

Category 1 assessment of opioid vaping: A focus of FDA Advisory Committee interest

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Abstract

Aims: The use of e-cigarettes for administration of nicotine and cannabis products has become widespread in the United States and there are reports of their use for other drug classes, too. This commentary evaluates the potential use of e-cigarette devices as an alternate means of opioid administration.

Commentary: The success of vaping devices for the delivery of nicotine vapor for inhalation has been substantial and the technology has improved markedly since its introduction in 2007. Inhalation provides rapid delivery of drug to blood and brain and may result in immediate reinforcing effects contributing to its abuse potential. Because these e-cigarette devices operate below combustion temperatures, the production of toxic components is reduced or eliminated. Vaping devices with similar features as e-cigarettes have also been developed and broadly used for vaping cannabis products. Additionally, there have been limited attempts to adapt vaping devices for delivery of psychoactive drugs such as synthetic cannabinoids, psychostimulants, and opioids. The success of these attempts will depend in large measure on the characteristics of the vaping device and the physicochemical properties of the drug of interest.

Typically, e-cigarettes are designed to vaporize liquids comprised of drugs dissolved in propylene glycol and glycerin. Drug potency, solubility, chemical form (salt or base), and vapor pressure are key elements in determining success of drug delivery by vaporization or aerosolization. Numerous Internet postings and several publications have indicated apparent success in use of e-cigarettes for vaping opioids; however, current prevalence appears low compared to other recreational drugs (e.g., cannabis).

Conclusions: The use of e-cigarettes for vaping opioids appears to be primarily in the "experimental" stage by drug abusers. Recent queries by FDA Advisory Committee members regarding the potential for vaping opioids suggest that further research and evaluation of vaping opioid products should be conducted as part of Category 1 assessments.

Introduction

While use of e-cigarettes is intended for the delivery of nicotine, concern has been raised that the devices could potentially be used to administer drugs other than nicotine, particularly given the ability of newer e-cigarettes to regulate evaporation temperature (Blundell et al., 2017). Use of vaping devices for the administration of various forms of cannabis (herbal material, extracts, and concentrates) has been shown to be a highly efficient drug delivery method (Abrams et al., 2007).

Some laboratory studies with rodents have reported success with other drug classes (e.g., methamphetamine, methylenedioxypyrovalerone [aka MDPV], alpha-Pyrrolidinopentiophenone [aka alpha-PVP]; Marusich et al., 2016). Queries and attempts to vaporize oxycodone with e-cigarette devices have been reported on the Internet, but successful outcomes have been uncertain. Importantly, similar questions have been posed by FDA Advisory Committee members regarding the potential for vaping opioids. To address the uncertainty of e-cigarette devices to successfully deliver opioids, a laboratory model was developed and tested with oxycodone. Because most opioid formulations contain the active ingredient in the form of a salt, initial investigations were conducted with oxycodone in the hydrochloride salt form.

What is Vaping?



Vaping is the act of inhaling and exhaling the aerosol, often referred to as vapor, which is produced by an e-cigarette or similar device. While there can be significant variation across devices, in general, e-cigarettes are comprised of a power source, a heating element or "atomizer", and a flavored liquid (often referred to as e-liquid). Liquid is drawn from a tank or cartridge by wicking material to the heating coil. Activation of the microprocessor heats the coil and vapor is emitted through the mouthpiece for inhalation.

Study Objective

Determine if oxycodone hydrochloride can be vaped in a commercial vaping device.

Methods

Laboratory Model to Evaluate the Potential for Vaping Opioids

A laboratory model was assembled that consisted of a commercial vaping device connected to an air vacuum sampling bag and flow meter control. The vaping device had an organic light-emitting diode touch screen and settings that allowed a wattage output range of 1-220 W and a temperature range of 200-600°F. Oxycodone hydrochloride (HCl, 20 mg) was dissolved in a small amount of deionized water, then diluted to a total volume of 2 mL with 50:50 propylene glycol: vegetable glycerin; for a final concertation of 10 mg/mL. The solution was transferred to the atomizer of the vaporizing device. The vaporizer was set to "TC" mode, which allowed the selection of maximum temperature and wattage. The vacuum device was started approximately 20 seconds ahead of the device to allow pressure to build and vacuum flow to start in the device. The vaping device was turned on for a single twelve second cycle. The vacuum device remained on until the vapor ceased and then the tubing was immediately clamped, and the vacuum device stopped. At the end of 12 seconds of vaping, the content of the collection bag was sealed, then analyzed for percent recovery of oxycodone HCl by a validated liquid chromatography-tandem mass spectrometry oxycodone assay.

Laboratory Vaping Model



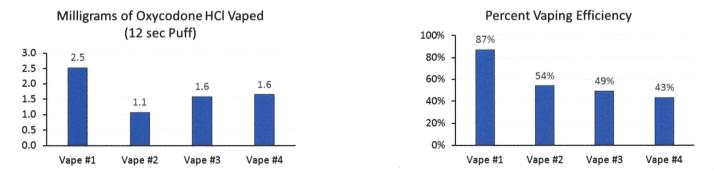


Laboratory Vaping Model



Results

Four laboratory vaping experiments were conducted with oxycodone HCl solution concentrations of approximately 10 mg/mL. Oxycodone HCl was delivered to the collection bag (simulating a single, long 12 second inhalation) in amounts ranging from 1.1 to 2.5 mg.



Conclusions

Based on this pilot study, a laboratory model for vaping oxycodone HCl was developed that successfully delivered puffs of oxycodone vapor (aerosol) from a commercial vaporizer in amounts that are likely to produce pharmacological effects. Given the popularity of vaping as a means of drug delivery (nicotine, cannabis), it is feasible that vaping opioids, such as oxycodone HCl, may offer an additional method of abuse that could be employed surreptitiously.

References

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