Objective Evaluation of Smoking Cessation Carbon Monoxide Monitoring

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Responding to the deficit of evaluative "hard data" on smoking cessation treatments, this study used CO monitoring to measure progress in a VA stop smoking clinic—as well as to address several controversies in smoking cessation research.

Both the U.S. Surgeon General and the CDC identify cigarette smoking as the chief preventable cause of illness and premature death in this country. According to the executive summary of the HHS clinical practice guideline *Treating Tobacco Use and Dependence* (which was sponsored jointly by a number of public and private not-for-profit organizations, including the CDC), approximately one third of all tobacco users die prematurely because of their tobacco dependence.[1] This translates to almost half a million premature, smoking-related deaths in the United States each year.[1]

Accordingly, the VA's efforts to treat tobacco dependence have both a moral imperative and an organizational benefit. Clinics devoted to smoking cessation provide veterans with preventive medical care that has the potential to result in substantial cost savings, given the expense of treating the conditions for which chronic smokers and their offspring are at increased risk, such as heart disease, various cancers, stroke, subfertility, low birth weight, and limited intrauterine growth.

The principles of evidence-based medicine require that such clinics—like all health care programs—be evaluated formally. The problem with many previous evaluations of smoking cessation clinics and programs, however, is that they rely on the self-report of participants. Self-reporting always carries a potential for unreliability or bias, and in the case of smoking cessation programs, there may be an even greater incentive for participants to tell providers "what they want to hear" due to social pressures.

At the Jacksonville VA Outpatient Clinic (Jax VA OPC), Jacksonville, FL, it was decided that an objective method for evaluating the facility's Stop Smoking Clinic was needed. This decision was made after a March 1999 telephone survey of a random sample of 41 of the first 77 clinic patients yielded a 75% self-reported quit rate (W.F.M., unpublished data, 1999). Believing that this unexpectedly high success rate might have been distorted by patients' desire for social approval, administrators implemented a new evaluative parameter that would reflect scientifically valid principles: measurement of exhaled carbon monoxide (CO) levels. CO levels in the body have been found to correlate directly to the amount of cigarette smoke a person inhales, and measurement of exhaled CO concentration has been "well validated

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as an indirect measure of cigarette consumption."[2]

In this article, I will describe a retrospective review conducted on the group treatment program in use at the Jax VA OPC Stop Smoking Clinic, which uses CO measurement to gauge a patient's progress or success. In addition, I will discuss the implications of the review's findings on several issues regarding smoking cessation that are being debated currently in the addiction treatment community.

THE CLINIC'S SMOKING CESSATION PROGRAM

The Jax VA OPC Stop Smoking Clinic is a multisession, multimethod group treatment program that involves both psychological and pharmacologic components (Table 1). The groups meet four times over a five-week period. The first three sessions, which are held weekly, focus on the psychological interventions, which include education on the health risks of tobacco and the rewards of abstinence, cognitive psychotherapy confronting the smoker's dysfunctional belief system, and self-control training that induces beliefs promoting abstinence. In addition, the social group format supports a commitment to abstinence and increases motivation.

At the third session, the program's pharmacologic component—nicotine replacement therapy in the form of transdermal patches—is introduced. Patients who are deemed appropriate for such therapy are instructed in the use of the patches and given a four-week supply. The titration model of nicotine withdrawal used progresses through the following nicotine dosages: 21 mg, 14 mg, and 7 mg.

Table 1. Design of the smoking cessation group treatment provided by the Jacksonville VA Outpatient Clinic Stop Smoking Clinic

Treatment session	Timing	Description
First session	Week 1	• Introduce patients to group's "reality therapy" treatment philosophy • Provide education for increased motivation
Second session	Week 2	• Teach cognitive strategies for coping with withdrawals and cravings • Develop individualized "quit date" plans
Third session	Week 3	• Instruct patients in use of nicotine replacement patches • Take initial CO* measurement • Give patients who qualify for nicotine replacement therapy a four-week supply of patches
Fourth session	Week 5	• Take follow-up CO measurement • Modify individual quit plans as needed • Give patients up to an additional eight-week supply of nicotine patches • Educate patients about preventing relapse

*CO = carbon monoxide.

The fourth session is scheduled for two weeks later, which gives the participants a sufficient trial of nicotine replacement therapy before meeting again with clinic staff and fellow group members. In addition to checking on the participants' pharmacologic therapy, this final session emphasizes maintaining abstinence. Afterwards, any further follow-up of the patient's progress in smoking cessation—including the monitoring of continued nicotine replacement therapy—is performed by the patient's primary care provider.

The treatment evaluation component of the Stop Smoking Clinic is designed to be an objective, one-group, pretreatment-posttreatment assessment. During the third session, before initiation of transdermal nicotine replacement therapy, clinic staff measure each smoker's exhaled CO concentration using the MicroCO meter (Micro Direct, Inc., Auburn, ME), a handheld, battery-operated device. Two weeks later, at the fourth session, participants undergo a follow-up CO measurement.

This type of evaluation provides some degree of internal validity in that each patient's CO levels are measured before and after the initial exposure to nicotine patch

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treatment. A statistical comparison then can be performed between the initial and follow-up CO measurements to ascertain whether the treatment leads to actual clinical improvement.

BEYOND INDIVIDUAL ACHIEVEMENT

In addition to their utility in tracking individual or group success in the program, the data generated through CO monitoring of patients at the Jax VA OPC Stop Smoking Clinic proved relevant to certain controversies in smoking cessation research. One of these is the debate over whether more heavily dependent smokers should be prescribed larger than standard dosages of nicotine replacement patches. Medical literature on this topic is conflicted. For example, Jorenby and colleagues found that doubling the standard starting dosage of nicotine patches to 44 mg/day did not prove to be more effective in subjects who were heavily dependent on nicotine,[3] whereas Dale and colleagues found that increasing the dosage of nicotine replacement patches did increase their efficacy.[4]

Another point of some contention is whether smokers who are unable to achieve complete abstinence can realize actual health benefits by reducing their level of smoking. The "harm reduction" model, a relatively new concept in the addiction field, supports this idea, emphasizing the beneficial effects of decreasing the amount of biologically relevant toxins in the body.[5] Because the mortality risk of cigarette smoking correlates directly to the amount of cigarettes consumed,[6] quantified reductions in cigarette intake—measured, for example, through exhaled CO levels—should represent reduction in the amount of harm to which the patient is exposed. When the HHS clinical practice guideline *Treating Tobacco Use and Dependence* was published in 2000, however, the authors reported that there was "insufficient evidence to support a recommendation regarding harm reduction."[1]

Given the usefulness of the data we had available to us, we at the Jax VA OPC Stop Smoking Clinic designed and conducted a retrospective study involving patients from 15 treatment groups that had completed the five-week program between June 5, 2001 and April 29, 2002. This analysis included both a basic comparison of initial and follow-up CO measurements to evaluate the overall effectiveness of our treatment approach and a two-group analysis comparing the change in CO levels in very heavy smokers versus average smokers in order to determine whether standard dosages of nicotine replacement therapy (which all clinic patients received) result in similar or different success rates for both groups. In addition, by examining the change in CO levels by the follow-up measurement, we were able to address the usefulness of the harm reduction model as well.

MEASURING AND CLASSIFYING CO LEVELS

Although the MicroCO meter can be calibrated to display results as a direct carboxyhemoglobin reading, we found the setting that gives CO parts per million (ppm) to be more convenient. Under this system, 1 ppm equals one cigarette, so a smoker who consumes one pack per day should have a CO level of about 20 ppm.[7]

A search of medical literature reveals some variation in definitions of heavy smoking. The HHS clinical practice guideline, for instance, defines heavy smokers as those who consume over 20 cigarettes (the equivalent of one pack) per day.[1] The Fagerstrom Tolerance Questionnaire, however, uses a slightly higher threshold, defining a highly dependent smoker as one who consumes over 25 cigarettes per day.[8] By any of these definitions, patients who enroll in the Jax VA OPC Stop Smoking Clinic tend to be heavily dependent—28% of the last 100 veterans treated reported smoking 40 or more cigarettes per day.

For the purpose of our analysis, smokers were classified according to the MicroCO meter's established calibration: 0 to 5 ppm—nonsmoker, 6 to 10 ppm—light smoker, and greater than 10 ppm—heavy smoker.[2] For the second part of our analysis, we further classified patients as very heavy smokers if they had a reading of more than 30 ppm and as average smokers if they had a reading between 11 and 30 ppm.

It's important to note that even a nonsmoker may expire low levels of CO due to exposure to toxic environments, such as heavy automobile traffic or faulty gas appliances. In the present study, therefore, success (or abstinence) was defined as achieving a posttreatment CO level of less than 6 ppm.

THE STUDY POPULATION

During the study period, a total of 389 patients registered for the Stop Smoking Clinic, but only 157 attended their first group meeting—a 40% attendance rate. On average, 26 patients were booked for each group, but the groups' attendance averaged only 10 patients (range, 5 to 14 patients per group).

Of the 157 patients who attended their respective group's

first session, complete data were collected on only 86 patients. The subsequent statistical analysis was performed on these six female and 80 male smokers. Shipley has argued that, in statistical analyses of stop smoking programs, every patient who attends even one treatment session should be included.[9] His position, however, is inappropriate for the present study, which incorporates the specificity of a biomarker to generate change statistics. A focus on quantifiable changes in patients' CO levels requires repeated measures and, thus, repeated attendance.

At the first treatment session, mean self-reported daily cigarette consumption was 26 cigarettes (range, 5 to 70 cigarettes; mode, 20 cigarettes). Initial CO expiration levels (measured during the third treatment session) supported these self-reports, with a mean level of 26 ppm (range, 1 to 75 ppm).

Table 2. Findings of first and second analyses in the Jacksonville VA Outpatient Clinic stop smoking study

Patient classification	Total no. of patients	No. (%) of patients who achieved success criterion* at two-week follow-up
Total study group	86	35 (41%)
Men	80	33 (41%)
Women	6	2 (33%)
Heavy smokers (initial CO† > 10 ppm)	63	35 (55%)
Average smokers (initial CO 11–30 ppm)	33	19 (58%)
Very heavy smokers (initial CO > 30 ppm)	30	16 (53%)

*Follow-up CO level of < 6 ppm. †CO = carbon monoxide.

ANALYZING THE DATA

The first analysis, revealed that, of the 86 patients included in the study, 63 (73%) could be classified as heavy smokers according to the criterion of an initial CO reading over 10 ppm (Table 2). Among these heavy smokers, 35 were able to reduce their CO levels to below 6 ppm at the follow-up measurement, resulting in a 55% success rate. In the total group of 86 patients, the overall success rate was 41%.

The second analysis examined the question of whether very heavy smokers require increased dosages of the transdermal nicotine patches to achieve the same level of success as average smokers. In our study population, there were nearly equivalent numbers of very heavy smokers and average smokers: 30 patients had an initial CO reading of over 30 ppm and 33 patients had an initial reading between 11 and 30 ppm. Of the very heavy smokers, 16 (53%) had reduced their CO levels to under 6 ppm by the follow-up reading. Of the average smokers, 19 (58%) had achieved this goal by the follow-up measurement. Statistical analysis revealed no significant difference between the two success rates, suggesting that very heavy smokers are no more likely than average smokers to require higher dosages of transdermal nicotine replacement therapy.

Finally, in order to address the question of harm reduction, we determined the number of smokers who were able to reduce their cigarette intake by at least half a pack by the end of treatment—in other words, achieve a follow-up CO measurement that was at least 10 ppm lower than the initial measurement. Of the 86 patients included in the analysis, 50 (58%) were able to reach this goal (Table 3). The mean reduction in CO levels at two-week follow-up was 20 ppm. Nine patients (10% of the full group and 14% of heavy smokers) reduced their CO levels by 40 ppm.

ADDING TO THE SMOKING CESSATION DIALOGUE

Evaluating whether a treatment has been successful is the major component of evidence-based medicine.[10] The present study evaluated a group treatment format that provided both psychological and pharmacologic therapies for nicotine dependence. Statistical analysis indicated a 41% rate of abstinence from cigarette smoking at two weeks of follow-up—a conclusion based not upon potentially unreliable self-report but instead upon objective measurement of an inhaled biological toxin, carbon monoxide. These data support Fuhrmann's contention that "patients' motivation to quit smoking is enhanced by the demonstrated presence of a toxin (CO) in their bodies."[11]

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In addition, the rate of abstinence in the present study compares favorably with that found by Shiffman, who also used a two-week follow-up design to examine smoking relapse rates. In his study, 37% of smokers were able to limit their lapses.[12]

Of course, the present study would be enhanced with a longer follow-up period—perhaps a six-month postcessation assessment. Even with this limitation, however, the results illustrate how evaluating treatment programs can add valuable data to clinical research controversies. For example, our analysis revealed similar rates of abstinence for average and very heavy smokers after treatment with standard dosages of nicotine replacement patches. This finding adds to the evidence supporting a recommendation that, at least in populations similar to ours, all smokers in cessation programs should be prescribed the standard dosage of nicotine replacement patches, regardless of their level of smoking.

Furthermore, our third analysis revealed an average decrease in expired CO of 20 ppm at follow-up, a reduction equal to a full pack of cigarettes. Among heavy smokers, 14% were able to reduce their CO levels by 40 ppm—or a two-pack equivalent—within two weeks. These results begin to answer a research question identified by the HHS clinical practice guideline as necessary to resolve the controversy surrounding the harm reduction model: "How effective are behavioral interventions in promoting reduced smoking (short and long term) without compensatory smoking?"[1] The present study objectively demonstrates that chronic smokers are able to reduce their smoking to a remarkable degree after a short-term group therapy program that emphasized behavioral intervention. ●

Table 3. Findings of third analysis (harm reduction) in the Jacksonville VA Outpatient Clinic stop smoking study

Total no. of patients	86
No. (%) of patients who reduced their CO* levels by at least 10 ppm† at two-week follow-up	50 (58%)
No. (%) of patients who reduced their CO levels by at least 40 ppm at two-week follow-up	9 (10%)
Mean reduction in CO levels at two-week follow-up	20 ppm

*CO = carbon monoxide. †Arbitrary value chosen to show reduction of harm; this CO concentration is equivalent to half a pack of cigarettes.

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