

Smoking Cessation Practitioners Views Towards Safety and Effectiveness of Electronic Cigarettes in Klang Valley, Malaysia: A Qualitative Study Approach

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Abstract

Electronic cigarette (EC) gaining recognition as a smoking cessation device among consumers. But it creates disputes among tobacco experts and smoking cessation practitioners. This study aims to identify the smoking cessation provider views towards EC safety and effectiveness as a smoking cessation aid. Besides EC prescribing or preventing factors as a smoking cessation aid been reported too. A qualitative study with a phenomenological approach was designed to include physicians and pharmacists who were practising as smoking cessation practitioner in Klang Valley, Malaysia. Data were collected by in-depth interview and open-ended questions. The data were then transcribed, and content analysis was carried out. All the study participants were aged between 25 to 55, having smoking cessation practice experience of one to twenty-five years. A total of ten themes were developed from interview conversations as follows 1) EC cannot be considered as a quit smoking aid. 2) EC may not help in complete stop smoking. 3) No benefits from the use of EC. 4) Side effects and physical injuries by EC; 5) EC may lead to addiction to nicotine. 6) No regulations for EC in Malaysia; 7) EC without nicotine will not help to stop smoking; 8) EC less smelly than traditional tobacco cigarettes; 9) Improper knowledge about the contents of EC; 10) EC as

a “fashion device”. The study showed a negative perception towards the safety and effectiveness of EC among smoking cessation practitioners in Malaysia. Lack of EC effectiveness for quit smoking, safety studies, nicotine addiction, non-regulation by the government of Malaysia and the FDA are the primary preventing factors for prescribing EC as a smoking cessation aid. Future EC related trials are needed to aware the smoking cessation physicians to appropriately guide the tobacco quitters based on scientific evidence.

Keywords: Smoking cessation practitioners, electronic cigarette, safety, effectiveness, Malaysia.

Introduction

Electronic cigarette (EC) is gaining recognition and their use has been increased in the last few years. EC device includes a battery, a compartment for holding an e-juice (a solution containing flavouring, solvent, and nicotine), a heating component and a mouthpiece (1). The battery controls the heating component, which heats the e-juice and creates an aerosol that is inhaled via the mouthpiece. The EC was developed to mimic the act of smoking by supplying nicotine but without harmful effects being produced by conventional tobacco cigarettes (CCG). ECs are comparatively unconventional, and their consumption is

spreading as an electronic nicotine delivery system worldwide. The chief constituents of EC liquids are nicotine, propylene glycol, glycerine, and a combination of other flavouring ingredients (2).

Presently, in Malaysia ECs are not banned but are regulated with only nicotine-free e-liquids permitted to be sold by vendors (3). Nicotine is classified as a class C poison under the Malaysian poisons act, 1952 and control of drugs and cosmetic regulations, 1984. This act prohibits the sale or supply of poisons to persons under 18 years old. Any breach of this act may be liable to a fine not higher than MYR 3000 and/or up to 2 years 'imprisonment. However, EC devices without nicotine are classified as electrical appliances and are legal to trade. But nicotine in e-liquids can be sold by licensed personnel, including pharmacists and physicians (4). Malaysia joined the WHO framework convention on tobacco control (FCTC) on 23 September 2003 and started the national smoking cessation services like "take nak and quit" to encourage smoking cessation among smokers. In Malaysia, the mQuit services were initiated on 27th November 2015 through a public-private partnership. The objectives of these services were to make smoking cessation services accessible throughout the public and private sectors (5). The services were additionally improved with a quitline counselling system and a website to support and facilitate registration of smokers to cessation program through www.jomquit.moh.gov.my. Currently, there are 160 private health care providers and 764 government health clinics and hospitals have become the mQuit providers. The numbers of registered patients for mQuit services have increased from 7757 in 2015 to 10791 in 2016 (5).

Even rapid worldwide market penetration of EC, their use is prominently disputed as a scientific viewpoint among tobacco experts and smoking cessation practitioners. Many questions related to the EC are unclear and its role as a smoking cessation aid and

impact on public health is still open-ended (2). There is uncertainty regarding EC as a smoking cessation aid since their use may renormalize smoking in ex-smokers, could attract the youngsters due to the availability of nicotine e-liquids with various flavours and assume it as a fashion gadget (1). Inadequate information regarding the long-term health effects of EC has become a significant issue due to the use of EC worldwide, including in Malaysia (6). Therefore, the current study aims to carry out qualitative research to investigate the smoking cessation practitioners' views towards safety and effectiveness of EC and its associated factors for prescribing or preventing it as a smoking cessation aid.

Materials and Methods

Study design and setting: A qualitative study design informed by phenomenological method, where the researcher takes the opportunity to explore in-depth perceptions about safety and effectiveness of EC. The research was conducted in the region of Klang Valley. Data were collected by in-depth semi-structured face to face interviews with smoking cessation providers such as doctors and pharmacists. The reason to conduct the qualitative study was due to the restriction of time and research cost. The interviews were conducted in the English language. The study was registered under National Medical Research Registration (NMRR) 19-1574-48749 Malaysia. Ethical approval was obtained from the Medical Research Ethics Unit (MREC) of Malaysia. Before the study, written informed consent was taken from each practitioner. A semi-structured interview guide was developed by reviewing preceding studies and by the discussion with expert academicians in associated disciplines. Socio-demographic data (table 1) was collected using a demographic data collection sheet that was attached to an interview guide. The interview guide comprised the questions, which mainly focused on the issues of efficacy, safety and prescribing and preventing factors as a smoking cessation aid. The open-ended

questions were asked, and appropriate investigative queries were applied whenever essential to draw out the facts necessary for the study. Moreover, the study participants were given full authority to express additional opinions on matters related to the safety and effectiveness of EC at the end of every interview session. The interviews were conducted at quit smoking clinics by the investigator at the time suitable for study participants. Each interview session lasted for about 45 minutes to 1 hour. The data obtained from the in-depth interview were then transcribed and content analysis was visualized in the form of interview experts and descriptive statistics.

Inclusion and exclusion criteria: All registered physicians and pharmacists who were practising as smoking cessation providers either in private or government mQuit clinics in Klang Valley were considered eligible for this study. The general physicians and pharmacists who were not practising as smoking cessation provider was excluded from this study.

Sample size: Purposive and snowball sampling were applied to recruit the study participants. The recruitment of participants was done until the saturation of the data occurs. Contacts with participants were done by face to face, emails, and phone calls or through references. The smoking cessation practitioners were enrolled on various smoking cessation clinics such as mQuit clinics in Klang Valley Malaysia from May to July 2020.

Data analysis: All interview conversations were audiotaped and transcribed verbatim. The transcripts produced from the audiotape were separately coded by two investigators for the search of descriptive and interpretive codes manually. The interviews and empirical data analysis were conducted simultaneously based on the theory of analytic induction. The phenomenological approach was applied to analyse the interview data. Both independent coders paid attention to the records repetitively to familiarize themselves with the data. Finally,

the coded transcripts from each researcher were confirmed for the entire points in the text data. Data saturation was reached after 20 interviews when both the researchers were not able to find the new themes. This was further confirmed by the replication of the study themes and reiterating terms. The socio-demographic data were presented descriptively.

Results and Discussion

The socio-demographic characteristics of the study participants were summarized in Table 1. Thematic content analyses were done and recognised the 10 main themes and 26 codes. The developed themes and the selected codes of the participants' have mentioned in table 2.

The current qualitative study among smoking cessation practitioner in Klang Valley gives a comprehensive understanding regarding the safety and effectiveness of EC as a smoking cessation aid which was not previously reported before in Malaysia. The current study participants reported that EC cannot be considered as a smoking cessation aid. One of the important marketing strategies from the EC manufacture is that EC is a useful tool for smoking cessation. Almost 90% of the study participants reported that they would neither recommend nor encourage ECs as an alternative tool for those who wish to quit tobacco smoking. Most of the study participants preferred conventional therapy like nicotine replacement therapy (NRT) such as nicotine patches and nicotine gums as smoking cessation aids. The reason for their impression is that these products have been approved by the FDA and free from harmful chemicals and flavouring agents. The current study also revealed that the participants do not actively recommend EC to their patients. However, they informed that they will not discourage interested patients from trying EC as a smoking cessation aid, particularly those who failed to quit with other smoking cessation methods.

The current study results were

consistent with other studies which found that the primary care providers were more inclined to recommend EC to patients with failed quit attempts (7,8). The physicians were more likely

Table 1. Socio-demographic characteristics of the study participants

Characteristics	Total number (N=20)	Frequency (%)
1. Age in years	(05)	25%
25-35	(12)	60%
36-45	(03)	15%
46-55		
2. Gender	(09)	45%
Male	(11)	55%
Female		
3. Marital status	(14)	70%
Married	(06)	30%
Single		
4. Race	(06)	30%
Malay	(05)	25%
Chinese	(09)	45%
Indian		
5. Occupation	(19)	95%
Government	(01)	5%
Private		
6. Smoking cessation practice	(08)	40%
experience (years)	(07)	35%
1-5	(04)	20%
6-10	(01)	5%
11-15		
16-20		
7. Speciality	(10)	50%
Physician	(10)	50%
Pharmacist		

to recommend EC when their patients asked about them or when the physician believed that EC was safer than conventional cigarettes. A recent online survey conducted in Malaysia revealed that Malaysians generally use EC as

a smoking cessation aid (9). The study further reported users believed that ECs have helped them to reduce their tobacco consumption, reduced the urge to smoke and helped them to stop smoking. Currently, there are conflicting data about the role of EC in smoking cessation (10-11,12).

The existing study participants also revealed that EC may not help in complete stop smoking. Most of them emphasized that self-confidence and strong determination among vapers play a vital role in the action of complete stop smoking (13-14). The study participants further alleged that the emotional and psychological support from family and peer may help in complete quit smoking. A meta-analyses study reported that self-confidence and strong will power plays a decisive role in smoking cessation (15). About two-thirds of the current study participants revealed that EC without nicotine may not be useful in smoking cessation. They specified that the use of nicotine in e-liquids reduces the withdrawal symptoms such as irritability, anger and so on. However, the earlier studies discovered that nicotine-free vaping triggers an immune system and may cause an inflammatory response throughout the body (16).

The current study participants also reported an insignificant benefit related to EC use and stated numerous side effects. The study participants informed that the EC device itself has no quality control. Regarding the side effects of EC, they revealed that ECs may induce countless side effects on human's health and physical injuries as well. However, unfortunately, existing available data on the safety of EC is limited and inconsistent. Self-reported adverse events have been identified during randomized clinical trials and by some observational studies (17-20). The previous clinical trials have reported minor adverse events with the use of EC like mouth irritation, cough, and nausea. The existing study participants also reported that EC may lead to shortness of breath, blurred vision, headache, palpitations, elevation in blood pressure and may develop serious health problems which end

up hospitalization (21). The FDA too reported that adverse events associated with the use of EC are headache, chest pain, nausea, cough. The literature studies have also been reported the major adverse events by EC use such as pneumonia, congestive heart failure, seizure, rapid heart rate and burns related to routine use, airway resistance, gastrointestinal system, and neurone system etc (22-23).

The current study participants also stated that E-cigarette or Vaping Use Associated Lung Injury (EVALI) seems to be a serious side effect of EC use. In June 2019, more than 1000 new cases of lung injury were evolved (EVALI) due to EC use in the USA. Patients suffering from EVALI showed symptoms such as dyspnoea, cough and hypoxaemia with bilateral airspace opacities on chest imaging (24). The evaluation of EVALI cases shown that in most cases the patients have vaped tetrahydrocannabinol (THC)-containing liquids in addition to nicotine-containing e-liquids (25). Later studies showed that the molecule vitamin E acetate was accountable for EVALI syndrome as it was identified in the bronchoalveolar lavage among 94% of the patients (25-26). The study further reported that most of the patients required management in the intensive care unit with steroid therapy to reduce airway inflammation. All patients recovered with the cessation of vaping, supportive care and steroid therapy and remained symptom-free at follow up.

In the present study, two-thirds of the study participants revealed that the battery (lithium) explosion is one of the chief causes of physical injury by EC use. Cases of individuals being injured by EC due to exploding of lithium batteries have been reported in the news and social media (27-28). Poorly lithium batteries with the use of low-quality materials are at high risk to cause physical injury by EC. Besides, improper use and handling of these batteries can contribute to thermal runaway, where the internal battery temperature increases and may causes fires or explosions.

Regulation of EC varies around the globe, ranging from no regulations to complete bans (29). The current study participants revealed that there are no comprehensive laws and regulations regarding the EC in Malaysia. Most of the study participants reported that EC may cause more harms to the public due to non-regulations of EC. The study participants mainly pointed out the non-regulation of the amount of nicotine in e-liquids. Malaysia has yet to do either and no specific regulations are governing the sale and use of EC. However, there are some restrictions made by the Ministry of Health Malaysia that, smoking, and vaping in restaurants, indoors or outdoors and within 3 metres of the perimeter of the restaurant are prohibited. The principal regulations, the Control of Tobacco products regulations 2004, impose a fine of up to 10,000 Malaysian Ringgit (RM) and up to two years of imprisonment on anyone caught smoking in a prohibited area (30). Such Strict regulations on EC should also be done in Malaysia to benefit the public's health.

Most of the study participants also revealed that EC may lead to nicotine addiction. It is acknowledged that vaping is maintained primarily by dependence on nicotine. Besides, currently, there are no fixed concentrations of nicotine in ECs. The nicotine concentrations in e-liquids are in the range of 6-18 mg generally provided in the marketed available e-liquids samples. However, certain previous studies revealed that the marketed e-liquids samples found to have variations in the quality along with discrepancies on the labelled vs actual nicotine concentration around the globe, including in Malaysia (31-33). The preceding studies revealed that EC users consuming nicotine up to 40-60 mg/ml in EC liquids such as in brand JUUL (34). The literature studies showed that smokers who quit smoking permanently may end up becoming addicted to EC nicotine. The addiction to nicotine via EC revealed like conventional tobacco cigarettes (35-36). Therefore, regulations of contents of nicotine in

Table 2. Developed themes and the selected codes extracted from the recorded conversation.

Theme 1:	Theme 2:	Theme 3:	Theme 4:	Theme 5:
<p>EC cannot be considered as a quit smoking aid.</p> <p>Nearly more than half of the study participants replied that EC cannot be considered as a quit smoking aid.</p> <p><i>I would not suggest people to use. I would not recommend and suggest to the conventional nicotine therapy. (Physician 2, Line 40)</i></p> <p><i>No, no. I will recommend our mQuit programme or any nicotine replacement therapy (Pharmacist 3, Line 33)</i></p> <p><i>For me, I support nicotine patches and nicotine gums that contain no harmful chemicals other than nicotine. (Physician 4, Line 54)</i></p>	<p>EC may not help in complete stop smoking.</p> <p>The study participants stated that EC may not aid in complete stop smoking. The participants pointed out that the self-confidence among the smokers may lead to a higher success rate than EC use in quitting the tobacco cigarette.</p> <p><i>Electronic cigarette will never help in stop smoking ... cessation ... it is more towards their mentality. If let's say, they are very high mentality to stop smoking, even without the EC, they themselves can stop smoking. (Physician 6, Line 14)</i></p> <p><i>Research had showed also that a lot of times when people try vaping will eventually, high percentage of them eventually goes to tobacco cigarette. (Pharmacist 4, Line 11)</i></p>	<p>No benefits using electronic cigarette.</p> <p>Most of the study participants found that there are no benefits received by using EC.</p> <p><i>I actually don't find many benefits from the electronic cigarettes. Some of the public might think it as a way for to help them to quit smoking, or maybe at least help them to reduce the number of cigarettes using every day. However, I think that it really depends on how ... on what is quality of EC and how the person is going to use it. (Physician 8, Line 8)</i></p> <p><i>I do not find the electronic cigarette benefits ... useful at all because in the first place, the gadget itself may not have quality control, it may be dangerous without the SIRIM, quality checking. It can be dangerous whether the gadgets contain accurate contents. So, I don't see any benefits of it. (Pharmacist 6, Line 9)</i></p>	<p>Side effects and physical injuries by EC.</p> <p>The study participants were aware that EC can cause side effects and physical injuries. As per literature, the use of EC is linked to serious health problems, such as severe lung injuries, seizures, nicotine addiction and poisoning, increased risk of heart attacks and strokes.⁸ The low-quality check of EC devices is closely linked to physical injuries.</p> <p><i>Electronic cigarette can have the explosion of the battery and may physically get injury. (Physician 8, Line 13)</i></p> <p><i>Yes, I have seen cases with the battery explosion in the news, maybe also risks of explosions, risk of fire ... (Pharmacist 2, Line 36)</i></p>	<p>EC may lead to the addiction of nicotine.</p> <p>Majority of the study participants were replied that EC may lead to addiction of nicotine, especially among the young generations and new vapers.</p> <p><i>especially the young one you know, the EC is still under developing if they have a high nicotine then it can cause long-term damage, so I do not encourage it because ... it can lead to another addiction. (Physician 5, Line 44)</i></p> <p><i>The problem is that ... people who never smoke before may start smoking because they think it is safer. If you already on nicotine, and this is pure nicotine, it may probably lead an addiction. (Physician 1, Line 21)</i></p> <p><i>EC has nicotine, definitely. it will lead to addiction, but it may also contain a lot of other hazardous chemicals ... (Pharmacist 6, Line 51)</i></p>

Conti ...table 2 Developed themes and the selected codes extracted from the recorded conversation.

<p>Theme 6: No regulations for electronic cigarettes in Malaysia.</p> <p>Majority of the study participants mentioned that there are no specific regulations acted on EC in Malaysia. No specific regulations are governing the use of non-nicotine vaporizers and on EC sale.</p> <p>Currently, the common problems will be non-regulations. (Physician 1, Line 33)</p> <p>It may do more harms as it is not regulated. (Pharmacist 1, Line 37)</p> <p>currently, we have no regulation on the amount of the nicotine that is put in EC and what are the ingredients put in and there is no formalize law to tell us for the manufacture to follow, that is no SOP for us. (Physician 4, Line 90)</p> <p>There are no proper regulations in most of the countries to control the use of EC and also no age limitation I think ... (Pharmacist 4, Line 44)</p>	<p>Theme 7: EC without nicotine will not help to stop smoking.</p> <p>The current study participants also specified that the EC without nicotine is not giving any support to quit smoking. The participants assume that EC users will not get satisfaction without nicotine in EC.</p> <p>because if it is absolutely without nicotine, withdrawal symptoms can be very bad, and this will strongly discourage users from stopping tobacco cigarette. (Physician 9, Line 34)</p> <p>Not very successful. If someone is a heavy smoker. (Pharmacist 9, Line 49)</p>	<p>Theme 8: EC is less smelly than traditional tobacco cigarettes.</p> <p>The study participants also pointed out that EC is less smelly than traditional tobacco cigarettes. This is one of the primary reasons, that why many youngsters attracting towards its use.</p> <p>less smelly compared to traditional tobacco cigarette. Less smelly ... so even it can be used in the indoor, it won't actually influence any other people or affect any people. (Physician 3, Line 30)</p> <p>The EC does not contain tar; therefore, it is less smelly compared to the traditional one. (Physician 9, Line 34)</p> <p>It is less smelly ... as it contains some flavorings. (Pharmacist 10, Line 30)</p>	<p>Theme 9: Improper knowledge about the contents of EC.</p> <p>The study participants reported improper knowledge about the contents of EC.</p> <p>Contents that I know all will be nicotine definitely, other chemicals we are not really sure because they are not being regulated. (Pharmacist 1, Line 3)</p> <p>I think electronic cigarette contain certain chemicals, it may be nicotine, it may be not, but I am not really sure what is the contents actually. (Physician 2, Line 3)</p> <p>I think there are no regulated contents. Generally, depends on what you mix inside is what you get. Some have nicotine some do not have and then you can add a lot of other things inside. So, I do not think that there is a fixed content for EC. (Physician 7, Line 6)</p>	<p>Theme 10: Youngsters assume EC as fashion device.</p> <p>Most of the study participants mentioned that EC is assumed as a fashion device among teens nowadays.</p> <p>I think it is more to a fashion device. A lot of youngsters outside I see using it as a fashion, just to show-off. (Physician 2, Line 10)</p> <p>Young one tends to try it you know, because ... since it's like the fashion, the trends (Pharmacist 5, Line 44)</p> <p>People around are using it as a smoking tool and young people that never smoke before are now starting to use EC because it is cool and fashion. (Physician 1, Line 29)</p>
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EC liquids should be done for consumers safety and to prevent nicotine addiction. The tobacco administrative authority in Malaysia should instruct all e-liquids suppliers and manufacturers to provide nicotine concentrations in safe ranges that would not lead to nicotine addiction.

The current study participants also pointed out that EC is generally less smelly than traditional tobacco cigarettes. Nowadays, the manufacturers add numerous flavourings agents in e-liquids for more sales and to attract youngsters. A study revealed that there is an astonishing number of "characterizing flavours" are available, by one estimate, over 7500 (37). Enticing flavours were banned from conventional cigarettes in 2009 to reduce youth smoking, as they were often used as a starter product (38). Toxic compounds like diacetyl, which has linked to severe respiratory disease, have been found in 75% of flavoured EC e-liquids (39-40). Flavours alone can be harmful to human's health. The appearance of countless combinations of hundreds of flavouring molecules extracted from natural ingredients or artificially made perceived not by taste, but by smell (41). The flavourings in EC mask the high nicotine concentration warning signals and thereby consumers perceptions by believing that vaping is benign. Regulations of flavours in EC liquids should be standardised and steps must take boldly to remove the youth attracting flavoured products from the world market.

The current study participants revealed inadequate knowledge about the contents of e-liquids. Most of the study participants were aware that nicotine and flavourings agents are the main components of EC e-liquids. However, the participants were not able to tell the exact chemicals in EC solutions. As per the literature, the chief constituents of ECs' e-liquids are nicotine, propylene glycol, glycerine, and a couple of other flavouring constituents (1-2). Smoking cessation practitioners should have adequate and comprehensive knowledge on the contents of EC to provide accurate

counselling to the vapers and public. Through their professional up-to-date knowledge, they can guide realistically to the vapers and public related to EC matters. Physician guidance has potential influences on patient behaviour. The physicians' advice may change over time in response to the evolving scientific evidence on EC.

The present study participants also exposed that youngster nowadays use EC with perceptions as a fashion device. Once youngsters hooked with ECs, most of them will become long-term users and then may lead to the use of tobacco cigarette (42-43). The concern now is on whether EC can replace traditional cigarettes or are they operating to induce a new audience of adolescents to tobacco products. At present, the empirical evidence looks more like the latter. Therefore, there is a need for surveillance and mechanism research to understand what EC may mean for youth risk status.

The main limitation of this study was in-depth interviews without the focus group discussion. We did not organize any focus group interviews because all the smoking cessation practitioners have different schedules. The opportunity to observe the interaction among the study participants was lost. However, the researcher managed to gain a more in-depth smoker cessation practitioners' experience with help of a semi-structured interview guide. Another, limitation of this study was it was carried out in one geographical location i.e., in Klang Valley Malaysia. This can be improved further by conducting the study in multiple locations of Malaysia by including a large sample size so that the results can be generalised.

In a conclusion, the smoking cessation practitioners' views towards the safety and effectiveness of EC in Klang Valley was negative. As per the smoking cessation practitioner views, EC may not be considered as an absolute smoking cessation aid. Lack of EC effectiveness and safety trials, nicotine addiction, non-

regulation by the government of Malaysia and the FDA are the primary preventing factors for prescribing EC as a smoking cessation aid. Therefore, future trials are required to aware the smoking cessation practitioners so that they can appropriately guide tobacco quitters about EC based on scientific evidence.

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Declaration of Competing Interest

The authors declare that they have no competing interests.

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Ethical approval

The study was registered in the National Medical Research Registration (NMRR) 19-1574-48749 Malaysia. The Ethical approval was obtained from the Medical Research Ethics Unit (MREC) of Malaysia. The participant's consent forms were taken before enrolment in the study. Participants who agreed to sign the consent form was only allowed to join the study.

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