MINDFUL PRACTICE

Is Smoking Reduction a Viable Strategy?

BY JON O. EBBERT, M.D., AND ERIC G. TANGALOS, M.D.

The Problem

A 58-year-old woman presents to you for follow-up of multiple medical issues. She reports smoking 30 cigarettes per day for the past 20 years. As at every prior visit, you encourage her to quit smoking, but she remains uninterested. In a radical attempt to circumvent this impasse, you ask her if she would be willing to reduce the amount smoked. She expresses interest in this. As a means to reduce her smoking rate, you consider the nicotine inhaler to act as an intermittent substitute for her cigarette smoking.

The Question

In smokers unwilling or unable to quit, do smoking reduction interventions result in maintained smoking reduction, or decrease the likelihood of future abstinence?

The Search

You log on to PubMed (www.pubmed.gov) and search "smoking reduction AND inhaler" and limit the results to randomized, controlled trials. You find a relevant study. (See box at right.)

Our Critique

This approach is controversial because it challenges the traditional paradigm of setting a quit date and encouraging complete abstinence beginning that day. Several critical issues need to be considered when engaging in a smoking reduction approach: Does smoking reduction decrease smoking harm? Does this approach undermine future quit attempts? Does the use of nicotine replacement therapy while smoking increase the risk for adverse medication events? First, no safe level of smoking exists. Smokers who reduce cigarette consumption may compensate by deeper inhalation, breath-holding, and smoking more of each cigarette, which negates any potential health benefit from smoking fewer cigarettes. Second, the current study suggests that future quit attempts are not undermined by higher abstinence rates in the active inhaler group. Third, although the use of nicotine replacement therapy in patients who reduce is an "off label" indication, the vast majority of randomized clinical trials of this approach have observed no significant increase in adverse events. Finally, insurance companies may not pay for medications used in a smoking reduction intervention.

Clinical Decision

After discussing the approach with her, you prescribe the nicotine inhaler and ask her to telephone you with an status update in 3 months. You encourage her to contact you at any time if she wishes to quit smoking completely, at which time you will consider adding other medications and picking a quit date.

DR. EBBERT *and* DR. TANGALOS *are with the Mayo Clinic in Rochester, Minn. They have no conflict of interest to report. To respond to this column or suggest topics for consideration, write to Dr. Ebbert and Dr. Tangalos at our editorial offices or e-mail them at imnews@elsevier.com.*

S.I. Rennard, et al.

Efficacy of the nicotine inhaler in smoking reduction: A double-blind, randomized trial. Nicotine Tob. Res. 2006;8:555-64.

► **Design and Setting:** Randomized, blinded clinical trial performed at three U.S. centers.

► **Subjects:** Potential subjects had to be at least 18 years old, smoke at least 20 cigarettes/day, have smoked for at least 3 years, have an exhaled carbon monoxide level of at least 15 ppm after 15 minutes, have failed at least one serious quit attempt within the previous 2 years, and want to reduce their cigarette consumption. Potential subjects were excluded if they planned to quit in the next 4 weeks, were contemplating quitting, were using a pharmacologic or behavioral smoking cessation/reduction program, were using other tobacco products, had cardiac disease or recent heart attack, were pregnant or lactating, were taking a psychiatric medication or under psychiatric care, or using drugs or alcohol that could interfere with trial participation.

► **Intervention:** Subjects were randomized to receive either a nicotine inhaler or a matching placebo inhaler. The inhalers could be used as needed with a recommended dose of 6-12 cartridges/day for up to 12 months. Subjects were instructed to reduce their smoking as much as possible with no additional supportive measures. Smoking cessation was recommended after 6 months but was not mandatory.

► **Outcomes:** The primary outcome was the self-reported reduction in number of cigarettes smoked per day by at least 50% at 4 months, compared with week 6 (baseline). Other outcomes included smoking abstinence and smoking reduction as measured by serum biomarkers.

► **Results:** A total of 429 subjects were randomized (215 to active inhaler and 214 to placebo). Subjects were similar at baseline, with an average age of 45 years and an average of 30 cigarettes smoked per day. The mean number of nicotine inhaler cartridges used at 4 months was 6.4 per day. At 4 months, 18% of active inhaler subjects had reduced number of cigarettes smoked by 50%, compared with 8% of the placebo group. At 12 months, 7.9% of the active inhaler group had quit smoking, compared with 2.3% of the placebo group, and 7.9% vs. 1.4% were still abstaining at 15 months. At 15 months, about 18% of subjects in both groups intended to quit and 84% of all subjects were more motivated to quit. Smoking reduction of 50% correlated significantly with reductions in carbon monoxide and serum biomarkers. No differences in reported adverse events were observed between the two groups.

Nicotine Dependence Rises in U.S. Smokers

BY MITCHEL L. ZOLER

PHILADELPHIA — American smokers have, on average, become significantly more nicotine dependent since 1989—which means that more aggressive interventions are needed to help them quit.

That's because most of the smokers who could more easily quit have already done so. "The low-hanging fruit has been plucked. The less-addicted smokers are out of the pool. We're left with people who are more dependent," Dr. David P.L. Sachs said at the annual meeting of the American College of Chest Physicians.

"The vast majority of patients we see now in actual clinical practice are more highly nicotine dependent," said Dr. Sachs, director of the Palo Alto (Calif.) Center for Pulmonary Disease Prevention. Dr. Sachs documented this shift by comparing the average level of nicotine dependence in patients who participated in three smoking-cessation studies that he collaborated on during 1989-2006. In all three studies, nicotine dependence at baseline was quantified with the Fagerström Tolerance Questionnaire (FTQ). (See box.)

Among 220 U.S. smokers enrolled in 1989 and 1990 in a study of a nicotine patch, the average FTQ score was 6.65. The next study enrolled 206 patients in 1994 in a study of sustained-release bupropion; their average FTQ score was 7.02, significantly higher than in the prior study. This average also fell into the category of "high" nicotine dependence, which applies to FTQ scores of 7 or greater.

The third study group cited by Dr. Sachs included 204 patients who were enrolled in 2005-2006 to assess an individualized treatment regimen. These people had an average FTQ score of 7.44, a significant jump above the 1994 average.

Thus, the percentage of patients rated as highly nicotine dependent was 56% in 1989-1990, 66% in 1994, and 73% in 2005-2006.

Dr. Sachs suggested measuring the FTQ score for each prospective quitter. "If you do not measure nicotine dependence, you can't know how physically dependent a person is," he said. "It would be like trying to manage hypertension without first measuring a patient's blood pressure."

If the smoker is highly dependent (FTQ score of 9 or 10), the physician will most likely need to prescribe several agents. Three or more standard, OTC nicotine patches worn simultaneously may be necessary, plus an additional nicotine source for times of stress, such as nicotine gum, nasal spray, inhaler, or lozenges. In addition, highly dependent patients will likely need treatment with bupropion (Zyban) or varenicline (Chantix). Some patients may need treatment with all four agents.

Some patients may require some type of maintenance treatment indefinitely, he added.

Dr. Sachs has received research grants from, been a consultant to, and been a speaker for Pfizer (Chantix) and GlaxoSmithKline (Zyban). ■

A related video is at www.youtube.com/InternalMedicineNews (search for 62685).

The Fagerström Tolerance Questionnaire (1991 Revision)

1. How soon after you wake up do you smoke your first cigarette?
► Within 5 minutes: 3 points.
► 6-30 minutes: 2 points.
► 31-60 minutes: 1 point.
► After 60 minutes: 0 points.

2. Do you find it difficult to refrain from smoking in places where it is forbidden, e.g., in church, at the library, in cinemas?
► Yes: 1 point.
► No: 0 points.

3. Which cigarette would you hate most to give up?
► The first in the morning: 1 point.
► Any other: 0 points.

4. How many cigarettes per day do you smoke?
► 31 or more: 3 points.
► 21-30: 2 points.
► 11-20: 1 point.
► 10 or less: 0 points.

5. Do you smoke more frequently during the first hours after awakening than during the rest of the day?
► Yes: 1 point.
► No: 0 points.

6. Do you smoke when you are so ill that you are in bed most of the day? (If you never get sick, give the most likely response.)
► Yes: 1 point.
► No: 0 points.

Source: Br. J. Addict. 1991;86:1119-27