 cigarettes of brand number 1 (score=1) Patient Z: Brand number 5×10 rods at 13 mg/rod=130 mg/day=22.8 cigarettes of brand number 1 (score=2)	Patient X=Brand number 2×10 rods at 1.01 mg/rod=10.1 mg nicotine/day=score of 0 Patient Y: Brand number 4×10 rods at 2.7 mg/rod=27 mg nicotine/day=26.7 bidis of brand number 1 (score=2) Patient Z: Brand number 6×10 rods at 4.8 mg/rod=48 mg nicotine/day=40 bidis of brand number 1 (score=3)
5	Do you smoke more frequently during the first hour after awakening than during the rest of the day	X, Y, Z=1		X, Y, Z=1	
6	Do you smoke even if you are so ill that you are in bed most of the day?	X, Y, Z=1		X, Y, Z=1	
Total score/ dependence	0-2=very low dependence 3-4=low dependence 5=medium dependence 6-7=high dependence 8-10=very high dependence	Patient X=4/low dependence Patient Y=4/low dependence Patient Z=4/low dependence	Patient X=4/low dependence Patient Y=4/low dependence Patient Z=4/low dependence	Patient X=4/low dependence Patient Y=4/med dependence Patient Z=4/high dependence	Patient X=4/low dependence Patient Y=6/high dependence Patient Z=7/high dependence

FS – Fagerstrom scale; NRT – Nicotine replacement treatments; FIND – Fagerstrom test for nicotine dependence

designing an improved and broadly applicable test for nicotine dependence.[12] Similarly, a recent study from India based on the FTND among smokers with poly-drug abuse concluded that FTND had low internal consistency and reliability and suggested a two-factor structure of FTND based assessment.[15] The limitation observed in the form of the absence of longitudinal assessment of efficacy of prescription of NRT based on nicotine quantitation altered scores. It also has implication of inclusion of nicotine quantitation scores for validation of FTND scores in the Indian context.

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Conflicts of interest
There are no conflicts of interest.

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