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Adverse effects of E-cigarettes or Vapes in otherwise Healthy Young and Middle-aged Adults who have No History of Smoking: A Systematic Review

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ABSTRACT:
Introduction: The use of Electronic cigarettes and Vapes have been widely accepted as a less-harmful means of smoking when compared to cigarettes. While this is true, the adverse effects and harms of E-cigarettes and Vaping are not inconsequential.
Methods: We searched the PubMed database exclusively for Randomized controlled trials, while limiting our search between 2007 - 2023. We initially identified 234 articles from PubMed which were then screened by abstract. Articles were screened for relevance based on the topic of E-cigarettes or Vaping and of adverse effects. Exclusion of 205 studies left 29 full-text articles to assess. Assessing based on our inclusion and exclusion criteria left 6 studies eligible for systematic analysis. Data extraction was performed on each study with focus on baseline demographics and covariates. Using the Jadad-scale, three independent reviewers assessed the methodological quality of each study on a 5 point scale. It was found that 1 study was of poor quality, 4 studies were of moderate quality and 1 study was of good quality.
Results: 6 RCTs were included in the analysis with 4 being performed in the United States, 1 in Italy and 1 in Canada. A total of 137 participants were included in the randomized controlled trials published between 2015 and 2021. Acute vaping indicated a positive correlation and dose-response relationship with an increase in CD14, CD16, T-cells, natural killers and monocytes. Furthermore, the findings from the review suggests that EC usage alters expression of the transcriptome in both small airway epithelium (SAE) and alveolar macrophages (AM).
However, acute electronic cigarette use does not affect lung and heart functions as long as they do not contain nicotine.
Discussion: This systematic review was conducted using Randomized controlled trials, which minimizes bias and adjusts for confounding, with a robust internal validity. Randomization also provides the best means for determining a causal relationship between an intervention and outcome. However the average quality of the included studies are not of good quality and sample size (137 subjects) may be considered quite small and not representative. Database for studies included was limited to only Pubmed. Moreover health-care practitioners must also actively inquire about the recreational use of vapes in youth and adults, as they are becoming popularized due to the misconception of having few harmful effects.
Conclusion: Acute use of electronic cigarettes show a significant increase in inflammatory cell and cytokine release, leading to oxidative stress, potential airway remodeling and DNA damage. It was found that acute E-cigarette usage also decreases FEV_1, however these changes were not clinically significant towards pulmonary function and cardiac function tests. While this study only assesses the acute effects of electronic cigarette vape usage, further studies must be conducted on the chronic usage of E-cigarettes and their clinical effects.

KEYWORDS: Adverse effect, Inflammation, E-cigarette, Systematic review, Vape, Vaping.

1. INTRODUCTION

Nicotine free E-cigarettes and Vaping devices have seen a surge in popularity within the recent years, after being introduced into the US market in 2007 [1]. As toxic emissions from the E-cigarettes have been advertised as “minimal” or “safer than cigarettes”, this has appealed to children and adults, leaving them susceptible to harms unbeknownst to them [2]. E-cigarette liquid is composed mainly of propylene glycol (PG), which is a glycol ether solvent found in cosmetics and industrial supplies.

Robbins Pathology defines glycol ether solvents as toxicants which have the chronic effects of urinary system toxicity and bladder cancer [3]. Additionally, Propylene glycol was named by the American Contact Dermatitis Society as the ‘Allergen of the Year’ in

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2018 [4]. While Electronic cigarettes and Vapes have been widely accepted as less-harmful than cigarette smoking, the adverse effects and harms of each are not inconsequential.

Outcomes of E-cigarettes have been generally termed as 'adverse effects'. One study has chosen to assess the pulmonary function tests of new E-cigarette users by focusing on exhaled nitric oxide and fractional concentration of carbon monoxide [6]. The next study measured the finger arterial pressure, muscle sympathetic nerve activity and observed an ECG to quantify adverse effects [7]. Another study opted to perform Bronchoalveolar lavage to assess the cell counts and array of inflammatory cytokines released following E-cigarette use [8]. The Fourth study measured the changes in CD14, CD16, T-cell, Monocyte and Natural Killer cells following E-cigarette use [9]. The Fifth study assessed lung function based on Pulmonary function tests, Spirometry and Methacholine challenge tests [10]. The last study looked at chest X-ray, plasma levels of endothelial microparticles and bronchoscopy for small airway particles and alveolar macrophages [11]. In all included studies except Marie-ÈveBoulay et al., it was found that acute usage of E-cigarette usage yields significant increases in negative-outcome adverse effects.

This systematic review was conducted on the subject of E-cigarettes and Vaping as they are both a novel means of smoking. Thus, there is a lack of literature for public and physician use on a potentially harmful activity which is increasing in popularity. In order to fill a gap in available information, this review aims to lay out and communicate the harmful effects of E-cigarettes and Vaping in adults in a systematic and quantitative manner.

2. METHODS

2.1 Search Strategy

We conducted our systematic review using the PubMed database (2007 - 2023). The research question was formulated according to the population, exposure, comparison, outcome and study design (PECOS) strategy. We first established our population using the MeSH term "Adult". From this, we used the boolean operator 'AND' to include our exposure which was 'Vaping OR Vape'. After compiling MeSH terms for outcomes, the boolean operator 'AND' was used to include "Lung OR Lung injury OR Oxidative stress OR Risk factors OR Harm OR Lung function OR Health impact OR Effects OR Acute effects". The database was then restricted to studies between 2007 and 2023, using the filters of Randomized Controlled Trials and observational studies respectively. The citations retrieved were exported to excel spreadsheet and screened by title and abstract by three different reviewers. Disagreements were resolved by consensus.

2.2 Study selection and Eligibility Criteria

Inclusion criteria:

Full text articles of the citations that met the abstract and title screening were screened by our PICO concepts. To be included in this review, the full text screening should mention the following: (i) Early & Middle aged adults who are never-smokers ; (ii) Adverse/Harmful effects; (iii) E-cigarettes or Vape and (iv) Study designs based on Randomized controlled trials

Exclusion criteria:

Articles were excluded if they: (i) Did not include Early & Middle aged adults who are never-smokers; (ii) were not based on Adverse/Harmful effects, (iii) were not related to exposure vaping (iv) were not RCT and (v) only included population with a history of smoking or any type of secondary exposure to smoke.

2.3 Measurement and Observation: Outcome, Exposure, Covariates

Primary outcomes varied by article. Primary outcomes are adverse/harmful effects measured in pulmonary function tests, fraction of exhaled nitric oxide (FeNO) and fractional concentration of carbon monoxide (FeCO) in exhaled breath tests, ECG, finger arterial pressure, and MSNA (muscle sympathetic nerve activity). Bronchoalveolar lavage (BAL) was conducted to assess cell counts, array of inflammatory cytokines released (Interleukins, TNF, etc.) and effects on gene expression. Lung function, plasma levels of endothelial microparticles (EMP) and bronchoscopy to obtain small airway epithelium (SAE) and alveolar macrophages (AM). Respiratory mechanics and lung function measured by the forced oscillation technique and spirometry respectively (and in that order).

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2.4 Assessment of Methodological Quality

For the assessment of methodological quality, Authors evaluated the articles independently using the **Jadad-scale,** The Jadad scale is a 5-point scale for evaluating the quality of randomized trials in which three points or more indicates superior quality. The Jadad scale is commonly used to evaluate RCT quality. The scale contains two questions each for randomization and masking, and one question evaluating reporting of withdrawals and dropouts [1]. The scale has a maximum score of 5, in which answers can be Yes or No. If Yes, 1 point can be given and if No, there will be 0 points given towards the article. For our study, any study under 3 points was considered to be "low quality", 3 points was considered "moderate quality" and above 3 points was considered as "good quality".

The first question asked was if the study was described as randomized. Next, the second question asked whether the methods used to generate the sequence of randomization was appropriate. The third question asked if the study was described as double blinded. The fourth question asked if the method of double-blinding was described and/or appropriate. Finally, the fifth question asked if there was a description of withdrawals and dropout, if any.

3. RESULTS

3.1 Search Results

Abstract screening using relevant Mesh terms originally identified 234 records which potentially met our inclusion criteria. Of these, 205 were excluded by screening of title and abstract as non-relevant to the purpose of the study. The full text of 29 publications were assessed for the adverse effects of electronic cigarettes and whether they satisfied our selection criteria. After obtaining 10 studies, we chose to only include Randomized controlled trials, as they are a rigorous means to examine cause-effect relationships. This left a final number of 6 studies which were eligible for inclusion in our systematic review (**Figure 1**).

3.2 Methodological Quality

The methodological assessments can be seen in **Table 1**. After applying the Jadad-scale for methodological assessment of the included studies, 4 studies had moderate quality, 1 study had low quality and 1 high quality study.

3.3 Study Characteristics

Table 2 shows the study characteristics of the 6 included RCT's, a total of 137 participants were included in the randomized controlled trials. The studies were published between 2015 and 2021 and the number of participants per study ranged from 15 to 32. Studies reporting on age, country: 6[6][7][8][9][10][11], Sex: 5[6][7][8][9][10], Other covariates: 4[6][7][9][10] (Other covariates include race, height, weight, bmi and etc.).

3.4 Findings

Findings from analyzing the data collected can be seen in **Table 3**; we can see that in Joshua E. Gonzalez et al. [6], During inhalation on the **JUUL**, heart rate and mean arterial pressure increased, but did not change during inhalation on the placebo e-cigarette. Following the use of the JUUL, heart rate returned to baseline, but mean arterial pressure remained significantly elevated compared with placebo throughout recovery. During inhalation on the JUUL, burst incidence and burst frequency declined abruptly, and remained suppressed into recovery. While inhaling on the placebo, participants did not show any significant changes in MSNA. The marked decrease in MSNA activity with nicotine inhalation was paralleled by increases in mean arterial pressure during both inhalation and recovery.

Juul Labs, Inc. is an American electronic cigarette company that spun off from Pax Labs in 2017. Juul Labs makes the Juul electronic cigarette, which atomizes nicotine salts derived from tobacco supplied by one-time use cartridges [12].

In Marco Ferrari et al.; E-cigarettes did not have any significant effects on FeCO, FeNO, FEV_1/FVC, FVC, FEV_1, FEF25, FEF50, FEF75 or PEF.

In Theodoros Kelesidis et al.; Acute vaping increased CD14 count by 1 fold, CD16 by 1.25 fold, monocytes by 0.9 fold, T cells by 1.05 fold and Natural killer cells by 1.05 fold. In Min-Ae Song et al.; Positive correlation of Propylene glycol in vapes with increases of total cell concentration (r=0.60), lymphocyte count (r=0.65) and macrophage count (r=0.51), IL-8 (r=0.60), IL-13 (r=0.66) and TNF (r=0.73).

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In Michelle R. Staudt et al. Using significance criteria of $p < 0.05$ and fold-change $> \pm 1.5$

- a total of 71 genes were significantly altered in small airway epithelium (SAE) following exposure to EC with nicotine, including 19 up-regulated and 52 down-regulated ,
- a total of 27 genes were significantly altered in alveolar macrophages (AM) following exposure to EC with nicotine, including 6 up-regulated and 21 down-regulated

In Marie-Ève Boulay et al.; 1-h acute vaping session of a high-grade and contaminant-free mixture of propylene glycol does not significantly impact pulmonary functions, respiratory mechanics or symptoms in healthy or asthmatic subjects

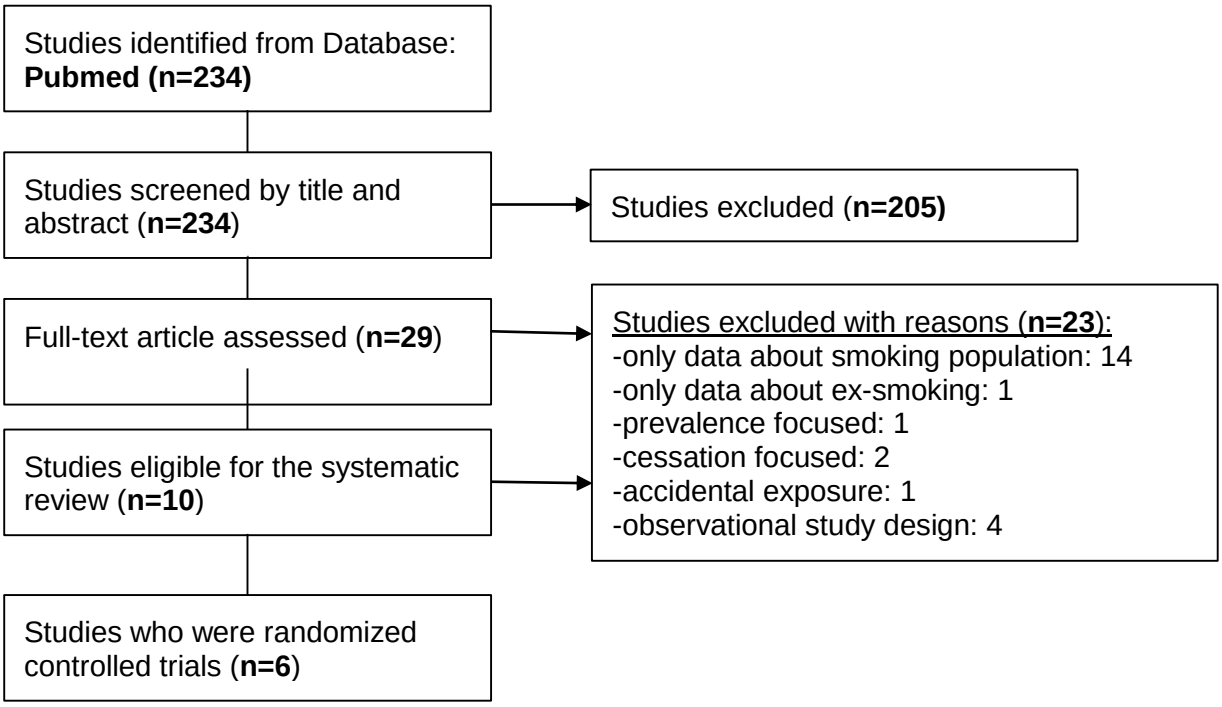

Figure 1. Diagram for literature search process based on inclusion and exclusion.

Table 1. Study Characteristics

Studies (year)	Population	Intervention	Ages (Mean)	Sex M/F	Other Covariates
Joshua E. Gonzalez et al. 2021 (United states)	All 15 participants had no history of autonomic dysfunction, hypertension, respiratory disease, diabetes, tobacco or vaporized nicotine usage, and were not taking any prescription medications	Each participant was tested twice; once with a JUUL e-cigarette containing 59 mg/mL of nicotine and once with an e-cigarette containing 0 mg/mL of nicotine. Trial order (nicotine vs. placebo) was randomized, and tests were performed ~1 mo apart.	21 ± 1	9/6	Height of 174 ± 3 cm. Weight of 78 ± 4 kg
Marco Ferrari et al. 2015 (Italy)	Twenty normal subjects, recruited among pulmonary fellows or attending physicians	Both smokers and non-smokers were randomized to smoke both the NF e-cigarette and a commercial "popular	39.3 ± 12.6	11/9	Weight of 67.9 ± 10.4 kg

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	were studied: 10 were smokers (minimum of 5 pack-years) and 10 were non-smokers	brand" standard cigarette ad libitum for 5 min in two different sessions according to a cross-over design			Height of 169. ± 10.0 cm BMI: 23.5 ± 2.5 kg/m2
Theodoros Kelesidis et al. 2021 (United states)	32 participants; Nine individuals had long-term (more than 1 year) TCIG use, 12 had long-term ECIG use, and 11 did not have any history of TCIG or ECIG use.	Measures of COS were determined among groups according to tobacco use at baseline and after a single exposure to electronic cigarette vaping with an electronic cigarette with 5% nicotine (labeled as vaping) or sham vaping (puffing on a straw labeled as sham).	24	19/13	-
Min-Ae Song et al. 2020 (United states)	Thirty never-smokers.	Study subjects (n=30) were randomized to either e-cig use or no use controls. For the intervention participants, one week after bronchoscopy, e-cigs were provided with an Innokin iTaste VV 4.0 refillable tank device and e-liquids that contained 50% PG and 50% VG , without nicotine or flavors.	25 ± 4.5	12/18	Black/White/Hispanic/Asian/Other ethnicities respectively: 2/22/0/5/1
Michelle R. Staudt et al. 2018 (United states)	Ten never-smokers, without exposure history to tobacco products or EC	Of the $n = 10$ total subjects, $n = 7$ were randomized to Blu EC with nicotine and $n = 3$ to Blu EC without nicotine.	40.2 ± 9.7	5/5	Black/White/Hispanic/Other ethnicities respectively: 7/0/3/0
Marie-ÈveBoulay et al. 2017 (Canada)	Twenty healthy volunteers had no documented lung disease and had normal response to methacholine and Ten asthmatic volunteers had received a diagnosis of asthma and had airway hyperresponsiveness as shown by a positive methacholine challenge. All volunteers were non-smokers and none were active e-cigarette users. Moreover, none of the volunteers were exposed to secondary tobacco or e-cigarette vapors at home.	In the following two sessions (experimental and placebo), volunteers were asked to inhale three times per minute, in sitting position, for a total duration of 1 hour. The e-liquid consisted of a mixture of 70% USP-grade PG and 30% USP-grade glycerol (Gly), Volunteers were aware of using full (experimental) or empty (placebo) e-cigarettes as no vapors were coming out of the empty placebo device.	Healthy volunteers: 28.5 ± 8.5 Asthmatic volunteers: 30.5 ± 9.5	-	-

Legend: ECIG=Electronic Cigarette, TCIG=Tobacco Cigarette, PG= Propylene Glycol, VG=vegetable glycerin

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Table 2. Methodological quality assessment for the studies included in the systematic review of RCTs

Studies	Was the study described as Randomized?	Was the method used to generate the sequence of randomization described and appropriate?	Was the study described as a double blind?	Was the method of double blinding described and appropriate?	Was there a description of withdrawals and dropouts?	Results
Joshua E. Gonzalez et al. 2021	1	1	0	0	1	**3**
Marco Ferrari et al. 2015	1	1	0	0	1	**3**
Theodoros Kelesidis et al. 2021	1	1	1	0	1	**4**
Min-Ae Song et al. 2020	1	1	0	0	1	**3**
Michelle R. Staudt et al. 2018	1	1	0	0	1	**3**
Marie-Ève Boulay et al. 2017	1	0	0	0	1	**2**

Legend: <3 = Low Quality, 3 = Moderate Quality, >3 = Good Quality

Table 3. Findings from studies included in the systematic review of adverse effects on E-cigarettes in healthy adults, 2007-2023

Study	Study design	Main findings	Notes
Joshua E. Gonzalez et al.	Randomized controlled trial	<u>During inhalation on the JUUL;</u> -Heart rate: 74 ± 3 to 79 ± 3 to 75 ± 3* -Mean arterial pressure: 86 ± 3 to 92 ± 3 to 91 ± 3* -MSNA, bursts/min: 22 ± 2 to 18 ± 2 to 17 ± 2* -MSNA, bursts/100 heartbeats: 31 ± 3 to 24 ± 3 to 25 ± 3* <u>In placebo e-cigarette;</u> -Heart rate:75 ± 4 to 75 ± 4 to 74 ± 4* -mean arterial pressure: 88 ± 3 to 90 ± 3 to	SMOK FIT Kit was used to deliver the placebo because JUUL currently does not make a pod compatible with their system that does not contain nicotine. The effect of vaporized nicotine from the JUUL and placebo on muscle sympathetic nerve discharge was determined in 10 of the 15 participants due to complexities associated with recording MSNA twice in all subjects.

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		89 ± 3* -MSNA, bursts/min: 20 ± 2 to 21 ± 2 to 20 ± 2* -MSNA, bursts/100 heartbeats: 29 ± 3 to 31 ± 3 to 29 ± 3* *note: numbers are in the order of "Baseline to Vaping to Recovery"	
Marco Ferrai et al.	Randomized controlled trial	Depicted in **Figure 2,** E-cigarettes had no significant effects on FeCO, FeNO, FEV_1/FVC, FVC, FEV_1, FEF25, FEF50, FEF75 or PEF	
Theodoros Kelesidis et al.	Randomized controlled trial	Acute vaping increased CD14 count by 1 fold, CD16 by 1.25 fold, monocytes by 0.9 fold, T cells by 1.05 fold and Natural killer cells by 1.05 fold.	A single vaping session in never-smokers resulted in an increase in oxidative stress via various cellular subtypes. A vaping session in those who already vaped previously and whose baseline oxidative stress levels were consequently already increased, did not have a further increase.
Min-Ae Song et al.	Randomized controlled trial	Positive correlation of Propylene glycol in vapes with increases of total cell concentration (r=0.60), lymphocyte count (r=0.65) and macrophage count (r=0.51), IL-8 (r=0.60), IL-13 (r=0.66) and TNF (r=0.73).	Positive correlations indicated a dose-response, strengthening the possibility of a biological real effect. Findings were assessed in a span of months, thus not depicting chronic effects.
Michelle R. Staudt et al.	Randomized controlled trial	Using significance criteria of $p < 0.05$ and fold-change > ± 1.5.Following exposure to EC with nicotine, • 19 genes were up-regulated and 52 genes were down-regulated in SAE • 6 genes were up-regulated and 21 were down-regulated in AM	There were no consistent changes in vital signs like the lung function tests, O2 saturation, blood carboxyhemoglobin levels or urine nicotine metabolite levels, bronchoalveolar lavage cell differentials or small airway epithelium cell differentials
Marie-ÈveBoulay et al	Randomized controlled trial	1-h acute vaping session of a high-grade and contaminant-free mixture of propylene glycol and does not significantly impact pulmonary functions, respiratory mechanics or symptoms in healthy or asthmatic subjects	Limitation of this study and similar studies is that individuals were fully aware of using full or empty (placebo) cigarettes - inability to blind. Therefore only physiologic measurements such as pulmonary functions can be truly considered

Legend: SAE= small airway epithelium, MSNA=muscle sympathetic nerve activity, AM=Alveolar Macrophages, EC=Electronic Cigarette, SAE=Small airway epithelium

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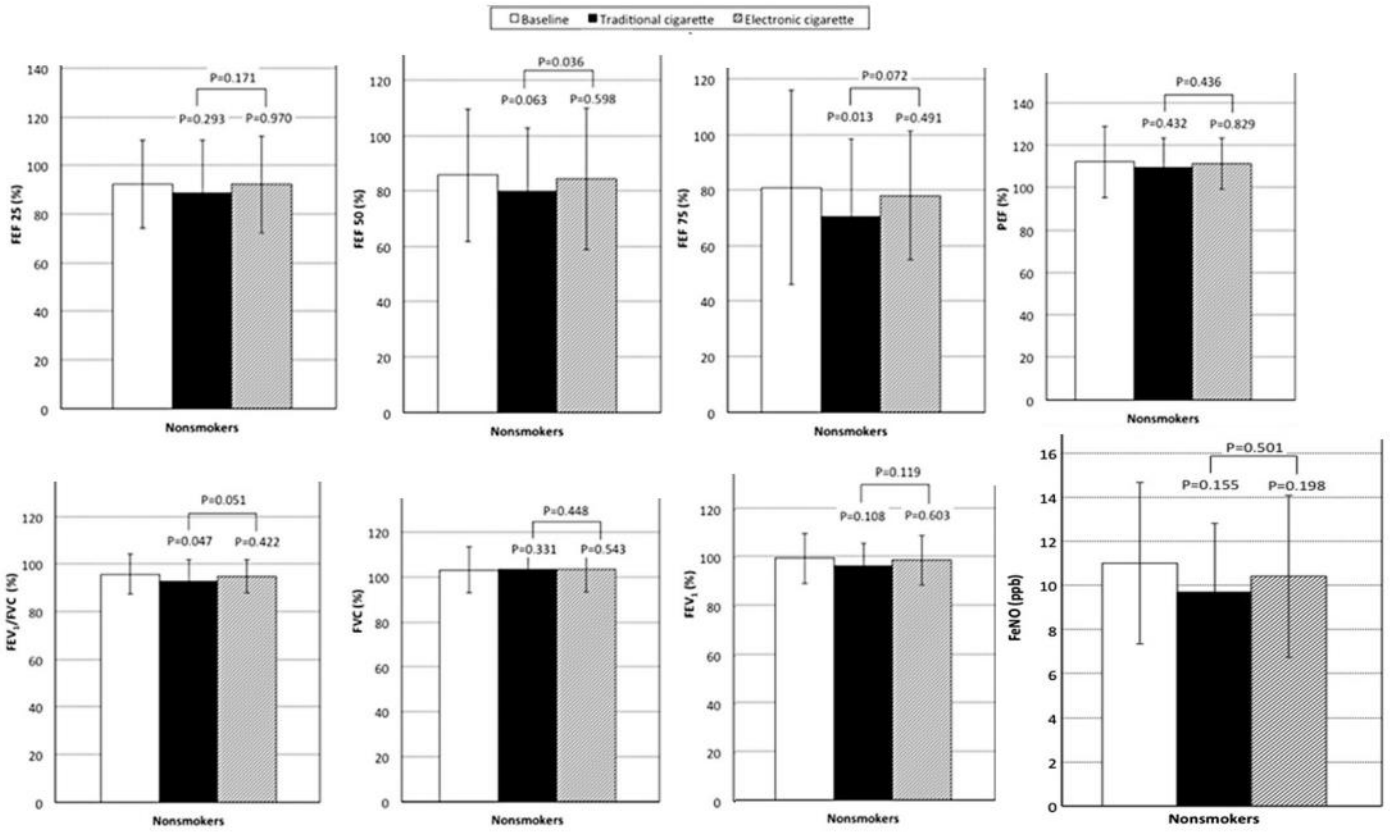

Figure 2. Data extracted from Marco Ferrari et al. 2015 (Italy) showing significant values of non-smokers compared with traditional cigarettes and electronic cigarettes.

4. DISCUSSION

Electronic cigarettes and Vaping devices have risen in popularity since their introduction into the market, yet few know about their adverse effects. In this systematic review, we determined the effects of acute E-cigarette usage on pulmonary functions, cytokine release and nerve activity. Based on relevant literature that used randomized controlled trials, we identified 6 studies relating to our outcome of interest.

This systematic review suggests that acute usage of Electronic cigarettes or Vapes will cause harmful effects on healthy adults. A single vaping session in adults who had no history of smoking resulted in an increase in oxidative stress by release of various cells [8]. As depicted in Table 3, there was a significant rise in lymphocytes, macrophages, IL-8, IL-13, natural killers and TNF following E-cigarette usage. The release of these cells leaves potential for massive airway remodeling by inflammatory infiltration from: tumor necrosis factor, lymphocytes, macrophages, and neutrophils via IL-8 which is a chemotactic factor. IL-13 has also been shown to cause airway hyperresponsiveness and airway remodeling, adding towards the negative effects of E-cigarette usage. It was also found that Acute vaping indicated a positive correlation and dose-response relationship with an increase in CD14, CD16, T-cells, natural killers and monocytes. These inflammatory markers further support the harmful effects of Electronic cigarettes and Vaping by strengthening the possibility of a 'biological real effect' [9].

Furthermore, the findings from the review suggests that EC usage alters expression of the transcriptome in both SAE and AM. In the SAE, altered expression of p53 downstream targets were noted with activation of the p53 dependent signaling pathway (p53 signaling pathway plays a major role in cell cycle arrest and DNA damage response). This is indicative of a cellular response to environmental stress or more importantly DNA damage[10] .

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However, it is also shown that acute electronic cigarette use does not affect lung and heart functions as long as they do not contain nicotine [6][7]. Contrary to this, JUUL, the most commonly sold e-cigarette brand in the United States [13] only produces nicotine-containing electronic cigarettes. Furthermore many issues around electronic cigarette long-term adverse effects remain unanswered, but evidence suggests an association between initial use of e-cigarettes and subsequent cigarette smoking [14] and other electronic cigarettes containing nicotine can become addictive and One JUULpod appears capable of delivering the nicotine equivalent to smoking about a pack of cigarettes, with variability [15].

Strengths:

This systematic review was conducted using Randomized controlled trials, which has several strengths towards the study. The randomization minimizes bias and adjusts for confounding, with a robust internal validity. Randomization also provides the best means for determining a causal relationship between an intervention and outcome.

Limitation:

The study has some limitations that need to be discussed. First, the average quality of the included studies are not of good quality. Second, the sample size (137 subjects) may be considered quite small and not representative. Database for studies included was limited to only Pubmed, excluding potential studies to be included in the Meta-analysis, prone to bias and not on par with many other systematic reviews which uses many databases.

Implications for clinicians and policy makers:

Our findings indicate a necessity for policymakers to educate the public on the consequences of vaping and electronic cigarettes due to their harmful effects. Health-care practitioners must also actively inquire about the recreational use of vapes in youth and adults, as they are becoming popularized due to the misconception of having few harmful effects.

Future research and unanswered questions:

As the introduction of Electronic cigarettes and vapes remains novel in the United States, there is a severe lack of information and long-term critically appraised studies. This raises a number of further research questions, summarized respectively in priority order:

1. What are the chronic effects of vaping over a 6 month period, with respect to pulmonary function tests, cytokine release or sympathetic nerve activity?
2. What are the psychosocial or dependence effects of vaping over a long period of time?
3. What are the effects of nicotine-free vapes on a developing fetus during pregnancy?

5. CONCLUSION

Acute use of electronic cigarettes show a significant increase in inflammatory cell and cytokine release, leading to oxidative stress, potential airway remodeling and DNA damage. However, these changes were not clinically significant towards pulmonary function and cardiac function tests. While this study only assesses the acute effects of electronic cigarette vape usage, further studies must be conducted on the chronic usage of E-cigarettes and their clinical effects.

Conflict of interest

The author(s) declared no potential conflicts of interest.

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