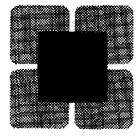

Transdermal nicotine patches: How effective are they?

HOW HAVE TRANSDERMAL NICOTINE patches fared since becoming available to US physicians in December 1991? Have clinical experiences met initial expectations? Are nicotine patches much more effective than nicotine gum? Which patients are most likely to benefit from the patch?

Although important questions remain, 1.5 years of clinical experience offers valuable insights into how well transdermal nicotine patches work.

Transdermal nicotine systems, or "nicotine patches," use rate-control membrane technology to deliver nicotine through the skin into the blood stream. By providing nicotine in gradually decreasing dosages, they minimize the withdrawal effects that commonly occur when smokers quit smoking.

PATCH VS GUM

Transdermal nicotine delivery has several advantages over nicotine replacement gum, which it has largely supplanted. It does not require chewing, whereas nicotine gum requires a specific chewing technique.[1] Moreover, issues of unpleasant taste, gastrointestinal distress, or mandibular fatigue are eliminated. Transdermal nicotine has some adverse effects, however. In a large multicenter trial, about 50% of the patients reported transient itching or burning at skin sites, with 14% having definite or severe erythema at least once.[2] Because transdermal nicotine patches are applied only once a day, achieving the proper dosage appears to be simpler than with nicotine gum. When taken as prescribed, most transdermal systems automatically taper the amount of nicotine delivered, in a manner designed to minimize unpleasant withdrawal effects.

As with nicotine replacement gum, nicotine patches should *not* be used in conjunction with smoking (even smoking at a reduced level), since adding transdermal nicotine to nicotine obtained from smoking exposes the patient to a potentially toxic acute nicotine overdose.

MEASURING THE PATCHES' EFFECT ON CESSATION RATES

Transdermal nicotine systems have been shown to enhance smoking cessation rates when used as directed (ie, in conjunction with a behavior-oriented smoking cessation program). In a large multicenter study of transdermal nicotine, more than 900 patients were studied at nine separate centers.[2] At 6 weeks and 24 weeks transdermal nicotine produced higher cessation rates than placebo. Patients reported significantly reduced withdrawal symptoms and nicotine craving while on transdermal nicotine.[2] A study using either 24-hour transdermal nicotine delivery or transdermal nicotine delivery during waking hours only found significantly enhanced cessation rates at 6 months.[3] One German study that combined transdermal nicotine with behavioral therapy recorded a 1-year cessation rate of 35%.[4] The authors of that study concluded that "a simultaneous behavioral smoking cessation program is thus an essential precondition for successful application of the nicotine patch."[4] Other European researchers using transdermal nicotine alone (ie, without a smoking cessation program) achieved a rather modest 1-year abstinence rate of 12.5%.[5]

At present, four major transdermal nicotine systems are available in the United States (*Table*). The literature provided with all the patches indicates that they should be used "as part of a comprehensive behavioral smoking cessation program." The patches

differ in construction and characteristics, and each manufacturer claims that its product possesses certain advantages over its competitors; however, no studies have demonstrated any superiority of one patch over another in aiding smoking cessation.

TABLE
DOSAGE OF FOUR TRANSDERMAL NICOTINE SYSTEMS

Product (manufacturer)	Dose length	Regimen
Habitrol (Ciba-Geigy)	24 hours	21 mg/day for 6 weeks, 14 mg/day for 2 weeks, 7 mg/day for 2 weeks
Nicoderm (Marion Merrell Dow)	24 hours	21 mg/day for 6 weeks, 14 mg/day for 2 weeks, 7 mg/day for 2 weeks
Nicotrol (Parke-Davis)	Daytime (16 hours)	15 mg/day for 4-12 weeks, 10 mg/day for 2-4 weeks, 5 mg/day for 2-4 weeks
ProStep (Lederle)	24 hours	22 mg/day for 4 to 8 weeks, 11 mg/day for 2 to 4 weeks

ADJUNCTIVE THERAPY

Transdermal nicotine appears to be a promising adjunct to smoking cessation programs. As with nicotine chewing gum, research suggests that transdermal nicotine is rather ineffective when used alone (long-term cessation rates are barely higher than, or no different from, placebo), but that it shows considerably more promise when used in organized smoking cessation programs, especially those that are behavior-oriented.

WHICH PATIENT IS MOST LIKELY TO BENEFIT?

The types of patients most likely to benefit from transdermal nicotine have yet to be identified. Several studies have concluded that nicotine gum works best with subjects highly dependent upon nicotine[6]; it is too soon to conclude if the same pattern will hold for transdermal nicotine.

NO MAGIC BULLET

Transdermal nicotine systems are being aggressively marketed, and on that basis alone are likely to become an important element of the smoking cessation effort among physicians. However, despite their potential, they are not a "magic bullet" that will effortlessly eliminate a patient's smoking addiction. No magic bullet exists. However, when used properly, transdermal nicotine does appear to help some smokers quit. It helps minimize physiologic withdrawal effects, allowing patients to concentrate on mastering the many psychologic, behavioral, and social aspects of quitting that remain. Whether transdermal nicotine is used or not, persistent encouragement and support from physicians to their smoking patients is one of the most powerful smoking cessation interventions of all.[7]

GARLAND Y. DENELSKY, PHD
Director, Cleveland Clinic Smoking Cessation Program
Head, Section of Psychology
Department of Psychiatry and Psychology
The Cleveland Clinic Foundation

REFERENCES

1. **Fiore MC, Pierce JP, Remington PL, Fiore BJ.** Cigarette smoking: the clinician's role in cessation, prevention, and public health. Dis Mon 1990; **36(4):**181–242.
2. **Transdermal Nicotine Study Group.** Transdermal nicotine for smoking cessation. JAMA 1991; **266:**3133–3138.
3. **Daughton DM, Heatley SA, Prendergast JJ, et al.** Effect of transdermal nicotine delivery as an adjunct to low-intervention smoking cessation therapy. A randomized, placebo-controlled, double-blind study. Arch Intern Med 1991; **151:**749–752.
4. **Buchkremer G, Minneker E, Block M.** Smoking-cessation treatment combining transdermal nicotine substitution. Pharmacopsychiatry 1991; **24(3):**96–102.
5. **Ehrsam RE, Bouhler A, Muller P, et al.** Weaning of young smokers using a transdermal nicotine patch. Schweiz Rundsch Med Prax 1991; **80(7):**145–150.
6. **Schwartz JL.** Review and evaluation of smoking cessation methods: the United States and Canada, 1978–1985. US Department of Health and Human Services. Public Health Service, National Institutes of Health. 1987: NIH Publication No. 87-2940.
7. **DeNelsky GY.** Smoking cessation: strategies that work. Cleve Clin J Med 1990; **57:**416–417.