Influence of Phase-Related Variability in Premenstrual Symptomatology, Mood, Smoking Withdrawal, and Smoking Behavior during Ad Libitum Smoking, on Smoking Cessation Outcome

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Abstract

Emerging evidence suggests that women have a more difficult time quitting smoking than men—possibly due, in part, to sex hormones. The present study characterized mood, premenstrual symptomatology, and smoking withdrawal, as well as smoking behavior, in the follicular and luteal phases during ad libitum smoking in 25 women intending to quit. We also investigated the possible influence of phase-related variability in these measures on likelihood of study adherence and smoking cessation. We found that premenstrual symptomatology, as well as some measures of mood and smoking withdrawal, were significantly higher during the luteal phase than in the follicular phase. Cigarettes/day did not vary by menstrual cycle phase. Phase-related variability in premenstrual symptomatology [$F(3, 20) = 2.82$, $p = 0.0650$)] and urge to smoke [$F(2, 21) = 4.85$, $p = 0.0186$)] were associated with relapse. These data support the inference that sex hormones influence smoking cessation outcome. This knowledge may contribute to the development of more rational and effective smoking cessation interventions for women.

Keywords

Smoking; Relapse; Women; Menstrual Cycle; Premenstrual Symptomatology; Smoking Withdrawal

1. Introduction

A growing literature indicates that women are less likely than men to quit smoking successfully (e.g., Perkins, 2001; Bohadana, Nilsson, Rasmussen, & Martinet, 2003; Collins, Wileyto, Patterson, Rukstalis, Audrain-McGovern, Kaufmann, et al, 2004). Identified barriers for women include negative affect (Borrelli, Bock, King, Pinto, & Marcus, 1996; Gritz, Nielsen, & Brooks, 1996), lack of social support (Gritz et al, 1996), and weight concerns (Pomerleau

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& Kurth 1996; Perkins, Levine, Marcus, & Shiffman, 1997). In addition, non-nicotine reinforcers may be more important for women than men (Perkins, 2001).

Despite inconsistencies in the literature, due in part to differences in methodology and difficulty separating premenstrual from withdrawal symptomatology, there is considerable support for the role of cycle-related hormonal changes in making quitting more difficult for women (see Carpenter, Upadhyaya, LaRowe, Saladin, & Brady, 2006 for a review). Attempts to assess the effects of menstrual cycle phase on ability to abstain from smoking have typically relied on either collection of data during ad libitum smoking followed by a time-limited period of attempted smoking abstinence (e.g., Allen, Hatsukami, Christianson, & Brown, 2000; Craig, Parrot, & Coomber, 1992; Franklin, Napier, Ehrman, Gariti, O'Brien, & Childress, 2004; DeBon, Klesges, & Kleges, 1995; Marks, Hair, Klock, Ginburg, & Pomerleau, 1994; Pomerleau, Garcia, Pomerleau, & Cameron, 1992) or on assessments collected in the context of a trial (e.g., O'Hara, Portser, & Anderson, 1989; Perkins, Levine, Marcus, Shiffman, D'Amico, Miller, Keins, Ashcom, & Broge, 2000).

By contrast, the possible influence of individual differences in phase-related measures of premenstrual symptomatology, mood, and smoking withdrawal during ad libitum smoking upon smoking cessation outcome has been underexplored. To fill this gap, we studied women seeking smoking cessation treatment for a full cycle of ad libitum smoking prior to their quit day. Our aims were to characterize premenstrual symptomatology, mood, and smoking withdrawal during the follicular and luteal phases under conditions of ad libitum smoking; as well as actual smoking behavior, and to determine whether phase-related variability in these measures influences likelihood of completing the protocol and smoking cessation outcome. We hypothesized that during ad libitum smoking, negative affect, premenstrual symptomatology and smoking withdrawal would be higher in the luteal phase; and that women with greater phase-related variability in these measures would be less likely to complete the protocol and achieve smoking abstinence. Based on our own previous findings and those of others (Allen et al, 1996; Allen, Hatsukami, Christianson, & Nelson, 1999; Franklin et al, 2004), we did not expect phase-related differences in actual smoking behavior to emerge but were interested in the effect of variability in this measure upon outcome.

2. Methods

2.1 Participants

Thirty-three women enrolled in a prospective randomized intent to treat trial with behavioral counseling. Of these, six women withdrew prematurely from the study and two failed to provide at least four days of daily assessments during both the seven-day follicular (F) and seven-day luteal (L) phases during ad libitum smoking. The remaining 25 women were included in these analyses.

2.2 Procedure

This study was approved by the University of Minnesota Institutional Review Board. Participants were recruited via local television, radio, and newspaper advertisements. To be eligible, candidates had to be between the ages of 18–40, smoke at least 10 cigarettes per day for at least the past year, have regular menstrual cycles, and not be using any hormones or psychotropic medications. (See Allen, Bade, Center, Finstad, & Hatsukami, 2008 for a more detailed description of inclusion and exclusion criteria.). Participants were informed that the study aim was to examine the effects of menstrual cycle phase on smoking relapse. They were instructed to complete daily measures of premenstrual symptomatology, mood, smoking withdrawal, and number of cigarettes smoked. To reduce the confounding effects of diurnal mood fluctuation, they were asked to fill out forms at a standard, self-selected time each day.

To discourage inaccurate retrospective reporting, they were told there was no penalty for missing forms. Menstrual cycle was monitored via menstrual calendars and urine LH testing. (For further detail, see Allen, Hatsukami, Christianson, & Nelson, 1996; Allen, Hatsukami, Christianson, & Nelson, 2000; Allen et al, 2008). The F phase was defined as the seven days prior to the LH surge and the L phase as the seven days prior to the onset of menses. Participants were randomized to begin data collection during either the F phase (day 4–8) or the L phase (6–8 days after LH surge), with day 1 defined as the onset of menses.

Following the ad libitum smoking month, participants were asked to quit smoking. They were given *Clearing the Air*, developed by the National Institutes of Health, and provided with smoking cessation behavioral counseling by trained counselors who focused on personally relevant coping strategies. Counseling sessions were about 15 minutes in length and were conducted at weekly clinic visits beginning the week before the participants' assigned quit date (see Allen, et al, 2008 for more details). Participants randomized to begin data collection in the F phase also attempted to quit smoking during the F phase; likewise for participants assigned to the L phase. Menstrual calendars and smoking logs were reviewed at weekly clinic visits and then collected. Smoking status was confirmed via breath CO ≤5 ppm. Participants were paid for volunteering.

2.3 Subjective Assessments

Measures collected at baseline included standard demographic data and the Fagerstrom Test for Nicotine Dependence (FTND; Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991).

The following measures were collected during the follicular and luteal phases: The Shortened Premenstrual Assessment Form (PAF; Allen, McBride, & Pirie, 1991) consists of 10 items rated on 6-item likert type scale; it yields a PAF-Total score as the sum of three subscales: PAF-Pain, PAF-Affect, and PAF-Water. The Positive and Negative Affect Scale (PANAS; Watson, Clark, & Carey, 1988) is a 10-item mood-assessment scale using a five-point likert type scale. In the 20-item Center for Epidemiological Studies – Depression (CES-D; Radloff, 1977), depressive symptoms are rated on a scale of 0 to 3, with a score of 16 representing a standard cut-point for the presence of clinically meaningful depression. The Minnesota Nicotine Withdrawal Scale (MNWS; Hughes & Hatsukami, 1986) queries craving (MNWS-Craving; 1 item) and total withdrawal (MNWS-Withdrawal; 7 items). The Questionnaire of Smoking Urges – Brief (QSU; Tiffany & Drobes, 1991) (10 items rated on a scale of 1 to 7) assesses two types of smoking urges: QSU-Factor 1 (intention or desire to smoke), and QSU-Factor 2 (overwhelming desire to smoke in anticipation of relief from negative affect).

2.4 Outcome measures

Participants were grouped based on three measures of outcome: *Study adherence* was defined as completion of the second month of data collection. *Lapse* was defined as taking one or more puffs during attempted smoking cessation. *Relapse* was defined as smoking at least seven cigarettes with 24 hours or less between each cigarette (Hughes, Keely, Niaura, Ossip-Klein, Richmond, & Swan, 2003). In addition, participants who were randomized to quit in the L phase were compared with those who quit in the F phase.

2.5 Statistical Analysis

Mean scores for premenstrual symptomatology, mood, smoking withdrawal, and smoking behavior were computed for F and L phases and compared using paired t-tests. Participants were required to have at least four days of non-missing data during each seven-day menstrual cycle phase, and means were computed using the data available (that is, 4–7 days). Differences in demographic and baseline smoking variables based on outcome group were assessed using independent t-tests and chi-square tests. Analysis of Variance (ANOVA) and Multivariate

Analysis of Variance (MANOVA), using Wilks' Lambda criteria, were used to test the association between outcome measures and phase-related variability (L phase score minus F phase score during ad libitum smoking) in premenstrual symptomatology, mood, smoking withdrawal, and cigarettes per day.

3. Results

3.1 Baseline characteristics

Participants (n=25; 76% White) had a mean ±SD age of 30.04±5.25 years and 14.08±1.63 years of education. They reported smoking a mean of 17.32±5.10 cigarettes/day and had a mean FTND score of 4.36±2.02. Compared with women who withdrew prematurely from the study or failed to provide sufficient data (n=8), participants completing the first month began smoking at an older age (18.68±3.02 v. 15.50±2.14, t=2.75, p=0.0099) and had marginally lower FTND scores (4.36±2.02 v. 5.89±2.37, t=1.89, p=0.0717).

3.2 Cycle Phase Differences during Ad Libitum Smoking

Cycle phase differences in premenstrual symptomatology, mood, smoking withdrawal, and cigarettes/day are shown in Table 1.

3.3 Predictors of outcome

No difference in quit rates was observed based on assigned quit phase (F Phase: 5/11 quit; L Phase: 5/14 quit; χ^2=0.245; p=0.6217). Participants who relapsed (n=15) had marginally higher FTND scores (4.93±1.91) than those who did not (n=10) (3.50±1.96; t=1.82, p=0.0815). No other baseline differences emerged for study adherence, lapse or relapse outcome groups. Differences in phase-related variability in premenstrual symptomatology, mood, smoking withdrawal and smoking behavior based on outcome (study adherence, lapse, and relapse) are shown in Table 2.

4. Discussion

During ad libitum smoking, all measures of premenstrual symptomatology, as well as some measures of mood (negative affect, depression) and smoking withdrawal (anger, anxiety, concentration, appetite, depressed mood, total withdrawal and desire to smoke), were significantly higher during the luteal phase. These differences emerged despite the fact that a subset of participants (i.e., those who withdrew from the study prematurely or failed to comply with instructions to complete questionnaires), who were more dependent and therefore might be expected to show more prominent effects, were excluded from our analyses. Although the clinical importance of the observed significant differences in withdrawal symptomatology cannot be ascertained, the pattern of elevation across multiple symptoms is suggestive. Some measures were not affected by menstrual phase, including positive affect, craving, restlessness, insomnia, and urge to smoke to relieve negative affect. As predicted, daily cigarettes smoked did not significantly differ by menstrual phase during ad libitum smoking.

Phase-related variability in premenstrual (water, affect, and pain) symptoms and urge to smoke did not predict study adherence or lapse but was significantly associated with relapse, suggesting the need for special attention to relapse prevention in women reporting elevated phase-related variability in these symptoms during ad libitum smoking. Despite the expected lack of differences in smoking behavior across subjects overall, those who smoked more during the luteal phase than during the follicular phase (possibly suggesting greater reliance on smoking as a coping mechanism during the luteal phase) were marginally more likely to relapse. Phase-related variability in mood and withdrawal symptomatology did not affect any of our outcome measures (i.e., study adherence, lapse, or relapse). Thus, in our small and

relatively nondepressed sample, depression did not compromise ability to quit, consistent with some reports (Hitsman, Borrelli, McChargue, Spring, B., & Niaura, 2003) though not others (e.g., Niaura, Britt, Shadel, Goldstein, Abrams, & Brown, 2001; Glassman, Covey, Stetner, & Rivelli, 2001).

Some caveats are in order: 1) Although randomization group did not differ on demographics, smoking behavior, ad libitum symptomatology, or smoking cessation outcome, the possible impact of the cycle phase in which a participant's quit attempt was started cannot be completely ruled out and limits the interpretability of our results. 2) The small size of our sample and of the subgroups based on outcome compromises the comparison of the two cycles. Replication in a larger sample, using a design uncomplicated by differences in randomization to quit phase, will be needed to confirm and refine the impact of phase related variability of symptoms on retention and quitting.

In summary, premenstrual discomfort and some smoking withdrawal symptoms, though not negative mood, increased in severity during the luteal phase, supporting the inference that sex hormones influence smoking effects and behavior. Moreover, our finding that greater phase-related variability in premenstrual symptoms, urge to smoke, and cigarettes per day during ad libitum smoking predicts relapse may contribute to the development of more rational and effective smoking cessation interventions for women.

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Table 1

Premenstrual, Mood and Smoking-Related Symptoms by Menstrual Cycle Phase during Ad Libitum Smoking (n=25)

	F Phase	L Phase	t-value / χ^2	p-value
Premenstrual Symptomatology				
Water (PAF)	3.87 ± 1.99	5.91 ± 2.23	4.12	0.0004
Affect (PAF)	6.26 ± 2.92	7.70 ± 2.82	2.85	0.0091
Pain (PAF)	3.86 ± 1.57	6.29 ± 2.39	5.20	<0.0001
Total (PAF)	13.99 ± 6.19	20.60 ± 6.80	4.90	<0.0001
Measures of Mood				
Positive Affect (PANAS)	26.04 ± 5.22	25.23 ± 7.09	−0.83	n.s.
Negative Affect (PANAS)	13.85 ± 2.89	16.02 ± 3.50	2.94	0.0072
Depressive Status (CES-D ≥16)	16%	24%	6.79	0.0092
Smoking Withdrawal Symptomatology				
Craving (MNWS)	2.58 ± 0.55	2.63 ± 0.61	0.58	n.s.
Anger (MNWS)	1.08 ± 0.84	1.64 ± 0.88	3.20	0.0038
Anxiety (MNWS)	0.79 ± 0.71	1.18 ± 0.85	2.75	0.0112
Concentration (MNWS)	0.89 ± 0.65	1.08 ± 0.75	1.82	0.0812
Restlessness (MNWS)	0.82 ± 0.82	0.92 ± 0.91	0.74	n.s.
Appetite (MNWS)	0.68 ± 0.82	1.00 ± 1.04	2.18	0.0395
Depressed (MNWS)	0.75 ± 0.78	1.03 ± 0.84	1.85	0.0770
Insomnia (MNWS)	0.73 ± 0.75	0.73 ± 0.90	0.01	n.s.
Total Withdrawal (MNWS)	5.73 ± 4.33	7.58 ± 4.77	2.64	0.0144
Factor 1 (QSU)	16.57 ± 6.30	17.71 ± 7.36	2.01	0.0563
Factor 2 (QSU)	6.41 ± 3.37	6.78 ± 4.09	1.09	n.s.
Smoking Behavior				
Cigarettes Smoked per Day	14.37 ± 3.80	14.72 ± 7.66	0.56	n.s.

Table 2

Phase-Related Change Scores by Study Adherence and Smoking Cessation Outcome Groups

	Non-Complete (n=6)	Study Adherence Complete (n=19)	ANOVA/MANOVA	Lapse (n=18)	Lapse No Lapse (n=7)	ANOVA/MANOVA	Relapse (n=15)	Relapse No Relapse (n=10)	ANOVA/MANOVA
Premenstrual Symptomatology									
Water (PAF)	2.38±2.95	1.94±2.39	-	2.31±2.82	1.34±1.03	-	2.62±2.28	1.17±2.61	-
Affect (PAF)	3.24±2.62	1.03±2.41	-	1.66±2.71	1.08±2.32	-	1.87±2.05	0.96±3.20	-
Pain (PAF)	2.84±3.23	2.29±2.07	$F_{(3,20)}=1.17$	2.38±2.41	2.54±2.29	$F_{(3,20)}=1.00$	2.39±2.29	2.47±2.51	$F_{(3,20)}=2.82$[†]
Mood									
Positive Affect (PANAS)	-0.53±3.13	-0.90±5.39	-	-1.41±3.99	0.74±6.82	-	-1.36±4.14	0.02±5.97	-
Negative Affect (PANAS)	4.48±4.61	1.45±3.17	$F_{(2,22)}=1.72$	2.59±3.87	1.22±3.25	$F_{(2,22)}=0.75$	2.26±3.98	2.06±3.44	$F_{(2,22)}=0.23$
Depressive Symptoms (CES-D)	5.12±5.94	1.67±6.31	$F_{(1,22)}=1.38$	3.08±6.96	1.23±4.39	$F_{(1,22)}=0.42$	2.73±5.49	2.27±7.55	$F_{(1,22)}=0.03$
Smoking Withdrawal									
Craving (MNWS)	0.25±0.55	-0.01±0.38	$F_{(1,23)}=1.80$	0.09±0.45	-0.06±0.39	$F_{(1,23)}=0.69$	0.10±0.41	-0.02±0.47	$F_{(1,23)}=0.46$
Anger (MNWS)	1.21±0.69	0.36±0.85	-	0.61±0.95	0.44±0.73	-	0.55±0.91	0.58±0.88	-
Anxiety (MNWS)	0.77±0.43	0.27±0.74	-	0.40±0.70	0.37±0.79	-	0.31±0.58	0.51±0.88	-
Concentration (MNWS)	0.56±0.46	0.08±0.51	-	0.26±0.62	0.02±0.10	-	0.19±0.58	0.20±0.49	-
Restlessness (MNWS)	0.19±0.54	0.07±0.73	-	0.15±0.70	-0.04±0.65	-	0.08±0.56	0.13±0.86	-
Appetite (MNWS)	0.23±0.52	0.35±0.81	-	0.40±0.86	0.12±0.24	-	0.39±0.86	0.23±0.55	-
Depressed (MNWS)	0.45±0.95	0.23±0.71	-	0.29±0.81	0.26±0.67	-	0.20±0.76	0.40±0.78	-
Insomnia (MNWS)	0.27±0.61	-0.08±0.64	$F_{(7,17)}=1.44$	0.01±0.66	-0.02±0.64	$F_{(7,17)}=0.35$	-0.08±0.62	0.12±0.68	$F_{(7,17)}=0.38$
Factor 1 (QSU)	0.58±2.34	1.22±2.78	-	0.79±2.99	1.82±1.56	-	-0.02±2.54	2.64±2.04	-
Factor 2 (QSU)	0.58±2.61	0.35±1.59	$F_{(2,21)}=0.34$	0.62±2.04	-0.14±0.77	$F_{(2,21)}=2.34$	0.24±1.79	0.62±1.83	$F_{(2,21)}=4.85$[*]
Smoking Behavior									
Cigarettes Smoked Per Day	-0.81±2.73	0.68±1.82	$F_{(1,23)}=2.41$	0.16±2.24	0.67±1.84	$F_{(1,23)}=0.25$	-0.40±2.04	1.48±1.96	$F_{(1,23)}=3.48$[†]

[†] $0.05 < p < 0.10$

[*] $p < 0.05$