Electronic cigarettes: navigating the vapor

Andrew S. Nickels, MD; Avni Y. Joshi, MD; and Chitra Dinakar, MD

1 Division of Allergic Diseases, Department of Internal Medicine, Mayo Clinic, Rochester, Minnesota
2 Division of Allergy and Immunology, Department of Pediatrics, Mayo Clinic, Rochester, Minnesota

Electronic cigarettes are electronic nicotine delivery systems that have the potential to drastically change the landscape of nicotine addiction and tobacco use. Their increasing popularity has raised concerns that e-Cigarettes might undercut the gains associated with tobacco cessation efforts and limits on public use and advertising. Particularly worrisome is the increasing use of e-Cigarettes in youth. The goal of this piece is to introduce the reader to e-Cigarettes, describe safety concerns and the limited evidence supporting potential benefits, and discuss pertinent regulatory issues. The authors conclude by suggesting proactive responses that medical professionals can take regarding this developing issue.

Introduction

Electronic cigarettes (e-Cigarettes) are novel nicotine delivery systems that have the potential to drastically change the landscape of nicotine addiction and tobacco use. Their increasing popularity has raised concerns that e-Cigarettes might undercut the gains associated with tobacco cessation efforts and limits on public use and advertising. Particularly worrisome is the increasing use of e-Cigarettes in youth. The goal of this piece is to introduce the reader to e-Cigarettes, describe safety concerns and the limited evidence supporting potential benefits, and discuss pertinent regulatory issues. The authors conclude by suggesting proactive responses that medical professionals can take regarding this developing issue.

Electronic Cigarettes

Electronic cigarettes are electronic nicotine delivery systems that have a similar look and handheld feel of traditional cigarettes. They have 3 essential components: a liquid cartridge, an atomizer, and a battery (Fig 1). The liquid typically contains varying concentrations of nicotine and flavoring dissolved in propylene glycol and water. Nicotine-free liquids also are available. Flavors include tobacco, menthol, and different fruit flavors. In contrast to the combustion of tobacco into smoke, e-Cigarettes achieve nicotine delivery by heating the liquid into an inhalable vapor. As such, the use of e-Cigarettes is often referred to as “vaping.” Some brands contain disposable batteries, whereas others can be recharged using a USB port. Disposable e-Cigarettes last for approximately the same time as 2 packs of traditional cigarettes, and the rechargeable ones last for a slightly shorter time. The popularity of e-Cigarettes has grown steadily since their introduction to the US market in 2007, with sales projected to reach $1.7 billion in 2013. Another sign of growing popularity is that Internet searches for the terms e-Cigarettes and vaping are steadily increasing, as reflected by Google search data (Fig 2).

Nicotine delivery by e-Cigarettes is variable and incompletely understood. Studies measuring levels of plasma nicotine and/or craving have shown disparate results ranging from no nicotine delivery to levels similar to traditional smoking. Analysis of nicotine delivery using a respiratory tract model has suggested 7% to 18% alveolar delivery, 9% to 19% venous absorption (mostly through oral mucosa), and 73% to 80% loss by exhalation. These preliminary reports suggest that inconsistencies among products and vaping techniques can undermine effective nicotine delivery. This might affect their utility as a nicotine replacement intervention.

Anticipated Benefits

The anticipated benefits of e-Cigarettes are 2-fold. First, e-Cigarettes might be a useful tobacco cessation tool, similar to other nicotine replacements agents (gums, patches, etc). Bullen et al performed a randomized trial of 657 participants comparing e-Cigarettes (16 mg/mL) with nicotine patches (21 mg/24 hours) and nicotine-free e-Cigarettes. Analyzed with an intention to treat, the primary outcome of continuous smoking abstinence at 6 months (measured by self-reporting and certified by exhaled carbon monoxide) did not show a statistically significant improvement in abstinence rates (7.3%) compared with the placebo e-Cigarettes (4.1%) or the patch (5.8%). Using a post hoc analysis with 5% non-inferiority limits, the investigators claimed that nicotine e-Cigarettes “might be as effective as patches for achieving cessation at 6 months” and concluded e-Cigarettes are “modestly” beneficial in smoking cessation. Unfortunately, the study was underpowered to evaluate the superiority of nicotine e-Cigarettes given the relatively low abstinence rates. Despite the paucity of evidence for efficacy, several survey-based studies have reported that a large number of e-Cigarette users use them to aid in smoking cessation, suggesting a significant level of therapeutic optimism is present in active users.
The second potential benefit lies in the “harm-reduction” model, which suggests that current smokers will benefit from any decrease in tobacco smoke exposure and e-Cigarettes provide a “safer” form of nicotine. In the randomized trial described above, e-Cigarette users had a larger decrease in cigarettes consumed per day compared with the patch at 6 months, at 9.7 fewer cigarettes per day vs 7.7 cigarettes per day, respectively (P = .002). Another trial investigating the use of e-Cigarettes, with and without nicotine, by 300 smokers who did not intend to quit showed a decrease in the number of cigarettes smoked per day at all visits up to end of the trial at 52 weeks. Most studies supporting e-Cigarette use are survey based and are limited by convenience sampling, social desirability, and response rate biases. As highlighted in a recent editorial, “there clearly is a need for a multicenter clinical trial of the value of e-cigarettes in smoking cessation programs, documenting nicotine capsule consumption, serum concentration of metabolic products such as cotinine, markers of systemic and airway inflammation, and rates of smoking recidivism.”

Figure 1. Simple anatomy of the electronic cigarette. Used with permission of the Mayo Foundation for Medical Education and Research, all rights reserved.

Safety Concerns and Unintended Consequences

Although there is considerable evidence about the addictive potential of nicotine, the safety data regarding e-Cigarette use are limited. According to the US Food and Drug Administration (FDA), “As the safety and efficacy of e-Cigarettes have not been fully studied, consumers of e-Cigarette products currently have no way of knowing whether e-Cigarettes are safe for their intended use, how much nicotine or other potentially harmful chemicals are being inhaled during use, or if there are any benefits associated with using these products.” FDA evaluations of 2 brands of e-Cigarettes found low levels of tobacco-specific carcinogenic nitrosamines and other impurities. Diethylene glycol, a component of antifreeze, was found in 1 product. Metals, silicate beads, and nanoparticles also were found in the aerosolized product.

More than just user safety, the reintroduction of nicotine-containing products for use in public might undermine this progress made by previous smoking bans and produce a new generation of nicotine dependence. An analysis of the 2011 and 2012 National Youth Tobacco Survey by the Centers for Disease Control and Prevention reported a doubling of e-Cigarette use and experimentation related to increased exposure to pro-tobacco advertising. In middle school and high school students, “ever use” of e-Cigarette use increased from 1.4% to 2.7% (P < .05) and from 4.7% to 10.0% (P < .05) in 2011 and 2012, respectively. Overall, 6.8% of students had tried e-Cigarettes as of 2012. The lack of regulation in e-Cigarette marketing renders impressionable adolescents vulnerable to its appeal, and the availability in a variety of flavors, such as peach schnapps, java jolt, piña colada, peppermint, and chocolate, makes it alluring to children. Fairchild et al articulated this concern well: “If e-Cigarettes prove to be a ‘gateway’ or ‘bridge’ product, leading to an increase in underage smoking, that would represent a serious setback in the fight against tobacco-related illness.” Even more concerning is that a vulnerable younger generation might model a behavior of dual use of traditional cigarettes and e-Cigarettes. Also disheartening is that patients with asthma might continue to be

Figure 2. Google Trends: normalized search frequency worldwide—electronic cigarettes and vaping. Search frequency, normalized for regional variation by Google Trends, suggests a striking increase in Internet queries for electronic cigarettes and vaping.
exposed to secondhand smoke in the homes of nicotine-dependent e-Cigarette users. The unintended consequences of the harm-reduction model deserve further exploration.

Regulatory Affairs

The current US federal regulatory and legislative status of e-Cigarettes is quite lax; there are neither federal prohibitions on distributors’ ability to sell or advertise nor laws prohibiting the public use of these products. In 2009, the FDA banned imports of e-Cigarettes, claiming they met the definition of a combination drug-device product under the Federal Food, Drug, and Cosmetic Act. E-Cigarette manufacturers were granted an injunction in the US District Court for the District of Columbia, which was upheld in the Federal Appeals Court.19 The higher court recommended regulation of e-Cigarettes under the Family Smoking Prevention and Tobacco Control Act of 2009 using the FDA Center for Tobacco Products, which regulates other tobacco products. Central to the case is the nuanced position that e-Cigarettes are an alternative product to traditional cigarettes and not intended for a therapeutic use such as smoking cessation.

Currently, local governments are responsible for legislating limits on e-Cigarettes, as exemplified by New York City’s ban on e-Cigarette use in public places, including restaurants. Many states have banned sales to minors, and institutions such as the Mayo Clinic have banned e-Cigarette use across their premises. Nevertheless, e-Cigarettes continue to be marketed as a way to smoke in “smoke-free” places. Cognizant of these issues and challenges, national organizations such as the American College of Allergy, Asthma, and Immunology are advocating for enhanced scrutiny and regulation by the FDA. In their statement, the American College of Allergy, Asthma, and Immunology “recognizes that nicotine delivered by any mechanism represents a drug exposure, and that vaporization instruments are a drug delivery system, both of which are within the Federal Drug Agency’s scope of regulation.”20 Although regulatory scrutiny will help minimize safety and efficacy concerns, it might lead to less competition and fewer products on the market, thus potentially adversely affecting potential harm reduction and cessation efforts. Knowing the appropriate balance to strike is difficult and is currently being rigorously debated.

Navigating the Vapor

Electronic cigarettes are rapidly changing the landscape of nicotine addiction. It is critical that the medical community takes an active role in assessing and educating themselves on the effects of e-Cigarettes to help shape public opinion on this important issue. Existing data are scant, and the issues of quality, publication bias, and conflict of interests should be considered. With the long-term safety profile and efficacy related to e-Cigarettes use unclear, allergists would be wise to be aware of potential errors of therapeutic optimism and continue to educate themselves on this new phenomenon. They should address tobacco use/nicotine addiction and alternative smoking cessation resources with all patients. Advocating for regulatory oversight by federal agencies and legislation that restricts the advertising and use of e-Cigarettes in public should be encouraged. Research on the efficacy and safety of e-Cigarettes should be actively pursued and promoted.

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References