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The Fagerström Test for Nicotine Dependence-Smokeless Tobacco (FTND-ST)

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Abstract

Few nicotine dependence measures have been developed for smokeless tobacco (ST) users. Existing measures are limited by the requirement to rate the nicotine content of ST brands for which data is scarce or non existent. We modified the Fagerström Test for Nicotine Dependence (FTND) for ST users, referred to this scale as the FTND-ST, and evaluated its characteristics in a population of 42 ST users. The correlation between the FTND-ST total score and the serum cotinine concentrations was 0.53 ($p < 0.001$). Internal consistency reliability assessed using the coefficient alpha was 0.47. Correlations and the coefficient alpha are similar to those reported for commonly used nicotine dependence measures. Development and refinement of nicotine dependence measures for ST users are essential steps in order to advance the field of ST research.

Keywords

smokeless tobacco; tobacco use disorder; tobacco alkaloid; nicotine; dependence measure

Abbreviations

ST = smokeless tobacco; FTQ = Fagerström Tolerance Questionnaire; FTND = Fagerstrom Test for Nicotine Dependence; FTND-ST = Fagerström Test for Nicotine Dependence — Smokeless Tobacco

1. Introduction

While measures of nicotine dependence have been developed and validated for cigarette smokers (Fagerstrom, 1978) (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991) (Heatherton, Kozlowski, Frecker, Rickert, & Robinson, 1989), few nicotine dependence measures have been evaluated for research and clinical use among smokeless tobacco (ST) users.

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Response to Reviewers
None indicated.

In 1995, Boyle and colleagues published two modified versions of the Fagerström Tolerance Questionnaire (FTQ) for measuring nicotine dependence in ST users (Boyle, Jensen, Hatsukami, & Severson, 1995). Assuming that higher nicotine exposure reflected greater nicotine dependence, they assessed the association of scores on these modified scales with the concentration of salivary cotinine. The scales correlated 0.33 ($p < .01$) and 0.47 ($p < .0001$) with the cotinine concentrations for the 9-item and 10-item scale, respectively. Similar correlations have been reported with FTQ and cotinine concentrations among cigarette smokers (Fagerstrom & Schneider, 1989). The development of the modified FTQ for ST users was an important step forward in the research on ST users.

However, the FTQ for cigarette smokers requires a cigarette brand nicotine content rating, and this item was retained in both the 9-item and 10-item modified FTQ scales for ST users rendering the administration of these scales for ST users problematic. Reliable information on nicotine content is scarce for popular U.S. ST brands (Centers for Disease Control and Prevention, 1999; Djordjevic, Hoffman, Glynn, & Connolly, 1995) (Richter & Spierto, 2003) and non-existent for newer ST brands. While ST manufacturers possess this information and report it to the government, it is a treated as a "trade secret" and not disclosed to researchers or the public (Richter & Spierto, 2003). Furthermore, variability exists in the nicotine content between batches of the *same* ST product purchased in different areas of the country as a consequence of the duration and conditions of storage (Djordjevic et al., 1995).

To avoid the need to rate ST brand nicotine content, we adopted the Fagerström Test for Nicotine Dependence (FTND) (Heatherton et al., 1991) and modified it for use in ST users. The FTND was originally developed based upon a study of the FTQ and biochemical measures in 254 cigarette smokers (Heatherton et al., 1991). Heatherton and colleagues observed that both the cigarette nicotine content rating item and a cigarette inhalation item on the FTQ were unrelated to biochemical measures. Therefore, they removed these items and developed a 6-item scale that is closely related to biochemical indices of heaviness of smoking with an acceptable level of internal consistency.

The purpose of the present study is to describe the FTND modified for ST users (FTND-ST) and to investigate the relationship between serum cotinine as the criterion variable, the modified FTQ (Boyle et al., 1995) and the FTND-ST in a population of adult ST users.

2. Methods

2.1. Subjects

The analysis is based upon data from subjects recruited for a randomized, controlled clinical trial of high dose nicotine patch therapy for ST users conducted at the Mayo Clinic in Rochester, MN. The Mayo Foundation Institutional Review Board (IRB) reviewed and approved the study protocol. Subjects were recruited from the local community between November 2003 and October 2004. Only subjects consuming at least 3 cans or pouches per week were eligible for enrollment.

Subjects were 42 ST users with a mean age (±SD) of 35.7 ± 7.5 (range 20–56) years. They used an average of 5.9 ± 2.9 cans per week for 17.0 ± 7.3 years. Subjects used an average of 12.5 ± 7.3 dips/chews per day which they kept in their mouths for an average of 52.1 ± 33.1 minutes. Eighty-three percent (N = 35) had made one or more serious quit attempts prior to study entry.

2.2. Procedures

Following an initial telephone screening, eligible ST users reported to the research center, informed consent was obtained, and questionnaires were completed. A blood sample was

obtained for serum tobacco alkaloids (Moyer et al., 2002). Subjects were then randomly assigned to 1 of 4 groups in a double-blind fashion to nicotine patch doses of 21, 42, or 63 mg per day or placebo to be used for 8 weeks. For the 42 ST users included in this investigation, the mean baseline serum cotinine concentration at baseline was 517 ± 309 ng/mL with a range of152 to 1892 ng/mL. The current report is based upon data collected at the time of the baseline assessment.

2.3. Measures

2.3.1. Criterion Variable—Cotinine, the principal metabolite of nicotine, was selected as the criterion variable as was previously done (Boyle et al., 1995). However, we used serum cotinine rather than salivary cotinine but both are highly correlated (Curvall, Elwin, Kazemi-Vala, Warholm, & Enzell, 1990). All serum alkaloid analyses were conducted in the Mayo Medical Laboratories (Moyer et al., 2002).

2.3.2. Dependence Scales—Subjects completed two nicotine dependence scales at baseline: the modified FTQ (Boyle et al., 1995) and the Fagerström Test for Nicotine Dependence-Smokeless Tobacco (FTND-ST). We selected the 10-item modified FTQ scale for this study as the total score on this scale had a higher correlation with salivary cotinine (Boyle et al., 1995). Items on the FTND were modified to address ST use behaviors. These modifications were based upon our clinical and research experience in ST users (Ebbert, Dale, Nirelli et al., 2004; Ebbert, Dale, Vickers et al., 2004; Ebbert et al., 2005) as well as existing measures (Boyle et al., 1995). The 6 items of the FTND-ST are shown in the Table.

2.4. Statistical Analysis

The FTND-ST total score was calculated as the sum of the individual items. The 10-item modified FTQ total score was calculated using the approach described by Boyle and colleagues (Boyle et al., 1995). The internal consistency of the scales was assessed using Cronbach's coefficient alpha (Cronbach, 1951). In addition, Pearson product-moment correlation was used to assess the association of FTND-ST item responses to FTND-ST total score and also to assess the association of FTND-ST and the modified FTQ with serum cotinine concentration. Consistent with the approach used by Boyle (Boyle et. al., 1995), cotinine concentration was analyzed using a log transformation. In all cases, two-tailed p-values ≤ 0.05 were considered statistically significant.

3. Results

3.1. FTND-ST Characteristics

The FTND-ST, item response frequencies, and correlational coefficients with the total score are presented in the Table. The total possible score on the FTND-ST is 10. The mean total score for our sample (±SD) was 6.0 ± 1.9 (range 1 to 9). The correlation between the FTND-ST total score and the serum cotinine concentrations was 0.53 ($p < 0.001$). Internal consistency reliability assessed using the coefficient alpha was 0.47.

All items were significantly correlated with the total score except the number of cans/pouches per week. However, subjects were selected for this study based upon their high rate of ST use (≥ 3 cans per week), which may account for the lack of an observed association.

Single items that correlated with serum cotinine concentrations were: "How often do you intentionally swallow tobacco juice?" ($r = 0.44$, $p = 0.003$), "Which chew would hate to give up most?" ($r = 0.48$, $p = 0.001$), and "Do you chew more frequently during the first hours after awakening than during the rest of the day?" ($r = 0.31$; $p = 0.047$)

3.2. Modified FTQ Characteristics

The total possible score on the 10-item modified FTQ ranges from 4 to 19. The mean total score for our sample (±SD) was 15.2 ± 2.1 (range 10 to 19). The coefficient alpha (Cronbach, 1951) was 0.47. A positive correlation between the modified FTQ total score and serum cotinine concentration was observed ($r = 0.29$, $p = 0.059$).

The strongest association between single items on the modified FTQ and serum cotinine concentrations was observed with the questions: “After a normal sleeping period waking, do you use within 30 minutes of waking?” ($r = 0.39$, $p = 0.01$) and “How often do you swallow tobacco juice?” ($r = 0.41$, $P = 0.008$). The modified FTQ and the FTND-ST total scores correlated with each other ($r = 0.65$, $p < 0.001$).

4. Discussion

In this study, we describe a scale that can be used to assess nicotine dependence in ST users which is comparable to previously proposed scales but avoids the difficulty associated with rating ST brand nicotine content. Our correlations are comparable to previous publications on ST users (Boyle et al., 1995) and cigarette smokers (Fagerstrom & Schneider, 1989; Pomerleau, Pomerleua, Majchrzak, Kloska, & Malakuti, 1990). Consistent with previous research (Boyle et al., 1995), we observed that the strongest association with serum cotinine levels on the modified FTQ related to using ST within 30 minutes of awakening.

We observed low internal consistency reliability with the FTND-ST (Cronbach’s $\alpha = 0.47$). However, as suggested by Boyle and colleagues (Boyle et al., 1995), this value is similar to previously reported alpha coefficients of self-report scales measuring cigarette smoking dependence (Lichtenstein & Mermelstein, 1986; Pomerleau et al., 1990).

Our study is limited by the small sample size and the population of subjects that was selected for a high use rate of ST (≥ 3 cans/pouches per week) which limits generalizability of the findings. As a result, we did not observe significant correlations between serum cotinine concentration and items that gauge dependence based upon amount of use (Item 4). This may also explain why the modified FTQ total score did not correlate significantly with the serum cotinine concentrations, although a trend was observed. However, the total score and Items 2, 3 and 5 on the FTND-ST correlated with serum cotinine concentrations suggesting that, even among a restricted sample of ST users with high levels of use, items on the this scale can distinguish between ST use behaviors indicative of higher nicotine exposure.

The elimination of the ST brand nicotine content rating is an important step forward in the assessment of nicotine dependence among ST users. Future research is needed using larger samples of ST users to examine the psychometric properties of the FTND-ST.

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Table

FTND-ST Item Responses and Correlations with FTND-ST Total Score in a Population of 42 Smokeless Tobacco Users

Item	Answers	Points	Response (%)	r^a
1. How soon after you wake up to do you place your first dip?	Within 5 minutes	3	8 (19)	0.77[c]
	6 – 30 minutes	2	22 (52)	
	31 – 60 minutes	1	6 (14)	
	After 60 minutes	0	6 (14)	
2. How often do you intentionally swallow tobacco juice?	Always	2	12 (29)	0.59[c]
	Sometimes	1	18 (43)	
	Never			
3. Which chew would you hate to give up most?	The first one in the morning	1	25 (60)	0.61[c]
	Any other	0	17 (40)	
4. How many cans/pouches per week do you use?	More than 3	2	37 (88)	0.23
	2 – 3	1	5 (12)	
	1	0	0 (0)	
5. Do you chew more frequently during the first hours after awakening than during the rest of the day?	Yes	1	7 (17)	0.31[b]
	No	0	35 (83)	
6. Do you chew if you are so ill that you are in bed most of the day?	Yes	1	24 (57)	0.50[c]
	No	0	18 (43)	

[a] Item-total correlation

[b] $p < 0.05$

[c] $p < 0.0001$