Nicotine Patch Plus Lozenges Best for Cessation

BY MARY ANN MOON

Combining the nicotine patch with nicotine lozenges appears to be the most effective approach for smoking cessation, according to a report in the November issue of the Archives of General Psychiatry.

In a study directly comparing the effectiveness of five pharmacotherapies for smoking cessation against placebo, the patch-plus-lozenge combination "emerged as the only efficacious treatment… at 6 months post quit," said Megan E. Piper, Ph.D., of the Center for Tobacco Research and Intervention at the University of Wisconsin, Madison, and her associates.

This particular combination therapy "has not been previously evaluated," they noted.

The study involved 1,504 adult smokers who agreed to participate in a 3-year trial of smoking cessation, which reflects their high motivation to quit. Most of the study subjects were white (83%) and female (58%).

These subjects were randomly assigned to one of six treatments for 8 weeks: daily sustained-release bupropion (264 patients), nicotine lozenges (260 patients), nicotine patches (262 patients), nicotine lozenges plus nicotine patches (267 patients), bupropion plus nicotine lozenges (262 patients), or matched placebo (189 patients). All also received six individual counseling sessions of 10- to 20-minute duration with case managers who were supervised by a clinical psychologist.

In the initial analysis, all the active treatments yielded higher rates of cessation at day 1, week 1, the end of treatment, and 6 months after completing treatment. However, further analysis showed that only the combination of nicotine patches plus nicotine lozenges was significantly more effective than placebo at all of these time points.

Patients who received the combination of nicotine patches plus nicotine lozenges also had a longer interval until first "lapse" and a longer interval until full relapse than did subjects in the other study groups, Dr. Piper and her colleagues said (Arch. Gen. Psychiatry 2009;66:1253-62).

It is important to note that the placebo group in this study achieved a much higher smoking cessation rate (22%) than is usual with placebo. This "may have been due to the intensive counseling participants received, or to the high level of motivation required to participate in a 3-year longitudinal trial," the investigators added.

Treatment effects diminished significantly as soon as the course of therapy was completed. This suggests that longer-term treatment might be more effective, they said.

On average the study subjects used only approximately 77% of their study medication, but the rate of adherence varied widely between groups. Patients assigned to nicotine lozenges used significantly less of that medication—67% of what they were given—than patients in any other group.

This suggests that smokers may be "especially unlikely to use as-needed medications adherently (i.e., a recommendation of nine lozenges per day)," the researchers said.

The investigators cited two limitations of the study. First, because the study was longitudinal, it might have "selected participants with greater motivation to quit than smokers in the general population," they wrote. Also, the study did not include among the tested medications varenicline—which had not yet been approved by the Food and Drug Administration for smoking cessation. "Therefore, it is unknown how these agents would have fared relative to varenicline, the monotherapy designated as most effective by the 2008 [Public Health Service] Guideline."

Still, these findings and the 2008 guideline update suggest that a combination of pharmacotherapy made up of the patch and nicotine replacement therapy should be routinely considered for smoking cessation treatment, they wrote.

GlaxoSmithKline provided the medication to patients at no cost under a research agreement. Dr. Piper reported no financial conflicts of interest. ■