Original investigation

Measurement of Electronic Cigarette Frequency of Use Among Smokers Participating in a Randomized Controlled Trial

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Abstract

Background: The United States Food and Drug Administration has prioritized understanding the dependence potential of electronic cigarettes (e-cigs). Dependence is often estimated in part by examining frequency of use; however measures of e-cig use are not well developed because of varying product types. This study used an e-cig automatic puff counter to evaluate the value of self-reported e-cig use measures in predicting actual use (puffs).

Methods: Data were collected from a two-site randomized placebo-controlled trial evaluating the effects of e-cigs on toxicant exposure in smokers attempting to reduce their cigarette consumption. Participants randomized to an e-cig condition self-reported their e-cig frequency of use (times per day—one “time” consists of around 15 puffs or lasts around 10 minutes) on the Penn State Electronic Cigarette Dependence Index (PSECDI) and kept daily diary records of the number of puffs per day from the e-cig automatic puff counter. A linear mixed-effects model was used to determine the predictive value of the times per day measure. Correlations were used to further investigate the relationship.

Results: A total of 259 participants with 1165 observations of e-cig use were analyzed. Self-reported e-cig use in times per day was a significant predictor of e-cig puffs per day ($p < .01$). The Spearman correlation between measures was r equal to .58. Examination of individual participant responses revealed some potential difficulties reporting and interpreting times per day because of the difference in use patterns between cigarettes and e-cigs.

Conclusion: This study provides evidence that the self-reported PSECDI measure of times per day is a significant predictor of actual frequency of e-cig puffs taken.

Implications: Self-reported measures of e-cig frequency of use are predictive of actual use, but quantifying e-cig use in patterns similar to cigarettes is problematic.

Introduction

In 2016, the United States Food and Drug Administration gained regulatory authority over all tobacco products, including the diverse product group known as electronic cigarettes (hereafter e-cigs).^{1,2} One regulatory concern about products like e-cigs is their potential for dependence, as dependence increases the likelihood of long-term use.² To understand the potential for dependence on e-cigs, a standard reliable method to measure dependence is needed.

Traditionally, dependence on conventional cigarettes has been estimated largely based on consumption (cigarettes per day [CPD]), using questionnaires such as the Fagerström Test for Nicotine Dependence³ and the Heaviness of Smoking Index.^{4,5} Although similar methods are being applied to understand e-cig dependence, reporting e-cig consumption is more difficult than reporting cigarette consumption because users report that e-cig use typically occurs in short, frequent sessions not directly comparable to cigarette use that are often difficult to count.^{6,7} Consequently, current studies evaluating e-cig use and dependence have used several different methods to report e-cig consumption.

Some studies have attempted to characterize e-cig use consumption by quantifying the amount (mL) of e-liquid used per day,^{8–11} whereas others have attempted to measure e-cig consumption similarly to CPD. However, those studies measuring e-cig use similarly to CPD have used varying definitions of use episodes, or “e-cigs per day.”^{12–17} For example, in Etter and Eissenberg’s modified version of the Fagerström CPD question to measure e-cig use, one “time” was defined as 10 puffs. Results from the study indicated that exclusive e-cig users reported a mean of 200 puffs per day (ie, 20 times per day at 10 puffs per time).¹⁵ Another study of exclusive e-cig users assessed the frequency of e-cig use using an item from the Penn State Electronic Cigarette Dependence Index (PSECDI), which defines a “time” as around 15 puffs or as lasting around 10 minutes. This measure was intended to quantify the approximate number of “cigarette-sized” quanta of e-cig use, regardless of the specific number of puffs. Mean e-cig use was 24 times per day, which also matched the mean daily cigarette consumption of those individuals when they were exclusively smoking cigarettes.¹² Because varying methods of measurement were used, it is not possible to compare consumption across studies nor understand how consumption impacts dependence.

Because understanding e-cig consumption is related to understanding product dependence, and e-cig consumption is difficult to measure, studies are needed to evaluate and better understand measures of e-cig consumption. A recent study by Pearson et al.¹⁸ compared self-reported e-cig puffs collected via an ecological momentary assessment (EMA) system to puffs as measured by a counter embedded in an e-cig device. The authors found a significant moderate correlation between the EMA-reported puffs and the puffs recorded on the e-cig embedded device; however, the number of puffs collected on the device was consistently higher than that reported by the participants in the EMA system.¹⁸ Because most studies are not able to use an EMA system to aid participants in self-reporting their e-cig use, evaluation of a self-reported survey question in comparison to actual use is needed. This study evaluated the predictive value of self-reported e-cig consumption by comparing the “times per day” question from the PSECDI to puffs per day as recorded on an embedded e-cig puff counter.

Methods

Data were collected from a large US two-site randomized controlled trial evaluating the effects of e-cigs on toxicant exposure in smokers

attempting to reduce their cigarette consumption (Clinical Trials identifier: NCT02342795). Details of the study can be found in Lopez et al.¹⁹ Only participants randomized to an e-cig condition were included in this analysis.

Measures

Participant use of the e-cig was measured in two ways at each study follow-up visit (eight follow-up visits in total at 1 week [first follow-up visit], 2 weeks, 1 month, 2 months, 3 months, 4 months, 5 months, and 6 months after initiating e-cig use), including:

1. Puff counter (puffs per day)—puffs per day were measured by an automatic puff counter embedded in a battery-operated e-cig device (Figure 1). To activate the production of vapor, the user was told to press the button on the device and inhale simultaneously. One puff was automatically recorded on the device counter each time the button on the device was pressed. To ensure that only actual full puffs were counted (not accidental presses), the counter only recorded a puff if the button was depressed for at least 1 second or more. Users were instructed to use the device throughout the day and to write the number of puffs displayed on their puff counter in a daily diary at the end of the day. The puff counter automatically reset at each recharge. At each visit, users were asked to complete a 7-day timeline follow-back using the daily diary and the mean number of puffs per day was calculated from the past 7-day data.
2. Self-reported use (PSECDI times per day)—times per day were measured using the self-reported PSECDI. The PSECDI question regarding use times per day asked, “How many times per day do you usually use your e-cigarette? (assume one “time” consists of around 15 puffs or lasts around 10 minutes).”¹²

In addition, because participants also smoked traditional cigarettes in the trial, they were asked to keep a daily diary to record CPD and to report the data using a 7-day timeline follow-back procedure. Mean CPD was calculated at each visit from data reported from the 7-day timeline follow-back procedure.

Data Analysis

Participants included in analysis attended at least one of the eight follow-up visits after receiving their e-cig. Each follow-up visit where the participant reported complete details about their e-cig and cigarette use (ie, reported diary information for both products and completed the PSECDI times per day question) was considered an observation for the analysis. Dual use (use of e-cig and cigarettes) was defined as more than 0 mean e-cig puffs per day and more than 0 mean CPD in the past 7 days for that observation. Exclusive e-cig use was defined as more than 0 mean e-cig puffs per day and no cigarette use in the past 7 days for that observation. Only observations of e-cig use more than zero puffs were included in the analysis.

All data analyses were performed using SAS software, version 9.4 (2013 SAS Institute Inc., Cary, NC). Means and frequencies were used to describe the sample and frequency of e-cig use at each follow-up visit. A *t* test was used to determine the difference in mean number of puffs between dual and exclusive e-cig users. Next, to investigate the relationship between PSECDI times per day and mean e-cig puffs per day from the puff counter, a Spearman correlation²⁰ was performed using observations from only one timepoint (the first follow-up 1 week after initiating e-cig use). This timepoint was

chosen since the most observations were available (fewest dropouts) and it provides a chance to evaluate the accuracy of the PSECDI question with users' naive to the question, which is the most likely use case. Scatterplots to display the relationship between PSECDI times per day and mean puffs per day were included with a regression line. Finally, the predictive value of the self-reported PSECDI times per day question was measured using a linear mixed-effects model with the puff counter average as the dependent variable and the PSECDI times per day, follow-up visit number, and exclusive e-cig use status (yes/no) as the independent variables.

Secondary Analysis

The data for PSECDI times per day were not normally distributed, leading researchers to further investigate outlying responses in a secondary analysis. Assuming that participants used their e-cig in a pattern consistent with the guidelines set in the PSECDI question (with a "time" of e-cig use considered as 10 minutes or around 15 puffs), it was hypothesized that some participants may have incorrectly reported times per day as the total number of puffs taken per day. Times per day (use lasting 10 minutes or 15 puffs) and puffs per day (actual number of puffs on the device) are not equivalent measures, unless the participant only takes, on average, just one puff every 10 minutes. Outlying participant responses that were considered numerically impossible or did not follow the expected patterns

of use were removed from the data for a secondary analysis. The removed responses were those greater than 72 times per day (equivalent to using the e-cig every 10 minutes for a total of more than 12 hours per day), where self-reported times per day was greater than puff counter puffs per day (impossible to use more times than puffs taken) and those where the puff counter average was at least 10 puffs per day but not at least twice the reported times per day (the rationale being because that such participants were using their e-cig at least 10 times per day, it is unlikely they would take only one puff at a time, suggesting they were confusing puffs per day and times per day). For the secondary analysis, mean times per day were recalculated and a *t* test was run to determine if the mean times per day changed after removing the outlying observations. In addition, the correlation was repeated and a predictive model was run with outlying observations removed.

Results

A total of 259 participants (with characteristics as shown in [Supplementary Table 1](#)) with 1165 complete observations were included in the analysis. The average puffs per day, times per day, and CPD reported at each timepoint in the study for all observations are shown in [Figure 2](#). Times per day and puffs per day were moderately positively correlated ($r = .58$), using observations from the puff counter and PSECDI data collected from the first follow-up visit (1 week after initiating use) ([Figure 3a](#)).

Although the majority of participants reported use of cigarettes and their e-cig at the follow-up visits (dual use), 4.5% of total observations ($n = 52$) self-reported exclusive e-cig use. Compared with dual use observations, observations of exclusive e-cig use were associated with significantly greater e-cig puffs per day (dual mean 71.8 puffs per day vs. exclusive mean 172.3 puffs per day, $p < .0001$) and e-cig use times per day on the PSECDI (dual 13.7 times per day vs. exclusive 19.1 times per day, $p = .0454$), implying also an increased mean number of "puffs per time" (5 vs. 9). After controlling for differences in dual use status, the linear-mixed effects model determined the self-reported PSECDI times per day question was positively associated with the puff counter average. The model also revealed that

Figure 1. EGO electronic cigarette device with automatic puff counter.

Figure 2. Electronic cigarette frequency of use (puffs and times per day) and cigarettes per day at each study visit ($n = 1165$ observations).

Figure 3. Comparison of puff counter puffs per day to times per day as reported on the Penn State Electronic Cigarette Dependence Index (PSECDI). (a) All observations; Spearman $r = .58$, $p < .0001$, $n = 243$. (b) After removal of outlying observations; Spearman $r = .74$, $p < .0001$, $n = 194$.

Table 1. Predictive Model of Actual Use (Puffs Per Day)

	Estimate	SE	T	p
Penn State times per day	0.21	0.06	3.69	.0003
Dual use	-29.35	8.45	-3.47	.0006
Follow-up visit				
1 wk	-6.2	6.9	-0.9	.3706
2 wk	4.3	6.9	0.63	.5282
1 mo	14.2	6.5	2.2	.0287
2 mo	11.5	6.0	1.93	.0544
3 mo	10.1	5.2	1.95	.0528
4 mo	6.2	5.1	1.22	.2246
5 mo	6.9	5.5	1.25	.2133
6 mo	Ref			

SE = standard error.

the average puffs per day on the puff counter had a convex trend related to time in the trial. These results are displayed in Table 1.

Secondary Analysis

Sixteen percent of the observations considered to be outliers were removed ($n = 185$ observations from $n = 108$ participants [41.6% of participants in the sample]), leaving 980 observations. In this subsample, the mean PSECDI times per day reported dropped from 13.6 (SD = 24.4) to 8.2 (SD = 7.9, range 0–65) times per day. In addition, the correlation between times per day and puffs per day became far stronger ($r = .74$) (Figure 3b). Finally, the predictive model results remained very similar to results without observations removed.

Discussion

This study found that the self-reported PSECDI measure of times per day was a significant predictor of the actual number of daily puffs taken on an e-cig and the two measures were moderately positively correlated. This finding is similar to that of Pearson et al.¹⁸ who found that self-reported e-cig use via an EMA system was moderately positively correlated with actual use as measured on an embedded puff counter. The study of Pearson et al.¹⁸ also found that

self-reported puffs per day on the EMA system were consistently approximately 50% lower than the actual puffs taken. In this study, although the measures of puffs per day and times per day were not intended to be directly comparable, we found the opposite. Assuming that users reported as the question prescribed (15 puffs per time), users were self-reporting greater use times than indicated by the actual number of puffs taken. This is important to consider when using such a measure to understand dependence since overestimation of self-reported use would lead to overestimation of dependence.

Although we found that the self-reported PSECDI measure was predictive of and correlated with actual use, there were a large number of outliers in the data, highlighting the challenges of collecting self-reported e-cig consumption. The outlying observations may represent participants who used their e-cig in patterns different from their cigarette smoking patterns, a phenomenon that is not uncommon.^{6,7} For example, a participant in a qualitative study of e-cig use patterns stated, “It’s just kind of always there. I almost do it without thinking about it now. I don’t go pick it up, and intentionally vape for five or ten minutes, set it down, and go do something else.”⁶ In effect, the PSECDI times per day question asks users to equate their e-cig use to a pattern similar to cigarette smoking.

The guideline for reporting a “time” (10 minutes or 15 puffs) in the PSECDI question was intended to allow users who vape in discrete “chunks” and users who vape a few puffs intermittently throughout the day to be able to answer the question. Although the design of the question allowed users of all device types and use patterns to report their use, this flexibility meant that the measure could only provide an approximate estimate of puffs per day, which could be explain the moderate correlation between the two measures.

One recent study examined puff topography in 34 current second generation e-cig users in their everyday lives using a portable wireless monitor.²¹ This study found two types of vaping sessions, each of which had a mean of 15–16 puffs but with a fourfold variation in puff volume. This suggests that the estimate of one session consisting of approximately 15 puffs is in approximately the correct range for exclusive e-cig users (as opposed to the largely dual users in this study) and also suggests considerable variation in inhalation pattern between puffs, in addition to the variation

in number of puffs identified here. In a previous similar study, the same group found that among ex-cigarette smoker, current first generation e-cig users, the average length of a “session” of e-cig use was 566 seconds (ie, around 10 minutes), again suggesting that asking e-cig users who have difficulty estimating use in terms of puffs, to do it in terms of chunks of time of 10 minutes, is roughly consistent with typical use.²²

It is also possible that some of the outlying observations may have been reported erroneously due to the trial design. Because participants were asked to log puffs per day regularly, some participants may have simply reported times per day as the number of puffs taken per day since this was the most prominent number in their mind. This would explain observations where times per day and puffs per day were similar numbers and are supported by the finding that times per day decrease when the possibly misinterpreted data is removed.

This study has several limitations. First, the use of puff counter data as the standard for measuring e-cig frequency in puffs per day required that the participant accurately record the number of puffs displayed on their puff counter at the end of each day. It is possible some participants did not record these data reliably. Second, as already noted, the use of a puff counter likely made the puff number prominent in the participant’s mind and potentially led to a greater likelihood of misinterpreting the study instructions regarding reporting times per day. In addition, because all users were asked to initiate e-cig use as part of the study, these users had little to no prior experience using an e-cig and therefore may have had more difficulty understanding and reporting their use than more experienced users. Also, these users were mainly dual users and results may be different for exclusive users using different brand e-cigs. It should also be acknowledged that the precision in our measurement of cigarette consumption is also somewhat rudimentary (ie, frequency takes no account of the actual number of puffs per cigarette, the frequent “digit bias” in which smokers round to the nearest 5 or 10 cigarettes per day, and takes no account of the substantial differences in actual size and amount of tobacco/nicotine contained in different cigarettes).

In conclusion, this study provides evidence that the self-reported PSECDI measure of times per day is a significant predictor of the actual number of daily puffs taken on an e-cig. However, the measurement of e-cig use remains challenging because of limitations in the available tools to measure use patterns that are far more complex than cigarette smoking. Measuring puffs per day may be the most accurate method currently available but not all studies will have access to such tools, thus having to rely on a self-report. Further research to more precisely measure real-world e-cig consumption is needed.

Supplementary Material

Supplementary data are available at *Nicotine and Tobacco Research* online.

Funding

This study was supported by the National Institute on Drug Abuse of the National Institutes of Health (NIH) under Award Number P50DA036105 and the Center for Tobacco Products of the US Food and Drug Administration (FDA). JY, JF, SV, SA, and SH are also supported by the NIH and the US FDA under Award Number P50DA036107. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or the US FDA.

Declaration of Interests

JF has done paid consulting for pharmaceutical companies involved in producing smoking cessation medications, including GSK, Pfizer, Novartis, J&J, and Cypress Bioscience. TE is a paid consultant in litigation against the tobacco industry and is named on a patent application for a device that measures the puffing behavior of electronic cigarette users. There are no other competing interests to report for other authors.

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