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Mouth Level Exposure and Similarity to Machine-smoked Constituent Yields

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Abstract

Objectives—The goal of this review was to evaluate which standard machine-smoking regimen may be most appropriate to inform tobacco product regulation based on the fraction of cigarette smoke yields that best represents the range of human smoke exposures.

Methods—We searched PubMed and Web of Science to identify peer-reviewed studies that reported percentages of smokers who smoked more or less like a particular machine-smoking regimen based on human mouth level exposure (MLE) tobacco constituent yields.

Results—Three studies met our inclusion criteria and were reviewed. Studies found that Canadian Intense (CI) yields were equal to or greater than 86% to 97% of smokers' nicotine and tar MLE yields.

Conclusions—MLE yields indicate that a small percentage of individuals (less than 14%) are exposed to nicotine and tar yields equal to or greater than those measured by the CI regimen. Whereas no machine-smoking regimen reflects human puffing behavior with complete accuracy, based on MLE data, CI constituent yields constitute the best representation of exposure that encompasses the majority of smokers, and may be the most informative for regulatory purposes.

Keywords

mouth level exposure; machine smoking regimen; human smoke exposure; tobacco constituent yields; Canadian Intense

Standard machine-smoking methods are currently the primary means of determining mainstream cigarette smoke constituent yields for reporting and regulation purposes.

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Conflict of Interest Statement
The authors report no conflicts of interest to disclose.

Although the International Organization for Standardization (ISO)[1] smoking regimen and Cambridge Pad Method (CPM; previously referred to as the Federal Trade Commission method) were originally developed as arbitrary standards to provide comparative information on products' tar and nicotine yields in mainstream smoke,[2] they have been used to estimate smokers' exposures. However, these smoking regimens have been shown to underestimate actual human exposure to smoke constituents.[3] The ISO regimen is nearly identical to CPM; therefore, discussion of the ISO regimen also applies to CPM. The ISO regimen, which does not block any cigarette ventilation holes, allows air to be drawn into the cigarette during a puff, resulting in dilution of smoke constituents. However, as a result of smoke dilution, smokers of highly ventilated cigarettes typically alter their smoking behavior to increase smoke intake by taking larger, deeper puffs, and by blocking ventilation holes with their fingers and/or mouths.[4] These behaviors result in higher smoke yields than those estimated by ISO. Thus, levels measured using these regimens do not reflect true smoking behaviors.

The Massachusetts Department of Public Health (MDPH)[5] and Canadian Intense (CI)[6] smoking regimens increase the puff volume and decrease the interpuff interval compared to ISO, and require blocking of either 50% or 100% of the ventilation holes, respectively. These regimens were adopted to supplement ISO yields and provide additional information about cigarette smoke yields when cigarettes are smoked more intensely. However, because individual smokers exhibit a wide range of smoking intensities and puffing behaviors, individual exposure to mainstream smoke constituents varies considerably among smokers and cigarette varieties.[7,8] Thus, these regimens by themselves are not more representative of human smoking behavior than ISO and do not provide better predictors of human exposure to smoke constituents.[3,9] Furthermore, when using the MDPH regimen, because 50% of the ventilation holes are physically blocked (eg, with tape), there is room for error and variability when utilizing this method. Smoking machine parameters for the ISO, MDPH, and CI regimens are shown in Table 1.

Additional methods for determining smokers' exposure to cigarette smoke constituents include analysis of biomarkers of exposure (eg, nicotine, tobacco specific nitrosamines),[3,10] machine smoking settings based on actual human puff topography parameters,[3] and estimates of smokers' mouth level exposure (MLE) yields from chemical analysis of the filters of spent cigarette butts.[11] A variety of chemicals can be assessed using filter analysis, including tar (total particulate matter), nicotine, solanesol, and other chemicals.[11–14] MLE yields can provide indirect estimates of nicotine and tar yields achieved by individual smokers of individual cigarettes; filter analysis has been shown to correlate well with salivary cotinine and urinary nicotine metabolite levels.[10,15] Filters from cigarette butts are collected from smokers smoking their regular brand in their natural environment as opposed to human puffing behavior recorded using machinery in a laboratory or clinical setting. Thus, MLE yields can account for differences in smoking behaviors and patterns, and provide more accurate estimates of human smoked cigarette constituent yields than smoking machine regimens.[11]

The goal of this report was to examine peer-reviewed literature to determine the smoking regimen that may be used for tobacco product regulation based on the fraction of cigarette

smoke yields that best estimate the range of human smoke exposures. Whereas previous reports have typically compared machine smoking regimen yields to human smoking topography,[3,16] the current review compares studies of machine smoking regimen yields to human MLE yields. Studies reporting the percentage of smokers who smoke more or less like a particular smoking regimen, based on MLE data, were examined.

METHODS

PubMed and Web of Science were searched to identify studies that reported percentages of regular smokers who smoked more or less like a particular smoking regimen based on MLE tobacco constituent yields. Searches were conducted September 10–22, 2014. Combinations of the following search terms were used: “mouth level exposure,” “cigarettes,” “smoking regime,” “machine smoking,” “smoking machine yields,” “ISO,” “Canada Intense,” ”smoking topography,” “tar,” and “nicotine.” Studies comparing MLE to smoking regimen yields were included if they were: (1) in English; (2) published in a peer-reviewed journal; and (3) reported the percentage of individuals who smoked more or less like a particular regimen, or presented results in such a way that this information could be extrapolated. Review articles and articles that did not meet inclusion criteria were excluded. Reference sections of included articles were hand-searched for additional studies. The “Related Citations” link in PubMed for the selected articles also was searched. After removal of duplicates, the search returned 127 articles, 3 of which met the inclusion criteria. Study results were taken directly from the 3 articles and were not manipulated, reanalyzed or combined.

RESULTS

Three studies[17–19] presented findings on the percentage of regular smokers who, as a result of their smoking behavior, achieve MLE yields less than ISO or greater than CI machine yields. Two studies included comparisons with the MDPH regimen.[17,18] The studies included current regular adult smokers (N = 784,[17] N = 1330,[18] and N = 1086[19]) from several sites across the US and Canada who smoked a variety of commercially available menthol or non-menthol cigarette brands of varying tar and nicotine yields. Table 2 summarizes details and results from these 3 studies.

Based on MLE nicotine and tar yields, the 3 studies found that 0.1% to 3% of individual smokers achieved MLE tar yields greater than CI yields, and 0.9% to 14% of individual smokers achieved MLE nicotine yields greater than CI. These findings indicate that 86% to 97% of smokers’ exposures were equal to or less than CI regimen yields, with a small percentage exceeding those levels. Therefore, even the most intense machine-smoking regimen underestimates exposure to tar and nicotine in a small percentage of the population. A higher percentage of the population achieves MLE yields greater than MDPH, with 7% to 20% of individuals reaching greater tar yields, and 7% to 31% reaching greater nicotine yields. A minority of smokers also smoked either as intensely as, or less intensely than, the least intense machine-smoking regimen, ISO. Results indicate that only 14% to 27% and 7% to 27% of individuals, respectively, achieve MLE tar and nicotine yields that are equal to or less than ISO during smoking (Table 2).

Percentages of actual participant tar and nicotine yields separated by tar band (ie, categories based on the mg tar per cigarette) were assessed in 2 studies.[17,18] For both ISO and MDPH, the percentage of individuals who smoked more or less like the regimen varied based on reported tar yield (mg/cigarette). Results are provided in Table 2. Although the tar band ranges used in each study differed slightly, results for ISO and MDPH were consistent between studies. As the tar yield increased, the percentage of individuals who achieved MLE yields less than ISO increased, whereas the percentage of individuals who achieved MLE yields greater than MDPH decreased. St. Charles et al[17] did not detect a similar pattern for individuals who achieved MLE yields greater than CI, as there was little variation in MLE yields for these individuals based on tar or nicotine yield. Based on tar yield, this study showed only one person (0.1% overall, Band C) had an MLE tar yield greater than CI. For nicotine content, 7 participants (0.9% overall; 3 smokers from Band A, 2 from Band B, one from Band C, one from Band D) achieved MLE nicotine yields greater than CI. Similarly, there was little variation in the percentage of individuals with MLE tar yields greater than CI across cigarettes of increasing tar band reported in Nelson et al[18] (Table 2). However, greater variation was observed for MLE nicotine yields, with up to 21% of individuals who smoked mid-range nicotine content cigarettes (Bands B, C) achieving MLE nicotine yields greater than CI, compared to 8% to 9% of low (Band A) and high nicotine (Band D) content cigarette smokers. Despite this variation, within the mid-range nicotine content cigarettes (Bands B, C), fewer smokers achieved MLE nicotine yields greater than CI compared to other regimens; up to 44% of smokers achieved MLE nicotine yields greater than those predicted by MDPH, and up to 91% greater than ISO.

DISCUSSION

Studies based on MLE yields were reviewed to determine which machine-smoking regimen best captures the range of tar and nicotine exposures in the majority of smokers. Three studies found that CI regimen yields included 86% to 97% of the smokers based on MLE nicotine and tar yields. These findings suggest that less than 14% of smokers smoke in a way in which they achieve MLE yields greater than CI yields, and a small percentage of smokers achieve MLE yields equal to or less than ISO yields.

Comparison of human puff topography and constituent exposure to machine-smoking yields indicates considerable variability in smoking behaviors and resulting constituent exposure, though it has been reported that on average, human smokers' puffing behaviors were more similar to CI parameters than ISO parameters.[16] However, with lower tar and nicotine cigarettes, the average puff volume was greater in human smokers than that utilized by CI.[3,16] These findings suggest that many low tar and nicotine cigarette smokers are exposed to a greater level of tobacco constituents than predicted by the CI regimen. Yet, results from comparisons to human MLE yields suggest that there is minimal variation in the percentage of smokers with MLE yields greater than CI across cigarettes of varying tar bands.[17,18]

The percentage of smokers who achieve MLE yields greater than CI either does not vary significantly by nicotine content,[17] or may be greater with mid-range nicotine content cigarettes relative to low or high nicotine content cigarettes.[18] Because Nelson et al[18] included more cigarette brand varieties and more study participants, their findings may be

more representative of the smoking population. These MLE data suggest that the majority of smokers achieve yields equal to or less than those predicted by CI under a range of different tar and nicotine yields, whereas ISO and MDPH yields vary significantly based on tar or nicotine yields. Because MLE yields are obtained from spent cigarette butts and do not require use of machinery in a laboratory setting that may interfere with natural smoking behaviors, using MLE yields for comparison to machine-smoked yields may be a more appropriate method for determining the accuracy of different machine smoking regimens in predicting human exposure than comparisons to human puff topography.

Despite advantages over other methods of predicting smoke constituent exposure, MLE does not account for differences in smoke-holding times or depth of inhalation,[11] aspects of human smoking behavior that may affect exposure to nicotine and other tobacco constituents.[20] Another limitation is that the findings presented here are based on 3 peer-reviewed studies; however, the studies analyzed several varieties (eg, menthol, non-menthol, varying length, tar, nicotine content) of cigarette brands in regular cigarette smokers of both sexes and varying races, from several sites across the US and Canada. The studies reviewed also used similar methods for filter analysis and results were generally consistent across studies

IMPLICATIONS FOR TOBACCO REGULATION

The current findings on estimated MLE yields, which account for differences in smoking behaviors and patterns, suggest that CI yields include exposure levels that encompass the majority of smokers across cigarettes of different tar and nicotine yields. No currently available machine-smoking regimen is capable of encompassing the entire smoking population by reproducing the variety of human puffing behaviors. Thus, using a machine-smoking regimen that captures exposure in the majority of the population is critical for providing maximum estimates of constituent exposure, as well as accurate reporting and regulation of tobacco constituent levels in products. Based on MLE data, CI yields may best represent constituent exposure that encompasses the majority of smokers across different cigarette brands, and tar and nicotine yields, and may be the most useful regimen for reporting and regulatory purposes to protect public health at the population level.

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Table 1

Puff Parameters for 3 Machine Smoking Methods

Smoking Method	Puff Volume(mL)	Inter-puff interval (s)	Mean flow rate (mL/s)	Ventilation blocking (%)
ISO	35	60	17.5	0
MDPH	45	30	22.5	50
CI	55	30	27.5	100

Note.

Puff duration is 2 seconds for all methods.

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Table 2

Total Percentage of Smokers with MLE below the ISO and above the CI Machine Regimens

Study	N	Study population	Description of cigarette (cig) brands analyzed	ISO Tar/Nicotine yields (mg per cigarette)	Percent (%) < ISO	Percent (%) > MDPH	Percent (%) > CI [d]
St. Charles et al [17] *a,b*	784	Participants age 21 + having smoked ≥ 10 CPD for at least 6 months. Recruited from 5 U.S. cities (Portland, OR; San Diego, CA; Chicago, IL; New York, NY; Atlanta, GA). Sex and race chosen to approximate the national demographics for particular brand studied.	17 varieties of Carlton, Now, Doral, GPC, VA Slim, Misty, Capri, Salem, Kool, Basic, Newport	Tar: 0.7– 17.7	Tar/nicotine total: 27%	Tar/nicotine total: 7%	Tar: 0.1– 0.3% Band C: 1 subject
				Nicotine: 0.05– 1.35	Band A: 4% Band B: 19% Band C: 34% Band D: 59%	Band A: 17% Band B: 8% Band C: 2.6% Band D: 2%	Nicotine: 0.9– 1.4% Band A: 3 subjects Band B: 2 subjects Band C: 1 subject Band D: 1 subject
Nelson et al [18] *c*	1330	Male and female, black and white smokers who have smoked one of the brands studied as their usual brand for more than 3 months, currently smoking ≥ 7 CPD. Smokers recruited from 24 sites across the U.S. Age range was not provided.	26 varieties of Carlton, Doral, Camel, Marlboro, Pall mall, Newport, Kool	Tar: 0.6– 17.4	Tar total: 14 % Band A: 2% Band B: 8% Band C: 10% Band D: 23%	Tar total: 20% Band A: 56% Band B: 24% Band C: 20% Band D: 8%	Tar: 3% Band A: 1% Band B: 3% Band C: 4% Band D: 3%
				Nicotine: 0.10– 1.19	Nicotine total: 11 % Band A: 3% Band B: 8% Band C: 9% Band D: 16%	Nicotine total: 31% Band A: 57% Band B: 44% Band C: 33% Band D: 15%	Nicotine: 14 % Band A: 8% Band B: 21% Band C: 18% Band D: 9%
Côte et al [19]	1086	Male and female smokers age 19–54, regular users of the target products for at least 6 months, and smoking ≥ 5 CPD. Recruited from 3 major Canadian cities (Montreal, Toronto, Vancouver).	12 king size or regular size flue-cured Virginia commercial cigarettes	Tar: 0.9– 14.7	Tar: 15%	Not evaluated	Tar: 0.1%
				Nicotine: 0.11– 1.30	Nicotine: 7%		Nicotine: 2%

Note.

[a] Tar and nicotine values were not separated for ISO and MDPH in this study; percentages in this study represent less than or equal to (≤) ISO or greater than or equal to (≥) MDPH and CI.

[b] Tar band descriptors are as follows; Band A: 1–3 mg (0.05–0.30 mg/cig nicotine), Band B: 4–6 mg (0.39–0.49 mg/cig nicotine), Band C: 7–12 mg (0.62–0.87 mg/cig nicotine), Band D: 13+ mg (0.85–1.35 mg/cig nicotine).

[c] Tar band descriptors are as follows: Band A: < 2 mg (0.10–0.17 mg/cig nicotine), Band B: 2–8 mg (0.41–0.51 mg/cig nicotine), Band C: 8–14 mg (0.65–0.87 mg/cig nicotine), Band D: > 14 mg (1.04–1.31 mg/cig nicotine). CPD, cigarettes per day.

[d] Data are presented in this column as described in the study. Upper range values of 0.3% (tar) and 1.4% (nicotine) were obtained after allowing for an additional 1 mg tar and 0.1 mg nicotine to the highest tar band.)