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Short Communication

Electronic cigarettes for adults with tobacco dependence enrolled in a tobacco treatment program: A pilot study

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HIGHLIGHTS

- Electronic cigarettes can be incorporated into a tobacco treatment program.
- Half of the smokers who quit cigarettes were using e-cigarettes at follow up.
- Low or zero strength nicotine e-liquids were preferred by some smokers.
- Behavioral cues of e-cigarettes were important for modifying smoking behavior.

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ABSTRACT

Introduction: Electronic cigarettes (ECs) have emerged as a potential harm-reducing alternative for tobacco smokers. However, the role ECs might play in treatment settings is unclear. We conducted an exploratory study of treatment-seeking smokers enrolling in a standard tobacco treatment program who were provided with either a nicotine or non-nicotine EC to use as needed to cease tobacco smoking.

Methods: Treatment-seeking smokers received standard tobacco treatment for 8 weeks and were given nicotine transdermal patch therapy, behavioral counseling, and either a nicotine or non-nicotine EC to use as needed. Smoking and EC use patterns were tracked longitudinally to week 24.

Results: 40 subjects were enrolled into the study. At week 24, 6 subjects (15%) were abstinent, and the mean reduction in reported cigarettes smoked per day was 6.8 ± 12. There were no significant differences in smoking outcomes between those who received a nicotine or non-nicotine EC (proportion abstinent at 24 weeks: nicotine EC = 4/20 (20%); non-nicotine EC = 2/20 (10%); p = 0.66). Among subjects assessed at follow-up, 62.5% were EC non-users.

Conclusions: The addition of a 2nd generation EC to outpatient tobacco treatment among tobacco smokers is feasible. Among those who quit smoking, half were still using the EC at 6-month follow-up. Appeal of the EC among smokers was variable, and those who had quit smoking tended to switch to lower strength nicotine solutions. Further research is needed to determine whether ECs can reduce harm and be an effective adjunct to existing tobacco treatment interventions.

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1. Introduction

Electronic cigarettes (EC) have emerged as an alternative for tobacco smokers. ECs may appeal to smokers because in addition to providing nicotine in an aerosolized and non-combustible form, the products allow users to mimic the rewarding behavioral patterns that reinforce smoking. EC use for treatment of tobacco dependence in adults is controversial, and evidence for EC efficacy in promoting cessation from tobacco smoking is limited. The most recent systematic review of the efficacy of ECs for smoking cessation found limited low-quality evidence of a trend toward smoking cessation in adults using nicotine ECs exists compared with other therapies or placebo (Baker, Piper, Stein, et al., 2016). Of note, the review found only 5 suitable studies (4 RCTs and 1 Controlled Pre-Post study) out of 569 total articles. The largest randomized controlled trial of ECs enrolled 657 smokers from a single center (Behar, Hua, & Talbot, 2015). While the investigators found no significant differences in 6-month abstinence rates between groups, significant reductions in average cigarette consumption were observed in the EC group as compared to the nicotine patch.

The use of an EC as part of a structured tobacco treatment program has not been adequately studied, and longitudinal effects of ECs on smoking behavior and pulmonary function have not been well characterized. We conducted a preliminary exploratory study of treatment-seeking smokers enrolling in an outpatient tobacco treatment program who were provided with either a nicotine or non-nicotine EC to use as needed to cease tobacco cigarette use. Our goals were: (Khoudigian, Devji, Lytvyn, et al., 2016) to establish the feasibility of adding an EC to outpatient tobacco treatment as part of a standard care regimen (Bullen, Howe, Laugesen, et al., 2013) to determine if there are differences in smoking behavior and lung function changes between individuals receiving nicotine versus non-nicotine containing ECs; (Miller, Crapo, Hankinson, et al., 2005) to characterize EC use patterns and perceptions in a real-world setting among treatment-seeking smokers; and (Farsalinos, Spyrou, Stefopoulos, et al., 2015), to generate hypotheses regarding potential benefits, risks, and challenges of introducing ECs into tobacco treatment settings.

2. Materials and methods

2.1. Participants

Participants were recruited from the Yale-New Haven Hospital outpatient pulmonary and primary care clinics, Tobacco Treatment Service, and through referrals from medical providers in the Yale-New Haven Health system. Inclusion criteria were (Khoudigian et al., 2016) Age 18 years or older; (Bullen et al., 2013) Smoking 1 or more tobacco cigarettes per day; (Miller et al., 2005) Willing to quit smoking. Exclusion criteria were: (1) Unstable psychiatric or medical conditions requiring hospitalization within the past 4 months; (Bullen et al., 2013) Acute coronary syndromes or stroke within the past 30 days; (Miller et al., 2005) History of allergic reactions to adhesives; (Farsalinos et al., 2015) Women who were pregnant, nursing, or not practicing effective contraception; (Robinson, Hensel, Morabito, et al., 2015) Current use of an EC for the purpose of stopping tobacco cigarette smoking.

2.2. Randomization

Participants were randomized using a random number generator with 1:1 blocked randomization (block size n = 8) to ensure equal numbers in each treatment group. Both groups received standard care (nicotine patch and counseling) and were randomized to: (Khoudigian et al., 2016) *nicotine EC* or (Bullen et al., 2013) *non-nicotine EC*. Treatment assignment was blinded to both the investigators and participants. This research was approved by the Yale University Institutional Review Board.

2.3. Treatment and assessment contacts

Questionnaire assessments and exhaled breath carbon monoxide (exCO) measurements occurred at baseline, bi-weekly at each scheduled treatment visit (week 2, 4, 6, 8), and follow-up (week 24). ExCO levels were measured using a Bedfont Micro + Smokerlyzer Monitor. Spirometry and fraction of exhaled nitric oxide (FeNO) were performed at baseline and 6-month follow-up using a Nspire Koko spirometer and NiOx Mino FeNO detector per American Thoracic Society guidelines (Benowitz, 2010). Subjects received nicotine patches and ECs for the first 8 weeks and were assessed every 2 weeks. This initial intervention was followed by a 16-week period of observation during which subjects were permitted to use any available therapies for tobacco treatment. Subjects were paid $25 at intake and $50 at 24-week follow-up to try to optimize recruitment and maximize study adherence and follow-up. The study had a modest loss to follow-up (20%) at week 24.

2.4. Standard treatment

All participants were asked to set a quit date within a week of their first study visit. Subjects who smoked > 10 cigarettes per day were initially given the 21 mg patch, and subjects who smoked 10 or fewer cigarettes per day were given the 14 mg patch. The dose of the medication was reduced if they were abstinent from tobacco and EC use, or if they reported difficulty tolerating higher doses due to side effects. If they continued smoking, were non-adherent, or were using the EC, the patch dose was not reduced (or was increased to 21 mg if they were started at a lower dose). All participants were given a two-week supply of nicotine patches at each study visit for the first 8 weeks of the study.

The initial study visit and each subsequent study visit consisted of intensive counseling sessions with an Advanced Practice Registered Nurse (APRN) behavioral tobacco treatment specialist or a clinical psychologist trained in motivational interviewing techniques and tobacco dependence pharmacotherapy.

2.5. Experimental conditions

Subjects were given a 2nd generation eGO style EC (650 mAh battery, EVOD clearomizer, 3.7 V, 1.8 Ω single bottom coil), provided with e-liquid purchased from an online vape shop (0 or 24 mg/ml nicotine strength, 70/30 propylene glycol/vegetable glycerin, tobacco flavor), and were instructed to use it as needed as a substitute for tobacco to try to satisfy cravings to smoke. If the patch alone proved adequate to prevent withdrawal and smoking cravings, the subject was advised not to use the EC. Use of the EC as a substitute for cigarette smoking was encouraged but not considered mandatory and was at the discretion of study subjects. Since EC use differs significantly from tobacco smoking (Bullen et al., 2013; Farsalinos et al., 2015; Khoudigian et al., 2016; Kotz, Brown, & West, 2014; PHS Guideline Update Panel La, and Staff, 2008), subjects were advised to take longer and slower puffs (i.e. 3–4 s per puff). Additional EC devices, replacement coils, and liquid were provided as needed for the first 8 weeks of the study.

2.6. Outcome measures

The primary outcome was the change in reported number of cigarettes smoked per day at weeks 8 and 24. Secondary outcomes were smoking status (defined by 7-day point prevalence abstinence and confirmed by exCO ≤ 6 ppm) at weeks 8 and 24, change in percent predicted FEV_1 and FVC from baseline to week 24, and EC use patterns.

2.7. Statistical analysis

SAS v9.4 was utilized for the statistical analyses. Descriptive statistics were calculated by group to determine if statistical differences existed between the nicotine and non-nicotine EC participants. For