The Role of Pharmacist-Managed Clinics

A Tobacco Cessation Program for Veterans

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When primary care providers lack the time to devote to effective, individualized tobacco cessation counseling and treatment, clinical pharmacists can help.

Until the mid 1970s, active service members received cigarettes as part of their daily rations. Despite the dramatic shift in views regarding tobacco use that has occurred since then, smoking remains a serious health concern—especially for older veterans who started smoking decades ago. In 1999, 30% of all veterans who received their health care through the VHA—and 47% of those who served during the Vietnam era—smoked cigarettes, compared with 23% of the general U.S. population.[1] Furthermore, according to the 1999 Large Health Survey of VHA Enrollees, veterans are twice as likely as the general population to smoke more than one pack of cigarettes per day.[1]

The health tolls of this type of long-term heavy smoking can be devastating. Diseases linked to tobacco use—which include numerous forms of cancer, cardiovascular diseases such as stroke and hypertension, coronary artery disease, and such chronic pulmonary diseases as asthma and emphysema—are the leading causes of death in the United States today. And the financial costs are extremely high: The direct health care costs of smoking in this country have been estimated at $50 billion annually, with an additional $47 billion in lost earnings and productivity.[2] It's clear that effective smoking cessation programs are essential not only to improve the health and quality of life of a large portion of the population but also to help contain soaring health care costs.

Unfortunately, 79% of practicing physicians feel they lack the required training to offer smoking cessation counseling.[3] In addition, many primary care providers, particularly in the VHA, are working under extremely tight schedules that leave them little time to provide smokers with detailed education, individualized treatment, and close follow-up. Who, then, can fill this void?

One possible answer is clinical pharmacists. In the VHA, these practitioners are experienced at

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providing patient education and often have limited prescribing authority, making them ideal candidates to run smoking cessation programs. This was the reasoning behind the development of a pharmacist-managed tobacco cessation clinic at the Fargo VA Medical and Regional Office Center (VAMROC), Fargo, ND in 1998.

In this article, we describe this clinic and present data on a group of patients who enrolled in the program between April 1998 and August 2001. The study included only cigarette smokers, with a primary outcome measure of tobacco abstinence at 12-month follow-up. We chose this length of follow-up, rather than the six-month interval used in most previous studies, in order to get a more accurate picture of long-term cessation rates. Secondary goals of the study were to determine whether there were any significant relationships between length of smoking history, age, baseline level of tobacco use, duration of smoking cessation treatment, presence of craving triggers (such as alcohol or coffee), and cessation rates.

THE CLINIC

Patients were enrolled in the pharmacist-managed tobacco cessation clinic through referral from their primary care providers. In addition, cigarette smokers (who made up the vast majority of referrals) had to be smoking at least five cigarettes per day at the time of referral in order to undergo treatment through the clinic. Because of difficulties determining the level of tobacco use among patients who used other forms of tobacco (such as pipes or smokeless tobacco), these patients were enrolled based solely on physician referral and desire to quit. At enrollment, all patients agreed to be available for follow-up telephone calls or appointments.

The clinic pharmacist provided one-on-one, individualized treatment to each patient. The therapeutic approach was based on the pharmacist's prior experience working with patients attempting to quit smoking and on published guidelines (Figure 1).[4,5] Although the approach was basically similar for all types of tobacco users, there were some differences between the counseling and prescribing methods used with cigarette smokers and those used with patients who used other forms of tobacco. Since most clinic patients were cigarette smokers and since our study focused exclusively on these patients, we describe the approach used for cigarette smokers here.

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At the initial clinic appointment, the pharmacist counseled the patient on the benefits of tobacco cessation, goals of treatment, strategies for controling cravings, and the role of pharmacotherapy. The pharmacist also urged the patient to develop a personal support system and to vocalize his or her own motivations for quitting. Based on these expressed motivations and the patient's interest in cessation, the pharmacist and patient determined whether the patient was truly ready to initiate tobacco cessation therapy.

If so, a quit date was established and the pharmacist prescribed and dispensed either nicotine patches or bupropion. Bupropion was reserved for patients who had a past failure with or contraindication to nicotine patch therapy. Contraindications to nicotine patches included hospitalization for a cardiovascular event within the past two weeks, a history of severe adverse effects from nicotine patch therapy, a history of severe skin allergy or dermatitis involving the upper body, or pregnancy. Contraindications to bupropion therapy included a current diagnosis or history of anorexia nervosa, bulimia, seizures, or other central nervous system disorders that increase the risk of seizures; current bupropion therapy for depression; or use of monoamine oxidase inhibitors within the past two weeks.

For patients initially prescribed nicotine patch therapy, addition of bupropion was considered if cravings were uncontrolled after the patient had been taking a nicotine patch dosage of 28 mg/day for one to two weeks, as assessed during the follow-up telephone call—or sooner, if the patient contacted the pharmacist directly. For patients initially prescribed bupropion, nicotine patches were added if significant cravings persisted after four weeks of therapy.

Nicotine patches were available in 21-, 14-, and 7-mg strengths. The

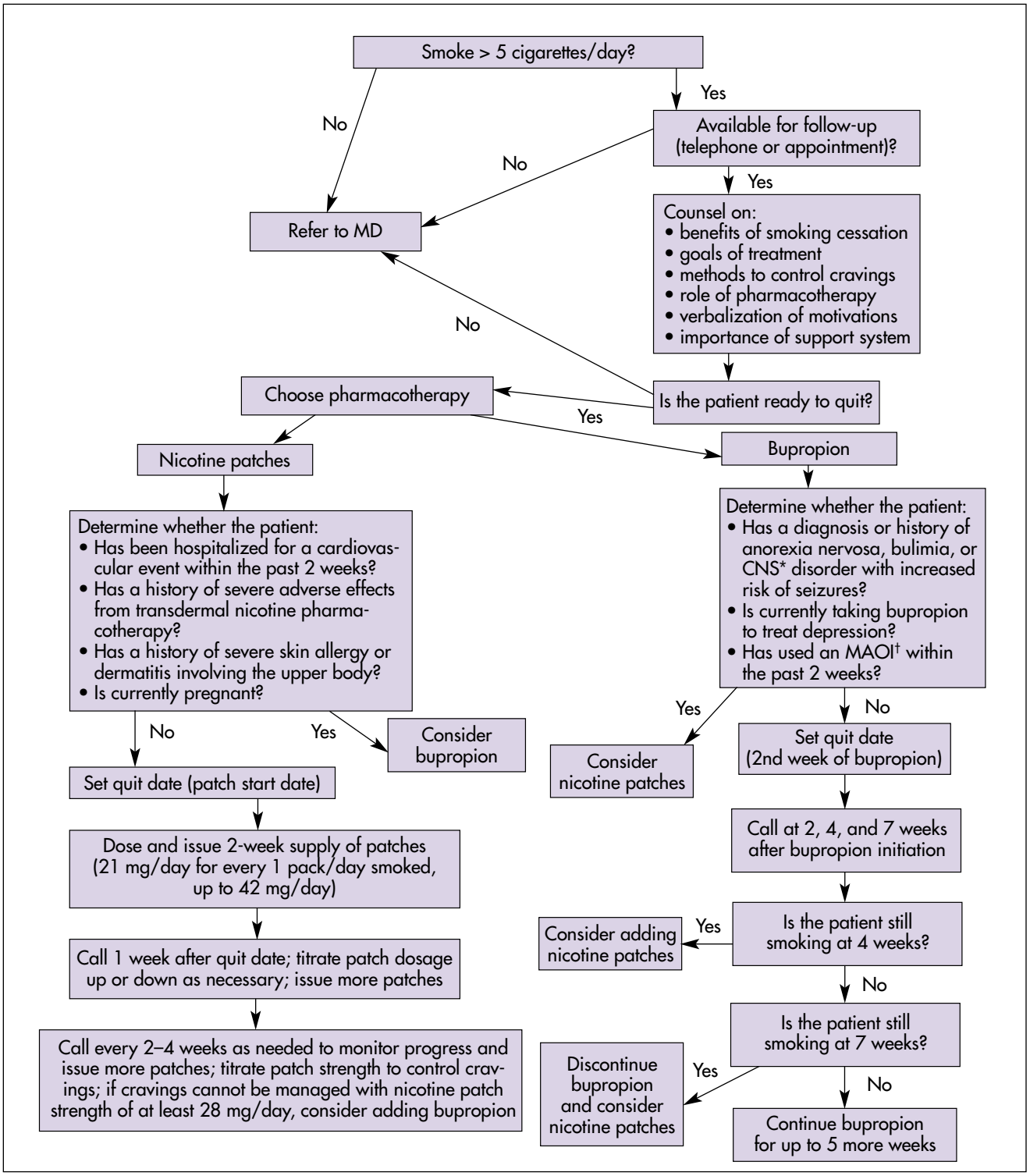

Figure 1. Overview of treatment approach used for cigarette smokers at the pharmacist-managed tobacco cessation clinic at Fargo VA Medical and Regional Office Center.[4,5] *CNS = central nervous system. †MAOI = monoamine oxidase inhibitor.

Continued on page 23

Continued from page 16

initial dosage was calculated based on current tobacco use: Patients who used the equivalent of one pack of cigarettes per day typically began with a daily patch dosage of 21 mg; those who used more began with higher dosages, which were achieved through the use of multiple patches.

Patients were given a two-week supply of patches to start on their chosen quit date. Follow-up was performed primarily by telephone, starting about one week after the initial interview and continuing every two to four weeks thereafter as needed, depending on patient travel distance, previous attempts to quit, and control of cravings. If the patient reported physical withdrawal symptoms during the first few follow-up interviews, the nicotine patch dosage was titrated upward in 7-mg increments until withdrawal symptoms were controlled, to a maximum of 42 mg/day. Nicotine patch dosage reduction was entirely dependent on control of withdrawal symptoms. If the patient remained abstinent from tobacco use at the current nicotine patch dosage but was unable to tolerate a dosage reduction, the current dosage was continued and progress was reevaluated within two weeks. Treatment was considered complete when the patient either was able to abstain from smoking without the use of nicotine patches or reached the end of the six-month limit for nicotine patch treatment.

Patients who were prescribed bupropion were instructed to start taking the drug seven to 10 days prior to their established quit date at a dosage of 150 mg once daily for three days and 150 mg twice daily thereafter. Progress was evaluated at after two, four, and seven weeks of treatment, most often by telephone. If the patient was abstinent from tobacco use at seven weeks, the bupropion was continued for up to five weeks more (for a total of up to 12 weeks). If not, the bupropion was discontinued and nicotine patches were reconsidered.

At the conclusion of pharmacotherapy, 26 (50%) of the 52 patients had quit smoking. At one year, 11 patients (21%) were still abstinent from tobacco.

STUDY DESIGN

For our study of the pharmacist-managed tobacco cessation clinic, we included only cigarette smokers enrolled between April 1998 and August 2001. These patients were contacted by telephone or scheduled for a clinic appointment one year after completing the program. They were interviewed regarding such issues as their initial success with the smoking cessation program, the length of their therapy at the clinic, their current tobacco use, the total time they spent abstinent from tobacco, and the presence of such craving triggers as coffee or alcohol (past and present).

For the statistical analysis, we used the chi-square or Fisher's exact test to evaluate associations between pack-year smoking history, age, baseline level of tobacco use, length of therapy at the clinic, and presence of craving triggers. A P value of .05 or less was considered significant.

OUR FINDINGS

During the study period, 70 cigarette smokers were referred to the clinic. Of these patients, 18 were excluded from the study: eight who did not respond to multiple attempts at follow-up, seven who were unreachable because they no longer had an active telephone number listed, two who had died, and one who refused to participate in the study.

The remaining 52 patients were contacted successfully one year after completing the clinic's tobacco cessation program. These patients ranged in age from 42 to 82 years (mean, 60.1 years). They had an extensive mean smoking history of 61.1 pack-years (range, 20 to 135 pack-years) and, at the time of treatment, were smoking a mean of 1.24 packs per day (range 0.25 to three packs per day). All but one (98%) of the patients were male.

At the conclusion of pharmacotherapy, 26 (50%) of the 52 patients had quit smoking. At one year, 11 patients (21%) were still abstinent from tobacco. The 15 patients who had started smoking again had relapsed a mean of 10.5 weeks (range, two to 24 weeks) after completing therapy.

Overall, patients were treated for a mean of 9.7 weeks (range, two to 36 weeks): 36 patients (69%) with nicotine patches, nine (17%) with bupropion, and seven (14%) with both. Of the 36 patients using nicotine patches alone, 19 (53%) had quit smoking at the conclusion of pharmacotherapy and 10 (28%)

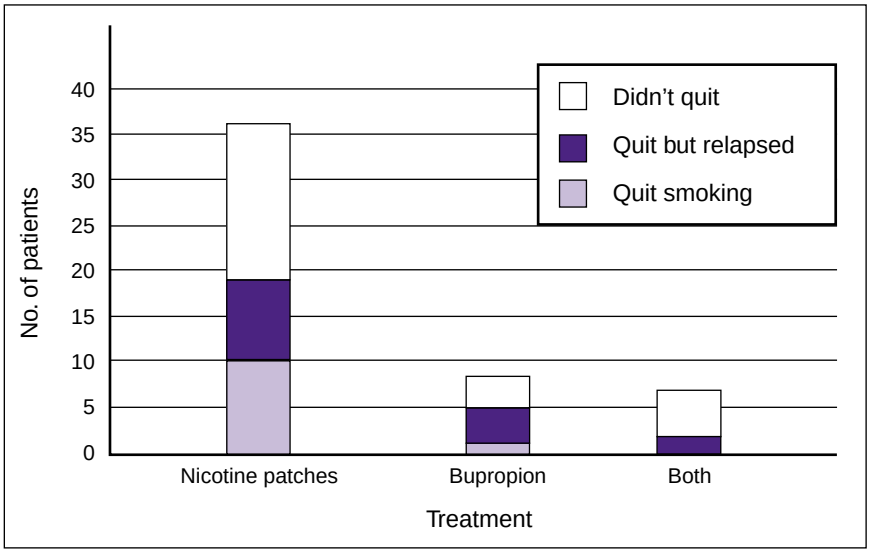

Figure 2. Outcomes of 52 smokers enrolled in the pharmacist-managed tobacco cessation clinic at Fargo VA Medical and Regional Office Center between April 1998 and August 2001.

were still abstinent from smoking after one year (Figure 2). Of the nine patients who took bupropion alone, five (56%) initially stopped smoking and one (11%) was still tobacco free after one year. Of the seven patients who ultimately received both bupropion and nicotine patches, two (29%) were initially successful but both relapsed within one year.

Our statistical analysis revealed no significant correlations between pack-year smoking history, age, baseline tobacco use, duration of clinic treatment, alcohol or coffee intake, and successful smoking cessation. With regard to alcohol and coffee intake, 12 of the 52 patients reported that drinking coffee triggered cigarette cravings, two reported that alcohol triggered cravings, and seven reported that both substances triggered cravings. Of these 21 patients, only two tried to cut back on alcohol or coffee intake—both by eliminating alcohol and coffee completely. Although they were initially successful in their attempts to quit smoking, both patients eventually relapsed.

HOW DO WE MEASURE UP?

In our study, which involved a patient sample that was characteristic of the general veteran population (predominantly older adult men), half of the participants had quit smoking at the conclusion of pharmacotherapy and 21% remained abstinent one year later. This rate of sustained abstinence is substantially lower than that found by Shipley and colleagues in a study of 94 patients—all comparatively young DoD beneficiaries—who completed a tobacco cessation program at Buckley Air Force Base in Aurora, CO.[6] The Buckley program used the QuitSmart treatment protocol (QuitSmart Stop Smoking Resources, Inc., Durham, NC), consisting of four individual treatment sessions, nicotine patch or bupropion therapy, and two follow-up telephone calls.[6] In this study, the six-month tobacco abstinence rate was 66%.[6] Although our patients were older and had been smoking longer than this population, the lack of significant correlations between successful smoking cessation and age or smoking history in our study suggest that these demographic differences may not fully explain the disparate success rates.

When compared with rates reported for other tobacco cessation programs, however, our results appear more typical. In fact, our overall cessation rate falls at the upper end of the range reported by most smoking cessation programs provided to the general public (9% to 22%).[7–9]

Our results seem particularly similar to those found by Kennedy and colleagues in a recent study of a smoking cessation program run by pharmacists in a retail setting in Virginia.[10] Of the 48 patients recruited in this study to undergo individualized smoking cessation counseling, 12 (25%) were tobacco free after six months.[10] Despite the difference in follow-up time between our study (12 months) and this one (six months), we found that all of our patients who relapsed did so within the first six months.

In our study, the 12-month abstinence rate was higher for patients treated with nicotine patches alone (28%) than it was for either patients treated with bupropion alone (11%) or those who received both nicotine patches and bupropion (0%)—possibly because bupropion was reserved for refractory patients and those with contraindications to nicotine patches. Overall, 58% of the patients in our sample who initially stopped smoking relapsed. Other studies have found that 70% of current smokers have made prior attempts to quit.[11] Finally, while our

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study did not demonstrate a statistically significant association between alcohol or caffeine intake and smoking cessation success, both substances are known to trigger cigarette cravings in many patients.[12,13]

Our study has several weaknesses, including the use of descriptive data and a small sample size. In addition, information about smoking abstinence was subjective, based on the patient interview. Objective testing of smoking abstinence (such as monitoring of serum nicotine levels) was not available to us. Furthermore, the inclusion of data from refractory patients with histories of therapeutic failures may have skewed the results. We did so, however, in an effort to describe quit rates that could be expected in everyday practice.

FUTURE DIRECTIONS FOR RESEARCH

The high incidence of cigarette use among veteran patients, combined with the proven hazards of smoking and the high costs associated with smoking-related morbidity, make smoking cessation programs a priority for the VHA. In this study, patients followed by the pharmacist-managed tobacco cessation clinic at the Fargo VAMROC effectively achieved an abstinence rate similar to those of most previous studies. We conclude, therefore, that VA pharmacists, as members of the health care team, can play an important role in improving veterans' quality of life through their involvement in smoking cessation therapy. Randomized, controlled studies are needed to determine the most effective dosing regimen for pharmacologic treatments and the factors that affect smoking cessation success most strongly for the veteran population. ●

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IN THE WINNER'S CIRCLE

Unfortunately, there were no winners for October's Seek & Decode game.

The hidden message was:

Your huddled masses yearning to breathe free,
The wretched refuse of your teeming shore,
Send these, the homeless, tempest-tossed to me, I lift my lamp by the golden door.

Look for November's winner in the January issue of *Federal Practitioner*.