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Review of Nicotine nasal spray neither effective nor well-tolerated by adolescent smokers

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Nicotine nasal spray neither effective nor well-tolerated by adolescent smokers

Rubinstein ML, Benowitz NL, Auerback GM, Moscicki A. A randomized trial of nicotine nasal spray in adolescent smokers. Pediatrics 2008;122:e595-e600.

Question Among adolescent smokers who wanted to quit smoking, is nicotine nasal spray effective at increasing cessation rates?

Design Randomized, open-label, 12-week trial.

Setting Five San Francisco Bay Area high schools.

Participants Forty adolescents, ages 15 to 18 years of age, who smoked ≥5 cigarettes daily for at least 6 months.

Intervention Participants were assigned to receive either weekly counseling alone (control) for 8 weeks or 6 weeks of nicotine nasal spray along with 8 weeks of counseling.

Outcomes Self-reported smoking abstinence, as verified by both expired-air carbon monoxide and salivary cotinine levels.

Main Results There was no difference in cessation rates, the number of cigarettes smoked per day, or cotinine levels at 12 weeks. Fifty-seven percent of participants stopped using their spray after only 1 week. The most commonly reported adverse effect was nasal irritation and burning (34.8%), followed by complaints about the taste and smell (13%).

Conclusions The unpleasant adverse effects, poor adherence, and consequent lack of efficacy observed in this pilot study do not support the use of nicotine nasal spray as an adjunct to counseling for adolescent smokers who wish to quit.

Commentary This is an important and well-designed first study of the effect of nicotine nasal spray (NNS) on adolescent smoking cessation that supports current evidence-based guidelines that nicotine replacement therapy is neither effective nor recommended for adolescents.[1] NNS theoretically

could succeed for adolescents where other forms of nicotine replacement failed. Consistent with adolescent tobacco use patterns, potential benefits of NNS over other forms of nicotine replacement include the following: (1) NNS can be used intermittently, (2) in response to environmental influences, such as smoking to relieve stress, NNS has a relatively fast delivery of nicotine with reinforcing effects, and (3) compared with other forms of nicotine replacement, NNS allows greater self-control and ownership of the intervention, which adolescents prefer. Admirably, this study uses a validated nicotine dependence questionnaire for adolescents, a withdrawal symptom scale, biochemical validation of self-report, and an intention-to-treat analysis. Two noteworthy design limitations exist: First, this is an open-label trial without a placebo group. Second, although originally designed to be an effectiveness study, failure to meet sample size requirements forced the authors to truncate the study for feasibility. These limitations are relatively minor, however, because this study convincingly shows that NNS is not tolerated by adolescents. Although the delivery system holds promise for adolescent smokers, the negative side effects of the spray, in particular burning associated with use, led to such poor adherence that discussion of efficacy is moot. If future NNS preparations are better tolerated, this study deserves replication with adequate power to reexamine the issue of effectiveness for adolescents.

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REFERENCE

1. Fiore MC, Jaén CR, Baker TB, et al. Treating tobacco use and dependence: 2008 update. Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.