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[Intervention Review]

Electronic cigarettes for smoking cessation

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ABSTRACT

Rationale

Electronic cigarettes (EC) are handheld electronic vaping devices that produce an aerosol by heating a liquid. People who smoke, healthcare providers, and regulators want to know if EC can help people quit smoking, and if they are safe to use for this purpose. This review update was conducted as part of a living systematic review.

Objectives

To examine the safety, tolerability, and effectiveness of EC for helping people who smoke tobacco achieve long-term smoking abstinence, in comparison to non-nicotine EC, other smoking cessation treatments, and no treatment.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase, and PsycINFO to 1 March 2025, reference-checked, and contacted study authors.

Eligibility criteria

We included trials randomising people who smoked to an EC or control condition. We also included uncontrolled intervention studies where all participants received an EC intervention. Studies had to measure an eligible outcome.

Outcomes

Critical outcomes were abstinence from smoking after at least six months, adverse events (AEs), and serious adverse events (SAEs). Important outcomes were biomarkers, toxicants/carcinogens, and longer-term EC use.

Risk of bias

We used the RoB 1 tool to assess risk of bias for each study and GRADE to assess evidence certainty.

Synthesis methods

We followed standard Cochrane methods for screening and data extraction. Where appropriate, we pooled data using random-effects models to calculate risk ratios (RRs) with 95% confidence intervals (CIs) for dichotomous outcomes. For continuous outcomes, we calculated mean differences with 95% CIs.

Included studies

We included 104 completed studies (14 new to this update), representing 30,366 participants, of which 61 were randomised controlled trials (RCTs). We rated 11 included studies as being at low risk of bias, 70 at high risk (including all non-randomised studies), and the remainder at unclear risk overall.

Synthesis of results

Nicotine EC result in increased quit rates compared to nicotine replacement therapy (NRT) (high-certainty evidence) (RR 1.55, 95% CI 1.28 to 1.88; I^2 = 0%; 9 studies, 2703 participants). In absolute terms, this might translate to an additional three quitters per 100 (95% CI 2 to 5 more). The rate of occurrence of AEs is probably similar between groups (moderate-certainty evidence (limited by imprecision)) (RR 1.00, 95% CI 0.73 to 1.37; I^2 = 58%; 7 studies, 2241 participants). SAEs were rare, and there is insufficient evidence to determine whether rates differ between groups due to very serious imprecision (RR 1.22, 95% CI 0.73 to 2.03; I^2 = 30%; 8 studies, 2950 participants; low-certainty evidence).

Nicotine EC probably result in increased quit rates compared to non-nicotine EC (moderate-certainty evidence, limited by imprecision) (RR 1.34, 95% CI 1.06 to 1.70; I^2 = 0%; 7 studies, 1918 participants). In absolute terms, this might lead to an additional two quitters per 100 (95% CI 0 to 4 more). There is probably little to no difference in the rate of AEs between these groups (moderate-certainty evidence) (RR 1.01, 95% CI 0.95 to 1.08; I^2 = 0%; 5 studies, 840 participants). There is insufficient evidence to determine whether rates of SAEs differ between groups, due to very serious imprecision (RR 0.98, 95% CI 0.55 to 1.73; I^2 = 0%; 10 studies, 1717 participants; low-certainty evidence).

Compared to behavioural support only or no support, quit rates may be higher for participants randomised to nicotine EC (low-certainty evidence due to risk of bias) (RR 1.78, 95% CI 1.42 to 2.25; I^2 = 13%; 11 studies, 6819 participants). In absolute terms, this represents an additional three quitters per 100 (95% CI 2 to 5 more). There was some evidence that (non-serious) AEs may be more common in people randomised to nicotine EC (RR 1.22, 95% CI 0.96 to 1.55; I^2 = 66%; 8 studies, 2485 participants; very low-certainty evidence) but the evidence is uncertain and, again, there was insufficient evidence to determine whether rates of SAEs differed between groups (RR 0.93, 95% CI 0.67 to 1.29; I^2 = 0%; 15 studies, 4716 participants; very low-certainty evidence).

Data from non-randomised studies were consistent with RCT data. The most commonly reported AEs were throat/mouth irritation, headache, cough, and nausea, which tended to dissipate with continued EC use. Very few studies reported data on other outcomes or comparisons; hence, evidence for these is limited, with CIs often encompassing both clinically significant harm and benefit.

Authors' conclusions

There is high-certainty evidence that nicotine EC increase quit rates compared to NRT, and moderate-certainty evidence that they probably increase quit rates compared to EC without nicotine. Evidence comparing nicotine EC with behavioural support or no support also suggests benefit, but is less certain due to risk of bias inherent in the study designs. CIs were, for the most part, wide for data on AEs, SAEs, and other safety markers, with no evidence of a difference in AEs between nicotine and non-nicotine EC nor between nicotine EC and NRT, but low-certainty evidence for increased AEs compared with behavioural support/no support. Overall incidence of SAEs was low across all study arms. We did not detect evidence of serious harm from nicotine EC, but longer, larger trials are needed to fully evaluate safety. Included studies tested regulated nicotine-containing EC; illicit products and/or products containing other active substances (e.g. tetrahydrocannabinol (THC)) may have different harm profiles.

The main limitation of the evidence base remains imprecision for some comparisons and for safety outcomes due to the relatively small number of RCTs contributing, often with low event rates. Further RCTs are underway. To ensure the review continues to provide up-to-date information to decision-makers, this is a living systematic review. We run and screen searches monthly, with the review updated when relevant new evidence becomes available. Please refer to the *Cochrane Database of Systematic Reviews* for the review's current status.

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Registration

Original 2012 protocol available via DOI: 10.1002/14651858.CD010216. Updated 2023 protocol available via DOI 10.17605/OSF.IO/ZWGSK (https://osf.io/ZWGSK/). 2025 updates to protocol available via DOI: 10.17605/OSF.IO/59M4U (https://osf.io/59M4U/) and DOI: 10.17605/OSF.IO/UPGJC (https://osf.io/UPGJC/).

PLAIN LANGUAGE SUMMARY

Can electronic cigarettes help people stop smoking, and do they have any unwanted effects when used for this purpose?

Key messages

· Nicotine e-cigarettes can help people to stop smoking for at least six months. Evidence shows they work better than nicotine replacement therapy, and probably better than e-cigarettes without nicotine.

· They may work better than no support, or behavioural support alone, and may not be associated with serious unwanted effects.

· However, we still need more evidence, particularly about the effects of newer types of e-cigarettes that have better nicotine delivery than older types, as better nicotine delivery might help more people quit smoking.

What are electronic cigarettes?

Electronic cigarettes (e-cigarettes) or vapes are handheld devices that work by heating a liquid that usually contains nicotine and flavourings. E-cigarettes allow users to inhale nicotine in a vapour rather than smoke. Because they do not burn tobacco, regulated e-cigarettes do not expose users to the same levels of chemicals that can cause diseases in people who smoke conventional cigarettes.

Using an e-cigarette is commonly known as 'vaping'. Many people use e-cigarettes to help them to stop smoking tobacco. Here we focus primarily on e-cigarettes containing nicotine.

Why did we do this Cochrane review?

Stopping smoking lowers the risk of many diseases. Many people find it difficult to stop smoking. We wanted to find out if using e-cigarettes could help people to stop smoking, and if people using them for this purpose experience any unwanted effects.

What did we do?

We searched for studies that looked at the use of e-cigarettes for stopping smoking.

We looked for randomised controlled trials, in which the treatments people received were decided at random. This type of study usually gives the most reliable evidence about treatment effects. We also looked for studies in which everyone received e-cigarettes, and studies that gave e-cigarettes to people who smoked and monitored their health even if there was no randomisation, so we could learn about their health effects.

We were interested in:

· how many people stopped smoking for at least six months; and

· how many people had unwanted effects, reported after at least one week of use.

Search date

We included evidence published up to 1 March 2025.

What we found

We found 104 studies including 30,366 adults who smoked. Studies compared nicotine e-cigarettes with:

· nicotine replacement therapy (e.g. patches or gum);

· varenicline (a medicine to help people stop smoking);

· e-cigarettes without nicotine;

· heated tobacco (products that heat tobacco to a high enough temperature to release vapour, without burning it or producing smoke; these differ from e-cigarettes because they heat tobacco leaf/sheet);

· oral nicotine pouches (pouches that contain no tobacco but release nicotine when kept in the mouth);

· other types of nicotine-containing e-cigarettes (e.g. pod devices, newer devices);

· behavioural support (e.g. advice or counselling); or

· no support for stopping smoking.

Most studies took place in the USA (48 studies) and the UK (21).

What are the results of our review?

People are more likely to stop smoking for at least six months using nicotine e-cigarettes than using nicotine replacement therapy (9 studies, 2703 people) or e-cigarettes without nicotine (7 studies, 1918 people).

Nicotine e-cigarettes may help more people to stop smoking than either no support or behavioural support only (11 studies, 6819 people).

For every 100 people using nicotine e-cigarettes to stop smoking, 8 to 11 might successfully stop, compared with only 6 of 100 people using nicotine-replacement therapy, 6 of 100 using e-cigarettes without nicotine, or 4 of 100 people having no support or behavioural support only.

We are uncertain if there is a difference between how many unwanted effects occur using nicotine e-cigarettes compared with nicotine replacement therapy, no support or behavioural support only. There was some evidence that non-serious unwanted effects were more common in groups receiving nicotine e-cigarettes compared to no support or only behavioural support, but the evidence is uncertain. Low numbers of unwanted effects, including serious unwanted effects, were reported in studies comparing nicotine e-cigarettes to nicotine replacement therapy. There is probably no difference in how many non-serious unwanted effects occur in people using nicotine e-cigarettes compared to e-cigarettes without nicotine.

The unwanted effects reported most often with nicotine e-cigarettes were throat or mouth irritation, headache, cough, and nausea. These appear similar to what people experience when using NRT. Unwanted effects were reduced over time as people continued using nicotine e-cigarettes.

How reliable are these results?

We found evidence that nicotine e-cigarettes help more people to stop smoking than nicotine replacement therapy. Nicotine e-cigarettes probably help more people to stop smoking than e-cigarettes without nicotine, but more studies are still needed to confirm this.

Studies comparing nicotine e-cigarettes with behavioural or no support also showed higher quit rates in people using nicotine e-cigarettes, but provide less certain data because of issues with study design.

Most of our results for the unwanted effects could change when more evidence becomes available.