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Effectiveness of continuing nicotine replacement after a lapse: A randomized trial



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HIGHLIGHTS

- We randomized smokers to either stop or continue NRT after a lapse.
- Continuing NRT after a lapse did not increase return to abstinence.
- This may be because both groups quickly regained abstinence and returned to patch.

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ABSTRACT

Introduction: Four post-hoc analyses of prior trials found smokers using nicotine patch following a lapse were less likely to progress to relapse compared to those using a placebo patch following a lapse. We attempted a conceptual replication test of these results via a randomized trial of instructions to continue vs. stop nicotine patch after a lapse.

Methods: Smokers trying to quit ($n = 701$) received nicotine patch (21/14/7 mg) and brief phone counseling (six 15-min sessions). We randomized smokers to receive instructions for and rationale for stopping vs. continuing patch after a lapse. The messages were repeated before and after cessation and following lapses via counseling, phone and written instructions.

Results: Among those who lapsed, those told to Continue Patch did not have a greater incidence of 7-day abstinence at 4 months (primary outcome) than those told to Discontinue Patch (51% vs. 46%). Most (81%) participants in the Discontinue condition stopped patch for only 1–2 days and then resumed abstinence and patch use. Analyses based on all participants randomized were similar. Adverse events were as expected and did not differ between conditions.

Conclusion: Instructions to continue nicotine patch after a lapse did not increase return to abstinence. These negative results may have occurred because actual use of patch after a lapse was similar in the two conditions. Also, allowing patch use while smoking may have reduced motivation to stay abstinent.

1. Introduction

Over-the-counter (OTC) nicotine patch is by far the most commonly used treatment for smoking cessation (Shiffman, Brockwell, Pillitteri, & Gitchell, 2008). Across six meta-analyses of 33–41 randomized controlled trials (RCTs) of over 20,000 smokers, nicotine patch increased the odds of long term quitting 1.6–2.0 fold (Hughes, 2009).

Over 80% of those using OTC nicotine medications will lapse (i.e., first use a cigarette after abstinence) and go on to relapse (i.e. return to daily smoking) (Stead et al., 2012). One possible reason for this high

rate of lapse and then relapse is that, until recently, nicotine package labeling stated “do not use if you continue to smoke”. As a result, in one survey, 77% of smokers reported they discontinued patch after a lapse (Hughes, 2012), plus treatment guidelines for clinicians do not recommend continuing NRT after a lapse. This practice is strikingly different from what clinicians recommend for those on agonist therapies for other drug dependencies; e.g. most clinicians advise opioid-dependent persons who lapse to increase, not stop, the agonist treatment (Kleber et al., 2006). We and others (Bader, McDonald, & Selby, 2009; Shiffman, Ferguson, & Gwaltney, 2006a) believe continuing nicotine

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patch following a lapse may a) relieve craving and withdrawal (West & Shiffman, 2001), b) block the reinforcing effects of smoking (Perkins, Fonte, Meeker, White, & Wilson, 2001; Rose & Behm, 2004), c) block the effect of cues to prompt smoking, and d) help smokers smoke less (Hughes & Carpenter, 2005), all of which should help smokers re-establish abstinence. In addition, a recent US Food and Drug Administration (FDA) review concluded that concurrent use of nicotine patch and smoking is safe (US Food and Drug Administration, 2016).

Secondary analyses of four trials of nicotine patch vs. placebo patch found those who continued the nicotine patch after a lapse were less likely to progress to relapse or were more likely to re-establish abstinence than those who continued placebo patch after a lapse (ORs = 1.9–11.0) (Shiffman et al., 2006b), (Ferguson, Gitchell, Shiffman, & Sembower, 2009; Japuntich, Piper, Leventhal, Bolt, & Baker, 2011) (Ferguson, Gitchell, & Shiffman, 2012). These data suggest those trying to quit with nicotine patch should continue the patch after a lapse. To more directly test this suggestion, we undertook a randomized, parallel-groups trial comparing two instructional sets: one to stop vs. one to continue nicotine patch after a lapse. The primary hypothesis was that, among those who lapsed while using nicotine patch, those assigned to the Continue Patch instructions would be more likely to re-establish abstinence by the 4-month follow-up than those assigned to the Discontinue instructions. One secondary hypothesis was the same would be true at 6-month follow-up. Another secondary hypothesis was that time between lapse and relapse would be longer in the Continue Patch condition. A final secondary hypothesis focused, not just on those who lapse, but on all participants randomized (i.e. “Intent to Treat”). The University of Vermont Committee on Human Research in the Medical Sciences approved the study, and we registered the study at www.clinicaltrials.gov (NCT01807871).

2. Methods

2.1. Study design

Smokers ($n = 701$) trying to quit received phone counseling before and after their quit date and nicotine patches for 10 weeks after their quit date. At study entry, we randomized smokers to a “Continue Patch” (after a lapse) condition or a “Discontinue Patch” condition. Smokers received instructions for each condition at least eight times. These occurred before and after quitting via written material, phone counseling, and messages from the Interactive Voice Recording (IVR) including messages on the first day of a lapse. Participants recorded cigarettes/day nightly via the IVR system for 12 weeks and via monthly surveys up to 6 months post-quit day.

2.2. Participants

The major inclusion criteria were a) ≥ 18 year old daily smoker of ≥ 10 cigs/day for ≥ 1 yr; b) probably or definitely intend to quit smoking in the next month; c) no medical caution to use of patch, and d) no use of other nicotine or tobacco products (e.g. electronic cigarettes) in the last month. We sought to detect a doubling of odds of re-establishment of abstinence (21% vs. 12%; OR = 2.0) with power of 0.80 and a two-tailed alpha of 0.05. We estimated this would require 490 smokers who lapsed while using patch, and to obtain these 490 participants, we anticipated needing to enroll 770 participants. The most common sources of smokers were Craigslist (37%), other internet sites (28%), and friend referrals (21%). We recruited 701 smokers prior to the end of funding. The major reasons for ineligibility were low intention to quit, smoking < 10 cigarettes/day, and use of other tobacco products (Fig. 1). About half of smokers were women; half were minorities, and half were employed (Table 1). Most had greater than a high-school education. About a third were married, a third divorced, and a third never-married. The mean age was 45. Participants smoked about a pack a day and scored moderately dependent on the Fagerstrom

Test for Cigarette Dependence (FTCD). Most had tried to quit but few had used nicotine patch (Table 1). Participant characteristics were similar to those of smokers trying to stop in a US population based sample (Cha, Erar, Niaura, & Graham, 2016), except we had more minorities, fewer employed, fewer married, more daily smokers and fewer with prior quit attempts. Except for age started smoking and prior quit attempts, participant characteristics did not differ between treatment groups.

2.3. Procedures

Participants were recruited between 4/13 and 7/15. All contact was via phone and provision of patches was via mail. Participants provided written informed consent. The randomization schedule and implementation of randomization was conducted by a statistician who had no contact with participants. Stratification was based on assigned counselor so that counselors had a similar proportion of participants in each condition. Treatment condition was based on a stratified block design using the SAS procedure PLAN. Neither participants, research assistants, nor counselors were blind to condition. The behavioral counseling protocol was based on the USPHS Clinical Practice Guidelines that emphasize the provision of social support and problem-solving around high-risk-for-lapse situations. We delivered counseling in six proactive phone calls that occurred 7 and 3 days before, and 2, 7, 14, and 28 days after a designated quit date. The first call lasted about 20 min; subsequent calls were 10–15 min. Ten counselors experienced in smoking cessation or mental health counseling were trained in four 3-h sessions plus additional role-playing, feedback and ongoing supervision. The treatment manuals for counseling, and the actual instructions for the various media are available from the author.

2.4. Instructions

We mailed participants an initial 6-week supply of 21 mg patches followed by a later mailing of 2-weeks each of 14 and 7 mg patches. We matched the Continue Patch and Discontinue Patch use messages on length and frequency. Counselors delivered an appropriate message about post-lapse patch use at all six calls. Both patch shipments included a message as well. Finally, if the IVR detected a lapse while on patch, it provided the appropriate message. At the counseling session immediately before the quit date, those in the Discontinue condition were told: “If you smoke after quitting, take off your patch for the rest of the day. Using the patches while smoking may give you nicotine levels that are too high, and it’s not known if patch use while smoking helps smokers quit. So, if you slip and have a cigarette after quitting, return to not smoking as soon as possible, get rid of any cigarettes you may have, but stop using the patch the day you slip, and resume use on future days only if you completely stop smoking again. Do you have any questions or concerns about this?” Those in the Continue Patch condition were told: “If you smoke after quitting, continue to use the nicotine patches. Wearing the patches will make it easier for you to return to not smoking. We know that using the patches and smoking a few cigarettes is not harmful. So, if you slip and have a cigarette after quitting, return to not smoking as soon as possible, get rid of any cigarettes you may have, and continue to use the nicotine patches. Do you have any questions or concerns about this?” Other messages via counseling, IVR or mailings were similar but briefer. The Continue condition required concurrent smoking and patch use. To minimize possible adverse events (AEs), we instructed participants in that condition to use the patch while smoking only if they were smoking $\leq 75\%$ of their baseline number of cigarettes/day.

2.5. Measures

The baseline and IVR included measures to describe the sample and to examine moderators and mediators. They included a) demographic

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