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Experimentally Switching from Factory made to Self-Made Cigarettes: A Preliminary Study of Perceptions, Toxicant Exposure and Smoking Behavior

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Abstract

Introduction: There is currently the potential for a great deal of transition and product switching among cigarette smokers. Studies on the transition when cigarette smokers switch from one type of nicotine delivery product to another are needed to understand subsequent toxicant exposure.

Methods: A preliminary study was performed to determine the feasibility of experimentally replicating the transition from factory made (FM) to personal machine made (PMM) cigarette smoking. The adaptability and perceptions of the consumer and the consequent exposure to cigarette-delivered toxins were assessed. Six adults (4 men) were recruited for four laboratory visits (V1-V4) on study days 1, 5, 10 and 15, respectively. All of the participants agreed to switch from exclusive FM smoking to exclusive PMM cigarette smoking for the duration of the study.

Results: Compliance was very high among these participants. Participants progressively accepted the PMM cigarettes and became efficient producers of PMMs as evidenced in the reduced time to make 5 PMMs in the laboratory. Participants reported a preference for FM at visit 2 (V2), but had stated no preference by the fourth visit. Compared to the FMs, the PMMs at V3 ($p<0.05$) and V4 ($p<0.10$) had lower CO boost (7.3 vs. 4.1 ppm; $p<0.05$). Over all conditions, nicotine plasma levels averaged 18.0±2.4 ng/ml before smoking (for both FM and PMM) and 34.0±5.3 ng/mL after smoking; there were no significant differences in the plasma nicotine boost (average 17.7 and 15.4ng/ml after FM and PMM smoking, respectively). Although there were differences between individual subjects' filter butt levels of deposited solanesol the within-subject levels were remarkably similar. Puff topography measures did not vary across visits or cigarette type.

Conclusions: Although interpretation of study results must be conservative because of the small sample size, this study demonstrates that experimentally-induced transition from FM to PMM smoking is feasible for laboratory study and the subsequent toxicant exposure is comparable for FM and PMM cigarettes.

Keywords: Make your own; MYO; Solanesol; Tobacco product; Transition; Self-Made cigarettes

Introduction

Although there has been a decrease in domestic smoking of factory made (FM), cigarettes there has been a concomitant increase in the use of Make Your Own (MYO) in the United States [1-3] and abroad [4,5]. In a previous study [5] we reported on characteristics of MYO cigarettes and their consumers. Nearly all (92%) of current exclusive MYO smokers had begun smoking FM cigarettes and had subsequently switched to MYO smoking after an average of 18.3 years of exclusively smoking FM cigarettes. Generally, smokers switch among various types of cigarettes and tobacco products in response to price, health concerns or as an attempt at tobacco cessation [6,7]. One example of the transition is between FM and MYO cigarettes, a transition that is usually in response to increasing FM cigarette price [3,5,8], however, there have been no attempts to experimentally study the transition.

Rising prices prompted smokers to seek substitutes for premium cigarettes. Surveys of MYO cigarette smokers in the US [3,5]and abroad [3] indicate that smokers chose MYO cigarettes because they are cheaper than FM cigarettes. Changes in the US Federal tax on tobacco products in 2009 led to an increase in tax on loose tobacco labeled as cigarette rolling tobacco $21.95 per pound more than the tax on loose tobacco labeled as pipe tobacco [9,10]. This quickly led to dramatic increases (482%) in the sale of loose tobacco (labeled as pipe tobacco) [1]. The MYO smokers also state that they believe that MYO cigarettes are less harmful than FM cigarettes and they are more appealing because the user can control additives and ingredients of the cigarettes produced [4,6,11]. With increasing regulation and the price of FM cigarettes, the use of MYO cigarettes is likely to increase. In the United States, MYO smokers typically produce cigarettes by hand rolling tobacco in paper leaves, or by injecting tobacco into preformed, empty, filter-tipped paper tubes using an injector machine (Personal Machine Made, PMM) [6]. The present preliminary study was conducted to determine the feasibility of experimentally replicating the transition from FM to PMM smoking by examining the

adaptability and perceptions of the consumer and the consequent exposure to cigarette-delivered toxins from PMM cigarettes.

Methods

Participants

Six adults (4 men) agreed to participate in this crossover, open label study. The participants were recruited from the Baltimore, MD, metropolitan area via newspapers advertisements, direct mailers or Craigslist. All of the participants agreed to switch from exclusive FM smoking to exclusive MYO cigarette smoking for the duration of the study. Through a telephone screener, we determined eligibility and documented the smoking history. Inclusion criteria were: 1) regular (daily) smoker for at least 2 years; 2) age from 18 to 65; 3) smoking at least 10 cigarettes per day (at least 80% of cigarettes smoked were FM); 4) absence of smoking related illness or disease; and 5) not currently trying to quit smoking. Exclusion criteria were: 1) pregnancy or lactation; 2) high blood pressure or heart rate; 3) poor venous access; 4) general health problems (chronic bronchitis, asthma, etc.); 5) heart medications; and 6) history of blood draw complications. Participants were paid $350 for completion of all visits. Data collection occurred at Battelle's Human Exposure Assessment Laboratory (HEAL) in Baltimore, MD.

Study design and procedures

Visit 1: Participants signed an IRB approved informed consent document. They smoked a single cigarette (FM) of their usual brand through a CReSS smoking topography instrument. Blood and exhaled carbon monoxide (CO) samples were collected before and immediately after smoking. Participants were instructed on how to make cigarettes using Gambler Tobacco (Tube Cut), Gambler Tubes (filtered), and a TOP Premium Cigarette Machine (distributed by Republic Tobacco, Glenview, IL). To prepare a cigarette, tobacco was added to reservoir in the machine, distributed evenly and tamped, an empty tube was fixed to the nozzle and the tobacco was injected into the tube. Participants practiced making cigarettes in the lab. Participants who ordinarily smoked menthol cigarettes (n=3) were provided with menthol flavored tobacco. They prepared five cigarettes (timed observation). Participants answered questions on smoking history, level of tobacco dependence and subjective questions on cigarette liking. Beginning from the time they left the laboratory they were told to smoke only cigarettes they had made themselves using the tobacco, tubes and machine provided. They were given an ample supply of tobacco, tubes to take home and were instructed to return to the lab with the unused tobacco, tubes and the machine at V2. Participants were told to bring used filter butts from 4 cigarettes (first cigarette of the day, 2 mid-day cigarettes, and last cigarette of the day) that they had prepared and smoked the day before the visit.

Visits 2, 3 and 4: At five-day intervals participants returned to the lab. They brought with them the unused the tobacco and tubes since the last visit and four used filter butts of the homemade cigarettes they had smoked the day before the visit. The filter butts were collected for subsequent solanesol analyses. Blood and exhaled CO samples were collected before and immediately after smoking. Participants prepared 5 cigarettes under timed observation; these cigarettes were subsequently weighed. The tobacco and tubes were counted and more tubes and tobacco were provided for smoking until the next visit. Subjective questionnaires on cigarette liking and acceptance were administered. At V4 participants surrendered all of the unused tobacco tubes and the cigarette making device.

Dependent measures

Measures of compliance:Compliance to the protocol was determined through self-report, proficiency in preparing and smoking self-made cigarettes and by measures of tobacco use correlated with amount of tobacco used and cigarettes per day.

Subjective measures:Nicotine dependence was assessed using the Fagerström Test for Nicotine Dependence, FTND [12] scale. Cigarette liking and evaluation were determined using subjective questionnaires based on the Duke Sensory Questionnaire (DSQ) [13] and the Cigarette Evaluation Scale (CES) [14].

Measures of exposure:Self-reported cigarettes per day were recorded at each visit. Immediate exposure to nicotine and CO was determined at laboratory smoking by differences between post- and pre-smoking levels. Used filter butt analyses for solanesol were compared in home-smoked cigarette butts that were brought to the lab using methods described by Polzin et al. [15]. Solanesol is an organic alcohol found in tobacco and its levels in filters is a measure of mouth level exposure of nicotine and other semi-volatile components of tobacco smoke [16]. Typical measures of smoking topography: puff volume, puff duration, time to smoke and puffs per cigarettes were determined using Clinical Research Support System (CReSS®, Borgwaldt KC, Richmond, VA) on usual commercial cigarette (V1) and self-made cigarettes (V2, V3 and V4). Methods for measuring smoking topography are similar to those described in previous publications [17-19]. Nicotine and CO boost were calculated as the difference between the post- and pre-smoking levels.

Statistical analyses

All statistical analyses were conducted with StatSoft, Inc. (2013). STATISTICA (data analysis software system), version 12www.statsoft.com. Because of the small number of the participants, descriptive statistics were applicable; Analysis Of Variance (ANOVA) was performed to identify differences among participants as a function of tobacco product smoked.

Results

Participants

Participant ages ranged from 25 to 52 years with an average age of 36±13 years. Ethnic/racial composition was: 3 white, 2 black, 1 other. All of the participants were exclusive daily FM smokers (CPD=22±8; range 15-35) of commercially available "full flavored" filtered cigarettes (e.g. Marlboro, Newport, American Spirit). None of the participants was a current MYO cigarette user and smoked no MYO cigarettes during last 30 days. Volunteers were dependent on nicotine according to FTND test results (6.5±1.5) (Heatherton et al. 1991) [12].

Measures of compliance

Participants self-reported 100% compliance with the requirement to make and smoke all cigarettes using the materials provided. Participants became efficient producers of PMMs (Figure 1) as evidenced in the reduced time to make 5 PMMs in the lab (377 sec. at V1 to 211 sec. at V4). The average time to produce 1 cigarette at Visit 3 (43 sec.) and Visit 4 (43 sec.) were not significantly different from the

production time of experienced exclusive PMM users (42 sec.) [5]. The weight of tobacco used was determined from the difference between the weight of tobacco taken at one visit and the weight returned at the following visit. The theoretical weight was determined from the, self-reported cigarettes per day and the average weight of lab –produced cigarettes. There was a significant and high degree of correlation between the weight of tobacco used and the theoretical weight ($r=0.62$; $p<0.05$). The PMM cigarettes (0.78±0.11; range 0.58 - 0.96g) were significantly lighter ($p<0.01$) than the FM cigarettes (0.94±0.12 range 0.88 - 1.17g). Participants reported it easy and enjoyable to make and smoke PMMs. Upon completion of the study, a one-month follow-up revealed participants reverted to exclusively smoking FM cigarettes.

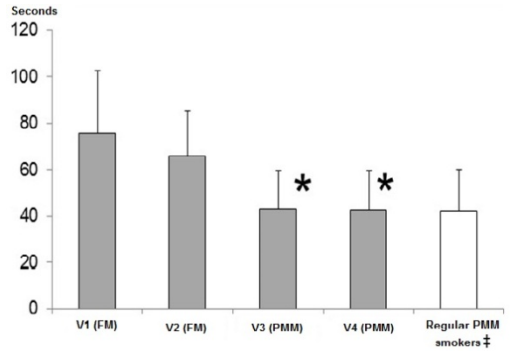

Figure 1: Proficiency in preparing self-made cigarettes. Time to produce one PMM cigarette is reported.*denotes $p<0.05$ vs V1; ‡ Data from Rosenberry et al. [5]. Regular PMM smokers (n=42) were timed as they made cigarettes in the lab. These smokers had an average of 4.4 years of experience making PMM cigarettes.

Subjective measures

Participants progressively accepted the PMM cigarettes. If given a choice, they would have preferred FM at V2, but had stated no preference at V4. The DSQ results indicate that compared to FM (V1), during V2 participants assessed PMM cigarettes as less satisfying; reported that the puffs were weaker; PMMs delivered less nicotine; and the PMMs were not similar to their own brand (-18 to -31% lower scores PMM compared to FM). However, during V3 and V4 participants were less critical of PMM cigarettes (0 to -18% changes). The CES results showed similar trends for satisfaction, psychological reward and negative effect comparing PMM to FM smoking.

Visit	1	2	3	4
Cigarette Type	FM	PMM	PMM	PMM
Experimental Day	1	5	10	15
Self-Reported CPD	22 (8)	21 (9)	22 (7)	22 (7)
CO Boost (ppm)	7.2 (1.5)	5.3 (4.6)	4.3 (2.8)	4.0 (1.9)
Nicotine Boost (ng/mL)	17.7 (4.1)	14.9 (5.1)	16.2 (11.0)	15.0 (9.8)
Cotinine (ng/mL)	361 (90)	352 (221)	305 (164)	277 (143)

Table 1: Toxicants exposure and CPD by cigarette and visit, FM: Factory Made Cigarette; PMM: Personal Machine Made Cigarette, Arithmetic means with standard deviations are reported.

Nevertheless, during each consecutive visit, participants evaluated PMM cigarettes as progressively less effective in relieving craving (-8 to -28% during V2 and V4, respectively).

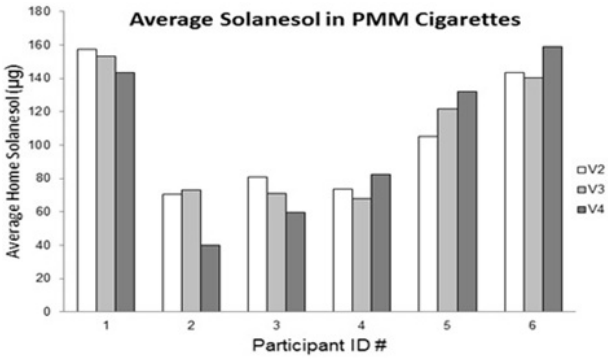

Figure 2: Average solanesol in PMM cigarettes illustrates consistent smoking patterns. Average used filter butt solanesol content from 4 home-smoked cigarettes (first of day, 2 mid-day and last of the day) on the day before laboratory visits V2, V3, V4 for each of the six participants. Values are collapsed across the four cigarettes because AVOVA indicated no significant differences in butt solanesol levels as time smoked.

Measures of exposure

The participants smoked an average of 22±8 CPD, regardless of cigarette type and visit. Differences for CPD were not statistically significant at the 95% confidence interval for any visit for each subject. Biomarkers of exposure results were measured and assessed (Table 1). Compared to the FMs, the PMMs at V3 ($p<0.05$) and V4 ($p<0.10$) had lower CO boost (7.3 vs. 4.1 ppm; $p<0.05$). Over all conditions, nicotine plasma levels averaged 18.0±2.4 ng/ml before smoking and 34.0±5.3 ng/mL after smoking; there were no significant differences in the plasma nicotine boost (average 17.7 and 15.4ng/ml after FM and PMM smoking, respectively).

Visit	1	2	3	4
Cigarette Type	FM	PMM	PMM	PMM
Experimental Day	1	5	10	15
Time to Smoke (sec)	292 (39)	272 (62)	307 (204)	278 (97)
Number of Puffs	10.8 (2.2)	9.2 (2.2)	14.8 (12.2)	10.3 (2.4)
Puff Volume (mL)	55.9 (12.5)	58.9 (13.3)	59.3 (18.1)	58.0 (7.9)
Total Puff Volume (mL)	613 (229)	531 (129)	754 (354)	597 (165)
Puff Duration (sec)	2.5 (0.5)	2.6 (0.7)	2.5 (0.8)	2.4 (0.6)
Puff Velocity (mL/sec)	25.9 (5.9)	26.6 (4.1)	28.6 (5.8)	29.1 (5.9)

Table 2: Smoking topography parameters by cigarette and visit, FM: Factory made Cigarette; PMM: Personal Machine Made Cigarette. Arithmetic means with standard deviations are reported.

Cotinine levels consistently decreased between V1 and V4 although the changes were not significant. Although there were differences

between subjects, filter solanesol levels of home-smoked cigarettes were similar across the three experimental visits for each participant (Figure 2) indicating that the home-produced cigarettes were smoked with equal intensity by the subjects over the 15 day experiment. Puff topography measures did not vary across visits or cigarette type (Table 2).

Discussion

Over the past 10 years, tobacco control efforts, new legislation and changes in taxation and price have led to a significant decrease per capita in consumption of conventional cigarettes from 2076 cigarettes/adult in 2000 to 1232 cigarettes/adult in 2011 [1]. There has been a concomitant increase in the sale of loose tobacco, small cigars and cigarillos and more recently electronic cigarettes [1,20]. Many users of these new products were former FM smokers [3,5]) that adopted self-manufacture of cigarettes (MYO) as their product of choice. There have been no studies that have systematically investigated the transition between FM and MYO smoking. An understanding of the processes involved and the exposure consequences of transition between tobacco products is important because implementation of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) [21] may change the smoking choices and use patterns of current FM smokers to self-made cigarettes. This present preliminary study demonstrates the feasibility and compliance of studying the transition in exclusive FM smokers to exclusive MYO (PMM) smoking over a two week period. The results indicate that FM smokers can readily adopt PMM preparation and smoking thereby exposing themselves to toxicant levels that were not significantly different than those seen after FM smoking.

We verified compliance to the transition to exclusive PMM cigarettes smoking in a number of ways and the results suggest that compliance was very high among these participants. All of the participants attended all of the visits as scheduled. At each visit the participants made five PMM cigarettes and the time needed to make the cigarettes decreased from the first to the second and the third visit - in fact by the third visit participants were making PMM cigarettes at a rate not different from experienced exclusive PMM smokers [5]. These data indicate that participants learned how to efficiently produce PMM cigarettes by practice. The theoretical consumption (based on weight of laboratory produced cigarettes and self-reported cigarettes per day) was compared to the amount of tobacco. The correlations between the reported consumption and the theoretical consumption exceeded $r=0.62$ ($p<0.05$).

Our data suggest that the self-made PMM cigarettes were smoked by the participants similarly to their usual FM cigarette. There were no significant differences in puffing variables and smoking rates after switching to PMM cigarettes. These data indicate that smoking patterns may be very ingrained among experienced smokers. The possibility that smoking pattern and behavior are “fixed” raises the question of whether switching from FM cigarettes to other combustible products (e.g. cigarillos or little cigars) may also be dependent on previous smoking patterns than on the novel tobacco article.

Smoking the PMM cigarettes appeared to yield the same toxicant exposure that the participants experienced with FM cigarettes. Exhaled CO and nicotine boost from laboratory cigarette smoking were similar and plasma cotinine levels, although reduced, did not statistically differ over the two week experiment. These findings tentatively indicated that both acute and chronic exposures of FM and PMM cigarettes were similar. The FM cigarettes were significantly larger than the PMM cigarettes suggesting that some of the decreased cotinine exposure could be accounted for by a reduction in tobacco consumption. Furthermore, although there were individual differences between cigarette filter butt solanesol levels of home-smoked cigarettes, the levels within each subject were remarkably constant over the two week exposure indicating that the smoking pattern remained constant. Subjective responses indicated that the participants preferred their FM cigarette to the PMM cigarette at the beginning of the two week study but at its end there was no differences in the preference suggesting that after a relatively short exposure there was general acceptance of the new cigarettes and the inconvenience imposed by making them. One month after the study all of the participants were smoking FM cigarettes indicating that a brief experimental exposure was not sufficient to change to consumption preference of participants with no stated desire to change. There are no standardized machine smoked data on the delivery of tar, nicotine and CO from the self-made cigarettes or how the self-made cigarettes compared to machine smoked toxicants from FM cigarettes. Kaiserman and Rickert reported that the differences between tar, nicotine and CO from 33 brands of Canadian loose tobacco were remarkably similar if the cigarette tube was the same; however there were large differences in toxicant delivery attributed to the different tubes [22]. In the present study all of the self-made cigarettes were prepared from the same tube however, comparisons between machine smoked PMM and FM cigarettes were not made. Although interpretation of study results must be conservative because of the small sample size and the differences between own cigarettes brands at baseline, this study, nevertheless, demonstrates that experimentally-induced product transition can be studied. Further studies on naturalistic product transition and the consequent toxicant exposure are needed to understand the public health implications of the prevailing dynamic of product transition in the tobacco market.

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