RISK ASSESSMENT AND SAFETY EVALUATION OF AN ELECTRONIC NICOTINE DELIVERY DEVICE (E-CIGARETTE) AS SUBSTITUTES OF TOBACCO CIGARETTE

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Abstract: Electronic cigarettes (e-cigarettes) are modern devices that release an aerosol by heating a solution characteristically containing nicotine in propylene glycol or glycerol with flavoring agents. The World Health Organization (WHO) has warned the mounting market for e-cigarettes in India, underscoring that the use of the products is no less harmful than traditional cigarettes. Arguments and debate continue around the potential benefits and harms of these devices. They have become popular and are profoundly promoted as a safer cigarette and help to quit smoking. Smart marketing and insufficient information on the nicotine content in e-cigarettes has created a false intuition that these products are not as harmful as regular cigarettes. But WHO has expressed concern over the belief that e-cigarettes help in kicking the smoking habit and has warned that there is not adequate evidence to conclude that e-cigarettes help users quit smoking.

From the present $ 3 billion, the bazaar for e-cigarettes is predictable to grow 17 times by 2013. Even though they may have value in reducing cigarette use among smokers, they are of limited value in smoking termination and create many problems, particularly in children. Nicotine is highly addictive and affects virtually all cells in the body. It is particularly harmful to developing brains and other organs. The electronic nicotine delivery systems are largely uncontrolled and safety risks are manifold. Initiating nicotine use and increasing dependence in the population may be linked with increased tobacco and other addictive substance abuse even if the individual electronic cigarette delivers less harm than a combustible cigarette does. In India these devices are easily obtainable through online shopping portals and with slight information out in the public domain about the health-effects of e-cigarettes. Besides, there is a misunderstanding that it is less harmful than traditional cigarettes. In the deficiency of guidelines, the use of e-cigarettes has grown and will grow as they are easily reachable to even the non smokers. In many countries these e-cigarettes are available in candy flavours, giving an impression they are not harmful. We have sought a regulation on their use to protect public health. There should be a ban on smoking of e-cigarettes in public as well and a restriction on their use.

Keywords: e- cigars, health, nicotine, youth.

Introduction: In general, smoking blemishes nearly every part of the body, causing many and variety of diseases and affecting the health. Approximately 900,000 Indians and 6 million worldwide die every year of tobacco-related diseases, and that number could reach 1.5 million by 2020 if the same trend continues (International Tobacco Control Project) [1]. The world's first electronic cigarette was invented in Beijing in 2003, the device was hailed as a boon for tobacco fiends. It used power from a small battery to vaporize a nicotine solution that delivered the hit smokers want with fewer toxins than tobacco smoke. In the present day over 95% of e-cigarettes are made in China, but the Chinese themselves have shown little interest in the product [2].

An electronic cigarette (e-cig or e-cigarette), personal vaporizer (PV) or electronic nicotine delivery system (ENDS) is a battery-powered vaporizer that gives experience similar to tobacco smoking. Here the consumer inhales vapor rather than cigarette smoke. This device in general have a heating element that atomizes a liquid solution which usually contain a mixture of propylene glycol, glycerin, nicotine, and flavorings[3].E-fluids are also accessible without propylene glycol, without nicotine, or without flavors[4],[5]. The business of e-cigarette is one of the world's fastest growing and has surpassed the traditional cigarette use among school children in United States. In 2014, 8.7% of 8th graders, 16.2% of 10th graders, and 17.1% of 12th graders used electronic cigarettes within the month of the survey, whereas only 1.4% of 8th graders, 3.2% of 10th graders, and 6.7% of 12th graders smoked combustible cigarettes [6].With this tendency, electronic cigarettes are on pace to become more popular than flammable cigarettes in the near future. There is a lack of long-term scientific research that confirms they are safe. Some critics fear they could lead to nicotine addiction and tobacco smoking. E-cigarettes are marketed via television, the Internet, and print advertisements (that often feature celebrities) as better alternatives to tobacco smoking, as useful for quitting smoking and reducing cigarette consumption [7].

The e-cigarettes are rapidly increasing in attractiveness but adequate information is not available on their potential toxic or carcinogenic effects. Scientists and policy makers often react in a confused way to these troublesome technologies. Negative reports on e-cigarettes tend to receive much media coverage, and, as a result, a fraction of smokers who think that e-cigarettes are more dangerous than combustible cigarettes is increasing [8]. In this

circumstance, it is vital to provide clinicians, regulators, media and consumers with evidence-based answers to their questions. Therefore we aimed to give a systematic and critical review of the existing literature on the health consequences of aerosol of ECs and discuss the implications of our findings for public health.

Methodology: Google Internet search was performed using the words "electronic cigarette forum" to identify online e-cigarette forums with "health and safety sections" that allowed posts on the health effects experienced when using e-cigarettes. We also searched for the latest information in Pub Med, EMBASE and CINAHL. We considered original publications describing a health-related topic, published before March 2015. Recommendations, expert statements, reviews, technical reports and other non-original papers were also examined. Searches were also conducted using the same search terms from the data bases of World Health Organization regional databases (WHO).

Results and Discussion: McRobbie et al in 2014 [9] conducted clinical trials and found no serious adverse effects from e-cigarettes. But recent report of Ebbert, Jon O et al [10] identified adverse effects like headache, chest pain, nausea, and cough among minors who use e cigarettes. They also observed major adverse effects like hospitalizations for pneumonia, congestive heart failure, seizure, rapid heart rate, and burns. Grana, R, et al [11] reported less adverse effects including throat and mouth inflammation, vomiting, nausea, and cough have resulted from e-cigarette use. However, Gualano, M. et al [12] in 2014 found that adverse effects are mostly linked with a short term of use, and their frequency was significantly lower after 52 weeks of use. But long-term studies regarding the effects of e-cigarettes after chronic exposure are unavailable. Commonly reported risks from e-cigarette use include upper respiratory tract irritation, dry cough, dryness of the mucus membrane, nose bleeding, release of cytokines and pro-inflammatory mediators, allergic air way inflammation, reduced levels of exhaled nitric oxide, headache, dizziness, nervousness, insomnia, sleeplessness, nausea, vomiting, dry mouth, tongue sores, black tongue, gum bleeding, gingivitis, gastric burning, constipation, palpitation, chest pain, eye irritation, eye redness, eye dryness, may result in eye damage, altered bronchial gene expression, chance of lung cancer, shortness of breath, and shivering [13].

A lot of the observed negative effects from e-cigarette use concerning the nervous system and the sensory system are most likely associated to nicotine overdose or withdrawal [14].In view of the fact that e-cigarettes are projected to be used repeatedly, they can easily be used for an unlimited period of time, which may contribute to increased adverse effects [15].Toxicity associated with e-cigarettes may happen by ingestion, inhalation, or absorption. But the adverse effects of e-cigarettes on cancer is still unknown [16]. So far, the short and long term effects of e-cigarettes remain unclear. In children, e-cigarette use risks involve accidental nicotine exposure. In child patients, accidental exposures include ingesting of e-liquids and inhaling of e-cigarette vapor; choking on e-cigarette components is also a potential hazard [17].

The majority of e-cigarettes use lithium batteries. The incorrect use of device may result in accidents. Rare major injuries have occurred from battery malfunctions such as explosions and fires. There is a possibility of high levels of nicotine exposure, in regard to e-cigarette cartridges, from inhalation, ingestion, or skin contact while replacing or handling of the e-cigarette cartridges. This may be especially risky to children, pregnant women, and nursing mothers. E-cigarette is supposed to be unsafe to the fetus during pregnancy if e-cigarettes are used by the mother [18]. Prenatal exposure has been connected with obesity, diabetes, high cholesterol and high blood pressure in children [19]. As of 2015, the long-term effects of e-cigarettes on both mother and unborn baby are unknown [20]. Use-related concerns with e-liquids also include leaks or spills and contact with contaminants in the e-liquid. Because there is a lack of production standards and controls, the e-liquid cleanliness frequently is not dependable, and testing of some products has shown the existence of toxic substances [21].

Conclusions: The emerging trend of e-cigarettes is raising concerns among the health community mainly from its long term use. USFDA [20] reported that e-cigarettes contain toxic chemicals and carcinogens which have potentially harmful effects on humans. Furthermore, WHO also cautioned that the "safety of e-cigarettes. Saitta, et al [6] recommended that e-cigarettes should be effectively regulated for consumer safety. However, various issues in methodology, conflicts of interest, and inconsistent research have been identified in the research regarding e-cigarettes. Available research reports advocate caution before designating e-cigarettes as beneficial but vapors continue to believe they are beneficial [22]. Many consumers believe that e-cigarettes are healthier than traditional cigarettes for personal use or for other people while few clients are concerned about the probable adverse health effects or toxicity of e-cigarettes [23]. The Forum of International Respiratory Societies [24] stated that e-cigarettes have not been demonstrated to be safe. Public health experts have expressed fear that e-cigarettes may increase nicotine addiction and tobacco use in young people. E-cigarettes may be particularly tempting to youth due to their high-tech design, wide range of available flavors, including

candy-and fruit-flavored cartridges, and also easy availability online and in shopping malls. Because in nearly all countries they are not taxed as tobacco products [25]. In view of the fact that e-cigarettes are not validated as cessation tools, may contain nicotine at unpredictable levels and added ingredients that are possibly harmful, allowing e-cigarettes to be used among youth to decrease smoking places this group at significant risk.

Scientific evidence regarding the human health effects of e- cigarettes is limited. Some research reports claim that it may facilitate smoking cessation, but definitive data are lacking. So far no e- cigarette has been approved by FDA as a cessation aid. The health impact of e-cigarettes, for users and the public, cannot be determined with currently available data.

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