



Nicotine and carbon monoxide exposure from inhalation of cigarillo smoke[☆]



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ARTICLE INFO

Article history:

Received 26 June 2015

Received in revised form 24 September 2015

Accepted 8 October 2015

Available online 13 October 2015

Keywords:

Cigars

Cigarillos

Topography

Biomarkers

Exposure

ABSTRACT

Background: There has been an increase in the use of cigarillos in the US. People who smoke cigarillos typically also regularly smoke cigarettes (dual users).

Methods: We compared puffing topography, biomarkers of acute exposure [exhaled carbon monoxide (COex) and plasma nicotine] and physiologic effects from usual brand cigarette and Black & Mild cigarillo smoking in dual users (N = 23) in two laboratory sessions.

Results: Participants (21 men) smoked an average of 17.5 cigarettes/day. Cigarillo consumption varied widely from as few as 1/week to daily. Participants were highly nicotine dependent (average FTND score: 6.3). There were statistically significant differences in smoking behavior between cigarette and cigarillo smoking in time to smoke, number of puffs, and total puff volume (all $P < 0.001$). Average puff duration, inter-puff interval average puff volume, and puff velocity did not differ between cigarettes and cigarillos. Nicotine boost was similar after both cigarettes and cigarillos. COex boost was significantly greater after cigarillo smoking compared to cigarette smoking ($P < 0.001$).

Conclusions: The smoking pattern and exposure profile indicate that dual users inhale cigarillo smoke just as they inhale cigarette smoke thereby exposing themselves to considerable amounts of nicotine and other components of tobacco smoke. COex exposure results imply that cigarillo smoking may be associated with higher exposure to smoke-delivered volatile components of mainstream cigarillo smoke including carcinogens when compared to cigarettes.

Impact: The findings that cigarillos and cigarettes are smoked similarly in dual users are relevant to health and regulatory considerations on cigar products.

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1. Introduction

Significant progress has been made in reducing cigarette smoking among U.S. adults over the past five decades (Agaku et al., 2014), however, cigar smoking has become popular recently. For example, large cigars consumption increased by 126.3% between years 2008–2011 (Centers for Disease Control and Prevention (CDC), 2012). Prevalence of cigar use was found to be highest among young adults and adolescents. In 2012, about 12.5 million (or 5.4%) adults in the U.S. reported to be cigar users, whereas 10.7% of individuals between the ages of 18–25 years reported current cigar use (US Department of Health and Human Service, 2014). The 2010 National Survey on Drug Use and Health reported that the rates of past month use among young adults

were 34.2% for cigarettes and 11.2% for cigars (Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services and RTI International, 2011). Among high school students, 23.3% reported use of some type of tobacco in 2012 with 12.6% reporting cigar smoking (Centers for Disease Control and Prevention (CDC), 2013). Some cigar smokers, former/current cigarette smokers, and the nonsmoking public misperceive cigar smoking to be less harmful than cigarette smoking (Malone et al., 2001; Nyman et al., 2002; Smith et al., 2007) even though cigar consumption is associated with a risk of heart disease, pulmonary disease, and many types of cancer (Centers for Disease Control and Prevention, 2010; Centers for Disease Control and Prevention, 2015). Several recent studies reported that smokers tend to use more than one tobacco product. Between 2012 and 2013, an estimated 19.2% of U.S. adults used a combustible tobacco product every day or some days of which 72.1% have used at least one combustible tobacco product daily (Agaku et al., 2014). Richardson et al. reported 12.5% of dual users consumed both cigarettes and cigars. Dual users were more likely to be male, ages 18–29, non-Hispanic Black, of low socioeconomic status, and either unemployed or out of the work

[☆] Funding: Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health under Award Number 1R01CA158045-01A1 to W.B. Pickworth. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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force (Richardson et al., 2012). An analysis of the 2012 National Adult Tobacco Survey showed that out of all dual users, the largest group used both cigarettes and cigars (37.0%), and multiple product use was most prevalent among young adults aged 18–24 at 62.4% (Lee et al., 2014).

The increase in cigar popularity and sales, over the past several years, may be an unintended consequence of tobacco regulation and taxation. With the reauthorization of State Children's Health Insurance Program (S-CHIP) and the approval of the tax on little cigars, the tax rate of little cigars became equal to that of cigarettes (Cullen et al., 2011). As a result, manufacturers increased the weight of some little cigars to over 3 lb per 1000 cigars thereby shifting their tax category from "little cigar" to the "cigar" and reducing their tax (Cullen et al., 2011). Cigarillos are typically between the weight of a little cigar and a large cigar, however there is no specific tax category and they have not been tracked systematically since there is no legal product definition (Cullen et al., 2011). Besides product cost, another reason that cigar products may appeal to youth consumers is their availability in a variety of flavors that are now prohibited from cigarettes – legislation enforced by the Family Smoking Prevention and Tobacco Control Act (FSPTCA) in 2009 (U.S. Food and Drug Administration, 2009; US Department of Health and Human Service, Centers for Disease Control and Prevention and Office on Smoking and Health Division of Adolescent and School Health, 2012). In April 2014, the Food and Drug Administration (FDA) proposed to extend their authority to regulate products that meet the statutory definition of a tobacco product (including cigars) (U.S. Food and Drug Administration, 2014). The increase in cigarillo popularity, higher consumption and the implications for FDA regulation emphasizes the importance for a better understanding of these products, their toxicant delivery and addiction potential. The goals of this study were to examine toxicant delivery, smoking patterns and subjective responses to the smoking experience of cigarillos.

2. Materials and methods

2.1. Participants

The participants were recruited from the Baltimore, MD metropolitan area using advertisements in local newspapers, flyers, personal referrals, and a laboratory database of smokers. The eligibility of the participant was determined with an initial telephone interview conducted by an experienced recruiting specialist who gathered basic demographic, health and product use information to determine if inclusion criteria were met. The inclusion criteria of the study were: 1) adult men and women aged 18–65; 2) ability to provide study consent, attend all laboratory sessions lasting approximately 2 h each and complete all study procedures; 3) smoke both a minimum of 10 cigarettes per day for at least 2 years and a minimum of 1 cigarillo per week; 4) absence of smoking related illness or disease; and 5) not actively trying to quit smoking. Participants were compensated \$70 for each of the 2 study visits, plus an additional \$25 completion bonus at the end of visit 2. Data from this study were collected between March 2013 and November 2014. The study was approved by Battelle's Institutional Review Board (IRB).

2.2. Study design, products and procedures

At the initial laboratory visit, participants read and signed a Battelle IRB-approved consent form. They answered various questionnaires on their personal smoking history, and cigarette and cigar use patterns. A Smoking History Questionnaire (SHQ) was administered at the first visit to collect demographics and tobacco and nicotine use history information as well as the Fagerström Test for Nicotine Dependence (FTND). The Questionnaire on Smoking Urges (QSU) was self-administered pre- and post-smoking at both visits to assess urge for smoking. The Duke Sensory Questionnaire (DSQ) and Cigarette Evaluation Scale (CES)

were self-administered post smoking to assess the subjective effects of the products. The NDSS, QSU, and DSQ questionnaires were modified to address either cigars or cigarettes based on their randomized visit. Participant height and weight were recorded and a urine sample was provided. Participants were randomized to smoke either an unflavored Black & Mild (B&M) cigarillo (John Middleton Company, Limerick, PA) or their own brand of cigarette at that session; at their next visit, they smoked the other tobacco product.

Participants attended 2 laboratory sessions, separated by at least 24 h without required abstinence periods. Exhaled carbon monoxide (COex) was measured and blood (10 mL) was drawn from a forearm vein using butterfly needles at baseline (before smoking). Participants were then instructed to smoke as they normally do (*ad libitum*): either the provided B&M cigarillo with the plastic tip removed or their own brand of cigarette through the mouthpiece of a smoking puff analyzer. Within 10 min post-smoking, COex was measured again. Venous blood samples were collected 5 min and 10 min post-smoking. Two post-smoking blood samples were collected to assess peak nicotine levels which may occur slightly later for cigarillo compared to cigarette smoking if significant buccal absorption occurs (Fant et al., 1999; Blank et al., 2011a). The cigarillos and cigarettes were weighed before and after smoking to determine the amount of tobacco smoked. Acute biomarkers of exposure (COex and plasma nicotine) were normalized using two methods: 1) exposure per gram of tobacco smoked and 2) exposure per 1000 mL of total puff volume. The procedures at the second visit were identical using the other tobacco product.

2.3. Dependent measures

2.3.1. Puff measures

Smoking topography measures how a person puffs (brings smoke into their mouth) a tobacco article. Measures of topography include: the number of puffs, puff volume, puff duration, puff velocity, interpuff interval (IPI), and time to smoke (TTS); total puff volume is obtained by adding the individual puff volumes. Smoking topography was measured using a SPA/D Puff Analyzer (Sodim Instruments, Mebane, NC). A cigarette or cigarillo was inserted into the mouthpiece. The product was smoked and data were saved to a computer. TTS was recorded by the topography unit and with handheld digital timers. The cigarillo (or cigarette) was lit by study staff to assure accurate measurement of smoking onset time. Participants were continually observed during smoking; at the end of the last puff they provided a specific visual cue to signal the end of smoking.

2.3.2. Toxicant exposure (tobacco smoke biomarkers)

2.3.2.1. Plasma nicotine. Venous blood samples were drawn to assess changes in plasma nicotine level, before and after smoking, as a biomarker of tobacco exposure. The blood samples were centrifuged and the plasma was separated and stored frozen until it was analyzed for nicotine concentration by the Bioanalytical Laboratory at Virginia Commonwealth University (VCU) School of Pharmacy. Plasma sample were analyzed using LC/MS/MS. With a lower limit of quantification of 2.5 ng/mL (Cappendijk et al., 2010).

2.3.2.2. Exhaled carbon monoxide. COex is a recognized biomarker of recent tobacco smoke exposure and smoke inhalation (Blank et al., 2011b; Koszowski et al., 2014a). COex was collected using the BreathCO Monitor (Vitalograph Inc., Lenexa, KS) at baseline and at 2 min post-smoking. This was used to determine the COex boost, which is the difference between the post-smoking and pre-smoking COex measurement (in parts per million; ppm).

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