

To Help Maximising the Potential Benefit of Tobacco Harm Reduction Products (Such as Electronic Nicotine Delivery Systems or 'Ends'), While Minimising It's Risks

Heino Stover*

Institute of Addictions Research, Frankfurt University of Applied Sciences, Frankfurt (ISFF), Germany

Abstract

The question of whether e-cigarettes are a useful tool for smoking cessation is part of an ongoing and highly controversial scientific debate. In practice, however, the number of people trying to quit tobacco consumption by using these products is steadily increasing. This discussion article provides an outline of the current state of research on the issue of whether and to what extent e-cigarettes can help people quit smoking.

Of course, e-cigarettes also have a certain potential for harm, especially if nicotine dependence is unnecessarily prolonged. Nevertheless, it can make an important contribution to harm reduction in nicotine consumption. Hence, the product should get treated as a serious alternative to nicotine replacement therapies (NRTs) in the scientific discussion. Like NRTs, e-cigarettes offer a less harmful way of consuming nicotine that greatly reduces many of the health risks associated with tobacco consumption, such as the absorption of carcinogenic substances. Recent studies and reviews suggest that the product can be at least as effective as nicotine replacement therapies in helping people quit smoking. Individual studies even demonstrate the increased effectiveness of e-cigarettes in supporting smoking cessation.

Nevertheless, the review of the current literature shows that more high-quality research is needed to further understand the product and its properties. In terms of the harm reduction approach, however, it would already be more appropriate to also rely on e-cigarettes instead of trying to force immediate and complete nicotine abstinence. After all, in the process of quitting smoking, the fastest possible cessation of the more unhealthy consumption of tobacco should be prioritized in order to immediately minimize unnecessary health risks.

Keywords: Addiction; Addiction research; Addiction therapy; Tobacco control; Harm reduction; Nicotine replacement

Introduction

Smoking tobacco is the cause of a multitude of diseases such as lung cancer, COPD (Chronic Obstructive Pulmonary Disease; an umbrella term for chronic obstructive bronchitis and emphysema)¹, or stroke. This means that smoking is the single most important and avoidable health risk as well as the leading cause of premature mortality [1]. Given that smoking has such a large number of negative effects on health, physicians, therapists and (health) politicians have made efforts for decades for this type of nicotine consumption to be replaced with less harmful forms of nicotine absorption [2].

It is in this context that the e-cigarette, being a relatively new product, has made it into the public and scientific discourse. One of the most frequently discussed questions in this debate is to which extent the e-cigarette is suitable for smoking cessation and how it might help achieve public health goals, such as lowering the smoking rate and preventing diseases associated with tobacco, among other things [3]. It is not only the scientific expert community that is engaged in this discussion. The intense debate about the product and its potential benefits also found its way into the media world quite some time ago [2,3,4,5].

This article is intended to provide an overview of the opportunities and risks of e-cigarettes. After describing the status quo of smoking cessation in Germany, the suitability of e-cigarettes as a cessation product for harm reduction purposes will be discussed as one of the two key dimensions of the ongoing debate. In this regard, the latest scientific evidence for its harm reduction potential will be discussed and assessed critically. Subsequently, this paper will address the suitability of e-cigarettes for smoking cessation, thus the second important

dimension. In this context, the comparability of e-cigarettes with other nicotine-containing cessation products such as nicotine replacement therapies (NRTs) will mainly be discussed.

1For further information on COPD: Guideline on the diagnostics and therapy of patients with chronic obstructive bronchitis and lung emphysema (COPD).

2E-Zigaretten: Das kleinere Übel? Deutsche Welle. <https://www.dw.com/de/e-zigaretten-das-kleinere-%C3%BCbel/a-48843810> (last retrieved: 16/09/2021).

3Zweifel an Studie zu Gesundheitsgefahr von Dampfen; ZEIT Online. <https://www.zeit.de/wissen/gesundheit/2019-12/e-zigaretten-rauchen-studie-lungenerkrankungen-risiko-wissenschaftler> (last retrieved: 16/09/2021).

4Die Verunsicherung um E-Zigaretten wächst; SPIEGEL Online. <https://www.spiegel.de/gesundheit/diagnose/e-zigaretten-moegliche-krebsgefahr-die-verunsicherung-waechst-a-1287167.html> (Last retrieved: 16/09/2021).

*Corresponding author: Heino Stover, Institute of Addictions Research, Frankfurt University of Applied Sciences, Frankfurt (ISFF), Germany, Tel: + 496915332822; E-mail: hstoever@fb4.fra-uas.de

Received: 23-Feb-2022, Manuscript No. jart-22-55306; **Editor assigned:** 25-Feb-2022, PreQC No. jart-22-55306 (PQ); **Reviewed:** 11-Mar-2022, QC No. jart-22-55306; **Revised:** 16-Mar-2022, Manuscript No. jart-22-55306(R); **Published:** 23-Mar-2022, DOI: 10.4172/2155-6105.100463

Citation: Stover H (2022) To Help Maximising the Potential Benefit of Tobacco Harm Reduction Products (Such as Electronic Nicotine Delivery Systems or 'Ends'), While Minimising It's Risks. J Addict Res Ther 13: 463.

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5Endlich E-Raucher; SPIEGEL Online. [https:// www.spiegel.de/wissenschaft/mensch/e-zigaretten-neue-dampf-zigaretten-sollen-beim-aufhoeren-helfen-a-00000000-0002-0001-0000-000174691266](https://www.spiegel.de/wissenschaft/mensch/e-zigaretten-neue-dampf-zigaretten-sollen-beim-aufhoeren-helfen-a-00000000-0002-0001-0000-000174691266) (last retrieved: 16/09/2021).

Status quo of smoking cessation in Germany

As far as tobacco consumption is concerned, Germany continues to be a high-consumption country. As the latest data show, a prevention success was admittedly achieved in the past years and consumer figures are declining steadily [4]; compared to other European countries, though, the figures continue to plateau at least on a medium level [5]. Recent estimates assume that the damage incurred to the German economy by tobacco consumption amounts to approximately € 97 billion per year. This exceeds by far the fiscal revenue that can be generated through the taxation of tobacco products [6]. At the same time, though, there is an increasing demand for smoking cessation programmes in the population. According to recent surveys, 53% of current smokers in the European Union (EU) have at least once tried to quit smoking [5].

Physicians as well as therapists have surely been aware of the need for evidence-based smoking cessation programmes for years. Aside from measures such as short counselling, behavioural therapy, prescription medicines or telephone counselling, a multitude of different preparations replacing nicotine, called nicotine replacement therapies (NRTs), has been available on the German market for quite some time. It is accepted scientific practice to substitute the tobacco cigarette as a source of nicotine with a less harmful source of nicotine, such as a nicotine patch or chewing gum, for a limited period of time [7]. The key focus of this form of therapy as recommended in the S3 Guideline on Smoking and Tobacco Addiction is to support smoking cessation by ameliorating symptoms of withdrawal. With the goal of harm reduction in mind, smokers unwilling to quit are even recommended to use nicotine replacement products for which there is little evidence available [8]. Various studies support this method. Correspondingly, studies having different kinds of research designs and trial groups have shown that NRTs are indeed effective and help patients to quit smoking [7]. In spite of the evidence-based recommendation to use this method of treatment, it does not seem to be particularly popular with smokers so far, at least in Germany [4].

By contrast, the consumer figures for e-cigarettes have been on a steady rise over the past years - especially in the context of attempted smoking cessation [9]. In the publication of the first results of the German Survey on Smoking Behaviour (DEBRA study), almost one out of ten participants said that they had tried to quit smoking with the help of e-cigarettes (with or without nicotine). Other cessation aids are clearly relied upon less often [4]. Across Europe, too, the consumer trend is moving towards trying to quit tobacco consumption with the help of e-cigarettes [10]. At the same time, it becomes apparent in Germany and abroad that there is much less demand for NRTs from consumers willing to quit [4, 11] and that the majority of all attempts to quit smoking are generally carried out without any supporting programmes or products [12]. This is dramatic given that nearly 95% of those non-assisted attempts remain unsuccessful within one year [4].

The e-cigarette as a nicotine replacement product for the purpose of harm reduction

In the scientific discussion, a disagreement has emerged as to whether e-cigarettes are suitable for smoking cessation, or not, based on various aspects. In spite of e-cigarettes being increasingly used in

attempts to quit smoking [4], there is no scientific evidence as yet that they do indeed result in more tobacco abstinence [13]. To achieve long-term, successful smoking cessation, it seems to make sense, though, to replace the previous source of nicotine (in most cases, tobacco cigarettes) with a less harmful source (e.g. e-cigarettes) in a first step, instead of aiming for abrupt tobacco and nicotine abstinence. This approach is intended to immediately reduce the health impact caused by the substances released during the combustion of tobacco cigarettes [14]. Following this logic, nicotine patches or nicotine chewing gums are also prescribed for a limited period of time [7]: Therefore, the first goal of treatment is not smoking cessation but harm reduction.

In principle, an e-cigarette can work this way, too: It replaces the harmful absorption of nicotine in the form of tobacco cigarettes with a less harmful source of nicotine [15]. E-cigarettes could just as well be employed in a clearly defined period of time and within a rigorously defined procedure. So far, however, e-cigarettes are not recommended as part of any therapy [8].

The proponents of e-cigarettes argue that the product bears a striking similarity to conventional cigarettes regarding its use and its handling, and that it accomplishes the emission of much fewer toxicants at the same time [16]. Also, some of the rituals of smoking can be maintained while absorbing fewer toxicants [17]. However, this is precisely a point that is viewed critically by some, arguing that the similar touch and feel could make complete nicotine cessation more difficult [17]. There is a concern that nicotine consumption will merely be reduced but not abandoned entirely [18].

At present, it is still unclear what kind of long-term health impact may result from sustained consumption of e-cigarettes in view of their nicotine content [7]. Two meta-studies have shown that long-term nicotine consumption is associated with various adverse health effects [19, 20].

Apart from the sustained consumption of nicotine, the continuous exposure to toxicants in the form of aerosols is also viewed critically. Granted, there is scientific consensus that the users of e-cigarettes expose themselves to fewer toxicants than smokers of tobacco cigarettes [16]. This is another area, though, where the long-term effects have not been sufficiently investigated or understood [16]. Data gathered so far in humans and animals have suggested that even just the aerosols may, at the very least, also pose a certain health risk [21].

A further aspect put forth by critics of e-cigarettes is what is known as dual use. In dual use, users do indeed consume e-cigarettes but continue to smoke tobacco cigarettes in parallel [22]. In 2018, 74.5 % of all users of e-cigarettes practised this form of dual consumption [23]. Shahab et al. [18] have established that only the consistent switch to e-cigarettes or nicotine replacement products is associated with long-term reduction of carcinogenic or other toxic substances in the organism. At the same time, the absorption of nicotine stayed on a comparable level in long-term users of e-cigarettes or nicotine replacement products in all groups [18]. Also, the results of 2 cohort studies indicate that complete smoking cessation is less likely in dual users than in people who use e-cigarettes exclusively [13]. Should this be confirmed, it would also speak against the hypothesis of long-term dual consumption. Recent studies have also shown, though, that the consumption of e-cigarettes has the effect of lowering the number of consumed tobacco cigarettes [24]: Therefore, dual users consume fewer tobacco cigarettes than they did before.

Nevertheless, the general principle should be that complete abstinence from tobacco consumption ought to be achieved as quickly

as possible. This is all the more desirable in the light of scientific evidence that is, at present, still very ambiguous about the health impact of dual use. There are studies which suggest that dual users absorb fewer toxic substances than participants who consumed tobacco exclusively [7]. Other studies, however, point exactly to the opposite direction [25]. Correspondingly, a complete switch should be achieved as quickly as possible as there are still no definitive conclusions about the health impact of this form of consumption [7].

However, in the discussion of this aspect it is often ignored that there is also a dual use (limited in time) when using NRTs. Interestingly, it is associated with an increased smoking cessation rate in the long term [26]. It can thus be established that dual use is a widely practised phenomenon in smoking cessation and happens with NRT, too. This is why this aspect cannot be used *per se* as an argument against e-cigarettes - particularly not if the desired long-term goal of complete tobacco abstinence is achieved nevertheless.

It is fair to say that e-cigarettes do indeed have the potential to be used as an instrument of harm reduction. Just as with established NRTs (e.g. nicotine patches), the treatment prioritises the fastest possible tobacco abstinence over nicotine abstinence. The goal is to reduce the body's exposure to toxicants. One must bear in mind, though, that e-cigarettes are not free from toxicants and that adverse health effects are possible, too. Moreover, the dual use, which is still being practised far too often today, must be terminated as quickly as possible to achieve the best harm reduction possible.

The question of whether the existing potential of e-cigarettes as a means for smoking cessation can actually be unlocked by users will be the subject of the next section. In this context, the necessary comparison with the effectiveness of established NRTs will also be discussed.

Effectiveness of e-cigarettes in smoking cessation

As early as in 2013, the effectiveness of e-cigarettes in smoking cessation was investigated [27]. The study showed that e-cigarettes supported smoking cessation both in the short term and in the long term while consumers did not develop any serious side effects. While the design of this study did not allow it to analyse conclusively how these figures compared with other NRTs, the results do suggest that e-cigarettes are as similarly effective as other smoking cessation products. Similar results were reported by Bullen et al. [26] in their study in New Zealand. Likewise, the findings of the Cochrane review [7] suggest that nicotine-containing e-cigarettes are presumably as effective in supporting smoking cessation as NRTs. However, it is not only the potential of successful smoking cessation that increases with the use of e-cigarettes but also the likelihood of even making an attempt to quit smoking in the first place [28]. Finally, the use of e-cigarettes has the effect that more smokers make an attempt to quit smoking and that this attempt actually results in at least three months of tobacco abstinence [28].

An analysis of the data of the National Health Interview Survey (NHIS; [29]) for the United States confirms the trend described above, according to which e-cigarettes are used ever more frequently for smoking cessation. The results of the study show that the consumption of e-cigarettes correlates positively with the attempt of having achieved smoking cessation in the past 12 months. An Increased tobacco abstinence also correlates positively with the use of the product [29]. In addition, it becomes apparent that users who have overcome both tobacco consumption and e-cigarette consumption have very little interest to start using e-cigarettes again. Furthermore, the majority of current users is planning to quit e-cigarette consumption in the near future [30].

However, not all smokers are convinced of e-cigarettes as a way to quit smoking. A study that looked at the example of Northern England showed [31] that many smokers refrained from switching to e-cigarettes. The reason they gave was that they feared substituting one addiction (tobacco cigarettes) with another addiction (e-cigarettes). It becomes evident that the e-cigarette is met with scepticism by a number of people who are part of its very target group.

Eisenberg et al. [32] also examined to which extent e-cigarettes support smoking cessation. In spite of the methodological deficits in the study design (insufficient provision of e-cigarettes by the manufacturer in the second survey phase, the resulting halt in recruitment and the shortening of the duration of the study), this study provides interesting insights into the effectiveness of e-cigarettes as a smoking cessation product. The results indicate that behavioural therapy in combination with e-cigarettes is clearly more effective to promote smoking cessation in the first 12 weeks than therapeutic support alone. When practised for a longer period of time, though, this effect levels out and e-cigarettes no longer make a significant difference. The result indicates that e-cigarettes should be used at least at the beginning of smoking cessation. This insight must be qualified, though, seeing that some of the participants used their own e-cigarettes in the second 12 weeks of the study due to the above-mentioned problems with the manufacturer. This might be associated with the relatively small effect in the second survey phase.

The results of Eisenberg et al. [32] are supported by Levy et al. [33] who conducted modelling on the basis of US health data, even though the basic assumptions of the modelling were indeed chosen very optimistically. According to the results of this study, it becomes apparent that the increased use of e-cigarettes and other novel nicotine products in the public health context can have a significant, positive effect on the smoking rate and the health impact associated with smoking. The various calculations that were carried out, each with slightly modified models, show a clear reduction in premature deaths for the various cohorts in all cases, due to the significant drop in tobacco consumption. On the basis of these model calculations, it can further be stated that other sources of nicotine, such as e-cigarettes or tobacco heating products, can also have a markedly positive effect on smoking cessation. It would therefore be smart to use them more widely. This would not only reduce the long-term costs in the public health system but actually protect human lives, too. Furthermore, the latest publications suggest that users of e-cigarettes steadily reduce the nicotine content of their e-cigarette liquid [31, 34, 35] and therefore lower their exposure to nicotine in the long run.

However, some individual studies also indicate that the reduced nicotine content is cancelled out by more frequent vaping [35], which means that a linear reduction of nicotine absorption is not achieved. At the same time, this leads to an increased exposure to toxicants contained in the vapour. This development is not ideal, but even these studies note that the exposure to toxicants in tobacco cigarettes would be far higher in comparison [35, 36]. Therefore, any assessment must take into account what a person's health situation would be like without any intervention. The mere reduction of exposure which happens due to a switch to e-cigarettes is so significant that e-cigarettes should absolutely be taken into consideration in smoking cessation programmes [7]. This reduction, though, is truly relevant only in cases where there is a complete switch from tobacco to e-cigarettes.

Hajek et al. [37] published a first study in 2018 in which they directly compared the effectiveness of e-cigarettes and various NRTs. In both groups of subjects, the attempts to quit with the respectively assigned

products were complemented with interventions of behavioural therapy such as group therapy or individual counselling. The results of the study show that the consumption of e-cigarettes leads to permanent smoking cessation twice as frequently as the use of NRTs. This effectiveness can presumably be ascribed partly to the fact that the consumption experience of an e-cigarette is perceived as being much closer to the original tobacco cigarette than to nicotine patches or sprays, and that physical symptoms of withdrawal can therefore be balanced out more easily. The results are viewed critically by the scientific community, though, as approximately 80 % of the individuals who had quit tobacco consumption with the help of e-cigarettes still consumed e-cigarettes one year later, and had thus not achieved full nicotine abstinence [8]. In the case of NRTs, the percentage of participants who still relied on the product (NRT) one year later was 9% and thus much lower [37].

However, it bears repeating at this point that, according to all the available scientific evidence, nicotine consumption has in itself a less serious health impact compared to tobacco consumption or compared to the toxicants contained in the vapour of e-cigarettes [7].

Further research has shown that users of e-cigarettes experience a similarly small degree of undesired side effects as smokers who try to quit with the help of NRTs [7]. Hence, this is another variable where NRTs and e-cigarettes do appear to be quite comparable [7].

The most recent Cochrane review on e-cigarettes confirms the opinion that e-cigarettes may possibly support smoking cessation just as effectively as NRTs [7]. Some of the presented studies even prove a higher effectiveness of e-cigarettes in supporting smoking cessation [26]. In spite of all the available scientific evidence that speaks in favour of e-cigarettes and their cessation potential [13], there is still no sufficient number of high-quality studies which would examine the health impact caused by the consumption of e-cigarettes [7]. Therefore, the scientific evidence available to date is to be evaluated with caution as there is also a multitude of studies which yield different results [16]. This scientific evidence, which is still evolving, should be taken into account in the public and scientific debate.

Final Discussion

There are sound scientific arguments as to why the assessment communicated up to now by McNeil et al. [15], i.e. that e-cigarettes are 95 % less harmful, can hardly be maintained from a toxicological perspective [38] and must also be criticised from a science communication perspective [39]. Still, it is widely accepted by scientists that users of e-cigarettes are exposed to fewer toxicants in the case of normal consumption than if they consumed tobacco cigarettes [16]. Therefore, the NASEM Report [16] also comes to the conclusion that a complete switch to e-cigarettes reduces the harmful health impact at least in the short term. For users of tobacco cigarettes, switching to e-cigarettes does not aggravate their health situation as long as they do not practice dual use. If they substitute smoking completely with vaping, e-cigarettes may constitute a quick and significant reduction of their individual health risk [13, 15].

In Germany, the plausible potential of the e-cigarette becomes evident in that it is currently the most popular way of trying to quit smoking, preferred even over nicotine replacement products or consultation by health professionals [4]. This is likely associated with the wider availability of the products and the increased public awareness of the devices in the past years. Simultaneously, their rising popularity and wider availability also ignite a scientific debate on whether e-cigarettes are a useful instrument for smoking cessation [7,13]. Notwithstanding, countries such as the United Kingdom [15, 40] or New Zealand [41]

chose to make use of the potential of e-cigarettes and turned them into one of the cornerstones of their smoking cessation programmes.

It is true that today, we see a lively debate in the scientific community about whether, and if so, to which extent e-cigarettes are useful for smoking cessation [13], and there are good arguments supporting both views. For a continued, evidence-based discussion of this topic, it is imperative to better understand the e-cigarette as a product and its effects on health [25]. While the body of studies on e-cigarettes and their health impact is steadily growing, there is a distinct lack of high-quality studies. The same is true for studies on the effectiveness of e-cigarettes in smoking cessation. As Hartmann-Boyce et al. [7] conclude, there is only a very small number of studies which deal with precisely the question of said effectiveness and which bear only a low risk of distortion. Hence, there is not only a need for a quantitative increase in studies but also a need for scientifically robust, randomised, controlled studies in order to better understand e-cigarettes as such but also their role in smoking cessation [13, 16]. The studies that have already been conducted on the basis of such standards, however, point to the potential of e-cigarettes to be a useful complement for attempted smoking cessation [7] and to be possibly superior to established NRTs. Therefore, the discussion should focus more on the latest scientific evidence and the product should be given the opportunity to make its contribution to tobacco cessation policy.

Conclusion and Outlook

This article has shown that there are scientific arguments supporting the use of e-cigarettes in smoking cessation. Their use should be based on clearly defined and scientifically supported criteria. To further develop these criteria on an ongoing basis and to adapt them to state-of-the-art knowledge, there is a need to better understand the product along with its risks and opportunities. Notwithstanding this limitation, the currently available scientific evidence does not speak against the notion of e-cigarettes playing a more important role in smoking cessation than they have up to now [42]. It would therefore be a welcome step if the next S3 Guideline on Smoking and Tobacco Addiction [8] would be in greater alignment with the current Cochrane review [7] on e-cigarettes. This would at least open up the possibility that treating therapists could consider e-cigarettes in smoking cessation.

In the light of the available research results, the question must be asked again whether, based on health policy considerations, the prime goal should still be to immediately achieve complete nicotine abstinence and thus risk a high dropout rate. Alternatively, the major focus could be on minimising each smoker's exposure to toxicants in a first step, and to only aim for complete nicotine withdrawal at a later stage. Given that in Germany, the number of annual attempts to quit smoking has been on a decline for several years now, there is an urgent need for action when it comes to the evaluation of the current tobacco cessation strategy: Between 2016 and 2019, merely around 20 % of all smokers in Germany tried to quit smoking. Conversely, this means that the vast majority of smokers (approx. 80%) did not even try to improve their health situation during this period by breaking away from tobacco consumption [4]. For this reason, all available tools should be used unless there are fundamental and serious arguments speaking against them. As can be concluded from the latest research [7], this is not the case with e-cigarettes.

Finally, it bears repeating that further, substantial research is required to be able to quantify the precise harm reduction potential of e-cigarettes [16,21]. Bearing in mind also that the devices and ingredients are constantly being developed further, there is a need to

examine the products available on the market in a continuous study with long-term design [38].

Funding

Open Access funding enabled and organized by Projekt DEAL.

Conflict of Interests

H. Stover states that there is no conflict of interests.

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