



A medical approach to nicotine addiction treatment

TOBACCO SMOKING IS OUR NATION'S leading form of substance abuse. In 1990, 25.5% of Americans smoked tobacco.¹ Many smokers are addicted and at least 70% would like to quit,² probably because they recognize the major health hazards of smoking.

Smoking cessation is not an event, but a process. Psychologists have studied the phases of smoking ("precontemplation," contemplation, action, relapse) for many years. Although their observations offer considerable insight into the nature of smoking and its addiction, they offer little practical information about how to get patients to stop smoking.

Controlled clinical trials have demonstrated the effectiveness of various pharmacologic agents for smoking cessation in a setting of behavioral modification, and it is likely that behavioral modification is at least as important as pharmacologic strategies or other methods used as adjuncts in smoking cessation.³ However, these studies, though positive, may not be relevant to the real world of private practice where many people seek help for tobacco addiction.

Most patients who quit do so on their own, but addicted smokers require a coordinated approach that includes medical assistance. Based on our recent attempts to develop such an approach, we propose a medical model for smoking cessation for use in the primary care physician's office.

AN OFFICE MODEL

Most patients see physicians in the ambulatory care setting, usually in private offices or clinics. This is the venue for the systematic care of asthma, diabetes, hypertension, and other diseases that require detailed office management.

The smoker, whether self-referred or physician-referred, should schedule an initial evaluation for nicotine dependency treatment. As in any other aspect of chronic medical care, the interview should begin with a history, a physical examination, and a limited array of laboratory tests.

History

The family history should focus on smoking-related diseases: ie, lung cancer (now the most common fatal malignancy in both men and women), other smoking-related cancers (larynx, bladder, cervix, esophagus, mouth and gum, and pancreas), heart attack, hypertension, stroke, and chronic obstructive pulmonary disease (COPD). A family history of any of these smoking-related disorders identifies an individual at extraordinary risk; familial aggregation is common in these disorders, particularly in COPD and lung cancer, which are closely related.^{4,5}

The age at which the patient started smoking, the amount currently consumed, and the type of cigarette smoked (ie, high- or low-tar) should be recorded, although the latter is of minor importance since smokers learn to extract the maximum amount of nicotine and tar through augmented inhalation strategies.⁶ The presence of morning cough and mucus is an important risk factor that helps predict the onset of lung cancer.⁷

A Fagerstrom Dependency Score should also be obtained.⁸ Although more complex estimates of the degree of nicotine addiction were originally proposed, a modified system focuses on six simple questions to identify the patients with the highest level of nicotine addiction (*Table*).⁹ Positive answers to questions 1, 3, and 4 correlate well with high blood levels of nicotine and cotinine, a metabolite

of nicotine. A Fagerstrom addiction score above 5 is considered high.

The patient's occupational history is also important. Tobacco acts synergistically with asbestos, cadmium, uranium, and some rare chemicals such as chloryl-methyl-ether, thereby increasing the risk of lung cancer.

Physical examination

In many smokers, the physical examination likely will reveal no abnormality. Nevertheless, elevated blood pressure, expiratory wheezes upon forced exhalation, increased exhalation time indicating airflow obstruction, cardiac arrhythmias, stained fingers, stained teeth, and tobacco odor can all be indicators of high-level tobacco abuse. It has recently been suggested that continued tobacco smoking should be recorded on the chart as a new "vital" sign, along with temperature, pulse, respiratory rate, and blood pressure.¹⁰

Laboratory

The most important laboratory test is simple spirometry. It is well established but not widely known that spirometric abnormalities identify patients at risk of premature morbidity and mortality from heart attack, lung cancer, stroke, and COPD.¹¹ Simple office spirometry with a dry direct recording device could identify the 430 000 persons at risk of dying from these devastating diseases each year. In the office setting, spirometry is more important than electrocardiography in identifying patients with risk factors of the smoking-related diseases.

Only two spirometric measurements are required: the forced expiratory volume in 1 second (FEV₁), and the forced vital capacity (FVC). The ratio between the two (normally greater than 70%) is also a valuable indicator of incipient airflow obstruction, since levels below 70% indicate patients at risk of premature and accelerated loss of

TABLE
ITEMS AND SCORING FOR THE FAGERSTROM TEST FOR NICOTINE DEPENDENCY

Question	Answers	Points
1. How soon after you wake up do you smoke your first cigarette?	Within 5 minutes	3
	Within 6 to 30 minutes	2
2. Do you find it difficult to refrain from smoking in places where it is forbidden, eg, in church, at the library, in the cinema?	Yes	1
	No	0
3. Which cigarette would you hate most to give up?	The first one in the morning	1
	All others	0
4. How many cigarettes per day do you smoke?	10 or fewer	0
	11 to 20	1
	21 to 30	2
	31 or more	3
5. Do you smoke more frequently during the first hours after waking than during the rest of the day?	Yes	1
	No	0
6. Do you smoke if you are so ill that you are in bed most of the day?	Yes	1
	No	0

ventilatory function.¹² The Framingham Heart Study showed that reduced vital capacity is a powerful predictor of premature morbidity and mortality from heart attack.¹³ Improvement in pulmonary function during smoking cessation can help reinforce the process.¹⁴

Exhaled carbon monoxide (CO) should always be measured as a semiquantitative estimate of tobacco abuse.^{15,16} Information from CO measurements, spirometry, and analysis of the patient's smoking-related symptoms can all be motivating factors in smoking cessation.¹⁶

A baseline electrocardiogram may be valuable, although this is controversial: electrocardiography can be normal despite severe coronary artery disease. The total cholesterol should be assessed in patients who are smoking and are at risk for smoking-related disease.

THE PHYSICIAN'S ROLE

The most important role of the physician is to educate, advise, and instruct. A simple, serious discussion about the risk of major smoking-related diseases, the fact that smoking cessation is a complex process, and the commitment of the physician to be available for assistance throughout the entire process can ease the patient's anxiety. A pamphlet

available from the National Cancer Institute, *How to Help Your Patient Quit Smoking* (call 1-800-4-CANCER; ask for Publication No. 90-3064), is designed to help patients plan to stop. Another very practical and simple brochure, *If You Smoke, Stop for Good*, is available from the American Medical Association.

At the first visit, many patients will ask for an aid to stop smoking. Our opinion is to wait until the second visit because approximately 5% of patients will stop without further instructions after the initial visit. Be sure to measure exhaled CO at each visit as an indicator of continued smoking. Many patients who participated in our controlled clinical trials of nicotine replacement therapy claimed to be abstinent but revealed elevated exhaled CO levels when tested (a state which we term "tobacco amnesia").^{15,16} Unfortunately, we do not have carefully recorded data on this phenomenon.

As already stated, it is unlikely that patients will have stopped smoking by the time of the second visit. However, if they have, reinforcement is important. It is wise to set up one more follow-up visit for further reinforcement at this time.

NICOTINE REPLACEMENT

Nicotine chewing gum

Most patients fail to stop smoking after the first examination; for them, adding a form of nicotine replacement seems reasonable. Although nicotine polacrilex gum (2 mg), released in 1984, has been useful in the setting of behavioral modification,¹⁷ it is not successful when used alone in a private practice setting.¹⁸ When prescribed on patient request, only a small percentage used the gum according to established guidelines. This finding illustrates the importance of patient education as the basis of successful use of nicotine-containing gum.¹⁹

Nicotine polacrilex has the disadvantages of bitter taste and gastrointestinal side effects; in addition, patients find difficulty chewing it at the right time and frequency for optimum absorption of nicotine through the buccal mucosa. A 4-mg formulation has just been released in this country; used with group counseling, it may produce higher success rates than the 2-mg product.²⁰

Nicotine patches

The newly released transdermal nicotine patches will likely be more convenient and better tolerated

by the patient.²¹⁻²³ Currently available patches are Habitrol, Nicoderm, ProStep, and Nicotrol, and the manufacturers of these products provide additional material to support smoking cessation. Aggressive advertising of these products is already directed at smokers via television and print media. This advertising will do far more good than harm in society's step-by-step movement away from tobacco abuse. Two multicenter controlled clinical trials of transdermal nicotine have shown considerable effectiveness after 6 months.²² Our participation in the multicenter studies of Nicoderm²⁴ and Habitrol showed clear-cut improvement in smoking cessation compared with placebo when used in a fairly complex behavioral modification program. The convenience of applying a daily patch may be a distinct advantage over the use of gum and may enhance patient compliance.

When transdermal nicotine is prescribed, a definite quitting date for smoking should also be selected. Here it is probably wise to refer to the American Lung Association (ALA) publication, *18 Days to Smoking Freedom*, which includes the quitting date strategy. Nicoderm and Habitrol come in 21-mg, 14-mg, and 7-mg formulations. The 21-mg patch should be used for patients who smoke more than a pack a day (these patients have a high Fagerstrom addiction score). The patch should be placed each day on the upper trunk or arms in a hairless area of the body; this allows absorption of a nicotine level close to one half the amount reached by cigarette smokers throughout a 24-hour period. The recommended regimen for Nicoderm and Habitrol is to use the 21-mg patch for 6 weeks, the 14-mg patch for 2 weeks, and the 7-mg patch for 2 weeks. Physicians may prefer to simplify the regimen by using each patch for 1 month.

ProStep is available in 22-mg and 11-mg patches for gradual replacement therapy. Nicotrol uses a 15-mg initial patch, which provides nicotine replacement for 16 hours; two smaller patches, 10 mg and 5 mg, also release nicotine over 16 hours. No comparisons have been made to indicate any advantage of one product over another in helping patients deal with nicotine withdrawal.

The only significant side effect reported by the manufacturers is mild skin irritation and itching at the patch site; the irritation usually subsides when the patch is removed. If irritation and itching persist after patch removal, over-the-counter corticosteroid dermatologic preparations can be used.

Transdermal nicotine can be augmented with nicotine polacrilex gum during times of "emergency," such as periods of heightened craving for nicotine while receiving transdermal replacement therapy. Some physicians are using the nicotine polacrilex to prevent relapse after the patch is discontinued.

OTHER PHARMACOLOGIC AGENTS

Clonidine, useful in the treatment of narcotic and alcohol withdrawal, has had limited success as an adjunct to smoking cessation.²⁵ Although not promoted for nicotine withdrawal, it can be prescribed for this purpose by a physician. This might be a consideration after other adjunctive therapies have been tried. Our participation in two double-blind, placebo-controlled studies using the clonidine patch showed no difference in smoking cessation, but a reduction in nicotine withdrawal symptoms.²⁶ All patients received counseling by trained interventionists along with the aforementioned ALA self-help booklet.

A short-term study found bupirone to be more valuable than placebo in smoking cessation.²⁷ Bupirone, an anxiolytic, is not indicated for smoking cessation, but it may be valuable in some clinical situations.²⁷

ACUPUNCTURE AND HYPNOSIS

Acupuncture appears to be somewhat effective in promoting smoking cessation in a few individuals.²⁸ We have no way of telling which patients will respond favorably to acupuncture, but some do respond. The physician should inquire locally for recommendations about acupuncturists.

Many patients believe that hypnotherapy will magically solve their smoking problem. Nothing could be further from the truth; nonetheless, some patients have been able to quit smoking after hypnosis.²⁹

FREQUENCY OF VISITS

As in any chronic disease state in need of complete control and "fine tuning," the physician and patient should see each other frequently. We strongly suggest seeing a patient for 30 to 45 minutes for the first workup; subsequent 15-minute appointments should be made at 2-week intervals. Nicotine

replacement should be tried first, possibly followed by clonidine or bupirone therapy. After that, other more unusual interventions may be considered.

RELAPSE AND SUCCESS

Nicotine addiction is a chronic and relapsing disease. Each year approximately 17 million Americans attempt to quit smoking; only 1.3 million (7.6%) succeed.³⁰ Relapses should not be discouraging, for the more times a patient has relapsed, the greater the likelihood of success on the next try. In fact, multiple relapses identify a selected population especially dedicated to smoking cessation and determined to succeed.

Our smoking cessation clinic has a motto: "We won't quit until you do." Sometimes patients are embarrassed to return while still smoking, but once they realize they are dealing with friends who can help them with a problem which otherwise will plague them for the rest of their lives, they will likely continue to return. Others will simply relapse into the addictive arms of lifelong tobacco abuse and its attendant morbidity and mortality. Office support staff—ie, receptionists and laboratory technicians—can also help reinforce the lifelong commitment to permanent smoking cessation.

Our overall success rate in the office setting is approximately 10% after the first year. Specifically, only 4 of 33 patients were abstinent at 1 year, as shown by CO testing; other patients stopped temporarily or reduced their smoking somewhat. The approach described here cannot be said to be very successful so far; however, we have been dealing with the most addicted smokers, those who have failed at least two serious attempts at smoking cessation. We believe that if every physician achieved a 10% success rate each year, major inroads would be made into the "critical mass" of addicted smokers who tend to sustain the problem through social acceptance.

SUMMARY

Smoking cessation is a complex process, not a simple event. The cues that cause a smoker to light up, the life-style, and the fallacies of each smoker are helpful information for the practicing physician. Behavioral modification aimed at eliminating cues that initiate smoking together with the systematic use of pharmacologic replacement therapy can help some patients quit. Transdermal nicotine replace-

ment appears particularly promising, and additional pharmacologic agents to deal with nicotine withdrawal may be worth trying.

Our advice to practitioners who would like to get involved in smoking cessation is to (1) set up your own smoking cessation clinic; (2) be systematic; (3) don't be discouraged; (4) follow your patients until

they either quit smoking or quit coming to your office; and (5) keep abreast of new developments in smoking cessation strategies.

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