A Physician's Guide to Smoking Cessation

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Claims of the effectiveness of smoking cessation services and products are often misleading. It is important that physicians be well informed in order to make appropriate recommendations to their patients who smoke. In this article smoking cessation products and programs are critically evaluated and issues such as cure rates and validation of self-reported abstinence are discussed.

Many commercial products are available to aid in cessation, although none has been proven effective. With the exception of nicotine polacrilex gum and transdermal patches in conjunction with a multicomponent clinic, medications are generally ineffective. Smoking cessation programs range from the provision of self-help materials to multisession groups and clinics. Multicomponent, behavioral-based group programs have been the most successful.

Physicians should raise the issue of smoking cessation as frequently as possible with smokers and should recommend the use of smoking cessation products and services as appropriate. Referrals should be made to programs that base their success rates on scientifically accepted standards, including a 1-year follow-up, inclusion of dropouts and nonrespondents in calculating outcome, and biochemical validation of self-reported abstinence. Reports of success rates of 80% to 95% at the end of a 1-year program should be viewed with skepticism. Ideally, whether working independently or through referral, the physician should actively promote smoking cessation for all patients who smoke.

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Numerous articles have been written advising physicians of effective ways in which to intervene with smokers.[1–3] Often, however, physicians have very little time to discuss smoking-related issues with their patients. Since many physicians do not have the necessary training to teach stop-smoking strategies, it is important that they have available a concise source of information about the myriad of techniques, medications, and products used in smoking cessation.

The purpose of this article is to provide physicians with a brief guide to smoking cessation and to the general types of services and products available. It is important that physicians be well informed in order to make appropriate referrals for patients; however, the sheer diversity of cessation methods and products complicates this task. Previous reviews[4,5] indicate marked variability in the outcomes of presumably similar interventions. This article provides some important evaluative suggestions that physicians may use to identify the ineffective smoking cessation products and techniques that are on the market.

Accuracy of Cessation Rates

Data Interpretation

Physicians need to carefully evaluate the claims for any programs, devices, or chemical products used for smoking cessation. Although commercial or community programs may not deliberately give false outcome data, there is evidence that their data are sometimes misrepresented, resulting in false high-cure rates. Different cure rates can be calculated from the same data since there are numerous ways in which outcome data can be reported, such as: no follow-up to a 1-year follow-up; selection of different times to determine the end of the treatment—1 day to 1 year; omission of original nonrespondents who do not attend all or most of the meetings; and omission of nonrespondents who do not answer requests for ces-

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sation information, probably because they have started smoking again. These different methods of reporting the final outcome can lead to wide variations in abstinence figures for the same participants.

Attrition, or recidivism, can also dramatically affect the outcome of a smoking cessation program.[6,7] Assume, for example, that a program attracts 100 persons, of whom 50 complete the treatment, 30 respond to follow-up, and 20 report abstinence. Reported outcomes could range from 20% to 67% depending upon how the data are computed. Research specialists who deal with smoking cessation programs would recognize 20% as the appropriate outcome figure because the majority of nonrespondents were probably recidivists who did not wish to report their failure.

The physician should be aware that the most widely accepted outcome is success at the 1-year follow-up. The criterion for success should be defined as nicotine abstinence for at least 1 year. Most, but certainly not all, relapses will have occurred by this time. Some programs publicize the end-of-treatment success rate, which may be no more than a few days or weeks after the assigned quit date. Such end-of-treatment report of results may indicate a 60% abstinence. However, at the end of 1 year, this abstinence figure may be as low as 3% to 5%.

Biochemical Validation

Even when rigorous standards of data interpretation are applied, the results still may not reflect actual cessation rates. Unfortunately, program participants sometimes falsely indicate that they are not smoking. Participants may be embarrassed to admit failure, or they may not wish to disappoint the clinic facilitator who worked to assist them in quitting. For this reason it is important that self-reports of abstinence be validated biochemically. Although several methods are available, the preferred indicator of cigarette use in clinical practice is the level of carbon monoxide in a sample of exhaled air. Carbon monoxide (CO) readings are easy to obtain, noninvasive, and inexpensive. Units for measuring CO can be obtained for under $1000 and used for thousands of tests. Although CO exposure can occur from sources other than cigarettes, such as automotive exhaust, smokers almost always have higher concentrations of CO than nonsmokers.

Other common biological validation measures include thiocyanate and cotinine levels. Both of these indicators can be obtained by testing saliva, urine, and blood samples. However, these tests have serious drawbacks; they are expensive and not always accurate.[8,9] In addition, these techniques can lead to a higher refusal rate among subjects, particularly when a clinic instructor who is not a physician requests that blood samples be obtained. Refusal of participants to be tested reduces the reliability of the results.

One weakness of carbon monoxide validation is that CO has a short half-life.[9,10] This presents a problem when a large pecuniary reward will be given to those who have successfully quit smoking at the end of the program. Although claiming they have quit, some participants may stop smoking for only a few days in order to obtain the reward. To avoid this problem, we recommend that no financial rewards be given for completion of a cessation program unless it has been validated by tests of the participant's CO level over a 1-year period. Although a few studies have shown very high cure rates associated with financial rewards,[4] none reported using CO testing to validate their cessation rates.

The short half-life of CO, however, has a useful advantage as well. Declining levels of CO can be rewarding psychologically to smokers who have just struggled through the first 24 to 48 hours of abstinence and who are experiencing few tangible benefits of cessation.

The greatest reason for inaccurate cure rates is the lack of the use of biochemical validation. Without this type of measurement, there is no way to determine the actual success rate of any program. Exaggerated success rates as high as 50% have been reported.[11,12]

Smoking Cessation Methods

Drug-Containing Products

LOBELINE SULFATE

Lobeline sulfate products have been sold over the counter for a number of years under such trade names as Nikoban and Bantron. Controlled studies have generally failed to reveal any advantage for lobeline sulfate over a placebo.[4,13] We therefore do not recommend it.

SILVER ACETATE

Silver acetate preparations are also available under such trade names as Healthbreak. These preparations produce distinctly unpleasant tastes when combined with cigarettes. The disagreeable taste is presumed to assist in the cessation of cigarettes use. Unfortunately, there is no scientific evidence to indicate that such preparations are effective aids in cessation.[14–16]

CIGARREST

Cigarrest appears to combine lobeline sulfate with vitamins. However, very few data are available either on its

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composition or on its effectiveness. All study results are controlled by the manufacturer (who has impressive sales figures of almost 2 million units), and little research has been published. Based on the results of the research that is currently available on the ineffectiveness of lobeline sulfate,[13] Cigarrest would appear to have a low success rate.

NICOTINE CHEWING GUM

Nicotine chewing gum (trade name: Nicorette) may represent a coping mechanism for smokers. Results of studies of nicotine gum have been highly variable.[4] Much of the variability stems from the extent to which the gum is integrated with other smoking cessation methods. The manufacturer recommends against using the gum alone,[17] without a supportive program, yet encourages physicians to prescribe it to their patients. Systematic incorporation of nicotine gum into behaviorally sound treatment programs tends to produce better results. Alternatively, physician-prescribed use of nicotine gum in isolation tends to produce unsatisfactory outcomes.[18] A recent report indicates that many of the unsatisfactory results are due to requests by the patients to try nicotine gum on their own without entering a smoking cessation program.[19]

Side effects that have been associated with the use of nicotine gum include dizziness, nausea, and jaw muscle ache; in rare cases, overdosing has occurred.[17,19] These side effects in some cases were caused by the nicotine in the gum when the user did not adhere to the dosage instructions. Problems have also been caused by use of the gum over several months while continuing to smoke or by long-term use of the gum after stopping smoking. Use of nicotine gum while continuing to smoke is completely counterproductive. Ideally, nicotine gum should be used only during the first few months of complete cessation and then discontinued completely.

Absorption of nicotine into the bloodstream from the gum is far slower than absorption from cigarettes. Thus, the gum does not substitute for the immediate "hit" of nicotine produced by smoking. Patients may expect the gum to provide an effortless cure, but at best the gum can only help take the edge off severe nicotine withdrawal.

In evaluating abstinence results, the authors recommend that the follow-up interval for the 1-year cessation begin after the discontinuance of nicotine gum. The appropriate use of gum, together with other coping strategies and realistic expectations incorporated in a multifaceted clinic, can lead to improved cessation rates-[19–21]; however, an earlier report noting that nicotine gum is not a panacea should be kept in mind.[22]

NICOTINE TRANSDERMAL PATCHES

Alternative methods of nicotine delivery such as aerosols and patches have been investigated for a number of years.[23,24] The manufacturers of the products recently received approval from the Food and Drug Administration, and medical journals and news media have been deluged with advertisements for the transdermal patch. A number of studies have indicated the benefits of the transdermal patch.[25–30] Some of the trade names are Nicoderm and Habitrol. These products appear to have fewer side effects than nicotine gum, but more research is needed to determine their effectiveness.[24] Studies of both nicotine chewing gum (Nicorette) and the transdermal patch have shown the importance of determining the cessation rates after the use of these products is terminated.

Two studies have evaluated the effectiveness of the patch for two different periods of time. Tonnesen et al[25] demonstrated a 1-year abstinence rate of 17%, which was objectively documented. In comparison, the placebo patch was only 4% effective. The Transdermal Nicotine Study Group[26] showed that the active patch was 26% effective at the end of 6 months, 3 months after treatment had stopped. The placebo patch was only 12% effective at the end of 6 months. The nicotine patch does appear to aid in smoking cessation with a multimodel clinic, but more research is needed to accurately determine its effectiveness.

CLONIDINE

Unfortunately, the enthusiasm initially generated for clonidine tablets (Catapres) has not been validated in subsequent studies.[31,32] Glassman et al[31] showed clonidine tablets to be effective in 45% of patients at the end of 4 weeks. The fact that only women benefited from this agent made the data suspect. A subsequent large, placebo-controlled trial demonstrated no benefit in men or women at only 4 weeks.[32]

Similar disappointing results have been demonstrated in the use of the clonidine patch. A preliminary report suggested that transdermal clonidine was effective.[33] A well-designed multicenter trial, however, was unable to show that the patch was effective at any point during its use.[34]

Nicotine Reduction Devices

FILTRATION DEVICES

Nicotine reduction filters such as One Step at a Time were widely promoted in the 1970s. These filters were intended to allow smokers to gradually reduce their nic-

otine intake. It was hypothesized that dramatic nicotine reduction before quitting would greatly reduce withdrawal symptoms and therefore facilitate abstinence. Unfortunately, abstinence results associated with use of these filters were disappointing. One study[35] showed a very low cure rate of 3% at the end of 1 year.

A major problem with filter products is that the smoker tends to continue smoking at the lower levels of nicotine reduction rather than achieving total abstinence.[19,35] Although reduced nicotine intake may produce some health benefits, this has not been proven. Furthermore, it appears that many filter users were able to attain an increase in nicotine intake by inhaling more deeply.[18]

Filters of a new type are now available and are being marketed. These filters are more closely linked with behavioral strategies and recommendations for reaching total abstinence.[36,37] The initial data[38] have indicated that although reductions in nicotine levels have occurred, the filters have not produced any significant increases in rates of smoking cessation.

Filter products must be viewed as unproven at this point. Once smokers discard the nicotine reduction devices, they may resume the same or higher levels of smoking rather than becoming or remaining abstinent. Thus, use of the filters may lead to increased smoking and greater morbidity.[39] Furthermore, some studies have questioned the safety of the nicotine reduction filters since overcompensating may occur, resulting in the smoker inhaling more deeply, thus receiving additional accumulations of carcinogenic agents and higher concentrations of CO.[39] These observations have led to controversy over the benefits of lowering nicotine in cigarettes by filtration.

LIFESIGN

Lifesign is a small hand-held computer unit that signals smokers when to smoke. Lifesign comes with a detailed treatment manual and is primarily a preparation technique for cessation. Lifesign is supposed to lead to both reductions in cigarette use and disassociation of smoking from normal and environmental cues. There are no reports in the literature on its effectiveness in smoking cessation; the only available information is from the manufacturer. Since it is basically a nicotine-reduction device, however, it is highly unlikely that it would produce very significant increases in smoking cessation rates.

Self-help Manuals

Self-help manuals are available from several sources that are primarily nonprofit organizations, such as the American Lung Association,[40] the American Cancer Society,[41] and the National Cancer Institute.[42] There is little evidence that any specific self-help manual has a significant effect on the outcome of smoking cessation efforts, and these manuals may result at most in a 5% cure rate at the end of 1 year.[4] It should be noted that "cure rate" does not necessarily imply that the smoker may abstain permanently; those who are reported cured often go back to smoking.

Smoking Cessation Techniques

HYPNOSIS

Hypnosis has been used for a number of years and represents one of the most widely available methods in the treatment of smoking. There are practicing hypnotists in virtually every city. Some offer treatment to groups. A few hypnotists travel from city to city soliciting smokers to participate in mass sessions that may include over 1000 participants.

Reputable hypnotists are very straightforward in stating that hypnosis is not magic and will not work for everyone. Unfortunately, some hypnotists advertise claims that are dramatically inflated; for example, a cure rate for hypnosis as high as 95% can be seen in newspaper advertisements in many parts of the country. The physician should be aware of the difference between highly qualified hypnotists who have had success in smoking cessation and those who claim inflated cure rates.

Most reports of the effectiveness of hypnosis have not been subjected to rigorous examination. Published success rates vary widely, but overall rates are not impressive, even without carbon monoxide validation and when hypnosis is performed by qualified hypnotists.[4] Many smokers who undergo hypnosis are looking for an easy and effortless cure. Smokers who are highly suggestible appear to be the most likely to succeed and seem to experience no more than minimal withdrawal symptoms, while others who fail become very irritable. One of the very serious problems with hypnosis failure appears to be the extremely great resistance of recidivists to continued efforts in smoking cessation.

ACUPUNCTURE

Acupuncture cure rates are very low. Studies comparing theoretically "correct" needle placements with sham or placebo sites have tended to find no difference in outcome. Some smokers may respond well to the placebo effects of acupuncture, however.[43]

AVERSION TECHNIQUES

A number of programs, for example, Smoke Stoppers, Schick, and Smoking Cessation Centers, have incorporated aversion procedures into their treatment. The use of artificial stimuli such as electric shock has been ineffective.[4] Forms of aversion intrinsically related to smoking such as rapid smoking[44,45] or oversmoking[46,47] tend to produce better outcomes, although the findings are mixed. The primary benefit of aversion techniques may be to increase a smoker's distaste for smoking cigarettes, resulting in a high motivation to quit. One of the deficiencies of this method is that the participants who fail may become addicted to a higher level of nicotine and consequently smoke at an increased level after failure. Patient resistance to such procedures appears to have increased rather dramatically in recent years.[47]

Smoking Cessation Groups and Clinics

Many smoking cessation clinics offer intensive support to participants. These programs typically involve multiple sessions. They may include a considerable variety of treatment components. Multicomponent programs, especially those derived from a behavioral approach, tend to produce good long-term outcomes. A summary[4] reported a median 1-year abstinence outcome of 40% for this type of method; however, these results usually do not include carbon monoxide validation. The cure rates, therefore, are probably much lower.

It should be realized that clinics generally attract hard-core smokers who may have initiated numerous previous unsuccessful attempts to stop smoking. These clinics usually demand a considerable amount of time and effort from both the participants and the instructors. Yet this level of commitment appears to be essential in facilitating higher rates of abstinence among smokers.

Commonly offered nonprofit programs include those of the Seventh Day Adventist's Five Day Plan,[48] the American Lung Association's Freedom From Smoking clinics,[49] and the American Cancer Society's FreshStart program.[49] Judging from the research reports, it appears that the American Lung Association's clinic is somewhat more effective than that of the American Cancer Society[49]; however, the American Lung Association's program requires a substantially greater time commitment.[4] Programs that require a greater number of sessions have higher cure rates[50] than those with few sessions.

Commercial programs are also available. SmokEnders, Smoke Stoppers, Smokeless, and Schick are among the most common smoking cessation clinics.[4] In considering commercial programs, physicians should note that they are often substantially more expensive than the nonprofit programs. At present there is little evidence to demonstrate that the commercial programs are more effective than those of nonprofit organizations. Commercial vendors indicate correctly that, for many smokers, a substantial fee may represent their high level of commitment and serve as an incentive for quitting.

Few of the voluntary agencies or commercial programs include biochemical validation of reported abstinence. As indicated earlier, for various reasons patient-reported successes are often exaggerated. Therefore, we strongly recommend that biochemical validation be included in future reports of clinic success rates. Without carbon monoxide validation, there is no way to determine the actual success rate.

Physician Intervention

During the last decade, physicians have written articles for medical journals and introduced mini-courses in medical schools so that all physicians receive basic training in smoking cessation counseling.[50–56] Nevertheless, research has shown that an insufficient percentage of physicians provide smoking cessation counseling to their patients. We encourage all physicians to assist their patients who smoke by providing them with direct counseling or recommending an appropriate clinic with a high cure rate, or both.

Conclusions

Despite their most vehement denials, almost all patients who smoke know that they should quit. Since most physicians do not have the time or the expertise to lead formal stop-smoking programs, they need to be aware of the products, techniques, and programs that are available to assist patients in smoking cessation. Physicians should realize that their knowledge, skill, and attitudes toward smoking are significant, and that they should be the prime motivators in persuading their patients to stop smoking.

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