Two case reports of smoking behavior changes after self-initiated e-cigarette use and tobacco smoking cessation

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ABSTRACT

Objective: The purpose of this report is to increase the clinician's understanding of electronic nicotine-delivery systems (ENDS) by describing similar observations of two subjects "forgetting" to use self-initiated ENDS.

Observations: A 51 year old Caucasian female with severe persistent mental illness reported continued tobacco abstinence and "forgetting" to use the ENDS at week 24 and continued tobacco abstinence beyond week 52. Also, a 42 year old Caucasian healthy male with continued tobacco abstinence and "forgetting" to use the ENDS after approximately 14 weeks remained abstinent of conventional cigarettes beyond 52 weeks.

Discussion: ENDS do not continually produce smoke like conventional cigarettes; the absence of continuous smoke may not compel the user to continue inhaling. ENDS differ from conventional cigarettes because of the on-off feature of the device, requiring the user to inhale to activate a battery-powered nicotine delivery system (atomizer).

Conclusion: Additional research is needed to verify the impact of ENDS on smoking behavior in smoking cessation. Clinicians should monitor but not yet recommend the initial use of ENDS for smoking cessation until the FDA imposes regulations on ENDS companies to ensure consistency of labeling of ingredient amounts and the overall safety of the products.

KEYWORDS

smoking, mental health, smoking cessation, electronic nicotine-delivery systems

INTRODUCTION

Reports of patients using electronic nicotine-delivery systems (ENDS) or e-cigarettes ("vaping" as described on the street) to quit smoking is becoming more common in mental health practices and public settings. In April of 2012, an ENDS company (FIN Electronic Cigarettes) launched a number of full page advertisements in Rolling Stone Magazine welcoming back smokers to use ENDS in public places (e.g., bowling alleys, bars, restaurants, etc.).[1] This coincides with increasing reports of people ignoring "no smoking" signs with ENDS. Anecdotally, a patient recently participating in the author's Assertive Community Treatment (ACT) smoking cessation group, stated that he recently started using "e-cigarettes" and was not prevented from "vaping" during his admission on a "smoke free" inpatient psychiatry unit. Since patients with severe persistent mental illness (SPMI) have high rates of nicotine dependence and a 25-year decreased life span, clinicians should be aware of the potential of ENDS use in the psychiatric population.

ENDS were first patented in the United States in 1963.[2] Four decades later, a Chinese pharmacist patented and introduced ENDS to the Chinese market through a company called Ruyan (meaning "almost like smoke").[3] Currently, the popularity of ENDS has increased since they were introduced in the United States.

Between 2008 and 2010, the FDA attempted to block importation of ENDS because it was an unapproved drug/device combination for smoking cessation use. Based upon a decision by the U.S. Court of Appeals for the D.C. Circuit in ***Soterra, Inc. v. Food & Drug Administration,*** it was decided that ENDS: 1) are not drugs/devices unless marketed for therapeutic purposes, 2) can be regulated as "tobacco products" under the "Tobacco Control Act", and 3) can be subjected to controls such as ingredient listing, etc.[4] Some ENDS

Table 1. Comparison of electronic nicotine-delivery systems.

Convenience	Nicotine Strengths	Propylene glycol (PG) and Glycerol (VG)	Flavors	Estimated $ Costs
Disposable, single use battery, one piece design	Low = 12mg Med = 18mg High = 24mg	Primarily PG but VG concentrations can be variable	Menthol Tobacco Coffee Vanilla	price ranges $6 - $12
Rechargeable, with pre-filled cartridges	0 mg, 6 mg, 12 mg, 18 mg, 24 mg, 32 mg	Primarily PG but VG concentrations can be variable	Many varieties	Starter kit (price ranges $20 - $80)
Two piece design: (most popular) **1) Rechargeable Battery** **2) Self-fill Cartomizer (combined reusable atomizer and cartridge)** **Cartomizers (Needs replacing after 5-6 uses)**	Customizable concentrations from zero to 48mg strengths Cartomizers sizes: X (0.8 mL), XL (1.6 mL), XXL (2.5 mL) and Mega (5 mL)	Customizable concentrations of propylene glycol (PG) and vegetable glycerin (VG) (i.e., 0% VG, 10% VG, 20% VG, 30% VG, or 100% PG)	Many varieties	$10 - $25 rechargeable battery ("Manual" activated or "Automatic" – inhalation activated) $7 - $17 per ounce of various solutions $7 - $10 for five cartomizers $1.50 - $3 for one cartomizer
Three piece design: (more economical) **1) Rechargeable Battery** **2) Atomizer (Requires cleaning and may last for about 1 month of use or 40 mL of e-liquid)** **2) Self-filled "blank" cartridges attached to the atomizer**	Customizable concentrations from zero to 48mg strengths Variety of sizes/options: (e.g., standard (1 mL), large (7 mL), e-cigar, e-pipe)	Customizable concentrations of propylene glycol (PG) and vegetable glycerin (VG) (ie., 0% VG, 10% VG, 20% VG, 30% VG, or 100% PG)	Many varieties	$10 - $25 rechargeable battery ("Manual" activated or "Automatic" – inhalation activated) $7 - $17 per ounce of various solutions $7 - $10 for one atomizer

companies are providing ingredient information possibly in anticipation of future regulations; but none are allowed to market them as smoking cessation devices.

Most ENDS companies provide a variety of options to attract new users. Most ENDS are a two-piece design consisting of a battery that is screwed into an atomizer or cartomizer (combined atomizer and cartridge). The user can either purchase or obtain a free on-line trial of a prefilled disposable ENDS atomizer in various nicotine strengths and flavors (See Table 1). Another option is to purchase a starter kit with a reusable atomizer and a limited quantity of attachable prefilled cartridges or cartomizers (additional pre-filled cartridges or cartomizers must be purchased separately) and accessories (e.g., rechargeable batteries, recharging cases with a USB cable or 3-prong outlet receptacle). There are many options to consider when selecting a rechargeable battery such as physical size, battery life, manual or automatic. An automatic rechargeable battery is activated when the END user inhales whereas the manual battery utilizes a switch or "button" which is activated by the END user.

The most economical option is to purchase a rechargeable battery, bulk quantities of various flavors with zero nicotine, a one fluid ounce bottle of plain "e-liquid" ("juice") of the desired nicotine strength (6mg, 12mg, etc.), and depending on the atomizer, quantities of reusable empty cartridges or cartomizers. The cost savings is due to the ENDS user's ability to dilute an e-liquid to the preferred nicotine strength. For example, if the user wants a 12 mg strength cartridge for "vaping", a 50:50 solution of a non-nicotine flavor vehicle and 24 mg nicotine "e-liquid" would be required. A "drip tip" is an accessory that makes it easier for the ENDS user to fill cartridges. Typically, it takes about 15-20 drops (20 drops = 1 mL) to fill a standard size cartridge.

In addition to modifying the flavors and amount of nicotine, the user can customize the concentration of propylene glycol (PG) and vegetable glycerin (VG) to improve the experience or mimic regular cigarettes

("analogs"). The primary ingredient, propylene glycol (PG), gives the user the oral sensation of smoke called the "throat hit" and the vegetable glycerin (VG) produces the visible vapor ("smoke") and the "smoke-like" feeling in the lungs.

An ENDS cartridge (0.9 mL) is equivalent to one pack of "analog" cigarettes (approximately 300 inhalations/ ENDS cartridge). Most ENDS manufacturers recommend that the user "prime" the ENDS with about 6 – 10 inhalations after replacing a cartridge or cartomizer. Although unverified, it is estimated that approximately 10 inhalations on an ENDS with a 36 mg cartridge is equivalent to one cigarette (approx. 1.2 mg nicotine/ cigarette).

The purpose of this report is to increase the clinician's understanding of ENDS by describing similar observations of two subjects "forgetting" to use self-initiated ENDS during nine months of smoking tobacco abstinence. Case 1 was seen in a mental health clinical setting and case 2 was seen in a non-clinical setting. Each participant consented to allow their case to be discussed.

CASE REPORTS

Case 1

The patient is a 51 year old Caucasian female who was referred to the psychiatric pharmacist for comprehensive medication management due to elevated liver enzymes and polypharmacy. At the time of her initial visit (April 19, 2011), she was severely depressed (PHQ-9 =24) and had suicidal ideations. Her Axis I diagnoses included bipolar I disorder, anxiety disorder NOS, and recent adjustment disorder (bereavement) along with alcohol dependency in remission, and tobacco dependency. Her past medical history included obesity, type II diabetes mellitus, coronary artery disease, hyperlipidemia, esophageal reflux, peptic ulcer disease, gastritis, myopia including astigmatism, adrenal nodules, and fatty liver.

The patient's social history consists of nine years of sobriety from alcohol and a 40 pack-year history. The patient's medications at the initial visit were: fluoxetine 20 mg/day, divalproex sodium 500 mg TID, loxapine 10 mg TID, mirtazapine 60 mg HS, clonazepam 1 mg TID, benztropine 1 mg QID, esomeprazole 40 mg daily, colesevelam 1875 mg BID, nitroglycerin 0.4 mg PRN, Lantus 90 units AM/86 units PM, aspirin 81 mg HS, fluticasone nasal inhaler PRN, and lisinopril 30 mg AM. Most recent labs on 4/6/11 included: ALT 43 (5-31 IU/L), AST 37 (10-40 IU/L), and valproic acid 45 mcg/mL (50-150 mcg/mL).

One of the subject's drug therapy problems included "unnecessary drug therapy" for tobacco smoking. The following time periods (number of weeks prior to and after date of smoking cessation) are the pharmacist's follow-up visits focusing on smoking cessation:

Week -8: Eight weeks prior to quit date, the subject disclosed her desire to quit smoking and was prescribed nicotine replacement therapy (nicotine patches (21mg/14mg/7mg) and nicotine lozenges 2mg to use as directed by her primary care provider (PCP). Her cigarette use had increased to 1.5 to 2 ppd. She was instructed on diet control, initiating weekly food logs, and setting a smoking quit date by the next visit in 2 weeks.

Week -6: The subject set a tobacco cessation quit date for July 4, 2011 and was given instructions to initiate the nicotine replacement therapy on her quit date. She was also counseled on diet control and how to prepare for smoking cessation.

Week -4: The subject had decreased her cigarette smoking back to 1.5 ppd after having chest pain that she thought was stress-related. The subject was educated on diet, exercise, and preparing for the quit date.

Week -2: The subject reports smoking less than 1.5 ppd.

Week 0: The subject described quitting smoking one day prior to her original quit date, because she purchased and started using an ENDS along with one nicotine lozenge per day. She stated that the nicotine patch "fell off" so she discontinued it. She reported using one ENDS cartridge/day (1.6% per mL or 16 mg nicotine) which is equivalent to 200 puffs/24 hours or a pack of cigarettes. She was educated to monitor for nicotine side effects and her diet and exercise regimen were discussed.

Week 3: The subject reported using one ENDS cartridge daily and not smoking cigarettes.

Week 6: The subject reported not smoking cigarettes and decreased her use of ENDS from a 1 ppd conventional equivalence (1 cartridge/day) to about 4 times a day (3 cartridges/week) as needed and using one nicotine lozenge per week.

Week 26: In November, the ENDS malfunctioned but she continued to use the nonworking e-cig as a "pacifier." In December she purchased a new ENDS and was using approximately 3 ENDS cartridges per week. In January she described that her ENDS use had decreased again and she sometimes "forgot" to use the ENDS. She denied using tobacco cigarettes for the past 4 months. No nicotine lozenges were needed.

Week 35: She denied smoking for the past 6 months and again used an inoperable ENDS pretending it was a cigarette. She denied tobacco craving. She claimed to have gained 35 lbs of body weight since the start of smoking cessation.

Week 40: Recent stressors (sick pet) caused her to restart using the ENDS again at about 3 cartridges of the 16 mg nicotine per week. She continued to deny using tobacco cigarettes.

Week 52 and currently: The patient complained of increasing depressive symptoms and stated she has been using about 1 cartridge per day for the past month; she denies any tobacco cigarette use.

Case 2

Patient is a 42 year-old Caucasian male with no psychiatric or medical diagnosis who was interviewed (see YouTube® Video Ecigarette Interview.mp4) about his ENDS use in December 2011. The subject reported a 15 pack-year history. He had a 2 year period of abstinence (without nicotine replacement) but then relapsed and continued smoking for another 10 years until July 2011. During his second attempt of abstinence, he was non-adherent with prescribed bupropion and nicotine patches, stating that he would "forget" to use them but felt that their mere presence helped him "psychologically." His smoking habits included triggers such as driving, work, and eating. He smoked an average of about 1 ppd. The subject decided to use ENDS after talking to other ENDS users and trying a friend's device. He considered varenicline but feared the side effects. He was smoking American Spirit cigarettes at $6.50 per pack compared to a self-filled ENDS cartridge (equivalent to 1 pack) at $1.80 each.

Week 0: Subject started using 18 mg (full strength) cartridges and purchased 15 cartridges of assorted flavors (menthol, cola, cherry, and vanilla). Upon initial use, he described the 18 mg cartridge as having too much nicotine at first, but then, he was able to tolerate it over time. The 15 cartridges lasted for 15 days.

Week 2: Subject decreased the nicotine strength to the medium strength (12 mg) cartridges (menthol/vanilla) for the next 40 days (40 cartridges).

Week 8: Subject decreased the nicotine strength to the light strength (6 mg) nicotine for 40 days. During the nicotine reduction he had increased stress (loss of pet) but tolerated the reduction.

Week 14: Subject decreased the nicotine strength to zero mg. He started pre-filling the zero nicotine cartridges with various flavors. After about 1-2 weeks of using the zero strength cartridges, his cravings subsided and he began to "forget" to use the ENDS.

Week 36: Denied regular tobacco use and uses ENDS (zero mg nicotine) occasionally when associating with other smokers or when he feels nicotine craving.

Week 52 and currently: Only intermittent ENDS use but no tobacco cigarette use.

DISCUSSION

Although the two cases were not matched for gender, diagnoses, and smoking history, both cases quit smoking conventional cigarettes using ENDS. Interestingly in both cases, the episodes of intermittent "forgetting" and then restarting the ENDS seemed consistent. These "forgetting" episodes started to emerge for both subjects sometime around weeks 26 (case 1) and 14 (case 2) of consistent ENDS use. Prior to the "forgetting" episodes both subject cases were at zero nicotine for approximately four weeks. For example, case 1 began using an inoperable ENDS and case 2 tapered down to a zero nicotine cartridge. Also, both restarted using ENDS when encountering stress (case 1) or triggers (case 2). The restarting of ENDS use after an extended abstinence is not surprising since smoking behaviors can be triggered by internal cues such as boredom, stress, depression, or other somatic reasons such as appetite and weight gain.[5,6]

There were no reports of side-effects to the ENDS in either subject case. However, case 2 described the following as a side-effect (see YouTube® Video). "...When you light a cigarette, you smoke it, you put it out...there is a start, middle, and end...with ENDS there is no end to it...I can hold it in my hand...without pressure to finish it...as a result, I smoke less." The "side-effect" described by case 2 could be more accurately described as a modification of smoking behavior resulting in the episodes of "forgetting" to use ENDS. Since ENDS do not continually produce smoke like conventional cigarettes, the absence of continuous smoke may not compel the user to continue inhaling. ENDS differ from conventional cigarettes because of the on-off feature of the device, requiring the user to either manually activate the ENDS or inhale to activate an automatic battery powered nicotine delivery system (atomizer/cartomizer). In addition, the ENDS user would need to remember to initially "prime" the ENDS and then continue to inhale at least 10 – 15 times to approximate the nicotine levels equivalent to an "analog" cigarette.

Also, Case 2 slowly self-tapered his ENDS nicotine exposure from 18 mg, 12 mg, 6 mg, and then zero

nicotine by week 14. Compared to other tobacco products, ENDS appears to be the only tobacco product that allows the user to select, increase or taper down nicotine exposure.

There is compelling evidence that lower nicotine levels might facilitate smoking cessation and may provide a clue to why ENDS may be effective. A study conducted by Hatsukami et al. determined that low yield (0.05 mg) nicotine cigarettes were associated with a significant decrease ($p<0.05$) in craving and withdrawal symptoms and an almost significant ($p=0.0508$) higher rate of smoking cessation compared to the nicotine lozenge or higher nicotine strength cigarette.[7] However, there are no studies comparing low yield nicotine cigarettes and ENDS in reducing craving, withdrawal, and increasing smoking cessation. In summary, the characteristics of ENDS may be important; since, changing or modifying triggers of smoking behavior and stepwise nicotine dose reductions with NRTs are common smoking cessation strategies.[8]

With regards to safety, the FDA has issued a strong warning that ENDS may contain toxic substances and may be an entry for youth to experiment and become dependent on other tobacco products such as conventional cigarettes.[4] Although there have been published reports of toxic substances in ENDS, there is little published evidence of increased ENDS use among adolescents at this time.[9] In a summary statement by the FDA, analyses of two products (Njoy e-cigarette and Smoking Everywhere Electronic Cigarettes) determined that both products had similar amounts of nitrosamides (carcinogens) compared to the nicotine inhaler (10 mg cartridge) control. In addition, the two ENDS products had significantly lower amounts of nitrosamides than tobacco cigarettes, and the release of nicotine from the ENDS were variable with each puff (27-43 ug nicotine/100 ml puff). Some of the cartridges labeled "no nicotine" contained small amounts of nicotine; one (Smoking Everywhere Electronic Cigarette) cartridge contained 1% diethylene glycol.[4]

A review by Etter et.al described conflicts of interest in non-clinical trials and summarized mixed safety findings associated with ENDS. For example, a private study funded by an ENDS manufacturer confirmed the nicotine levels as labeled on the cartridges; a study of a Japanese brand of ENDS found small amounts of aldehydes (formaldehyde) that was much less than tobacco cigarettes and suggested testing ENDS vapor for acrolein, a pulmonary irritant and byproduct of super-heated glycerol.[10]

Although not reported by the described case, additional potential danger of a glycerol additive is exemplified in two cases. The first published case consists of a 42 year-old female who was admitted to the hospital with symptoms of dyspnea, productive cough, and fevers after starting ENDS seven months prior; she was diagnosed with lipoid pneumonia.[11] It was thought that chronic inhalation of an oil-based substance (glycerol) was the cause of the lipoid pneumonia. The second case was an unpublished case report submitted to Medwatch regarding a 51 year-old female recently diagnosed with lung cancer who reported consistent coughing similar to an "asthma attack" related to the use of an ENDS over a period of 3 weeks. She was using an ENDS product (24 mg nicotine) that contained a glycerol additive distributed by www.acleancigarette.com. She was instructed to discontinue the product and follow-up in clinic. Although there may be less tobacco-related carcinogens compared to cigarettes, other ingredients (e.g., glycerol) may cause health risks.

The lack of independent and unbiased validity of ENDS ingredients adds to the confusion and controversy. Not all ENDS companies include glycerol in the ingredient listing. Some companies allow users to choose the glycerol (vegetable glycerine (VG) and the propylene glycol (PG) concentrations (http://www.tastyvapor.us/atomic-cinnacide-p-88.html). ENDS companies provide product information ranging from no ingredient information to ingredient batch verifications for nicotine cartridges. For example, case 1 used a brand of ENDS known as 21st Century (http://www.21stcenturysmoke.com/products) with 1.6% per mL nicotine (16 mg), which does provide an ingredient listing (100% of nicotine derived from tobacco plants, water, 20% vegetable glycerin, 80% propylene glycol, and flavoring) but no quality controls. Case 2 used an ENDS brand known as "V-2cigs" http://www.v2cigs.com/ which provides an ingredient list (see table 2) and allows the user to verify ingredients online by entering the batch number of the cartridge.

CONCLUSION

Treatment of nicotine dependency continues to present with significant challenges to the clinician providing smoking cessation therapy. In mental health settings, limitations include treatment contraindications (depression/suicidality), adverse reactions to medication interventions, and non-adherence, which can lead to treatment failures even with combinations of first-line FDA-approved pharmacologic therapies. Currently, there is little guidance or step-wise therapeutic approaches for

Table 2. Ingredients in V-2cigs.

Ingredients	% by Volume
Vanilla Extract	12
Linalool	12
2,3,5-Trimethylpyrazine	12
Menthol	1
1-Malic Acid	0.8
Beta-Damascenone	0.2
Acetylpyrazine	0.5
Tabanone	0.3
Vanilla	1.5
Ethylacetate	0.5
Ethyl maltol	0.5
Propylene Glycol	70.4

clinicians when first and second-line therapies are contraindicated or have been tried and exhausted. Multiple failed attempts at smoking cessation can be discouraging to both the patient and the healthcare provider as well. ENDS may appear to change smoking behaviors and allow patients to self-taper nicotine doses, which could be attributed to why they may be effective for smoking cessation. If all smoking cessation methods fail, the clinician may carefully suggest ENDS but notify the patient that they are not FDA recommended. The clinician should also educate the patient that they need to be aware that approximately 10-15 inhalations are equivalent to one cigarette and they should discontinue if they experience any lung or throat irritation.

In summary, clinicians need to be aware that patients may be tempted to try alternative means such as ENDS to stop smoking as described in the above cases. Therefore, when obtaining a medication history or assessing patients for smoking cessation, inquiry about the use of Smokeless Tobacco Products (STPs) or ENDS should include: 1) the use of pre-filled or self-filled cartridges and the concentration of the nicotine contained in the ENDS cartridge; 2) the daily frequency of ENDS use; 3) the ENDS ingredient list (check for the presence of glycerol); and 4) the name of the ENDS manufacturer in the event that an adverse reaction occurs. Any adverse reactions should be submitted to the FDA via the FDA's MedWatch Online Voluntary reporting form (3500) https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm. Also, clinicians should prohibit ENDS use in the hospital setting and caution patients about possible nicotine toxicity if combining NRTs, cigarettes, smokeless tobacco products (STPs), and/or ENDS.

Although some ENDS companies have been somewhat proactive in providing quality assurance and ingredient lists to counter the negative reviews from the FDA, these ingredient lists should be validated by independent sources. In the meantime, clinicians should monitor patients who self-initiate ENDS as a potential harm-reduction strategy for smoking cessation, especially in patients who have failed FDA-approved smoking cessation therapies. Clinicians should be careful not to widely recommend ENDS as first or second line treatment for smoking cessation, until the FDA imposes regulations on ENDS companies to ensure consistency of labeling of ingredient amounts and the overall safety of the products.

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