CLINICAL INQUIRIES

What interventions can help patients stop using chewing tobacco?

■ Evidence-Based Answer

Nicotine replacement therapy (NRT), including gum and patches, decreases cravings and short-term abstinence rates, but does not improve long-term abstinence (strength of recommendation [SOR]: B, meta-analysis of small randomized controlled studies [RCT]).

It is unclear if bupropion has an effect on cessation rates (SOR: B, small RCTs with conflicting results). Behavioral interventions increase abstinence rates for smokeless tobacco users (SOR: B, meta-analysis of small RCTs).

■ Evidence Summary

Use of smokeless tobacco can lead to nicotine dependence and cause periodontal disease, leukoplakia, cancer, and possibly cardiovascular disease. ¹⁻³ Patients who abruptly stop using smokeless tobacco may experience withdrawal symptoms similar to that observed in smokers.³

Nicotine gum

A small double-blind study randomized 79 male smokeless tobacco users to chew nicotine gum (0 mg, 2 mg, or 4 mg) for 5 days.4 Sixty patients completed the study. No significant differences in withdrawal symptoms, including cravings, concentration, or restlessness, were noted among the 3 groups (P>.05). However, further analysis demonstrated that patients with high blood levels of cotinine who received nicotine gum 2 mg experienced decreased cravings compared with placebo (P<.001), and a trend towards decreased cravings with 4 mg gum was noted (P<.06). Limitations of this study: quit rates were not reported, participants did not have to be motivated to quit smokeless tobacco in order to enroll, and it is not known if patients were counseled about the appropriate "chew and park" technique for nicotine gum.

Another study randomized 234 male smokeless tobacco users to receive group behavioral treatment plus nicotine gum 2 mg (B/NRT); group behavioral treatment plus placebo (B/Pl); minimal contact plus nicotine gum 2 mg (MC/NRT); or

minimal contact plus placebo (MC/Pl).5

Group behavioral treatment consisted of 8 group counseling sessions 45 to 60 minutes in length; minimal contact involved 4 brief one-on-one sessions with a nurse. Patients chewed a minimum of 6 pieces of nicotine or placebo gum per day.

At 4 weeks, point prevalence abstinence rates were as follows: B/NRT, 63.6%; B/Pl, 66%; MC/NRT, 35.3%; and MC/Pl, 48.1% (P<.01). Abstinence rates remained significantly different at 1 and 6 month follow-ups, but not at 12 months. Post-hoc logistic regression favored group behavioral therapy plus NRT at 6 months. Moreover, survival analysis of continuous prevalence rates demonstrated that the least effective treatment was minimal contact plus NRT.

The authors theorized that nicotine gum may actually worsen risk of relapse in smokeless tobacco users due to behavioral similarities associated with use, but that behavioral treatment may help regain abstinence after a lapse. Gum users experienced lessened withdrawal symptoms including cravings, irritability, anxiety, and difficulty concentrating (*P*<.01). Results indicate that behavioral interventions may be more effective than NRT; however, low doses of nicotine gum were used.

Nicotine transdermal patches

A randomized double-blind study examined nicotine transdermal patches in smokeless tobacco users. Researchers recruited 422 participants from a Minnesota college campus and surrounding metropolitan area through advertisements; they were randomly assigned to nicotine patch plus mint snuff (a nicotine-free product), nicotine patch and no mint snuff, placebo patch plus mint snuff, or placebo patch and no mint snuff. The patch was dosed as 21-mg patch for 6 weeks, 14-mg patch for 2 weeks, and 7-mg patch for 2 weeks. All patients participated in 8 weekly individual 10-minute sessions with a therapist.

Continuous 10-week abstinence rates were 69% for nicotine patch and mint snuff, 58% for nicotine patch and no mint snuff, 46% for placebo patch and mint snuff, and 51% for placebo patch and no mint snuff (P=.002). After 15 weeks the abstinence rates were no longer different between the treatment groups. Patch users experienced lower total withdrawal scores (P=.002) as well as decreased craving (P<.001), irritability (P<.001), and restlessness (P=.019). Total with-

drawal scores were not improved for mint snuff users; however, subsets of total withdrawal scores were lower for cravings (P=.005), irritability (P=.046), and anxiety (P=.012).

Meta-analysis

The Cochrane Database of Systematic Reviews published a meta-analysis of 6 studies that examined NRT or bupropion in smokeless tobacco users.³ The primary outcome for the meta-analysis was tobacco abstinence 6 months or more after the intervention. Neither nicotine patches (odds ratio [OR]=1.16; 95% confidence interval [CI], 0.88–1.54) nor nicotine gum (OR=0.98; 95% CI, 0.59–1.63) were shown to improve abstinence over placebo at 6 months. The authors highlight the need for larger studies that compare different NRT products, doses, and duration.

One small randomized trial of bupropion was included, but it found no effect on tobacco abstention (OR=1.00; 95% CI, 0.23–4.37). Another small RCT found an effect; however, it was excluded from the meta-analysis because subjects were followed for only 3 months. The meta-analysis also concluded that behavioral interventions appear to be effective for increasing tobacco abstinence rates. Results were heterogeneous, and study quality was mixed. One post-hoc finding appeared to show that most effective behavioral interventions were coupled with an oral exam with direct feedback.

■ Recommendations from Others

The United States Department of Health and Human Services recommends that smokeless tobacco users should be treated with the same counseling and interventions utilized for smokers, but commented that evidence is currently insufficient to suggest that NRT increases long-term abstinence.⁷ British guidelines concluded that no evidence clearly shows that nicotine gum or patches are effective cessation aids for smokeless tobacco users.²

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■ Clinical Commentary

NRT not recommended for smokeless users; try bupropion, behavioral therapy

Smokeless tobacco users are a special tobacco user population with a limited research base. Although it seems counterintuitive, nicotine replacement therapy (nicotine gum and the nicotine patch) is not recommended for this population. Using the tobacco use and guit history, treatment may include bupropion while employing standard behavioral therapies: intratreatment social support, extra-treatment social support, and problem solving skills training. After setting a quit date, prepare the patient for the quit, and following the quit attempt focus on relapse prevention. Frequent follow-up visits provide intra-treatment social support and promotes development of extra-treatment (eg, telephone or computer based guit lines or individuals) social support while providing practical problem solving.

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