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Effect of Nicotine Patch on Energy Intake and Weight Gain in Postmenopausal Women during Smoking Cessation

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Abstract

Introduction—Post-cessation weight gain is a commonly cited barrier to smoking cessation. Some evidence suggests nicotine replacement therapy may limit post-cessation weight gain by reducing energy intake. This project aims to assess differential changes in energy intake and body weight during smoking cessation in a sample of postmenopausal women randomized to receive 21 mg nicotine or placebo patch for 12 weeks.

Methods—Postmenopausal women who smoked 10 cigarettes/day were enrolled in this double-blind randomized placebo-controlled study. Total energy intake (via four-day food diaries), body mass index (BMI; kg/m²), cigarettes per day and smoking status (self-report verified by exhaled carbon monoxide) were assessed at three time points: 2 weeks prior to quit date, 12 weeks after quit date, and 12 months after smoking cessation treatment.

Results—Participants (n=119) were, on average, 55.8±6.7 years old with a baseline BMI of 27.0±5.2 and average cigarettes/day was 21.1±8.6. At Week 12, participants randomized to nicotine patch increased their mean caloric intake by 146.4±547.7 kcals/day whereas those on placebo patch decreased their caloric intake by 175.3±463.2 (f-value=10.1, p-value=0.002). Despite the differences in caloric intake, body weight remained similar between groups.

Conclusions—The results of this study indicate that nicotine patch may increase energy intake during treatment, and does not prevent post-cessation weight gain in postmenopausal smokers. Additional research is needed to replicate these findings and assess whether different forms of

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nicotine replacement therapy influence caloric intake and post-cessation weight gain in postmenopausal smokers.

Keywords

Postmenopausal; nicotine patch; smoking cessation; weight gain; energy intake

1. Introduction

Although three out of four current smokers report wanting to quit smoking, more than 90% relapse to smoking within six months of a quit attempt (CDC, 2010; Benowitz, 2009). Compared to men, women are at a higher risk of smoking-related morbidity and mortality (USDHHS, 2001; Prescott et al 1998; Zang & Wynder, 1996) and also may have lower rates of smoking cessation (USDHHS, 2001; Perkins, 2001; Perkins & Scott, 2008). Postmenopausal women may have a more difficult time quitting smoking as they tend to smoke more cigarettes per day, have higher levels of dependence and are less confident in their ability to quit smoking compared to their younger counterparts (Perkins, 2001; McVay & Copeland, 2011). Therefore, addressing the barriers postmenopausal women face when attempting to quit smoking is critical.

One of the most commonly cited barriers to smoking cessation by women is a fear of weight gain (e.g. Perkins, 2001; Pomerleau et al 2001; Copeland et al, 2006; McVay & Copeland, 2011). On average, women report a willingness to tolerate up to a six pound weight gain during cessation (Filozof et al 2004). However, the average post-cessation weight gain in women is over eight pounds and nearly 20% of women gain more than 20% of their pre-cessation body weight (Williamson et al 1991; O'Hara et al, 1998; Filozof et al 2004; McVay & Copeland, 2011).

Explanations for post-cessation weight gain include an increase in energy intake along with changes in energy expenditure and resting metabolic rate (Filozof et al 2004; Hatsukami et al, 1993; Audrain-McGovern & Benowitz, 2011). Nicotine could alter brain chemicals and hormones, thereby reducing appetite and increasing satiety leading to a reduction in energy intake (Audrain-McGovern & Benowitz, 2011). Indeed, animal studies show that nicotine administration reduces caloric intake and reduces body weight (Mangubat et al., 2012).

Nicotine replacement therapy has been shown to delay cessation-related weight gain and, therefore, has been suggested as a possible intervention for reducing post-cessation weight gain (McVay & Copeland, 2011; Farley et al, 2012). However, few studies have assessed whether nicotine replacement therapy merely delays or prevents weight gain. Further, it has been suggested that preferences for sweets increases with smoking cessation, but it is not known how that is altered by use of nicotine replacement therapy beyond the first few weeks of treatment (Allen et al, 2005). Therefore, the overall goal of this report is to explore both the short- (i.e. 12 weeks) and long-term (i.e. 12 months) effect of nicotine on energy intake and weight gain. Secondary data analyses were performed on a dataset from a randomized clinical trial where postmenopausal women received behavioral counseling and nicotine patch (active or placebo) for smoking cessation. Specifically, this project addresses the following two research questions: (1) are the changes in energy intake and composition during smoking cessation associated with randomization to transdermal patch (active/placebo), and (2) does the change in total energy intake explain post-cessation weight gain? We hypothesized that both randomization groups would have a significant increase in their energy intake. Further, we expected that those randomized to the placebo transdermal patch would experience a greater increase in energy intake compared to those in the active transdermal patch group. We also expected that calorie composition will vary by

randomization status. Finally, we anticipated that increases in total energy intake will have a significant positive association with post-cessation weight gain.

2. Methods

2.1. Study Sample

Participants included postmenopausal females (i.e., self-report of no menstrual period within the last year), who smoked at least 10 cigarettes per day, and were in stable physical and mental health. Participants were enrolled into a double-blind randomized placebo-controlled study that aimed to investigate the effectiveness of the transdermal patch in postmenopausal women. This report is a secondary data analysis of participants who had complete data for dietary intake, body weight, and smoking status. All procedures were approved by the human subjects committee at the University of Connecticut Health Center. (For additional details, including a CONSORT flowchart, as well as smoking cessation intervention and outcomes, see Oncken et al, 2006 and Oncken et al, 2007).

2.2. Procedures

Participants were randomly assigned 21 mg active or placebo nicotine patch using a 3:5 assignment ratio to result in approximately equal number of abstainers in each group. Participants were instructed to start using the patch on their quit date. After the 12-week treatment period, participants received instructions on how to titrate down by using the 14-mg active (or placebo) patch for two weeks followed by the 7-mg active (or placebo) patch for an additional two weeks. In addition, all participants received four sessions of group smoking cessation behavioral counseling and attended seven clinic visits over a 12-week treatment period. Participants then completed a follow-up visit one year after smoking cessation treatment.

The specific energy intake variables included total daily calorie intake (kcal/day) and calorie composition including sugar intake (grams) and percent intake of protein, carbohydrates, and fat. These dependent variables were computed based on a self-reported food diary that was analyzed by a food processor computer program (Version 8.2, ESHA Research, Salem, OR). Food diaries included the prospective collection of all food and beverage intake for the four-day period, regardless of day of the week, immediately prior to the clinic visits at the following time points: two weeks prior to quit date (Week -2), and 12 weeks after the quit date (Week 12) and 12 months after smoking treatment (Month 12). The two body weight variables included weight (kilograms) and body mass index (BMI, kg/m^2), and were also collected at each time point.

Covariates included demographics (age, race, education) and the Fagerstrom Tolerance Questionnaire (FTQ; Fagerstrom & Schneider, 1989). These items were collected via self-report at the Screening Visit and were selected for inclusion in the analysis based on preliminary results indicating associations with the outcome variables. Smoking rate at each time point (Week -2, Week 12, and Month 12) based on self-report with biochemical confirmation of carbon monoxide levels (≤ 8 ppm indicating abstinence) was also included as a covariate.

2.3. Statistical Analysis

The analysis included descriptive statistics to describe the study sample based on randomization assignment. Multiple linear regression was used to assess the impact of randomization status (active versus placebo) on outcome measures at each follow-up time point (i.e., Week 12 and Month 12). Each analysis was adjusted for the following covariates: baseline level of outcome measure, FTQ score, smoking rate at follow-up time point, and

age. To assess the association between the change in energy intake from baseline to follow-up and the change in body weight from baseline to follow-up, change scores were computed. The association between these change scores was assessed using multiple linear regression adjusting for FTQ score, smoking-rate, and age. Statistical Analysis Software (SAS) version 9.2 was used.

3. Results

3.1. Study Sample

The final sample size for this study was 119, with 47 randomized to active and 72 randomized to placebo transdermal patch. Those randomized to placebo patch were significantly older compared to those randomized to active patch (57.5 ± 6.7 vs. 53.2 ± 5.7 , p -value<0.001). There were no other statistically significant group differences (Table 1).

3.2. Effect of Nicotine Patch on Energy Intake & Composition during Smoking Cessation

At Week 12, randomization assignment was a significant independent predictor of total energy intake such that those who were randomized to active patch took in more calories per day than those who were randomized to placebo (1818.1 ± 868.2 vs. 1533.7 ± 494.6 , f -value=10.07, p -value=0.0019). Similarly, at Week 12, sugar intake was significantly higher in those randomized to active patch compared to placebo patch (80.8 ± 63.8 vs. 61.8 ± 35.7 , f -value=6.54, p -value=0.0119). The differences in total energy intake and sugar intake at Month 12 were not significantly different by randomization status. Randomization was not a significant predictor for percent intake of protein, carbohydrates, or fat at Week 12 or Month 12 (Table 2). Similar results were observed in analyses controlling for smoking status (abstinent versus smoking). Identical results were observed when analyses were restricted to participants who successfully quit smoking (data not shown).

3.3. Effect of Nicotine Patch on Changes in Body Weight

There were no significant differences in either weight or BMI at Week 12 or Month 12 by randomization status (Table 2). The changes in energy intake from baseline to follow-up were not significantly associated with the change in weight or BMI (p -value>0.05; data not shown). Results were unchanged when analyses were restricted to participants who successfully quit smoking (data not shown).

4. Discussion

The results of this study indicate that, on average, total energy intake increased during nicotine replacement treatment in postmenopausal women randomized to active nicotine patch compared to those randomized to placebo, but there was no difference one year after smoking treatment. These findings are contrary to our hypothesis, that short-term use of nicotine replacement would reduce caloric intake compared to placebo. Next, active nicotine patch was also associated with an increase in sugar intake during treatment but not one year after smoking treatment. Further, despite the changes in energy intake, we did not observe any group differences in post-cessation weight gain. Finally, our results remained the same when restricting the sample to participants who achieved smoking cessation.

Several studies have attempted to explain post-cessation weight gain by conducting careful examinations of changes in energy intake, resting metabolic rate, as well as body composition and composition during smoking cessation (e.g. Stamford et al 1986; Moffart & Owens, 1991). However, we are aware of only two studies that examined the impact of nicotine replacement on energy intake. One study in male and female smokers found that transdermal nicotine reduced energy intake in abstinent smokers at six weeks, but had no

effect on weight gain (Hughes & Hatsukami, 1997). Energy intake was measured by a food frequency questionnaire over the previous 24-hours. The second study, in postmenopausal smokers, demonstrated that nicotine patch versus placebo was associated with less weight gain but consumption of more calories during the first two to three weeks of smoking cessation (Allen et al, 2005). Food intake in this study was measured by a food diary in the past seven days. The present study extends the literature by expanding the investigation of energy intake and post-cessation weight gain and nicotine replacement therapy in postmenopausal smokers to a longer period of time (i.e., after 12 weeks of NRT use and 12 months after smoking treatment). Our results concur with those by Allen and colleagues in that active nicotine patch, versus placebo patch, increases energy intake. Our results differ from Allen and colleagues in that we found a similar increase in body weight in the nicotine and the placebo groups after 12 weeks of medication treatment.

Recent publications have also suggested nicotine replacement therapy may be useful at preventing post-cessation weight gain (McVary & Copeland, 2011; Ferguson, et al 2010; Filozof, et al 2004). Specifically, Ferguson and colleagues (2010) observed less weight gain among those who complied with the dosing instructions for nicotine gum, as compared to those who did not comply with dosing instructions. The authors of this paper concluded that the effect of nicotine gum on post-cessation weight gain was driven by the pharmacological effects of nicotine. It is noteworthy that the delivery method (i.e. transdermal patch versus gum) of nicotine replacement therapy may be an important factor in post-cessation weight gain. Among the nicotine replacement products, the gum and the lozenge may have the most consistent effect on limiting post cessation weight gain (Fiore et al., 2008), perhaps due to the oral delivery which may act as a substitute for snacking. In our study, participants assigned to nicotine patch had a similar increase in BMI compared to those assigned to placebo patch despite a greater increase in energy intake. One possibility is that the effect of nicotine patch on reducing weight gain via an increase in metabolic rate was counteracted by an increase of energy intake observed in the nicotine versus placebo group. A second possibility could be that there is a difference in report in energy intake. However, given there were no group differences at baseline, this possibility is unlikely. A third possibility may be in group differences in energy expenditure. Unfortunately we did not measure energy expenditure in this study. It is possible that those who were randomized to the active transdermal patch became more physical active during attempted smoking cessation compared to those who were randomized to the placebo group. Additional research should be done to examine the causal mechanisms involved in this observation and explore the role of energy expenditure.

Despite the numerous strengths of this study, including the double-blind randomized longitudinal design, lengthy follow-up period, and detailed measurement of energy intake, there are some limitations. First, as noted above, we did not include any laboratory measures of energy expenditure. Second, the sample size was fairly small and homogenous and was restricted to participants who were compliant with data collection procedures, resulting in limited generalizability of our results. Third, the energy intake and composition variables were based on self-reported food records and are thus at an increased risk for bias. Although it is unlikely that this bias varied by study group. Finally, the placebo nicotine patch group was significantly older than those randomized to active nicotine patch. Although the differences in age were adjusted for in the analysis, the effect of age on these associations is unknown.

5. Conclusions

We found that those on the nicotine patch increased energy intake during treatment relative to those on placebo, but this effect does not continue after treatment. Further, this increase in

energy intake did not impact post-cessation weight gain in postmenopausal females in the current study. Research is needed to replicate these findings and examine mechanisms of these effects. Future directions could include objective measurement of energy intake and energy expenditure, and exploration of the possibility that alternative forms of nicotine replacement therapy (i.e. gum, lozenge) or other pharmacotherapies may alter caloric intake and prevent post-cessation weight gain in postmenopausal as well as other populations of smokers.

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Highlights

- The active nicotine patch group increased their total energy more during treatment.
- The active nicotine patch group had greater sugar intake during treatment.
- There were no differences in weight gain between by active and placebo patch.

Table 1

Demographics and Smoking Behavior by Randomization Assignment

	Total (n=119)	Placebo Patch (n=72)	Active Patch (n=47)	f-value, 2 (p-value)
Demographics				
Age	55.8 ± 6.7	57.5 ± 6.7	53.2 ± 5.7	13.21 (<0.001)
Education (% high school)	29%	33%	23%	4.63 (0.592)
Race (% white)	89%	88%	91%	2.11 (0.833)
Smoking Behavior				
FTQ	5.5 ± 1.9	5.4 ± 1.8	5.6 ± 2.0	0.48 (0.489)
Cigarettes/day	21.1 ± 8.6	21.0 ± 8.9	21.4 ± 8.2	0.01 (0.934)
Carbon Monoxide (ppm)	19.5 ± 10.2	19.1 ± 10.1	20.2 ± 10.3	0.33 (0.568)

Table 2

Calorie Intake and Body Weight by Randomization Assignment and Time Point

	Placebo Patch (n=72)	Active Patch (n=47)
Total Calorie Intake (kcal)		
Week -2	1698.6 ± 529.8	1628.7 ± 493.4
Week 12	1533.7 ± 494.6 ¹	1818.1 ± 868.8 ¹
Month 12	1562.9 ± 549.4	1445.74 ± 640.9
Protein Intake (%)		
Week -2	21.9 ± 5.9	22.2 ± 6.0
Week 12	26.1 ± 14.9	25.0 ± 15.4
Month 12	31.3 ± 21.4	25.3 ± 12.3
Carbohydrate Intake (%)		
Week -2	57.8 ± 9.43	58.1 ± 8.8
Week 12	55.7 ± 11.3	57.1 ± 12.7
Month 12	52.6 ± 15.0	56.1 ± 10.7
Fat Intake (%)		
Week -2	20.2 ± 6.0	19.8 ± 6.2
Week 12	18.1 ± 7.3	17.9 ± 7.2
Month 12	16.0 ± 9.4	18.5 ± 7.3
Sugar Intake (grams)		
Week -2	81.4 ± 40.8	74.1 ± 45.2
Week 12	61.9 ± 35.7 ²	2 80.9 ± 63.8 ²
Month 12	60.8 ± 56.1	62.6 ± 39.1
Weight (kilograms)		
Week -2	70.7 ± 14.2	72.2 ± 16.4
Week 12	72.4 ± 14.1	74.2 ± 16.9
Month 12	74.2 ± 14.7	76.2 ± 18.3
BMI (kilograms/meters ²)		
Week -2	26.8 ± 5.1	27.4 ± 5.7
Week 12	27.5 ± 5.1	28.2 ± 5.9
Month 12	28.1 ± 5.3	28.8 ± 6.4

All analyses were adjusted for covariates including baseline value of outcome variable, smoking rate each time point, FTQ, and age.

¹ f-value=10.07, p-value=0.0019;

² f-value=6.54, p-value=0.0119