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Short communication

Daily nicotine patch wear time predicts smoking abstinence in socioeconomically disadvantaged adults: An analysis of ecological momentary assessment data



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ABSTRACT

Introduction: Individuals who use the nicotine patch are more likely to quit smoking than those who receive placebo or no medication. However, studies have not yet examined the association between actual daily nicotine patch wear time during the early phase of a smoking cessation attempt and later smoking abstinence. The purpose of this study was to address this gap in the literature.

Methods: Participants who enrolled in a safety-net hospital smoking cessation program were followed for 13 weeks (i.e., 1 week pre-quit through 12 weeks post-quit). Participants completed in-person assessments and daily ecological momentary assessments on study provided smartphones. Multivariate logistic regressions were used to determine if daily patch wear time during the first week post-quit predicted 7-day biochemically verified point prevalence smoking abstinence 4 and 12 weeks following the scheduled quit date. Demographic characteristics and smoking behaviors were adjusted as covariates.

Results: Participants (N=74) were primarily non-White (78.7%) and most (86%) had an annual household income of <\$20,000. Greater average hours of daily nicotine patch wear time during the first week post-quit was associated with a greater likelihood of abstinence at the 4 and 12 week post-quit visits (aOR = 2.22, 95% CI:1.17-4.23; aOR = 2.24, 95% CI:1.00-5.03). Furthermore, more days of wearing the patch for \ge 19 h was associated with a greater likelihood of abstinence at the 4 and 12 week post-quit visits (aOR = 1.81, 95% CI:1.01-3.22; aOR = 2.18, 95% CI:1.03-4.63).

Conclusions: Greater adherence to the nicotine patch early in a quit attempt may increase the likelihood of smoking cessation among socioeconomically disadvantaged adults.

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1. Introduction

Although the prevalence of smoking has declined to 16.8% among adults in the United States, 30.4% of those living at or below the poverty threshold continued to smoke in 2014 (Jamal et al., 2015). Socioeconomically disadvantaged adults are less likely to quit smoking and to sustain long-term abstinence (Businelle et al., 2010; Fernandez et al., 2006; Kendzor et al., 2010; Siahpush and Carlin, 2006), despite having similar numbers of quit attempts compared with smokers of higher socioeconomic status (SES; Kotz and West, 2009). Recently, public health efforts have begun to focus on

these disparities; including offering pharmacotherapy (e.g., Nicotine Replacement Therapy (NRT), varenicline, bupropion) at low or no cost to help low income adults to quit smoking (Cutrona et al., 2005; Kofman et al., 2012; Miller and Sedivy, 2009).

The nicotine patch is the most commonly used NRT (Fiore et al., 2008b). With a once daily application, the patch provides a consistent level of nicotine, and medication compliance rates may be greater than other forms of NRT (Shiffman et al., 2000). Clinical trials have demonstrated that the nicotine patch reduces craving and withdrawal symptoms and increases the likelihood of long-term abstinence compared with placebo (Ahluwalia et al., 1998; Cummings et al., 1997; Fiore et al., 1994; Fiscella and Franks, 1996). Furthermore, the 24-h nicotine patch reduces withdrawal symptoms and has superior cessation outcomes compared with the 16-h patch (Aubin et al., 2006; Fiore et al., 2008a; Shiffman et al., 2000).

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The first week following a quit attempt is key to cessation success (Ashare et al., 2013; Cofta-Woerpel et al., 2011; Garvey et al., 1992). Cravings, negative mood, and other withdrawal symptoms often peak during the initial days of a quit attempt, making relapse common during this period (Businelle et al., 2010; Cofta-Woerpel et al., 2011; Garvey et al., 1992; Hendricks et al., 2006; Hughes, 1992, 2007; Kahler et al., 2002; Piper et al., 2008). Thus, consistent use of smoking cessation pharmacotherapy is especially important during this period (Ashare et al., 2013; Ferguson et al., 2009; Piper et al., 2008; Shiffman et al., 2008b). To date, little is known about the relation between daily nicotine patch wear time and the likelihood of achieving smoking abstinence. Evaluating the association between nicotine patch wear time during the early post-quit period and subsequent smoking status may provide useful information about the optimal use of the patch during a quit attempt.

Ecological momentary assessments (EMA) utilize handheld devices to collect data in near real-time in real-life situations (Businelle et al., 2014; Hammersley, 1994; Shiffman et al., 2008a). EMA is recognized as a means to reduce recall bias and errors in memory (Shiffman et al., 2008a). Although this approach has been commonly used in studies that examine substance use (i.e., smoking, alcohol consumption, drug use; Ferguson and Shiffman, 2011; Shiffman, 2009) and a variety of other health behaviors (i.e., physical activity, eating behaviors; Garcia-Palacios et al., 2014; Garcia et al., 2014; Marszalek et al., 2014), utilization of EMA techniques to examine the association between medication adherence and smoking cessation is understudied. Thus, the purpose of the current study was to use an EMA approach to measure daily nicotine patch wear time during the first week of a scheduled quit attempt, and to evaluate the association between patch wear time and biochemically-verified smoking abstinence at 4 and 12 weeks post-quit. Based upon previous research, it was also hypothesized that the number of days where the patch was worn for at least 80% of the day (e.g., \geq 19 h per day for 24 h patch; Catz et al., 2011; Hays et al., 2010; van Boven and Vemer, 2015) would increase the likelihood of abstinence at 4 and 12 weeks post-quit.

2. Methods

2.1. Participants

Study participants were recruited to participate in a randomized controlled trial of a smoking cessation intervention during their orientation visit to the Tobacco Cessation Clinic at the Dallas County safety-net hospital between August 2011 and April 2013 (for a description of the parent study see Kendzor et al., 2015). Individuals were eligible to participate if they: 1) demonstrated > 6th grade English literacy level, 2) were willing to quit smoking 7 days from their first visit, 3) were \geq 18 years of age, 4) had an expired carbon monoxide (CO) level \geq 8 ppm, 5) were smoking \geq 5 cigarettes per day, and 6) were able to attend all scheduled study visits.

2.2. Study design and procedures

Of 222 participants that were screened for the parent study, 146 were eligible and enrolled. All participants were seen individually by a physician at the baseline visit to discuss/prescribe medication (e.g., nicotine patch, varenicline, bupropion) and at subsequent visits to follow-up on progress with smoking cessation.

At the baseline visit, participants completed socio-demographic and smoking history questionnaires on study computers via Questionnaire Development System (QDS) software (NOVA Research, Bethesda, MD). Additionally, all participants received and were instructed on how to use a study provided LG Optimus smart-phone to complete three types of daily ecological momentary assessments (EMA) during their pre-quit (1 week) and post-quit weeks (1 week):

phone-initiated daily diary and random assessments, and selfinitiated event sampling assessments (e.g., pre-cessation smoking, post-quit urge, post-cessation lapse). A more detailed description of our EMA procedures is reported elsewhere (Businelle et al., 2014). The sample used in the present study was limited to those who were prescribed the nicotine patch (n = 74); while participants who received other types of pharmacotherapy or no medication (n = 72)were excluded. The first 19 participants in the parent study were not given the opportunity to be assessed at 12 weeks post-quit. Thus, the total sample size for those who were prescribed the patch who could attend the 12 week follow-up assessment was 68 participants. At the baseline visit, all participants were prescribed a standard 21 mg/24 h or 14 mg/24 h nicotine patch according to their level of smoking. Data from 480 daily diary assessments (92.7% of all assigned daily diary assessments were completed; M=6.5 assessments per participant) completed during the first week of the scheduled quit attempt were used in the current analyses.

2.3. Measures

2.3.1. Demographic and smoking characteristics. Demographic and smoking characteristics were assessed at baseline including age, race (White vs. Black or other racial/ethnic minority), sex (male vs. female), treatment group (Usual Care vs. Contingency Management), education level (< high school vs. ≥high school), years of smoking, and average cigarettes smoked per day. Note that race was dichotomized because the sample was predominantly Black or White, with few participants of other racial/ethnic backgrounds.

2.3.2. *Nicotine patch wear time.* Participants responded to a series of questions about their prescribed smoking cessation medication on the daily diary assessment each morning. Participants who were prescribed the nicotine patch and confirmed "taking their medication yesterday" were subsequently asked "how many hours did you wear the nicotine patch yesterday" (1 = did not wear it at all, 2 = less than 3 h, 3 = 4 - 6 h, 4 = 7 - 9 h, 5 = 10 - 12 h, 6 = 13 - 15 h, 7 = 16 - 18 h, 8 = 19 - 21 h, 9 = 22 - 24 h). The middle time point for the selected time category was used to indicate the period of daily patch wear time (i.e., 1=0 h, 2=2 h, 3=5 h, 4=8 h, 5=11 h, 6=14 h, 7=17 h, 8 = 20 h, 9 = 23 h). Thus, nicotine patch wear time was recoded to create a continuous variable. Each participant's average daily nicotine patch wear time was then computed by averaging wear time across the 7 day post-quit period. In addition, considering findings from previous studies that have indicated that 80% or greater adherence to smoking cessation medications is associated with better abstinence outcomes, (Catz et al., 2011; Hays et al., 2010; van Boven and Vemer, 2015) we calculated the number of days that each participant wore the patch for at least 80% of the day (i.e., 19 h or more) during the first post-quit week. Thus, average hours of daily patch wear time and number of days of wearing the patch for at least 80% of the day were separately examined as predictors.

2.3.3. Smoking status. Seven-day point prevalence abstinence at 4 weeks and 12 weeks post-quit were the outcome variables. Abstinence was defined as self-reported, and biochemically verified expired carbon monoxide (CO) levels of < 8 ppm. Participants with missing CO data were considered non-abstinent.

2.4. Statistical analysis

Participant characteristics were summarized with means and standard deviations for continuous variables and percentages for categorical variables. Multivariate logistic regression analyses were conducted to determine if average nicotine patch wear time during the first post-quit week predicted biochemically-verified abstinence at the 4 and 12 week follow-up visits. We also examined if the number of days where the patch was worn for 80% or more of

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