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## Addictive Behaviors



## A review of the validity and reliability of smokeless tobacco dependence measures

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## ABSTRACT

**Introduction:** With the growing marketing of alternate tobacco products, advocacy of harm reduction, and smoke free air policies, an overall increase in Smokeless Tobacco (ST) use has been observed since the 1970s. Numerous studies have been published addressing nicotine dependence measures for smokers; however, research in the field of ST dependence measures is scarce.

**Purpose:** The aim of this study is to summarize the psychometric properties of ST dependence measures by evaluating the reliability and validity of these scales through peer review research.

**Methods:** A systematic literature search was conducted within the databases of PubMed and OVID Medline. Four publications reporting on the psychometric properties of ST dependence measures were identified; two regarding FTQ based scales, one regarding an FTND based scale, and one comparing two of these modified scales. A predefined set of criteria was used to assess the psychometric properties of these measures.

**Results:** ST dependence measures depend heavily on two underlying factors, heaviness of tobacco use and withdrawal. The internal consistency of the measures was low to moderate, Cronbach's  $\alpha$  ranging from 0.30 to 0.52. Cotinine was used as criterion variable to validate the results of the dependence measures. Concurrent validity against DIS-IV-ND based diagnosis was not established for modified FTQ scale. Predictive validity of these ST dependence scales was measured as abstinence of ST use at three and six months. FTQ-ST was predictive of abstinence at three months however failed to predict six months abstinence.

**Conclusion:** FTQ and FTND based measures have inherited shortcomings and have limited psychometric properties. With ease of use and wide application in tobacco research, these measures provide preliminary foundation for studying ST dependence. However, the complexity of tobacco dependence requires a multidimensional measure with high validity and reliability for effective prevention care and for research purposes.

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## 1. Introduction

Smokeless tobacco products consumed in the United States have been evolving. Chewing tobacco remained the most widely consumed tobacco product until the early twentieth century when cigarette manufacturers started extensive marketing and sales of cigarettes. In the 1970s with increasing antismoking campaigns ST consumption started to increase. With aggressive marketing strategies and an evolution of new ST products, a significant increase was observed in ST sales from 1980s to 2003 (USDA, 2003). The Federal Trade Commission reported a continued upward trend in ST sales with annual revenue generated from ST sales for 2005 at \$2.6 billion (FTC, 2007). Currently 3.5% of the US adults are ST users (SAMHSA, 2010). Smokeless tobacco contains more than 30 carcinogens such as nitrosamines, polycyclic aromatic hydrocarbons, metals, and aldehydes (IARC, 2008). ST consumed in

the US is associated with a number of ill health effects ranging from oral lesions to cancer and cardiovascular disease. (Mushtaq, Beebe, Thompson, & Skaggs, 2010) ST use increases the risk of cancer of oral cavity, esophagus, and pancreas; 50% of oral cancer in Asia and 4.4% in the US is attributed to ST (Boffetta, Hecht, Gray, Gupta, & Straif, 2008; IARC, 2007). Increased risk of cardiovascular disease mortality has been observed among ST users (Bolinder, Alfredsson, Englund, & de Faire, 1994; Henley, Thun, Connell, & Calle, 2005).

Nicotine dependence, a predictor of maintenance and unsuccessful quit attempts of tobacco use, is defined by the American Psychiatric Association as a destructive pattern of nicotine use that leads to significant social, occupational, or medical impairment (Association, 1994). The Surgeon General's report of 1986 recognized ST as causing nicotine addiction and described an addiction pattern similar to other substance abuse (USDHHS, 1986). Clinical and laboratory studies have identified tolerance and withdrawal effects among ST users (Giovino, Henningfield, Tomar, Escobedo, & Slade, 1995; Hatsukami, Gust, & Keenan, 1987). ST is a nicotine delivery device; its psychoactive feature is one of the criteria used to assess nicotine dependence and has been

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found in animal studies of ST. Unlike cigarette smoking that delivers nicotine to arterial blood through the alveoli of the lungs, with ST use nicotine is absorbed through oral or nasal mucosal membranes into the venous blood (Henningfield, Fant, & Tomar, 1997).

Due to the multi-faceted nature of nicotine dependence, different types of methods have been used to determine nicotine dependence among smokers. These include generic definitions of substance abuse, physical dependence measures, consumption, and self-rated dependence.

Generic definition based methods include the American Psychiatric Association's Diagnostic and Statistical Manual (DSM) (APA, 1994), World Health Organization's International Classification of Disease (ICD), and their derivatives such as the Diagnostic Interview Schedule (DIS) and the Composite International Diagnostic Interview (CIDI). Both DSM-IV and ICD-10 are psychiatric diagnostic traditions which require a minimum number of criteria to be fulfilled. Since this approach involves a criterion derived directly from well-accepted formulations of dependence and their generic nature, comparison with other substance abuse or drugs is possible (Edwards, 1986).

The Fagerström Tolerance Questionnaire (FTQ) was developed in 1978, to measure nicotine dependence among smokers (Fagerstrom & Schneider, 1989). As FTQ was derived from theoretical notion of reliance on nicotine dependence, it consisted of consumption questions such as cigarettes per day (CPD), nicotine yield, time to first cigarette (TTF), and level of inhalation. It also included two additional questions, impaired control and difficulty with restrictions, related to dependence behaviors. The Fagerström Test for Nicotine Dependence (FTND) is similar to the FTQ except for the exclusion of questions related to inhalation and nicotine yield. FTND has a wider response range (0–3) for CPD and time to first cigarette (TTF) questions. Fagerström test based instruments are self-reported measures which provide continuous scores for the degree of physical dependence. In addition to ease of administering these measures have adequate test–retest reliability (Pomerleau, Carton, Lutzke, Flessland, & Pomerleau, 1994). FTQ and FTND are the most widely used measures in tobacco dependence assessment and their predictive validity has been studied among cigarette smokers (Fagerstrom & Schneider, 1989; Kozlowski, Porter, Orleans, Pope, & Heatherton, 1994; Pinto, Abrams, Monti, & Jacobus, 1987).

There are limitations to the FTQ and FTND. The FTQ was not developed according to standard psychometric methods. However, this questionnaire measures physical dependence as its aim was to provide a tool for smoking cessation treatments and to assess different levels of dependence of individual smokers. Thus FTQ and FTND do not assess other salient dimensions of dependence, as defined by DSM-IV and ICD-10. FTND is also criticized for its multifactorial structure as it does not measure a single construct of physical dependence (Etter, Duc, & Perneger, 1999; Heatherton, Kozlowski, Frecker, Rickert, & Robinson, 1989). The FTND could not prove its ability in predicting withdrawal symptoms and smoking cessation (Shiffman, Waters, & Hickcox, 2004); smoking cessation relies on psychosocial processes that are independent of the level of dependence as measured by FTND (Etter, 2008). Furthermore, it has lower internal consistency (Etter et al., 1999; Pomerleau, Pomerleau, Majchrzak, Kloska, & Malakuti, 1990), and the predictive validity of FTND can be attributed to CPD (measure of consumption).

In an effort to address the shortcomings of the FTQ based and DSM-IV based smoking dependence measures, the Cigarette Dependence Scale (CDS-12 and CDS-5), Nicotine Dependence Screening Survey, and Wisconsin Inventory of Smoking Dependence Motives (WISDM-68) were developed. These measures have improved psychometric properties as compared to FTQ based scales (Etter, Le Houezec, & Perneger, 2003; Piper et al., 2004; Shiffman et al., 2004).

Unlike various research studies conducted to address dependence among smokers, the number of studies in the field of ST dependence measures is scarce. The aim of this review is to summarize the psychometric properties of the ST dependence measures by evaluating reliability and validity of these scales through peer review research. This review will

critically analyze these measures in order to identify new avenues for future research.

## 2. Methods

### 2.1. Literature search

A systematic literature search was conducted within the databases of Ovid Medline, Embase, PubMed, and PsycARTICLES. We sought peer reviewed articles citing measures of smokeless tobacco dependence. The following terms were used in the search strategy for dependence measures; dependence scale, dependence measure, addiction, nicotine dependence, measure of dependence, test of dependence. Search terms describing smokeless tobacco were chew, dip, snuff, oral tobacco, spit tobacco, and smokeless tobacco. Various combinations of these terms for smokeless tobacco and dependence measures were used. MeSH terms and keywords for smokeless tobacco and dependence measure were used without any specific timeframe. In addition to the above mentioned databases, relevant journals publishing tobacco and dependence related articles were searched separately and Web of Knowledge was used to search for specific authors who have published relevant research. Articles were included if they evaluated nicotine dependence measures among smokeless tobacco users. Articles related to biochemical or pharmacological topics and not related to ST dependence measure were excluded. Similarly opinion letters, short reviews, articles not in English, or not containing information about dependence measures were excluded.

An initial reference database of 22 publications related to tobacco dependence was created and abstracts were screened to identify articles relevant to the research question. These were predominantly articles focused on smoking dependence measures. Exclusion of irrelevant papers led to four publications focused on ST dependence to be considered for this review (Fig. 1).

### 2.2. Data extraction

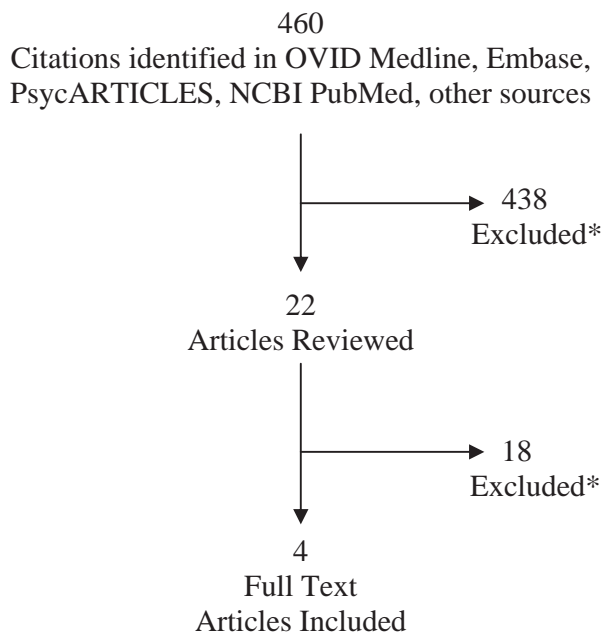
A set of predefined criteria was followed to evaluate the reported psychometric properties (reliability and validity) of the dependence measures. Internal consistency was considered for reliability. For the validity of the measures, face validity was assessed by qualitative methods whereas construct validity – concurrent, predictive, and convergent validity, was evaluated by considering criterion variables.

## 3. Results

ST dependence measures were studied among ST users, generally participants of randomized control trials in various settings. All four studies used dependence measures based on Fagerström Tolerance Questionnaire (FTQ) or Fagerström Test of Nicotine Dependence (FTND). These measures of smoking dependence were revised to be used among ST users and some of the items from the original scales were excluded. Table 1 gives an overview of the contents of the ST dependence measures. Characteristics of these studies are summarized in Table 2.

### 3.1. Reliability

Three studies used Cronbach's coefficient ( $\alpha$ ) to assess internal consistency. Analysis suggested low to moderate consistency for these dependence measures, ranging from 0.30 for the modified 9-item FTQ to 0.52 for the modified 10-item FTQ (Boyle, Jensen, Hatsukami, & Severson, 1995). Although the Cronbach's  $\alpha$  had variation for the FTQ based measures of ST dependence, the two studies evaluating the FTND-ST reported similar results for internal consistency (0.47 and 0.40) (Ebbert, Patten, & Schroeder, 2006; Ferketich, Wee, Shultz, & Wewers, 2007).



**Fig. 1.** Article eligibility flow chart.\*Exclusion criteria:1. Articles related to molecular and pharmacological topics not including relevant original data.2. Articles not in English.3. Opinion letter or short review.4. Articles related to smoking dependence.5. Contained no information about ST products used in the United States.6. Contained no information about dependence measure.

The item-total correlation calculated by Boyle et al. (1995) for the modified 10-item FTQ was moderate with the highest correlation (0.67) for “keeping dip in all time” and the lowest (0.31) for the brand of the product. Similar results were shown for the modified 9-item FTQ, but correlation between total score and the item “hardest chew to give up” was not statistically significant. The study of FTND-ST by Ebbert et al. (2006) reported significant correlation between total score and individual items except for number of cans/pouches per week.

### 3.2. Validity

#### 3.2.1. Content validity

FTQ and FTND based ST dependence measures retained the broader content of these scales and heavily relied on the items tapping physical dependence and tobacco use behavior. Items related to nicotine content

rating were included in the modified FTQ scales; however, such information is not readily available to the consumers (Boyle et al., 1995; Thomas et al., 2006). FTND based scales did not include items related to nicotine content rating and swallowing of tobacco juices. However, the study of FTND-ST retained an item about the quantity of ST product consumed per day, but the eligibility criteria required participants to be heavy ST users ( $\geq 3$  cans) (Ebbert et al., 2006).

#### 3.2.2. Criterion validity

Criterion validity is the ability of a scale to predict results obtained from an external criterion measure that is already valid or assumed to be valid (McDowell, 2006). It is further divided into concurrent and predictive validity, based on the correlation of a measure with the existing criteria or its ability to predict future outcome.

**3.2.2.1. Concurrent validity.** Concurrent validity pertains to the extent to which the measurement tool relates to other scales measuring the same construct and that have already been validated (Cronbach & Meehl, 1955). Cotinine levels were used in all smokeless tobacco dependence studies as a criterion variable. Results for the FTND based measures and the modified 9-item FTQ were significant and consistent across studies. However, the modified 10-item FTQ was reported to be significantly associated with salivary cotinine by Boyle et al. (1995) but no such association was observed in the study by Ebbert et al. for serum cotinine (Thomas et al., 2006).

The study of bupropion SR assessed concurrent validity with the DSM-IV based interviewer administered Nicotine Dependence Module of the Diagnostic Interview Schedule (DIS). The modified 9-item FTQ did not demonstrate statistically significant agreement with the dependence diagnosis as assessed by DIS ( $k = +0.20 (-0.03, +0.44)$ ) (Thomas et al., 2006). A high correlation ( $0.65 p < 0.001$ ) was found between FTND-ST and the modified 10-item FTQ by Ebbert et al. (2006). However the significant content overlap of FTQ and FTND-ST might have resulted in the observed level of agreement.

**3.2.2.2. Predictive validity.** Predictive validity is the extent to which a measure predicts a future variable or outcome. Tobacco use abstinence is commonly used as a predictor for tobacco dependence measures. Three-month and six-month abstinence were studied for the modified 9-item FTQ. The results of the study predicted significant three-month abstinence (OR 0.76 95%CI: 0.61–0.96). On the contrary, the scale failed to predict six-month abstinence (OR 0.86 95%CI: 0.69–1.00) (Thomas et al., 2006).

**Table 1**

ST dependence measures classified according to underlying constructs.

Factor/structure	Item	Modified FTQ		FTND-ST	Modified FTND
		10 item	9 item		
Withdrawal	Use after waking up	X (1)	X (1)	X (3)	X (1)
	Strong cravings	X (1)			
Heaviness of use	Heaviness of use in morning		X (1)	X (1)	
	Hardest ST use to give up		X (1)	X (1)	
	No. of tins/week		X (2)	X (2)	X (2)
	No. of days a tin last	X (3)			
	No. of days/week ST use				X(2 <sup>a</sup> )
	No. of dips/day	X (3)			
	Swallow juices	X (2)	X (2)	X (2)	X (1)
	Keep dip all the time	X (1)			
	Length fresh dip kept	X (3)			
	Length of dipping day		X (2)		
Compulsion	Nicotine contents/brand of ST	X (3)	X (2)		
	Difficulty refraining	X (1)	X (1)		X (1)
	Use when ill	X (1)	X (1)	X (1)	X (1)
Total score		19	13	10	5

X indicates that the item is included in the corresponding dependence measure.

Maximum score for individual item is mentioned in parenthesis.

<sup>a</sup> All participants were regular ST users therefore this item was not included in the final score.

**Table 2**  
Psychometric properties of ST dependence measures.

Study	Measure	Structure	Research base (sample size)	Reliability (Cronbach's coefficient)	Validity (criterion-related) r (p value)	
				Internal consistency	Concurrent validity	Predictive validity
Boyle et al. (1995)	Modified FTQ	10 items	RCT (n = 100)	0.52	Salivary cotinine 0.47 (<.0001)	Cotinine concentration F = 5.4 p < .0001
	Modified FTQ	9 items	RCT (n = 121)	0.30	0.31 (<.01)	F = 3.0 p < .003
Thomas et al. (2006)	Modified FTQ	9 items	RCT (n = 68)		Serum cotinine 0.40 (<.001)	Abstinence 3 months OR <sup>a</sup> 0.76 (0.61, 0.96)
					DIS-IV-ND K + 0.20 (− 0.03, + 0.44)	Abstinence 6 months OR <sup>a</sup> 0.86 (0.69, 1.06)
Ebbert et al. (2006)	FTND-ST	6 items	RCT (n = 42)	0.47	Serum cotinine 0.53 (<.001)	
	Modified FTQ	10 items		0.47	Modified FTQ 0.65 (p < .001)	
Ferketich et al. (2007)	Modified FTND	7 items	RCT (n = 216)	0.40	Serum cotinine 0.29 (0.059)	
					Salivary cotinine 0.34 (<.0001)	

FTQ = Fagerström Tolerance Questionnaire, FTND = Fagerström Test for Nicotine Dependence, DIS-IV-ND = Diagnostic Interview Schedule fourth edition for Nicotine Dependence, RCT = Randomized Controlled Trial.

<sup>a</sup> Odds ratio (95% confidence interval).

In the study of the modified FTQ, Boyle et al. (1995) used salivary cotinine concentrations to assess predictive validity. The results indicated statistically significant prediction of cotinine concentrations for both the modified FTQ scales (10 items and 9 items). Items related to frequency and duration of use contributed significantly to these predictions.

#### 4. Discussion

The aim of this study was to summarize the psychometric properties of different ST dependence measures. Four studies were identified; all using FTQ or FTND based measures. FTQ and its variant FTND are the most widely used dependence scales in smoking studies. Using these scales among ST users is an important step towards understanding ST dependence. The FTQ and FTND were initially developed to measure physical dependence and tolerance. These scales do not address other important aspects of dependence especially those related to psychological and social characteristics (Etter et al., 1999; Heatherington et al., 1989). Likewise, the scales used for ST dependence measured physical dependence through underlying multifactorial structure (Etter, 2008). The items on these scales can be grouped in three theoretical constructs, heaviness of use, refraining from use, and withdrawal.

Despite some variations in modified FTQ and variants of FTND to measure ST dependence, the items inherited the notion of reliance on physical dependence. The revision of original scales to measure ST dependence did not contribute in improving the limited content validity of these scales. Items such as cans per week and time to first chew/dip are direct measures of nicotine concentration. Analogue of these items, CPD and TTF, in the smoking dependence scales have been identified as Heaviness of Smoking Independence (HSI) which is also proposed to be an alternative to the FTQ. In ST dependence measures studies time to first chew/dip and swallowing of tobacco juices were consistently correlated with the cotinine concentration. Theoretically, swallowing of tobacco juices is a variant of smoke inhalation item of FTQ; however, unlike smokers who almost always inhale, not all the ST users swallow tobacco juices. This item is face valid in ST dependence measure as cotinine concentration increases among those who swallow tobacco juices because of the intestinal absorption in addition to the sublingual absorption of nicotine (Ebbert et al., 2004). Items related to refraining from use and withdrawal are important behavioral indices of tobacco dependence. However, inclusion of the item related to nicotine content in the modified FTQ scales lowered the face validity of the measure. It is difficult to determine the nicotine content of a tobacco product as it is not reported on the product.

Smoking dependence studies have shown moderate reliability for FTQ and FTND (Etter, 2008); however, among ST users it was even lower. Although a value of 0.7 for Cronbach's  $\alpha$  is recommended for such measures, the internal consistency for the ST dependence measures in the four reviewed studies ranged from 0.52 to 0.30 (Boyle et al., 1995; DeVellis, 2003). The reliability of these measures was consistent across studies. While FTND based measures had Cronbach's  $\alpha$  between 0.47 and 0.40 from two different studies, this variation can be explained by the fact that the number of items on a scale have impact on the reliability (Ebbert et al., 2006; Ferketich et al., 2007). The scale with  $\alpha = 0.40$  had seven items, but only five of the items were used for analysis; whereas, the other was a six item scale. Item-total correlation was also calculated by three studies to assess internal consistency. Most of the items on these scales had statistically significant association with the total score of the respective measure. Test-retest reliability, another important methodological approach to evaluate the reliability of a measure, was not performed by these studies.

A "gold standard" in the diagnosis of nicotine dependence is controversial. DSM-IV and ICD-10 based criteria of dependence are not comprehensive enough to address the complexity of tobacco dependence (Etter, 2008). The multidimensional nature of tobacco dependence and the paucity of research on smokeless tobacco dependence have hindered the development of such criteria. Cotinine is recommended as a biomarker to assess severity of dependence in tobacco control studies. It is commonly used as a criterion variable in tobacco research. In the studies we reviewed, salivary or serum cotinine concentrations were compared with the total score of the ST dependence measures. All the measures except the modified 10-item FTQ were significantly correlated with cotinine level. Despite strong correlation reported in the initial study of the modified FTQ (Boyle et al., 1995), the study comparing FTND-ST and modified 10-item FTQ could not find such an association for the modified 10-item FTQ. It is unclear whether this scale has lower performance as compared to other FTQ variant or the results are due to the limitations of the study such as smaller sample size and excluding light/mild ST users (Ebbert et al., 2006).

Unlike DSM-IV which emphasizes the adverse consequences of tobacco use and failed quit attempts, FTQ, FTND, and the measures derived from them rely heavily on heaviness of use and difficulty refraining from use. In the study of FTND-ST, DSM-IV based DIS was used as a criterion variable but it failed to validate the dependence measure. Also, DSM-IV measures psychological aspects of dependence. These results highlight the limitations of FTQ based measures in failure to assess other aspects of dependence than physical dependence. In an effort to assess the concurrent validity of FTND-ST, the modified 10-item FTQ was used (Ebbert et al., 2006). The strong correlation



between the two scales can be attributed to the fact that FTND is a variant of FTQ, and there is content overlap in these scales.

Tobacco use cessation is influenced by psychosocial processes and nicotine dependence level. The FTND-ST predicted three-month abstinence but did not predict six-month abstinence (Ebbert et al., 2006). These findings are in accord with previous smoking dependence studies which showed weak or no association between FTND score and smoking abstinence (Etter, 2008; Etter et al., 1999). In an effort to evaluate predictive validity of the modified FTQ scales, Boyle et al. (1995) used FTQ based scales as a predictor of salivary cotinine concentration. However, there is an overlap between validation criteria and items of FTQ. Both FTQ and FTND obtain information regarding heaviness of use which is a direct measure of nicotine intake. When cotinine is used as a criterion for predictive validity, the construct serves both as the facet of dependence and as a measure of dependence thus resulting in criterion contamination.

Due to limitations in these studies, the results based on these ST dependence measures should be interpreted with caution. These studies were based on randomized clinical trials; therefore, the participants were highly motivated for tobacco cessation, thus limiting the generalizability of the results. A standardized approach Eusers, and all of the items on the ST dependence scale were not included in the statistical analyses. Two of these studies had smaller sample size as compared to studies related to the cigarette dependence measures. The smaller sample sizes of the studies resulted in decreased power. Unlike other ST dependence measure studies, the studies by Boyle et al. and Ferketich et al. had sufficient sample size to assess reliability (Cronbach's alpha); however, the evidence of acceptable psychometric properties such as concurrent and predictive validity is little less clear due to the smaller number of participants. Statistical methods, such as correlation and regression analysis conducted for concurrent and predictive validity, require larger sample size for adequate power. Lack of sufficient sample size in methodological studies might be an explanation for the scarcity in published research related to ST dependence measures.

In addition to reviewing the psychometric properties of these scales, it is important to elucidate other methodological considerations such as levels of responses to the items, cut-off scores, and the use of these scales in different settings. Due to dichotomous or three level responses to the items in these scales, they capture less variation. Selecting optimal cut-off scores for different degrees or intensity of dependence will maximize the utility of scales in various settings. The basic aim of the FTQ and FTND was to develop individual level smoking cessation treatments. The role of these dependence scales for ST cessation in both clinical and research settings has yet to be established.

## 5. Conclusion

Despite inherent structural deficiencies and average psychometric properties, nicotine dependence measures based on Fagerström tests have been widely used in tobacco dependence research. FTQ and FTND based measures are an initial step towards understanding tobacco dependence among ST users. Nevertheless, further research is needed to study ST dependence with the help of a theory driven comprehensive scale that has superior psychometric properties. With the scarcity of research related to ST dependence, such a dependence measure will help in understanding various underlying motives associated with continued use of ST products, in addition to providing an efficient tool to tailor effective ST use cessation strategies.

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### Contributors

NM: Conception and design, literature search and summarizing previous research studies, drafting the article.

LAB: Conception and design, critical revision of the manuscript for important intellectual content.

All authors contributed to and have approved the final manuscript.

### Conflict of interest

All authors declare that they have no conflicts of interest.

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