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**WILEY**

[Intervention Review]

# Electronic cigarettes for smoking cessation and reduction

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## ABSTRACT

### Background

Electronic cigarettes (ECs) are electronic devices that heat a liquid - usually comprising propylene glycol and glycerol, with or without nicotine and flavours, stored in disposable or refillable cartridges or a reservoir - into an aerosol for inhalation. Since ECs appeared on the market in 2006 there has been a steady growth in sales. Smokers report using ECs to reduce risks of smoking, but some healthcare organisations have been reluctant to encourage smokers to switch to ECs, citing lack of evidence of efficacy and safety. Smokers, healthcare providers and regulators are interested to know if these devices can reduce the harms associated with smoking. In particular, healthcare providers have an urgent need to know what advice they should give to smokers enquiring about ECs.

### Objectives

To examine the efficacy of ECs in helping people who smoke to achieve long-term abstinence; to examine the efficacy of ECs in helping people reduce cigarette consumption by at least 50% of baseline levels; and to assess the occurrence of adverse events associated with EC use.

### Search methods

We searched the Cochrane Tobacco Addiction Groups Trials Register, the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase, and two other databases for relevant records from 2004 to July 2014, together with reference checking and contact with study authors.

### Selection criteria

We included randomized controlled trials (RCTs) in which current smokers (motivated or unmotivated to quit) were randomized to EC or a control condition, and which measured abstinence rates or changes in cigarette consumption at six months or longer. As the field of EC research is new, we also included cohort follow-up studies with at least six months follow-up. We included randomized cross-over trials and cohort follow-up studies that included at least one week of EC use for assessment of adverse events.

### Data collection and analysis

One review author extracted data from the included studies and another checked them. Our main outcome measure was abstinence from smoking after at least six months follow-up, and we used the most rigorous definition available (continuous, biochemically validated, longest follow-up). For reduction we used a dichotomous approach (no change/reduction < 50% versus reduction by 50% or more of baseline cigarette consumption). We used a fixed-effect Mantel-Haenszel model to calculate the risk ratio (RR) with a 95% confidence interval (CI) for each study, and where appropriate we pooled data from these studies in meta-analyses.

## Main results

Our search identified almost 600 records, from which we include 29 representing 13 completed studies (two RCTs, 11 cohort). We identified nine ongoing trials. Two RCTs compared EC with placebo (non-nicotine) EC, with a combined sample size of 662 participants. One trial included minimal telephone support and one recruited smokers not intending to quit, and both used early EC models with low nicotine content. We judged the RCTs to be at low risk of bias, but under the GRADE system the overall quality of the evidence for our outcomes was rated 'low' or 'very low' because of imprecision due to the small number of trials. A 'low' grade means that further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. A 'very low' grade means we are very uncertain about the estimate. Participants using an EC were more likely to have abstained from smoking for at least six months compared with participants using placebo EC (RR 2.29, 95% CI 1.05 to 4.96; placebo 4% versus EC 9%; 2 studies; GRADE: low). The one study that compared EC to nicotine patch found no significant difference in six-month abstinence rates, but the confidence intervals do not rule out a clinically important difference (RR 1.26, 95% CI: 0.68 to 2.34; GRADE: very low). A higher number of people were able to reduce cigarette consumption by at least half with ECs compared with placebo ECs (RR 1.31, 95% CI 1.02 to 1.68, 2 studies; placebo: 27% versus EC: 36%; GRADE: low) and compared with patch (RR 1.41, 95% CI 1.20 to 1.67, 1 study; patch: 44% versus EC: 61%; GRADE: very low). Unlike smoking cessation outcomes, reduction results were not biochemically verified.

None of the RCTs or cohort studies reported any serious adverse events (SAEs) that were considered to be plausibly related to EC use. One RCT provided data on the proportion of participants experiencing any adverse events. Although the proportion of participants in the study arms experiencing adverse events was similar, the confidence intervals are wide (ECs vs placebo EC RR 0.97, 95% CI 0.71 to 1.34; ECs vs patch RR 0.99, 95% CI 0.81 to 1.22). The other RCT reported no statistically significant difference in the frequency of AEs at three- or 12-month follow-up between the EC and placebo EC groups, and showed that in all groups the frequency of AEs (with the exception of throat irritation) decreased significantly over time.

## Authors' conclusions

There is evidence from two trials that ECs help smokers to stop smoking long-term compared with placebo ECs. However, the small number of trials, low event rates and wide confidence intervals around the estimates mean that our confidence in the result is rated 'low' by GRADE standards. The lack of difference between the effect of ECs compared with nicotine patches found in one trial is uncertain for similar reasons. ECs appear to help smokers unable to stop smoking altogether to reduce their cigarette consumption when compared with placebo ECs and nicotine patches, but the above limitations also affect certainty in this finding. In addition, lack of biochemical assessment of the actual reduction in smoke intake further limits this evidence. No evidence emerged that short-term EC use is associated with health risk.

## PLAIN LANGUAGE SUMMARY

### Can electronic cigarettes help people stop smoking or reduce the amount they smoke, and are they safe to use for this purpose?

#### Background

Electronic cigarettes (EC) are electronic devices that produce a smoke-like aerosol (commonly referred to as vapour) that the user inhales. This vapour typically contains nicotine without most of the toxins smokers inhale with cigarette smoke. ECs have become popular with smokers who want to reduce the risks of smoking. This review aimed to find out whether ECs help smokers stop or cut down on their smoking, and whether it is safe to use ECs to do this.

#### Study characteristics

We searched for trials published up to July 2014 and found 13 that help answer these questions. Two of the trials compared ECs with and without nicotine. These studies were judged to be at low risk of bias. They were conducted in New Zealand and Italy, and measured whether people had quit smoking for at least six months. In one study, people wanted to quit smoking, but in the other study, they did not. The trial in people who wanted to quit smoking also compared ECs to nicotine patches. The rest of the studies did not put people into treatment groups so could not directly compare ECs with something else. These studies can tell us less about how ECs might help with quitting smoking or with cutting down.

#### Key results

Combined results from two studies, involving over 600 people, showed that using an EC containing nicotine increased the chances of stopping smoking long-term compared to using an EC without nicotine. Using an EC with nicotine also helped more smokers reduce the amount they smoked by at least half compared to using an EC without nicotine. We could not determine if EC was better than a nicotine patch in helping people stop smoking because the number of participants in the study was low. More studies are needed to evaluate this effect. This study showed that people who used EC were more likely to cut down the amount they smoked by at least half than people using a patch. The other studies were of lower quality, but they supported these findings. There was no evidence that using EC at the same time as using regular cigarettes made people less likely to quit smoking. None of the studies found that smokers who used EC short-term (for 2 years or less) had an increased health risk compared to smokers who did not use EC.

#### Quality of the evidence

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The quality of the evidence overall is low because it is based on only a small number of studies. More studies of EC are needed. Some are already underway.