



## Defining and predicting short-term alcohol use changes during a smoking cessation attempt



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### HIGHLIGHTS

- Alcohol use decreased in the two weeks following tobacco cessation.
- Post-quit alcohol use was positively correlated with pre-quit alcohol use.
- Women and those with a history of alcohol dependence drank less post-quit.
- Participants who self-identified as non-white drank less post-quit.

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### ABSTRACT

**Introduction:** Alcohol and nicotine are commonly used substances in the U.S., with significant impacts on health. Using both substances concurrently impacts quit attempts. While studies have sought to examine changes in alcohol use co-occurring with tobacco cessation, results have not been consistent. Understanding these changes has clinical implications. The objective of this study is to identify changes in alcohol consumption that occur following tobacco cessation, as well as predictors of alcohol use patterns following a smoking cessation attempt. **Methods:** A secondary analysis of a randomized, placebo-controlled trial evaluating the efficacy of five tobacco cessation pharmacotherapies. Participants ( $N = 1301$ ) reported their smoking and alcohol consumption daily for two weeks prior to, and two weeks after, the target quit date (TQD).

**Results:** Generally, alcohol use decreased post-TQD. Smokers who reported less pre-quit alcohol use, as well as smokers who were female, non-white, and had a history of alcohol dependence tended to use less alcohol post-quit. Pre- and post-quit alcohol use were more strongly related among men and among those without a history of alcohol dependence.

**Conclusions:** For most smokers alcohol use decreased following smoking cessation. These results suggest that the expectation should be of decreased alcohol use post cessation. However, attention may be warranted for those who drink higher amounts of alcohol pre-cessation because they may be more likely to drink more in the post-quit period which may influence smoking cessation success.

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### 1. Introduction

Nicotine and alcohol are two addictive drugs that have a substantial impact on public health given that they are both prevalent and related to significant health risks. Tobacco use accounts for nearly half a million premature deaths annually in the United States (U.S. Department of Health and Human Services, 2014). Currently, approximately 18% of US adults smoke; however, certain subpopulations, including the less

educated and those with psychiatric comorbidities (including alcohol use and other substance use disorders), smoke at even higher rates (Centers for Disease Control and Prevention, 2014; Grant et al., 2004). Alcohol use is also very prevalent in the United States. Current surveys estimate that about 50% of US adults consume alcohol regularly (Centers for Disease Control and Prevention, 2010) and that alcohol use accounted for over 25,000 deaths in 2010 (Murphy, Xu, & Kochanek, 2013). The consequences of alcohol use, however, start occurring below thresholds of substance abuse definitions (Saunders & Lee, 2000). The concurrent use of alcohol and smoking is common, and ripe with complications, including a reduced likelihood of trying to quit smoking, a lower success rate for those who make an attempt (Cook et al., 2012; Weinberger et al., 2013), and an increased rate of relapse back to smoking in the presence of heavy drinking (Cook et al., 2012).

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Given alcohol's influence on smoking cessation success, one key question regarding the association between drinking and smoking is what happens to the rate of alcohol use when a person quits smoking. Specifically, does quitting smoking increase or decrease drinking, and are certain person characteristics or smoking cessation treatments related to changes in drinking behavior after a smoking cessation attempt? While a variety of studies have attempted to answer these questions, the findings have not been consistent. Older studies suggest that smoking cessation results in an increase in alcohol use (Carmelli, Swan, & Robinette, 1993; Gaudet & Hugli, 1969; Perkins et al., 1990), while more recent epidemiologic studies have found that alcohol use decreases (Dawson, Goldstein, & Grant, 2013; Hughes & Hatsukami, 1986; Karlamangla et al., 2006; Puddey et al., 1984; Stamford et al., 1986) and other studies have found that alcohol use does not change (Cooney et al., 2003; Kahler et al., 2010; Murray, Istvan, & Voelker, 1996; Murray et al., 2002; Nothwehr, Lando, & Bobo, 1995; Tang et al., 1997) as a result of smoking cessation. Most recently, Lisha et al. (2014) found that alcohol use did not change with smoking cessation; however this study used 90-day recall methods for substance use and the populations studied were either alcohol dependent patients in early recovery or HIV positive patients, representing specific subsets of the general population. The lack of consistent findings in the previous studies could be due to methodologic variability, non-naturalistic settings, limited external validity, recall bias, and the lack of temporal ordering to allow for causal inference. Defining the pattern of non-problematic alcohol use concurrent with smoking cessation in the general population is an important clinical question with potential counseling implications.

The goal of the proposed research is to address the question of changes in drinking behavior following smoking cessation in a manner not subject to the methodological constraints outlined above. The study uses data collected in real-time during the course of a planned smoking cessation attempt from a sample of nicotine-dependent, treatment-seeking smokers, who participated in a smoking cessation clinical trial, but who represented members of the general population. This approach mitigates problems with non-naturalistic settings, recall bias, and the limited generalizability that affected prior studies on this topic.

We will also explore potential predictors of post-quit drinking behavior, with a focus on predictors that could be considered in a clinical setting for counseling purposes. In other words, if clinicians could identify risk factors for drinking during a smoking cessation attempt, which would represent a significant risk for relapsing back to smoking as well as a health risk in and of itself, the clinician would be able to address alcohol use more comprehensively among such patients. The predictors we evaluated include pre-quit alcohol use, gender, age, ethnicity, nicotine dependence and heaviness of cigarette consumption, and history of alcohol abuse or dependence. Finally, we will examine the effects of active smoking cessation treatments on alcohol use.

## 2. Methods

### 2.1. Participants

The current project is a secondary analysis of the Wisconsin Smokers' Health Study, a smoking cessation study that enrolled 1504 adult smokers (58% female, 83% white) from the greater Madison and Milwaukee, Wisconsin area (Piper et al., 2009). Inclusion criteria included: smoking more than 9 cigarettes daily for the past 6 months, having an exhaled carbon monoxide (CO) level of at least 9 ppm, and being motivated to quit smoking. Exclusion criteria included: non-cigarette tobacco use, current bupropion use, ongoing psychotic or schizophrenic disorder, any medical contraindications for the pharmacotherapies, a high alcohol consumption rate (greater than 6 drinks daily on more than 6 days each week), a history of seizure or untreated hypertension or an eating disorder, a recent cardiac event, allergies to any of the

cessation medications, and pregnancy or breastfeeding. In addition, women were required to take steps to prevent pregnancy during treatment.

Additional methodological details and the full CONSORT diagram are available in Piper et al. (2009). The study was approved by the University of Wisconsin Health Sciences Institutional Review Board.

### 2.2. Procedures

Participants were screened to determine eligibility, and attended an information session where written informed consent was obtained. Baseline visits were completed to gather vital signs and a carbon monoxide (CO) breath test, as well as demographics, smoking history, and tobacco dependence data (i.e., Fagerstrom Test of Nicotine Dependence [FTND]; (Heatherton et al., 1991)). Participants were randomized to treatment groups in a double-blind fashion, stratified by gender and self-reported race (white/nonwhite). Study staff were blinded to treatment assignment. Treatment groups comprised: (1) bupropion SR 150mg twice daily for 9 weeks (1 week pre-quit, 8 weeks post-quit), (2) nicotine lozenge (2 mg or 4 mg based on smoking within the first 30 minutes of waking) for 12 weeks post-quit, (3) nicotine patch 21 mg/14 mg/7 mg 24-hour patches, titrated down over 8 weeks post-quit, (4) nicotine patch plus nicotine lozenge at doses and durations referenced above, (5) bupropion SR plus nicotine lozenge at doses and durations referenced above, and (6) placebo equivalents for all five active pharmacotherapy groups. Final analyses combined all active pharmacotherapies and compared them to the placebo group. In addition to the pharmacotherapies, all participants received six individual counseling sessions with bachelors-level, trained case managers supervised by a licensed clinical psychologist. Two sessions occurred prior to the quit date, and four sessions occurred post-quit.

Participants were prompted daily by a palmtop computer to record the number of cigarettes smoked and alcoholic drinks consumed during the two weeks prior to, and following, the target quit date (TQD) (Shiffman, Stone, & Hufford, 2008). Alcohol consumption is reported as the mean number of drinks consumed per day in the pre-quit period, and the mean number of drinks consumed per day in the post-quit period. The primary outcome tested was change in alcohol consumption after the TQD. Use of means allowed flexibility for missing data. For example, if only 12 days pre-quit included alcohol consumption data, the average alcohol consumption for that time period was averaged over 12 days instead of 14. Participants were excluded from this analysis if they did not have any data for pre-quit or post-quit alcohol use, as the change in alcohol consumption could not be calculated ( $n = 174$ ). They were also excluded if the mean amount of alcohol they reported consuming was more than three standard deviations above the average alcohol use recorded for all participants in the pre-quit period ( $n = 29$ ). These "heavier drinkers" were excluded to specifically focus on non-problematic alcohol use to reflect changes that may be seen in the general population.

Abstinence status post-quit was assessed by self-report of continuous abstinence, confirmed by exhaled carbon monoxide (defined as  $\text{CO} < 10$  ppm), from Week 1 post-quit to Week 8. This endpoint was chosen in concordance with recommendations of an initial grace period and use of prolonged abstinence as put forth by the Society for Research on Nicotine & Tobacco workgroup (Hughes et al., 2003).

### 2.3. Statistical analysis

All analyses were completed using SAS/STAT software, Version 9.4 of the SAS System for Windows, SAS Institute Inc. (Cary, NC). A paired  $t$ -test was used to examine the change in average alcohol use from pre-quit to post-quit. A multivariate linear regression analysis was used to identify significant predictors of post-quit alcohol use with pre-quit alcohol use entered as a covariate. Based on the model selection strategy proposed by Hosmer and Lemeshow (Hosmer, & L.S., 2013), each

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