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A Brief 7-Day Estimate of Alcohol Consumption for Use in Smoking Cessation Clinical Trials

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Abstract

Accruing evidence of an association between drinking and smoking relapse suggests that it is important to measure alcohol use in smoking cessation studies. However, most studies do not do so, often because of the extra time burden required for these assessments. Data from participants (N = 634) in two smoking cessation clinical trials were used to examine the relationship between short and longer periods of monitoring for a number of Timeline Followback (TLFB) drinking metrics at baseline and during treatment. High intercorrelations were found between short (7 & 14 days) and longer (30 & 60 days) time windows for baseline drinking data. Intercorrelations between short (last 7 days of treatment) and longer (entire treatment period) time windows of drinking data during the smoking cessation treatment period were also mostly in the high range. Although total abstinence was significantly overestimated with shorter time windows, for those who were misclassified, percentage of days abstinent was high and percentage of heavy drinking days and number of drinks per drinking day were low during the longer period. Thus, a brief estimate of alcohol use over 7 days at baseline is likely to provide a representative assessment of percentage of days abstinent, percentage of heavy drinking days, and number of drinks per drinking day. To estimate abstinence at baseline and during treatment, however, a more comprehensive period of monitoring may be required.

Keywords

Timeline Followback (TLFB); smoking cessation; alcohol; drinking; point prevalence

1. Introduction

Evidence from several clinical trials suggests that drinking alcohol during a smoking cessation attempt increases the likelihood of relapse to cigarettes (e.g., Humfleet, Munoz, Sees, Reus, & Hall, 1999). Moreover, alcohol is frequently cited as a precipitant of smoking relapse (Shiffman, 1986). In human laboratory models, alcohol consumption is associated with greater difficulty in resisting cigarettes (McKee, Krishnan-Sarin, Shi, Mase, & O'Malley, 2006). Despite these findings, most smoking cessation studies fail to include measures of alcohol consumption either at baseline or during treatment and follow-up (Leeman, Huffman, & O'Malley, 2007). One impediment to the collection of alcohol-related data is the effort required to collect this data. While there are a number of brief self-report measures of quantity and frequency of drinking, daily drinking estimation measures [e.g., the Timeline Follow-back

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(TLFB) or Form-90] are considered the “gold standard” (Sobell & Sobell, 2003). Data obtained with the TLFB have been shown to be valid for periods of up to 12 months, although most alcoholism trials obtain information for 60 to 90 days prior to treatment and during treatment as frequently as weekly (Anton et al., 2006).

In the smoking literature, meta-analyses have reported that point prevalence abstinence (abstinence during a time window immediately preceding follow-up) is the most commonly used measure of abstinence outcome (Fiore et al., 2000). This may be the case because recent abstinence can be confirmed with a biochemical test. For example, most large smoking cessation trials use carbon monoxide as biochemical confirmation of self-reports of smoking status (e.g., Gonzales et al., 2006), but this biochemical measure has a relatively short half-life and thus cannot be used to confirm long-term periods of abstinence (Jatlow, Toll, Leary, Krishnan-Sarin, & O'Malley, in press). Point prevalence is also felt to be less vulnerable to memory difficulties and is quickly assessed. Perhaps the most convincing reason to use this measure in smoking cessation research is that it correlates very highly with other outcome measures (e.g., continuous abstinence after the quit date; Velicer & Prochaska, 2004). Drawing parallels with the measurement of smoking abstinence, we sought to examine the relationship between different monitoring periods for a number of drinking metrics frequently derived from the TLFB (e.g., percentage of days abstinent) using data obtained during two smoking cessation trials.

2. Method

2.1. Participants and Procedure

The Message Framing Study (MF Study; N=249) was an investigation of varying messages to assist smoking cessation with open-label bupropion SR 300 mg/day (Toll et al., 2007). The Naltrexone + Patch Study (NP Study; N=385) was a dose ranging investigation of naltrexone for smoking cessation in which all subjects received the 21 mg nicotine patch and were randomized to receive placebo or 25, 50, or 100 mg/day of naltrexone (O'Malley et al., 2006). Both studies were approved by the Institutional Review Board of the Yale School of Medicine. Table 1 presents demographics for the MF and NP Studies.

For 6 weeks after their quit date participants came to the clinic for research appointments on a biweekly (for the MF Study) or weekly (for the NP Study) basis. Drinking was assessed using TLFB methodology at each weekly appointment using procedures outlined by Sobell and Sobell (2003). Baseline TLFB data was gathered for the 60 days (for the NP Study) or 30 days (for the MF Study) prior to the first screening session. At all subsequent appointments participants were verbally asked to indicate the number of alcoholic beverages that they consumed each day since they were last evaluated.

2.2. Data Analysis Plan

First, bivariate correlations and chi-squares were used to assess the association among 4 time windows (60, 30, 14, or 7 days before the quit attempt) for estimating baseline drinking (before quitting smoking). Four drinking metrics were examined: a) percentage of days abstinent, b) percentage of heavy drinking days (defined as 5 or more drinks per drinking day for men & 4 or more drinks per drinking day for women), c) number of drinks per drinking day (total number of drinks divided by total number of drinking days), and d) abstinence (no drinking at all for the specified time period). Second, bivariate correlations and chi-squares were used to analyze how well a shorter time window (last 7 days of treatment) related to a longer window (entire treatment period) of alcohol monitoring during smoking cessation treatment for the same 4 drinking metrics. These analyses included only participants who provided drinking data at the

end of treatment (MF Study, $n=177$) and only those in the placebo group ($n=79$) for the NP Study (due to naltrexone's effect on drinking; Srisurapanont & Jarusuraisin, 2005).

3. Results

3.1. Associations Using Baseline Data

As displayed in Table 2, correlations among all baseline drinking variables were significant ($p < .01$). Of note, virtually all correlations were high (approximately .8 or more), with the exception of the correlations for number of drinks per drinking day for which the correlations were in the moderate to high range (approximately .6–.9). For the analyses of abstinence, chi-square values between 60 days (for the NP Study) or 30 days (for the MF Study) of abstinence/drinking and each of the other time windows were all significant [NP Study: 30 days = $\chi^2(1, 385) = 256.97, p < .01$; 14 days = $\chi^2(1, 385) = 185.02, p < .01$; 7 days = $\chi^2(1, 385) = 133.81, p < .01$; MF Study: 14 days = $\chi^2(1, 249) = 178.94, p < .01$; 7 days = $\chi^2(1, 249) = 138.91, p < .01$], showing that abstinence was captured differently among the different time windows. The number of participants in each study classified as abstinent at the various time windows was as follows: NP Study [60 days, $n = 102/385$ (26.5%); 30 days, $n = 135/385$ (35.1%); 14 days, $n = 165/385$ (42.9%); 7 days, $n = 196/385$ (50.9%)]; MF Study [30 days, $n = 72/249$ (28.9%); 14 days, $n = 90/249$ (36.1%); 7 days, $n = 105/249$ (42.2%)].

Given that abstinence was overestimated by shorter periods of monitoring, we conducted additional descriptive analyses of drinking for the subset of participants who were misclassified on the basis of the 7-day period (i.e., abstinent for the 7-day period but not for the longer period). The average for each drinking variable over the 60-day baseline period for these participants in the NP Study was as follows: percentage of days abstinent = 30 days ($n = 33$), $M = 95.74\%$ ($SD = 6.98$); 14 days ($n = 63$), $M = 93.59\%$ ($SD = 8.77$); 7 days ($n = 94$), $M = 93.06\%$ ($SD = 7.82$); percentage of heavy drinking days = 30 days ($n = 33$), $M = 1.47\%$ ($SD = 6.15$); 14 days ($n = 63$), $M = 1.06\%$ ($SD = 4.65$); 7 days ($n = 94$), $M = 1.34\%$ ($SD = 4.70$); number of drinks per drinking day = 30 days ($n = 33$), $M = 2.42$ ($SD = 2.28$); 14 days ($n = 63$), $M = 2.28$ ($SD = 2.29$); 7 days ($n = 94$), $M = 2.47$ ($SD = 2.38$). The results for the 30-day baseline period for the MF Study were similar: percentage of days abstinent = 14 days ($n = 18$), $M = 92.78\%$ ($SD = 5.75$); 7 days ($n = 33$), $M = 91.72\%$ ($SD = 10.45$); percentage of heavy drinking days = 14 days ($n = 18$), $M = 0.74\%$ ($SD = 2.16$); 7 days ($n = 33$), $M = 0.91\%$ ($SD = 2.09$); number of drinks per drinking day = 14 days ($n = 18$), $M = 2.01$ ($SD = 1.15$); 7 days ($n = 33$), $M = 2.36$ ($SD = 1.74$).

3.2. Associations Using Treatment Data

Associations between a shorter (last 7 days of treatment) and a longer (entire treatment period) time window of monitoring during smoking cessation treatment for the NP Study were as follows: a) percentage of days abstinent, $r(79) = .89, p < .01$; b) percentage of heavy drinking days, $r(79) = .68, p < .01$; c) number of drinks per drinking day, $r(79) = .70, p < .01$; and d) abstinence, $\chi^2(1, 79) = 20.76, p < .01$. These associations for the MF Study were as follows: a) percentage of days abstinent, $r(177) = .93, p < .01$; b) percentage of heavy drinking days, $r(177) = .89, p < .01$; c) number of drinks per drinking day, $r(79) = .69, p < .01$; and d) abstinence, $\chi^2(1, 177) = 84.49, p < .01$. Similar to the baseline variables, abstinence was captured differently with the 2 time windows. The number of participants in each study classified as abstinent at the 2 time windows was: NP Study [entire treatment period, $n = 117/385$ (30.4%); last 7 days of treatment, $n = 178/385$ (46.2%)]; MF Study [entire treatment period, $n = 59/249$ (23.7%); last 7 days of treatment, $n = 80/249$ (32.1%)]. Hence, abstinence was overestimated by a shorter period of monitoring. Of the participants who were misclassified in the shorter time window, the average for each drinking variable for the longer treatment period was as follows: NP Study [percentage of days abstinent ($n = 85$), $M = 91.37\%$

($SD = 7.00$); percentage of heavy drinking days ($n = 85$), $M = 1.33\%$ ($SD = 3.69$); number of drinks per drinking day ($n = 85$), $M = 2.16$ ($SD = 1.95$); MF Study [percentage of days abstinent ($n = 30$), $M = 92.72\%$ ($SD = 8.65$); percentage of heavy drinking days ($n = 30$), $M = 1.89\%$ ($SD = 5.23$); number of drinks per drinking day ($n = 30$), $M = 1.74$ ($SD = 1.72$)].

4. Discussion

Mostly high intercorrelations were found among varying baseline time windows and within treatment time windows for 3 drinking variables derived from the TLFB. Abstinence was not shown to be consistent across the time windows. However, for individuals who were misclassified regarding abstinence status for the shorter window, percentage of days abstinent was high and percentage of heavy drinking days and number of drinks per drinking day were low over the entire window. Thus, the data from the present study suggest that smoking researchers could obtain TLFB data over a 7-day time window at baseline and during treatment and nonetheless obtain reasonable estimates of percentage of days abstinent, percentage of heavy drinking days, and amount of use per occasion. If information about whether or not a participant has been abstinent in the recent past is critical, covering longer time periods of monitoring appears to be warranted. If baseline and within treatment drinking are used to predict smoking cessation outcome in future studies, a more comprehensive drinking assessment (e.g., TLFB or Form-90) will likely be required, and until further research is conducted it is probably best to assess drinking over the entire treatment period.

Another concern when deciding which assessment of alcohol consumption to use is the time needed to administer the measure. The only well validated, very brief assessments of drinking are quantity/frequency measures, which can be administered in as little as 4 minutes (Sobell & Sobell, 2003). The major disadvantage of daily drinking estimation methods like the TLFB, which are considered the “gold standard,” is the time necessary to administer them, with time estimates ranging from 10 to 60 minutes (Sobell & Sobell, 2003). Our data suggest that a very brief, less labor intensive 7-day version of the TLFB can be used at baseline in smoking cessation studies to gather reasonable estimates of multiple alcohol consumption variables, thereby reducing this concern.

The fact that all participants were on an active pharmacotherapy limits the generalizability of the treatment results. The demographics of the two samples were significantly different for several variables, so differences between studies might be due in part to these dissimilarities as well as differences in the treatment procedures. Last, the participants in the samples used for these analyses reported relatively low levels of drinking at baseline, so these findings cannot be generalized to heavier drinking smokers.

In summary, nicotine and tobacco researchers should assess alcohol use in smoking cessation studies. Collecting a 7-day estimate of alcohol use at baseline would likely be an adequate measure of percentage of days abstinent, percentage of heavy drinking days, and number of drinks per drinking day. Longer periods of monitoring may be required to assess abstinence.

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Table 1**Sample demographics and baseline alcohol consumption**

Characteristic	Message Framing N = 249	Naltrexone + Patch N = 385
Age (years; <i>M</i> [<i>SD</i>])	42.65 (11.54) ^a	45.95 (11.17) ^a
Sex (% male)	48.2	51.9
Ethnicity (% white)	81.9 ^a	88.3 ^a
Cigarettes per day (<i>M</i> [<i>SD</i>])	22.61 (9.32) ^a	27.70 (10.30) ^a
Number of years smoking (<i>M</i> [<i>SD</i>])	25.01 (11.21) ^a	28.67 (11.09) ^a
Fagerström Test for Nicotine Dependence (<i>M</i> [<i>SD</i>])	5.37 (2.06) ^a	6.31 (2.04) ^a
Baseline (30 days) percentage of days abstinent from alcohol	79.13% (28.41)	81.44% (28.40)
Baseline (30 days) percentage of heavy drinking days	2.96% (6.97)	2.32% (7.69)
Baseline (30 days) number of drinks per occasion	1.83 (1.81)	1.76 (2.30)

^a In a given row, values with an ^a indicate that the difference between the samples is significant by t-test or chi-square at $p < .05$.

Note. A heavy drinking day was defined as 5 or more drinks per drinking day for men and 4 or more drinks per drinking day for women.

Table 2

Intercorrelations of baseline drinking variables using Naltrexone + Patch Study (N = 385) and Message Framing Study (N = 249) data

	30 days	14 days	7 days
<u>Percentage of Days Abstinent</u>			
60 days	.98	.96	.91
30 days		.98	.93
14 days	.97		.96
7 days	.91	.96	
<u>Percentage of Heavy Drinking Days</u>			
60 days	.87	.83	.76
30 days		.96	.89
14 days	.93		.95
7 days	.87	.94	
<u>Number of Drinks Per Drinking Day</u>			
60 days	.85	.76	.64
30 days		.92	.67
14 days	.93		.75
7 days	.77	.84	

Note. Intercorrelations above the diagonal are based on Naltrexone + Patch Study data and intercorrelations below the diagonal in italics are based on Message Framing Study data. Baseline data was measured for 60 days for the Naltrexone + Patch Study and for 30 days for the Message Framing Study. There were minimal changes in correlation coefficients when considering only those participants who were drinkers. All correlations are significant at $p < .01$.