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Transdermal Nicotine Replacement for Hospitalized Patients: A Randomized Clinical Trial[1]

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Background. **This study was undertaken to assess the safety and efficacy of a treatment involving brief counseling and the nicotine patch among hospital inpatients and to identify variables associated with long-term smoking cessation following hospitalization.**

Methods. **One hundred eighty-five patients were randomly assigned to one of three smoking cessation interventions: (1) A Minimal Care (MC) condition, consisting of a brief physician-delivered motivational message to stop smoking, (2) a Counseling + Active Nicotine Patch (CAP) condition in which patients received the motivational message, a 6-week supply of nicotine patches, and extended bedside and telephone counseling, and (3) a Counseling + Placebo Patch (CPP) condition identical to the CAP condition except the supplied patches contained no nicotine.**

Results. **At 6-month follow-up, abstinence rates for the three treatments were 4.9, 6.5, and 9.7% for the MC, CPP, and CAP treatments, respectively. These differences were not statistically significant. Patients admitted for respiratory disease were more likely to quit than patients with any other diagnosis. The nicotine patch was well tolerated by hospital inpatients.**

Conclusions. **The initiation of nicotine patch therapy during hospitalization appears to be safe when used among patients carrying a wide range of diagnoses . Our study provided no evidence of the superiority of nicotine patches versus placebo, but this does not preclude the possibility that future research using larger samples might detect differences between patch groups. Hospital interventions for smoking cessation may be most effective among patients hospitalized for a smoking-related illness such as respiratory disease.**

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INTRODUCTION

Cigarette smoking is the leading preventable cause of morbidity and mortality in our society, accounting for more than 400,000 premature deaths in the United States each year [*1*]. Smokers are in routine contact with the health care system, providing ample opportunity for health care providers to intervene [*2*]. Mounting evidence suggests that the relatively brief smoking cessation interventions that can be accommodated within the practical constraints of an outpatient encounter are effective and produce long-term smoking cessation rates of 5–10% [*3–6*]. While such interventions have important public health implications [*3,5*], their absolute effectiveness is relatively small compared with more intensive interventions [*5,7,8*].

In contrast to the outpatient setting, hospitalization represents a comparatively underexplored point of contact between smokers and the health care system [*9*]. Hospitalization may represent an ideal opportunity for the delivery of smoking cessation interventions for several reasons [*9*]. For instance, hospitalization may represent a "teachable moment" during which a smoker's vulnerability to disease is made apparent and the health benefits associated with smoking cessation become particularly salient and attractive [*10*]. Moreover, since January 1995, all hospitals in the United States are smoke-free in accordance with the mandate of the Joint Commission on the Accreditation of Healthcare Organizations [*11*]. Thus, hospitalization represents a period of enforced smoking abstinence that can lay the foundation for a successful quit attempt [*9*]. Finally, hospitalization represents a time when physicians and other health care professionals have convenient access to the smoker, as well as the time necessary to provide more detailed and personalized cessation advice than is

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possible during routine outpatient encounters. Perhaps for these reasons, studies of smoking cessation interventions delivered to inpatients have revealed long-term quit rates (20–25%) that begin to rival those produced by intensive outpatient treatment programs [*8,9,12–14*].

Nicotine replacement therapy has been demonstrated to be a powerful aid to smoking cessation [*15,16*], but its efficacy has not been well studied in hospitalized patients [*9*]. In the sole clinical trial with true random assignment to nicotine replacement reported to date, Campbell and colleagues [*17*] failed to find a difference in long-term cessation rates between groups treated with either nicotine or placebo chewing gum in a sample of 212 smokers hospitalized for smoking-related diseases. The nicotine patch may be better suited for inpatient interventions because, unlike nicotine gum, it has a simple dosing schedule, it does not require chewing ability, and prior research suggests that its relative efficacy (compared with placebo) does not depend upon adjuvant behavioral support [*8,15*].

In this paper, we report the results of a hospital-wide, randomized, double-blind, placebo-controlled study comparing three treatments: nicotine patch plus brief counseling, placebo patch plus brief counseling, and a minimal care intervention. The primary objectives were (1) to determine whether the nicotine patch plus counseling increased long-term (6-month), biochemically confirmed abstinence rates over those produced by either placebo patch treatment or minimal care; (2) to identify variables associated with long-term cessation after inpatient smoking cessation intervention; and (3) to assess the safety of the nicotine patch for inpatients.

METHODS

Patients

Patients were 185 individuals admitted to the University of Wisconsin Hospital and Clinics, a 500-bed teaching hospital in Madison, Wisconsin, between April 1, 1993, and February 1, 1995, who expressed an interest in quitting smoking. Inclusion criteria were: (1) age $\geq$18 years, (2) patient report of regular cigarette use for at least 1 year immediately preceding admission, (3) patient report of smoking 10 cigarettes or more in a single day during the week prior to admission, (4) expression of a personal commitment to quit smoking, (5) a willingness to participate in the study and ability to provide informed consent, (6) clearance from the patient's attending physician, and (7) medical appropriateness for nicotine patch treatment according to the ProStep nicotine patch package insert. Exclusion criteria were: (1) patient report of drug or alcohol abuse within 6 months of admission, (2) history of major psychiatric illness, (3) pregnant women or women of childbearing age not using an acceptable method of birth control, (4) use of nicotine-containing products other than cigarettes (e.g., smokeless tobacco, pipes, cigars, or nicotine gum), (5) generalized skin disorders or known skin sensitivities, (6) terminal illness, (7) discharge planned within 24 h of admission, (8) admission to intensive care unit, and (9) admission for unstable angina, acute myocardial infarction, unstable arrhythmia, major cardiac or vascular surgery, or angioplasty. The protocol was approved by the Institutional Review Board of the University of Wisconsin Center for Health Sciences.

Interventions

Patients were randomly assigned to one of three interventions in this study. In the Minimal Care (MC) condition, patients received only a brief (2–3 min) motivational message to quit smoking and were provided with a copy of the National Cancer Institute's *Clearing the Air* self-help smoking cessation pamphlet from the study physician (S.F.L.) on the day of randomization. In the Counseling + Active Nicotine Patch (CAP) and the Counseling + Placebo Patch (CPP) conditions the study physician answered questions about smoking cessation, dispensed nicotine patches, applied the first patch for the patient, and trained patients to use the patches properly. As in the MC condition, the physician provided a brief (2–3 min) personalized motivational message encouraging the patient to quit smoking. In all three treatment conditions, these physician-delivered motivational messages were tailored to the individual, incorporating when applicable patient's health status and responses to the Fagerstrom Tolerance Questionnaire.

The study nurse (J.E.A.) accompanied the study physician to the initial patient visits and provided brief (10–15 min) phone counseling at 1, 3, 6, and 24 weeks after the initiation of patch treatment. The phone counseling sessions incorporated basic techniques of cognitive-behavioral therapy and motivational interviewing. While counseling sessions did not follow a standardized script, a typical session can be described. In general, the nurse would introduce herself and remind the patient about the study. Patients were asked questions about patch compliance and whether they had smoked since the last contact with study staff. Patients who had discontinued patch use were encouraged to begin using them again. The importance of total abstinence was stressed to all patients, and its importance to both success in quitting and patch safety were emphasized. Any success in quitting smoking was praised. When patients had lapsed or were struggling with temptations to smoke, the nurse pointed out whatever success they had attained (e.g., quitting for several weeks or reducing smoking rate sharply) and offered this as evidence of the patient's interest in cessation and ability to quit.

The nurse also asked open-ended questions such as "How are things going for you in general?" to communicate concern and to gain context to help generate potential coping strategies for the patient for use in preventing relapse. Finally, the nurse frequently reminded patients of the *Clearing the Air* pamphlets they had been given while hospitalized and encouraged them to look over the pamphlet between sessions.

Procedure

As part of the admissions procedures, hospital staff screened all incoming patients with two questions: (1) "Do you smoke cigarettes?" and, if the patient said "yes," (2) "Are you interested in quitting smoking?" The names and room assignments of all patients who responded affirmatively to both questions were forwarded to the research staff. As soon as possible after admission, the study nurse reviewed the patient's chart, interviewed the patient in order to determine eligibility for the trial, and obtained consent from both the patient and the attending physician.

The patient was randomized to either the MC condition or a patch condition using a predetermined computer-generated randomization code. If the patient was assigned to a patch intervention (CAP or CPP conditions), s/he was given two sets of patches (ProStep, Lederle Laboratories) containing a total of 21 patches each. One set was labeled "Patches for Weeks 1–3" and comprised 21 22-mg patches (CAP condition) or identically appearing placebo patches (CPP condition). The other set was labeled "Patches for Weeks 4–6" and comprised 21 11-mg patches (CAP condition) or identically appearing placebo patches (CPP condition). Patches were packaged and labeled with subject numbers, and patch condition (active or placebo) was assigned according to a predetermined computer-generated randomization procedure. Both patients and study staff were blinded with respect to patch dose.

Self-reported smoking status was determined for patch condition patients during each phone counseling session. Patients in all conditions were called 24 weeks after their initial contact with the study physician for assessment of self-reported smoking status. Patients in any of the three conditions who reported not smoking during the 7 days preceding the 24-week follow-up telephone call were asked to come to the hospital for biochemical corroboration of abstinence via expired breath carbon monoxide.

Measures

At the initial nurse visit, all patients were administered a questionnaire that elicited information about inclusion and exclusion criteria. The patient questionnaire included the Fagerstrom Tolerance Questionnaire [*18*]. Patients also used 5-point Likert scales to rate their confidence in their ability to stay smoke-free after discharge, their motivation to quit smoking, the prevalence of smoking among their family and friends, and their perceived degree of social support for smoking cessation. Additional information regarding subject eligibility was obtained by chart reviews conducted by the study physician. The reason for admission was also obtained from patients' charts. Each patient's primary reason for admission was classified using the major categories of the *International Classification of Diseases (ICD-9)* [*19*] (e.g., patients with diagnostic codes from 390 to 459 were categorized as "circulatory" and diagnoses from 460 to 519 "respiratory").

Data Analysis

The primary endpoint of the study was 6-month point prevalence abstinence rate. Abstinence was defined as a self-report of no cigarettes in the 7 days prior to the 6-month follow-up phone call, confirmed by a CO reading of 10 ppm or less. Abstinence rates were calculated on an intent-to-treat basis; patients claiming abstinence but refusing to provide a breath sample were considered smokers in the primary outcome analysis, as were patients lost to follow-up. Three secondary outcome variables were available only for patients assigned to a patch condition (CAP and CPP groups). These patients were queried about their smoking status during phone counseling at 1, 3, and 6 weeks after the initial intervention. Biochemical corroboration of patient reports was not obtained at these time points. Finally, CPP and CAP groups were compared on self-reported patch use compliance at 1-week follow-up.

The characteristics of the subjects assigned to the three intervention conditions were compared using one-way ANOVAs for continuously distributed variables and the χ^2 statistic for categorical variables. The three conditions were compared on the primary outcome variable using the χ^2 statistic. For each intermediate follow-up point, we compared the proportion of CAP and CPP patients who reported that they smoked no cigarettes during the week prior to the phone contact, using the χ^2 test. A series of univariate analyses was performed, comparing abstinent and relapsed patients on baseline variables, in order to identify variables related to long-term outcome. Additionally, we conducted a χ^2 analysis limited to patch group patients only, testing whether patch regimen compliance was related to 6-month outcome.

Patients assigned to the CAP and CPP conditions were queried about adverse events during follow-up phone calls with the study nurse at 1, 3, and 6 weeks after initial intervention. These reports were tallied, and the frequency of each type of adverse event in CAP and CPP groups was compared using separate χ^2 tests to assess the safety/tolerability of nicotine patch therapy for hospitalized patients.

TABLE 1

Comparison of Treatment Groups on Baseline Variables

Measure[a]	MC (n = 61)	CPP (n = 62)	CAP (n = 62)
Age	43.0 (11.6)	44.7 (13.6)	43.4 (13.6)
Cigarettes per day	22.5 (10.6)	24.9 (10.9)	24.0 (15.8)
Years smoked	25.4 (12.7)	27.5 (13.8)	26.3 (13.4)
FTQ	6.6 (1.9)	6.9 (1.7)	6.6 (2.1)
Confidence[b]	3.7 (1.1)	3.8 (1.1)	4.0 (1.2)
Motivation[b]	4.0 (0.9)	4.2 (0.9)	4.1 (0.9)
Social support[b]	3.0 (1.0)	3.9 (1.3)	3.7 (1.1)
Sex (female)	26 (42.6)	32 (51.6)	27 (44.3)

[a] For all variables except sex, numbers represent means and standard deviations (in parentheses). For sex, number and percentage (parentheses) are presented.

[b] These variables were assessed using 5-point Likert scales. Higher values indicate stronger endorsement of the attribute listed.

Note. MC, Minimal Care condition; CPP, Counseling + Placebo Patch condition; CAP, Counseling + Active Patch condition; FTQ, Fagerstrom Tolerance Questionnaire.

RESULTS

Table 1 summarizes baseline characteristics for the three intervention groups. No statistically significant differences among groups were observed. The typical patient in the trial was in his/her mid-40s, was moderately nicotine dependent, smoked more than a pack per day during the week prior to admission, had smoked for over 25 years, reported "some" confidence in his/her ability to quit smoking, reported "a lot" of motivation to quit smoking, and reported his/her family and friends to be "somewhat" to "very" supportive of a quit attempt.

Table 2 summarizes outcomes across treatment conditions. At 6-month follow-up, 7 (11.5%), 7 (11.3%), and 9 (14.5%) patients in the MC, CPP, and CAP groups, respectively, self-reported abstinence over the 7 days prior to the phone call. However, 4 patients in the MC group, 3 in the CPP group, and 3 in the CAP group refused to provide CO samples. All remaining patients claiming abstinence produced CO breath samples less than 10 ppm. Thus, 6 (9.7%) patients in the CAP condition, 4 (6.5%) in the CPP condition, and 3 (4.9%) in the MC condition were biochemically corroborated to be abstinent at 6-month follow-up. Neither the self-reported nor the biochemically corroborated differences were statistically significant. Point-prevalence self-reported abstinence rates were higher in the CAP condition than in the CPP condition at all intermediate follow-up points, but the difference only reached statistical significance at 3 weeks postintervention. At 1-week follow-up, 34 (60%) of the CPP patients and 40 (70%) of the CAP patients reported having complied with the patch regimen during the first week of treatment. This difference was not significant.

TABLE 2

One-Week Point-Prevalence Abstinence Rates by Treatment Condition at Each Follow-Up Time Point

End point	MC (n = 61) N (%)	CPP (n = 62) N (%)	CAP (n = 62) (N (%)	χ^2 (df)	P
1 week[a]	—	20 (32.3)	29 (46.7)	2.73 (1)	0.10
3 weeks[a]	—	11 (17.7)	21 (33.8)	4.21 (1)	0.04
6 weeks[a]	—	11 (17.7)	19 (30.6)	2.81 (1)	0.09
6 months	3 (4.9)	4 (6.5)	6 (9.7)	1.11 (2)	0.57

[a] Only CPP and CAP patients were queried about smoking status at these end points. Biochemical confirmation of patient-reported smoking status was not obtained at these time points.

Note. MC, Minimal Care condition; CPP, Counseling + Placebo Patch condition; CAP, Counseling + Active Patch condition. P value for 6-month analysis reflects the results of an omnibus, three-group comparison.

Abstinent and relapsed patients were compared on all baseline variables listed in Table 1 to determine whether these variables could forecast treatment outcome. None of these variables was significantly different between relapsed and abstinent patients. Patch compliance was not related to outcome among patients assigned to patch conditions.

Reason for admission was strongly related to follow-up status ($\chi^2_{(15)} = 41.39$, $P < 0.001$). Patients admitted for disease of the respiratory system had the highest quit rate of all diagnostic groups; 6 (46%) of the 13 patients with respiratory diagnoses were CO-corroborated abstinent at 6-month follow-up. Quit rates were much lower in other diagnostic groups. Four (13%) of 31 patients with musculoskeletal diagnoses, 1 (3%) of 29 injury/poisoning patients, 1 (5%) of 21 patients with digestive system diagnoses, and 1 (25%) of 4 patients given supplemental codes were abstinent at 6-month follow-up. None of the 87 patients assigned to the remaining 11 disease categories was found abstinent at long-term follow-up. In a series of post-hoc χ^2 comparisons, respiratory patients were the only group with a quit rate higher than the combined rate of all other classes ($\chi^2_{(1)} = 32.76$, $P < 0.00001$). Of the 13 patients in the respiratory diagnosis group, 7 were admitted for asthma, 3 for pneumonia, 2 for bronchitis, and 1 for a pneumothorax chest tube replacement.

Among those patients randomly assigned to wear a patch (CAP and CPP groups), some 63 adverse experiences were reported in telephone contacts. For purposes of analysis, nonunique adverse experiences (e.g., patch site irritation that developed into erythema) were combined, resulting in a total of 59 unique adverse experiences in the two groups. Table 3 provides a summary of these reports. Dermal reaction at the patch site was by far the most common adverse experience reported. No significant differences were found between groups in the frequency of any adverse event, and the pattern of adverse events was very similar to that reported by

TABLE 3

Frequencies of Self-Reported Adverse Experiences in the Two Patch Conditions

Adverse experience	CPP (n = 62) N (%)	CAP (n = 62) N (%)
Dermal reaction at patch site	11 (18)	16 (26)
Nausea	3 (5)	4 (6)
Anxiety	1 (2)	0 (0)
Depression	1 (2)	0 (0)
Dizziness/lightheadedness	1 (2)	0 (0)
Upper respiratory infection	1 (2)	0 (0)
Headache	1 (2)	1 (2)
Diarrhea	2 (3)	1 (2)
Abdominal pain	1 (2)	0 (0)
Dyspnea	0 (0)	1 (2)
Other[a]	7 (1)	7 (11)
Total	29 (46)	30 (48)

[a] This category largely comprises complications of factors unrelated to patch use (e.g., infection of incision).

Note. CPP, Counseling + Placebo Patch condition; CAP, Counseling + Active Patch condition.

patients in outpatient smoking cessation clinical trials [*20–22*]. Thus, the patch appeared to be well tolerated by hospital inpatients.

DISCUSSION

This research evaluated the safety and efficacy of a smoking cessation treatment for hospitalized smokers. The program involved brief face-to-face physician counseling and low-intensity nurse-delivered telephone counseling supplemented by either active or placebo nicotine patches. Because of the small sample sizes used in this research, only very large differences could achieve statistical significance [*23*]. In fact, while the CAP group was found to have the highest cessation rate at all time points, treatment groups differed significantly on outcome at only one point in the follow-up period; at 3-weeks posttreatment, patients receiving counseling plus the active nicotine patch self-reported higher cessation rates than did subjects receiving counseling plus the placebo patch.

Despite the lack of significant differences in long-term follow-up results, we believe the results may encourage future research for several reasons. First, the results identified a population of smokers (those with diagnoses of respiratory illness) that may be especially receptive to smoking cessation treatment. The targeting of these patients for treatment might result in high cessation rates. Second, although overall cessation rates were low, the use of the nicotine patch + counseling intervention approximately doubled the likelihood that a hospitalized patient would stop smoking relative to minimal care. These results are consistent with those of another recent clinical trial involving counseling and nicotine replacement [*12*]. This trial investigated an intervention consisting of inpatient counseling with a nurse manager and the use of a videotape, workbook, relaxation audiotape, optional nicotine replacement therapy, and nurse-initiated follow-up phone counseling. This intervention increased cessation rates about 50% in comparison with usual care at 12-month follow-up. If the results of these two investigations accurately represent the impact of a brief cessation intervention at other hospital sites across the country, such treatments might yield considerable public health benefits. Approximately 6.5 million smokers are hospitalized each year [*9*]; a doubling of cessation rates for these smokers would meaningfully reduce the morbidity and mortality produced by smoking in this country.

It is a truism that any clinical trial failing to produce a significant result may be said to be underpowered, and thus, it is not necessarily surprising or informative to note that our trial lacked statistical power. What may be deemed informative for future investigators are the estimates of relative effect size (an improvement of 50%) and absolute cessation rates (ranging from 5 to 10%) found in our trial. Knowledge of these parameters—knowledge we lacked at the design phase of our trial—permits future investigators to compute more realistic sample size estimates for similar studies. The outcome data from our trial suggest that approximately 450 patients would need to be assigned to each cell of a future trial for a powerful test of the interventions used. While this sample size estimate may seem unusually large, samples of this size are often used to test the efficacy of minimal clinical interventions in outpatient settings [*3,6,7*].

The cessation rate for the total sample in this study (7%) was surprisingly closer to that typically observed for minimal smoking cessation interventions delivered in primary care conditions [*3–6,8*] than those reported in hospitalized samples [*9,13,14,17,24,27*] or outpatient nicotine patch trials [*15*]. Two facets of the research design may account for this observation. First, we used low-intensity behavioral interventions in this trial, whereas many interventions for hospitalized smokers and outpatient patch trials have utilized relatively intense, multimodal behavioral programs [*12,14,15,24–27*]. Prior research has shown that the intensity of behavioral support is an independent contributor to smoking cessation success in nicotine patch clinical trials [*15*]. A more aggressive counseling program featuring more frequent follow-up sessions, more face-to-face contact, and routine CO testing might have boosted cessation rates in the CPP and CAP groups. Second, because the nicotine patch is contraindicated for patients with serious cardiovascular disease (e.g., recent myocardial infarction or unstable or worsening angina) [*8*], we used strict exclusion criteria for patients with cardiovascular conditions, and eliminated many such

patients from this trial. Inpatients with serious cardiovascular conditions tend to be among the most successful at quitting smoking [*9,17,27*] and are either included in [*17,27*] or are the exclusive focus [*14,25,26*] of many studies of hospitalized smokers. Thus, our decision to not sample from this unique subpopulation may have undercut our long-term cessation rates. Two recent trials [*30,31*] have demonstrated that many of these patients can be safely treated with a conservative nicotine patch regimen, suggesting that future trials of the nicotine patch for hospitalized smokers could incorporate patients with coronary artery disease.

While modest, these success rates (5–10% long-term, biochemically corroborated abstinence) may reflect realistic cessation outcomes for smokers admitted to a general hospital. In fact, as noted above, these rates are consistent with typical *practice-wide* cessation rates resulting from outpatient minimal clinical interventions and are consistent with the meta-analytic results for brief interventions published in the AHCPR *Smoking Cessation Clinical Guideline* [*8*] Trials of minimal outpatient interventions and hospital interventions differ chiefly with respect to intervention intensity. While outpatient studies often test the impact of simple physician advice to quit smoking, inpatient trials have tended to use multimodal programs (i.e., written materials, tapes, and pharmacotherapy), a variety of providers, and multiple, lengthy counseling sessions. Our results may be interpreted as suggesting that the inpatient cessation programs studied to date have proven successful more as a result of the intensity of their interventions and less as a result of some unique state of readiness to quit produced by hospitalization. In other words, if hospitalization represents a "teachable moment," it is because it affords health care providers extended access to smokers during which intensive treatments can be delivered; inpatients and outpatients respond similarly to very brief interventions.

Consistent with other trials, we found that patients hospitalized for respiratory diagnoses were especially likely to quit smoking [*17,27*], regardless of the treatment condition to which they were assigned. The 13 respiratory patients in this trial constituted approximately 7% of the total sample. Six members of this group (46%) had quit smoking by 6 months. It may be theoretically and clinically important to explore the reasons why this diagnostic group was especially responsive to cessation intervention. For instance, these smokers might have been more likely to attribute their disease to smoking, they might have expected greater health benefits from quitting, they might have experienced more aversive effects of smoking secondary to their disease process, and so on. In contrast to other studies [*17,27*], none of the patients in our sample hospitalized for a circulatory diagnosis was successful in quitting smoking. However, as mentioned above, this study used strict exclusion criteria for patients with cardiovascular disease. Patients in the study with circulatory diagnoses largely suffered from peripheral vascular problems as opposed to more significant or life-threatening cardiovascular disease, and these conditions may not have been sufficiently distressing to inspire serious attempts to quit smoking.

An important finding of our study was that the nicotine patch was well tolerated by the noncardiac inpatients that were the focus of this study. The adverse events reported by CAP patients tended to be very mild and were very similar to the adverse events reported by CPP patients. No serious or life-threatening adverse event (i.e., arrhythmias or myocardial infarction) were reported in either patch group. Moreover, the adverse events profiles of both groups were very similar to those reported in outpatient clinical trials of the nicotine patch [*20–22*]. Thus, nicotine patch therapy appears to be appropriate and safe for medically screened and motivated hospital inpatients. Our efficacy analyses cannot be used to argue that the nicotine patch is a powerful intervention for use with hospitalized smokers. However, our safety findings may encourage wider use of the patch by attending physicians and consult services with their noncardiac inpatients who request it or otherwise appear to be good candidates for nicotine replacement therapy.

One procedural limitation needs to be kept in mind when interpreting our efficacy findings. Our physician advice and nurse follow-up interventions were designed to require no patient hospital visits after discharge and were intentionally brief to model the sort of treatment that might reasonably be expected to be delivered in the hectic "real world" of hospital practice. For this reason, we collected CO samples from patients at only the 6-month follow-up, well after they had exited the formal treatment phase of the study. Thus, one must eye the self-reported point-prevalence abstinence rates from intermediate follow-ups with caution. Because CO corroboration was not obtained at the intermediate follow-ups, we cannot know how seriously this affects the self-reported point-prevalence abstinence rates, but CO data from the 6-month follow-up may be used to speculate about the extent of the problem. No patient who reported abstinence at 6 months was found to have a CO greater than 10 ppm, but approximately 40% of those patch group participants who reported not smoking at 6 months declined to be tested. Assuming these patients were all attempting to deceive the outcome assessor, then 40% may serve as a loose estimate of the rate of inflation intratreatment abstinence rates. Thus, deception may, at least in part, explain the apparently high rate of relapse observed between the 6-week and the 6-month follow-ups in our trial. A related procedural limitation of the study was the fact that the nurse who performed the counseling was also responsible for

determining and recording patients' smoking status. Some patch patients who had slipped may have deceived the counselor during phone sessions to shorten the call or avoid embarrassment. Thus, some patch patients who refused to provide breath samples may have done so to avoid having their deception discovered. However, the fact that an even greater proportion of MC patients declined to provide breath samples suggests counselor contact and monitoring per se may not have skewed the results overmuch.

We conclude that the nicotine patch is safe for use among a general hospital population, but that larger, more inclusive studies will be necessary to establish its clinical efficacy in such a population. Patients who perceive a clear link between smoking behavior and their illness may be most likely to profit from smoking cessation interventions delivered in the hospital setting. In future research, relatively intensive behavioral support may be necessary to demonstrate the superiority of the active patches relative to placebo and produce quit rates comparable with those found in specialized outpatient smoking cessation clinics.

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