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Menstrual cycle phase at quit date and smoking abstinence at six weeks in an open label trial of bupropion*

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Abstract

Background—Quit attempts may have different outcomes based on menstrual cycle phase on quit day. This is the first preliminary study examining whether smoking cessation outcomes vary by menstrual cycle phase of quit date in women receiving a 6-week open trial of sustained release (SR) bupropion.

Methods—33 treatment-seeking premenopausal women were studied. Abstinence outcomes were compared for women quitting during the luteal versus follicular phase.

Results—Women receiving bupropion SR whose self-selected quit date occurred in the luteal phase had significantly higher rates of point prevalence abstinence during the final week of a 6-week post-quit treatment period than women quitting in the follicular phase (62.5% vs. 29.4%; p<. 05). A similar, but non-significant, pattern of findings was demonstrated for continuous abstinence during the treatment phase and for point-prevalence abstinence at 3-month follow-up.

Conclusions—Women receiving bupropion SR were significantly more likely to be abstinent at treatment completion if quitting occurred during the luteal phase. This is consistent with recent findings of outcome related to cycle phase at quit date in the absence of pharmacotherapy, and differs from findings utilizing nicotine replacement. Results add to emerging data suggesting that smoking cessation interventions with varying mechanisms of action may result in different outcomes for premenopausal women based on gonadal hormones at quit date.

Keywords

smoking cessation; gender; menstrual cycle phase; bupropion

*1A graph showing the survival curves for women quitting smoking in the follicular versus luteal phase can be found as supplementary material by accessing the online version of this article at doi :xxx/j.drugalcdep.xxx …

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1. Introduction

Women are reported to have more difficulty quitting smoking than men, whether quitting without assistance (Kabat and Wynder, 1987; Ward et al., 1997) or with behavioral interventions or nicotine replacement therapy (Bjornson et al., 1995; Bohadana et al., 2003; Perkins, 2001; Perkins and Scott, 2008; Royce et al., 1997; Swan et al.,1997; Wetter et al., 1999).

The contributing role of the menstrual cycle to the apparent reduced rate of smoking cessation for women has been supported by investigations showing higher rates of smoking during menses (DeBon et al., 1995; Marks et al., 1994; Steinberg and Cherek, 1989) and the luteal phase (DeBon, et al., 1995; Mello et al., 1987; Snively et al., 2000), greater desire to smoke and reduce negative affect in luteal versus follicular phases (Allen et al., 1999), and more intense cue-induced craving in luteal versus follicular phases or compared to males (Franklin et al., 2004). Although some reports have not shown menstrual cycle phase effects on smoking withdrawal symptoms (Allen, et al., 1999; Pomerleau et al., 2000), others have shown increased withdrawal symptoms and craving in the luteal phase (Allen et al., 2009; Carpenter et al., 2006; DeBon, et al., 1995; O'Hara et al., 1989; Perkins et al., 2000; Pomerleau et al., 1992) as well as increases in self-reported depressive symptoms (Perkins et al., 2000). Although it can be difficult to discriminate smoking withdrawal-related symptoms from premenstrual symptoms (Hughes and Hatsukami, 1986), Allen and colleagues (2009) in studying ad lib smoking showed premenstrual symptoms and withdrawal were significantly higher during the luteal phase.

Based on these findings, investigators have begun to examine whether smoking cessation success varies by menstrual cycle phase at quit date. Two reports using nicotine patch found premenopausal women quitting during the luteal phase were less likely to be successful. The first, a retrospective study of 37 treatment-seeking smokers given nicotine patch plus differing levels of behavioral intervention (Franklin et al., 2008), found women quitting during follicular phase did better at 3 days and 9 weeks post-quit date compared to women quitting during luteal phase and compared to men who quit. Subjects were not randomized by menstrual cycle phase to quit date, and cycle phase was determined by self-report. The behavioral intervention ranged from a smoking cessation instructional film plus one counseling session to individual cognitive-behavioral therapy; there was no significant effect of treatment condition on abstinence (Gariti et al., 2000). The other trial (Carpenter et al., 2008) randomized 35 women by menstrual cycle phase to quit date, and examined 2-week relapse rates using nicotine patch and 2 counseling sessions. This study also found point prevalence abstinence was greater when women quit during follicular phase. Luteinizing hormone (LH) assessed by self-monitoring kits confirmed the luteal phase; regular phone contact identified the start of menses as initiation of the follicular phase.

However, Allen et al (2008) in a carefully controlled prospective study randomizing women to quit date based on cycle phase, and using a behavioral intervention but no pharmacotherapy, found that women did less well if the quit attempt began during follicular phase. Thirty days after quitting, 86% of the follicular phase group relapsed compared to 66% of the luteal phase group. Daily menstrual calendars, urine LH testing and serum hormone level monitoring established and confirmed menstrual phase. Subsequently, Allen et al (2009) similarly found that women who self-selected a luteal phase quit date had significantly longer time to relapse than women choosing to quit in the follicular phase.

These mixed findings raise the question of whether studies of menstrual phase at quit date using nicotine patch generate different results than those not using replacement. The current preliminary investigation is the first to examine whether smoking cessation success varies

by the menstrual cycle phase of quit date in women receiving bupropion SR, and focuses attention on whether smoking cessation outcomes related to menstrual cycle phase may vary by type of smoking cessation intervention (Franklin and Allen, 2009).

2. Methods

2.1 Participants

This report uses data from a randomized controlled trial (RCT) of message framing as a behavioral intervention for smoking cessation (Toll et al., 2007). All participants were treatment-seeking, and exposed to messages emphasizing either the benefits of quitting smoking (i.e. gain-framed messages such as "If you quit smoking you will live longer") or the costs of continued smoking (i.e. loss-framed messages such as "If you continue smoking you will die sooner"). All received an open label trial of bupropion SR, an effective smoking cessation treatment in women and men (Piper et al., 2010; Scharf and Schiffman, 2004). All received a standard dose of 150 mg/day for 3 days, then 300 mg/day for duration of treatment (from 1 week pre- to 6 weeks post-quit). Medication adherence was monitored using electronic Drug Exposure Monitor caps.

For this report, we examined smoking abstinence in 33 premenopausal women not using hormone therapies, who reported regular menstrual cycles for 3 months (Cole et al., 2009), and for who menstrual cycle phase at the quit date could be determined. This subsample represented 62.3% of women in the RCT who reported regular periods. Subjects were ≥18 years old, smoking ≥ 10 cigarettes/day for ≥ 1 year with baseline expired carbon-monoxide (CO) levels of ≥ 10 parts/million. Exclusions were current neurologic or medical illness, major depression, alcohol dependence, or history of anorexia or bulimia. This study was approved by the Yale Institutional Review Board; written informed consent was obtained prior to participation.

2.2 Smoking Assessment and Quit Date

Smoking behavior was assessed using Timeline Followback (TLFB) methodology (e.g. Brown et al., 1998; Sobell and Sobell, 1992; 2003). Baseline TLFB data were gathered for 30 days prior to the first screening session; participants were asked the number of cigarettes smoked each day for 2 weeks preceding every regular appointment. Quit date was self-selected at entry into the trial. Bupropion SR was initiated one week prior to quit date; participants were seen every other week for six weeks after quit date.

Point prevalence abstinence (PPA) during the final week and continuous abstinence (CA) over the 6 week post-quit treatment period were assessed using self-report (no smoking, not even a puff) verified by CO level < 10 ppm (SRNT Subcommittee on Biochemical Verification, 2002).

2.3 Menstrual Cycle Status and Phase Assessment

Women were interviewed regarding their menstrual/gynecologic history at intake. Premenopausal status was determined using the Patient Health Questionnaire item 18 response "periods are unchanged" (Spitzer et al., 1999); a daily menstrual cycle calendar was used to document regular menstrual cycles retrospectively for 3 months prior to the trial. During the trial, subjects were asked to report any menstrual bleeding since their last appointment to document menstrual cycle phase and regularity. Follicular phase was defined as starting the first day of menstrual bleeding through day 14; luteal phase as the remaining days of the month.

2.4 Data Analysis

Baseline measures were compared using chi-square tests or General Linear Models. Logistic regression analyses were used to examine bivariate outcomes for women quitting during luteal versus follicular phases. The behavioral treatment conditions of "loss framed" versus "gain framed" messages and the interaction of treatment condition with cycle phase at quit date were tested in the models. Statistical significance was predetermined as alpha=.05; all p-values were two-tailed. SAS Version 9.1.3 (SAS Institute Inc., Cary, NC) was used.

3. Results

3.1 Baseline Characteristics

Participants smoked an average of 20.2 cigarettes per day (SD=5.15), an average of 19.7 years (SD=7.07), with a mean Fagerström Test for Nicotine Dependence score of 5.2 (SD=1.68). Mean menstrual cycle length was 28 days (SD=3, range 24–37). There were no significant differences in baseline characteristics for those quitting during the luteal (N=17) versus follicular phases (N=16) (Table 1). Although somewhat higher for those who quit in the luteal phase, cigarettes/day was not a significant covariate.

3.1 Smoking Abstinence

A significant difference favoring those who quit in the luteal versus follicular phase (62.5% vs. 29.4%; $p<.05$) was found for PPA during the final week of the 6 week post-quit treatment period. Similar relationships were demonstrated for CA and for PPA at 3-month post-quit follow-up (Table 2). Success on the quit date was high for both groups (15/17=follicular phase; 15/16=luteal phase).

An exploratory analysis of the relationship between menstrual cycle phase at quit date and cycle phase on relapse day (for those who relapsed, n=21) indicated that relapse was more likely to occur in the menstrual phase in which a subject quit (p=0.08, Fisher's Exact Test). A survival graph of time to the first day of smoking revealed that many relapsed shortly after the quit date[1].

4. Discussion

Women receiving bupropion SR were more likely to be abstinent at the end of a 6-week treatment trial if quit date occurred during the luteal phase of the menstrual cycle. This is consistent with Allen et al. (2008) who studied outcome related to cycle phase at quit date in the absence of pharmacotherapy, and differs from findings utilizing nicotine replacement (Carpenter et al., 2008; Franklin et al., 2008). Also consistent with Allen et al (2008), relapse was more likely to occur in the same phase (follicular versus luteal) as the one in which a quit date occurred, which may be due to the rapidity of relapse for many.

Our results and those of Allen and colleagues are supported by evidence that gonadal hormones likely influence the reinforcing effect of drugs such as nicotine (Lynch, 2006; Lynch et al., 2009), and other recent data suggesting that brain dopaminergic functioning in reward areas is enhanced during the mid-follicular phase when estrogen is relatively unopposed by progesterone (Dreher et al., 2007). Given that estrogen may sensitize women to the reinforcing properties of nicotine, lapse behavior during follicular phase may be more likely to progress to relapse (Allen et al., 2008).

[1]1A graph showing the survival cures for women quitting smoking in the follicular versus luteal phase can be found as supplementary material by accessing the online version of this paper.

Bupropion attenuates the reinforcing properties of nicotine (Cousins et al., 2001), and may contribute to quit success through reductions in negative affect and withdrawal symptoms (Hurt et al., 1997; Lerman et al., 2002; Shiffman et al., 2000). The latter are generally greater during luteal phase (Allen et al., 2009; Carpenter et al., 2006) and the positive effect of bupropion on these symptoms may account, at least in part, for better outcome when quitting in luteal phase. However, it is currently unknown whether bupropion differentially affects outcomes by menstrual cycle phase and our study could not address this question without a placebo or behavioral treatment only group.

Results of the current study differ from two investigations utilizing nicotine replacement showing better outcomes when quit date occurs during follicular phase (Carpenter et al., 2008; Franklin et al., 2008). The reason for this difference is currently unclear. While it is known that estrogen increases the metabolism of intravenous nicotine in healthy volunteers (Benowitz et al., 2006) and that faster metabolism of nicotine replacement has been associated with poor treatment outcomes (Lerman et al., 2006; Schnoll et al., 2009), it is unknown whether nicotine replacement alters estrogen-related increases in nicotine reinforcement during follicular phase. Studies assessing how various forms of nicotine affect metabolism and reinforcement across menstrual cycle phases would serve to clarify these outcomes.

Limitations in the current report are that women were not randomized to quit date by menstrual cycle phase, and phase was determined by retrospective daily menstrual cycle calendar, not by measurement of ovarian hormones. However, participants provided data for 3 menstrual cycles prior to enrollment and reported regular menstrual cycles during the trial, and self-reported cycle phase has demonstrated excellent convergence with biochemical confirmation of cycle phase (Allen et al., 2000). The study did not have a placebo control group, which would have allowed a more direct causal link between quit status and menstrual phase. Moreover, this could have enabled us to determine if bupropion SR provided additional assistance with moderating variables like negative affect, particularly in luteal phase. As strengths, this is the only study examining menstrual cycle phase in women taking bupropion, a pharmacotherapy that has been shown to be an effective smoking cessation treatment for women.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Baseline Characteristics (N=33)

	Follicular (N=17)	Luteal (N = 16)	Overall	P-value
Age (yr)	36.5±8.52	36.1±5.56	36.3±7.13	0.87
White race (%)	88.2	93.8	90.9	0.58
Body Mass Index	27.1±7.95	27.1±6.97	27.1±7.37	1
Education (%)				0.33
High-school graduate or less	47.1	33.3	40.6	
Some education after high school	41.2	33.3	37.5	
College graduate or more	11.8	33.3	21.9	
Marital status (%)				0.78
Married or cohabitating	47.1	50	48.5	
Divorced or separated	11.8	18.8	15.2	
Never married	41.2	31.3	36.4	
Full-time employment (%)	58.8	66.7	62.5	0.65
No. of cigarettes smoked per day	18.6±3.99	22.0±5.78	20.2±5.15	0.06
Years of smoking cigarettes	20.8±7.88	18.6±6.13	19.7±7.07	0.37
No. of previous attempts to quit	5.9±7.14	6.2±7.97	6.1±7.44	0.93
Expired carbon monoxide (ppm)	23.5±8.36	25.6±10.66	24.5±9.45	0.53
Serum cotinine (ng/ml)	257.9±115.07	272.7±109.79	264.8 ± 111.06	0.71
FTND* score	5.1±1.69	5.4±1.71	5.2±1.68	0.67
Previous use of nicotine replacement (%)	64.3	75	70	0.52
Other smokers in household (%)	41.2	43.8	42.4	0.88
CES-D** score	8.1±5.68	10.8±8.81	9.4±7.37	0.31
AUDIT*** score	3.0±3.36	3.0±2.39	3.0±2.88	0.96

* FTND: Fagerstrom Test for Nicotine Dependence (Heatherton et al., 1991)

** CES-D: Center for epidemiological Studies – Depression Scale (Radloff, 1977)

*** AUDIT: Alcohol Use Disorders Identification Test (Babor et al., 1992)

Table 2

Smoking Abstinence by Quit Date and Menstrual Phase (N=33)

Outcome	Quit during Follicular Phase (N=17)	Quit during Luteal Phase (N = 16)	Odds Ratio Estimates	95% Confidence Limits
Point prevalence assessing abstinence during final week of a 6 week post-quit treatment period	29.4% (5/17)	62.5% (10/16)	5.29*	1.03–27.22
Continuous abstinence over entire 6 week post-quit treatment period	17.7% (3/17)	31.3% (5/16)	2.02	0.32–12.62
Point prevalence assessing abstinence in the past 7 days at 3 months post-quit	11.8% (2/17)	18.8% (3/16)	1.84	0.259–13.09

* $p<0.05$