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Misleading Evidence of Electronic Cigarettes Efficacy for Tobacco Cessation

When alternatives are touted as "lesser" evils, virtue is artificially added as a measure of degrees. In the ever-evolving tobacco industry, the evil is clear and present, i.e., the Electronic Nicotine Delivery Systems (ENDS). The ENDS industry has seen a tremendous growth in the recent years.[1] Recently, the Government of India has moved to ban these products showing a welcome intolerance of the substances that negatively impact health and wellness among the people. The governments' swift action on this front was justified by the rapid increase in users, where the import of ENDS and their accessories to India was valued at 191,780$ between 2016 and 2019. After the Prohibition of Electronic Cigarettes Ordinance was cleared in 2019, production, import, export, sale, distribution, advertising, and storage of these systems are cognizable offence punishable with imprisonment or fine, or both.

Since the ill effect of these substances is established, they are now marketed as a superior alternative to other cessation therapies effectively spreading a propaganda of its safety over conventional methods.[2] More Americans, at present, use electronic cigarettes (ECs) than any other Food and Drug Administration (FDA)-approved cessation aid, despite never obtaining approval.[3] Most of the evidence for the efficacy of ECs as a cessation tool comes from the United Kingdom, with the results of a recent randomized trial by Hajek *et al.* being aggressively quoted by the vaping industry.[4] They demonstrated an 18.0% abstinence rate among EC users compared to 9.9% in the nicotine replacement therapy (NRT) arm at the end of 1 year. However, a critical analysis of the study reveals that this study has several limitations.

1. The study was performed among individuals who visited well-structured cessation clinics in the United Kingdom where subjects are likely to be highly motivated to quit. It is obvious that NRT/EC works best when used in hospital setting. Therefore, ECs have no proven benefit when used in the absence of strict medical supervision and the appropriate duration of use is also uncertain
2. The EC arm received uniform treatment in form of a standard device and refill, while the NRT arm had to choose from a range of products based on their preference, leading to significant heterogeneity. Subjects were encouraged to use combinations and could switch products at any time between the various choices prescribed (patch, gum, lozenge, nasal spray, etc.). This weak design may have resulted in a wide range of instant nicotine in the blood crucial for effectiveness. For example, nicotine administered intranasally is very quickly absorbed into the systemic circulation, and peak levels are achieved within 5–10 min which is considerably faster than the patches or gums.[5] Such effects (described as a "buzz") are usually considered rewarding by smokers and are not produced by other formulations
3. The management algorithm chosen in the NRT arm was flawed. As per the "NHS Stop Smoking Services," varenicline and bupropion should be offered as the second-line therapy to those not responding to NRT.[6,7] Treatment with addition of bupropion has shown to achieve abstinence rates of up to 26% at 6 months and 20% at 1 year. In fact, both these drugs are highly effective when used in combination.[8] Interestingly, another study by the same author among varenicline users reported a significant abstinence from smoking (17.5% vs. 4.8% in nonusers), vaping (12.5% vs. 1.6% in nonusers), and dual usage (8.8% vs. 0.8% in nonusers).[9] Therefore with the addition of varenicline and bupropion as a second-line NRT, the cessation rates are better than using ECs alone
4. Neither the subjects nor the counselors were blinded. Considering that the United Kingdom has already approved ENDS as a harm reduction strategy, the perception of the counselors/subjects is likely to be biased.[10] It is not clear from the article whether any effort was made to ensure that there was no conflict of interest or inducement (by vaping industry) among the counselors or subjects[11]
5. The most important concern is the high rate of continued EC use reported at the end of 1 year, i.e., 80% of the ECs group compared to 7.9% continued NRT. These startling results indicate long-term dependence to another form of usage among unsuspecting quitters. It also warrants serious ethical consideration, especially when we do not know how to help vapers quit ECs. This mandates justification by the patient safety committee of the hospital
6. The study was performed in a highly controlled cohort and needs to be replicated in a community setting before a conclusive comment can be made on its safety to be sold over the counter in the absence of structured cessation services. Its overall benefit in cessation of smokeless tobacco use is still not proven

EC sale is common among never-smokers as a form of recreation and current-smokers seeking safer alternatives.[12] When used by never-smokers, it is known to be a gateway for cigarette smoking and drug use and is likely to revive the declining smoking rates by luring former smokers to re-initiate nicotine dependence. When used by current smokers, it only prolongs their nicotine dependence and deprives them a chance of an addiction-free life.[13,14]

The WHO's Framework Convention on Tobacco Control suggests that these devices are unlikely to be harmless and long-term use is expected to increase the risk of chronic lung diseases, lung cancer, and possibly other diseases that were conventionally associated with smoking. Today, some of the most popular ENDS brands are owned by the tobacco companies' themselves, effectively controlling their so-called "competition."[15] If these devices were as effective a tobacco cessation tool as promulgated, the tobacco industry would never have invested in their own defeat. Much like the early denial by the tobacco industry prevented consumers from realizing the health consequences for several decades, ECs might pose to be an impending hazard willfully ignored by the ENDS industry.

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