Helping Hospitalized Smokers

A Factorial RCT of Nicotine Patches and Counseling

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Introduction: Most smokers abstain from smoking during hospitalization but relapse upon discharge. This study tests the effectiveness of two proven treatments (i.e., nicotine patches and telephone counseling) in helping these patients stay quit after discharge from the hospital, and assesses a model of hospital–quitline partnership.

Study design: This study had a 2×2 factorial design in which participants were stratified by recruitment site and smoking rate and randomly assigned to usual care, nicotine patches only, counseling only, or patches plus counseling. They were evaluated at 2 and 6 months post-randomization.

Setting/participants: A total of 1,270 hospitalized adult smokers were recruited from August 2011 to November 2013 from five hospitals within three healthcare systems.

Intervention: Participants in the patch condition were provided 8 weeks of nicotine patches at discharge (or were mailed them post-discharge). Quitline staff started proactively calling participants in the counseling condition 3 days post-discharge to provide standard quitline counseling.

Main outcome measures: The primary outcome measure was self-reported 30-day abstinence at 6 months using an intention-to-treat analysis. Data were analyzed from September 2015 to May 2016.

Results: The 30-day abstinence rate at 6 months was 22.8% for the nicotine patch condition and 18.3% for the no-patch condition (p=0.051). Nearly all participants (99%) in the patch condition were provided nicotine patches, although 36% were sent post-discharge. The abstinence rates were 20.0% and 21.1% for counseling and no counseling conditions, respectively (p=0.651). Fewer than half of the participants in the counseling condition (47%) received counseling (mean follow-up sessions, 3.6).

Conclusions: Provision of nicotine patches proved feasible, although their effectiveness in helping discharged patients stay quit was not significant. Telephone counseling was not effective, in large part because of low rates of engagement. Future interventions will need to be more immediate to be effective.

Trial Registration: This study is registered at www.clinicaltrials.gov NCT01289275.

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Introduction

Smokers are more likely to be hospitalized than nonsmokers.[1,2] Because accredited U.S. hospitals are required to be smoke free indoors, hospitalized smokers often have a period of imposed abstinence.[3,4] However, most return to smoking upon discharge.[5,6] Continued smoking is associated with re-admittance, higher morbidity, and higher mortality.[7–10] A health crisis that precipitates hospitalization can be a powerful motivator for behavior change and provides an opportunity to help smokers quit.[11,12] Helping smokers quit and stay quit after hospitalization can reduce the

human toll and the costs to the healthcare system from smoking-related disease.[13–17]

There are a number of interventions that have been proven effective for smoking cessation, including pharmacotherapies such as nicotine-replacement therapy, bupropion, and varenicline, and behavioral therapy.[18,19] But these interventions are not always well integrated into the hospital setting and, if provided, rarely extend after discharge. Clinical Practice Guidelines recommend screening, treatment, and follow-up of all hospitalized smokers, although they also acknowledge that system-level issues may make it difficult for hospitals to fully comply.[20] According to the 2015 annual report of the Joint Commission, hospitals had high rates of screening for tobacco use (94.1%), less success with providing or offering treatment during hospitalization (51.2%), and poorer showings on providing or offering treatment at discharge (36.4%).[21] Hospitals are focused on acute care, so even fewer follow up with tobacco users after discharge. Practical interventions are needed that can boost the effect of what hospitals are currently able to provide.

Given that many hospitalized smokers stop smoking during their hospital stay (not always willingly), but can be expected to relapse quickly, one possible intervention would be to increase the rate at which hospitals provide treatment at discharge. As patients often leave the hospital with other medications, it should be possible to ensure that all smokers who are willing leave the hospital with pharmacotherapy to use as they transition home. Another possible intervention would be to link hospitalized smokers to behavioral cessation treatment. Unlike hospitals, telephone-based quitlines are designed to provide ongoing support for smokers interested in quitting.[22] The quitline infrastructure is set up to receive referrals from healthcare providers and proactively contact smokers to offer services. Counseling services are focused and individualized.[23] Quitlines are scalable and can provide services to large numbers of smokers. They can also provide the extended care that has been shown to be associated with quitting smoking.[13,19]

A key to the success of these interventions would be creating a partnership between hospitals and quitlines that capitalizes on the strengths of each. Hospitals would identify smokers and offer services, such as pharmacotherapy, to help them cope during their stay. They could also provide patients with pharmacotherapy at discharge and refer the patient to the quitline for counseling and extended cessation support after leaving the hospital. Ideally, the process would be fully integrated into the hospital workflow so that patients would experience seamless and unified support. An integrated process would also make the intervention more scalable.

Although such a hospital–quitline partnership holds promise, the selected interventions have not been proven to be practical and effective in the hospital setting. This study tested the effect of providing nicotine patches as smokers leave the hospital, the effect of telephone counseling provided within days of discharge, and the possibility of an additive effect of the two interventions using a factorial design. Nicotine patches were purchased using grant funds and provided to the hospitals that were then responsible for dispensing them at discharge. Telephone counseling was provided by the state quitline, which was responsible for proactively contacting participants. In addition to testing the interventions effects, this study assessed the feasibility of a practical hospital–quitline partnership to extend treatment to hospitalized smokers to help them stay quit as they transition out of the hospital. This study is part of the Consortium of Hospitals to Advance Research on Tobacco, which was designed to translate proven smoking-cessation interventions into effective interventions.[24]

Methods

Study Design

This study used a 2×2 (nicotine patches by counseling) factorial design. Hospitalized patients were recruited from five hospitals across three healthcare systems: University of California, San Diego (UCSD), Scripps Healthcare in San Diego, and the University of California, Davis (UCD). Recruitment occurred between August 2011 and November 2013. Initial recruitment at Scripps was slow, so additional hospital systems were phased in; recruitment at Scripps started August 2011, followed by UCSD in May 2012 and UCD in January 2013.

The study protocol was reported previously,[25] but a brief overview is provided here. Subjects who provided consent were stratified by recruitment site and cigarettes per day (CPD; six to ten or ≥11) and randomly assigned by computer to one of four groups: usual care, nicotine patches at discharge, proactive quitline counseling, or both. Blocks of eight were used to balance characteristics across the four groups. Self-reported smoking status and quitting behavior were evaluated 2 and 6 months after enrollment with participants receiving $20 for each completed evaluation. Subjects who at 6 months reported 7-day abstinence were sent a saliva kit and asked to return a sample. Samples were analyzed at Salimetrics and results were used to biochemically confirm abstinence using 10 ng/mL as a cut off.[26] Embedded in the current study was a randomized trial comparing the effect of monetary incentives on return rate (half of them were offered $20 and the other half offered $100), which will be reported in a separate paper.

Participants

Hospitalized smokers were eligible for inclusion if they were aged ≥18 years, had smoked in the last 30 days, smoked at least six CPD on the days they smoked, were interested in quitting or staying quit, spoke English or Spanish, provided sufficient contact