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.

ARTICLE INFO

Keywords:
Smoking cessation
Nicotine patch
Nicotine replacement
Lapse
Relapse

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
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 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 as you quit may help. 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 ≤ 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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