

E-CIGARETTES VERSUS NICOTINE REPLACEMENT THERAPY FOR SMOKING CESSATION

QUALITY OF EVIDENCE: MODERATE



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THE BOTTOM LINE

Among adults who smoke, use of e-cigarettes results in mild increase in abstinence rates at 1 year with minor adverse effects; however, emerging concerns around vaping-induced lung injury may limit its use.

WHY IS THIS IMPORTANT?

Previous studies have suggested that e-cigarettes containing nicotine can help people stop smoking compared to e-cigarettes without nicotine¹. However, there is a lack of randomized controlled trials comparing smoking cessation outcomes in patients using nicotine containing e-cigarettes (EC) versus nicotine replacement therapy (NRT).

FACTS

■ Design:

- Two-group pragmatic, multicenter, unblinded randomized control trial²
- Participants were randomized to receive second generation refillable EC product (Aspire One Kit) or NRT (patch, gum, lozenge, nasal spray, inhalator, mouth strip, and microtabs) for smoking cessation treatment combined with weekly in-person behavioral support/counseling in each treatment group

- Primary outcome: sustained abstinence for 12 months by self-report validated with expired carbon monoxide levels
- Secondary outcome: abstinence at 4, 26, and 26–52 weeks from target quit date, carbon monoxide validated reduction in smoking by 50%.
- Participants:
 - Inclusion criteria: adults 18 years or older, current smoker, English proficiency
 - Exclusion criteria: pregnancy, breastfeeding, strong preference to use EC or NRT, enrollment in another trial
 - Important characteristics: median age of participants was 41 years, 52% were female, and 40% of study participants were entitled to free prescriptions

One Year Abstinence Rates among Patients Trying to Quit Smoking Using E-cigarettes versus Nicotine Replacement Therapy

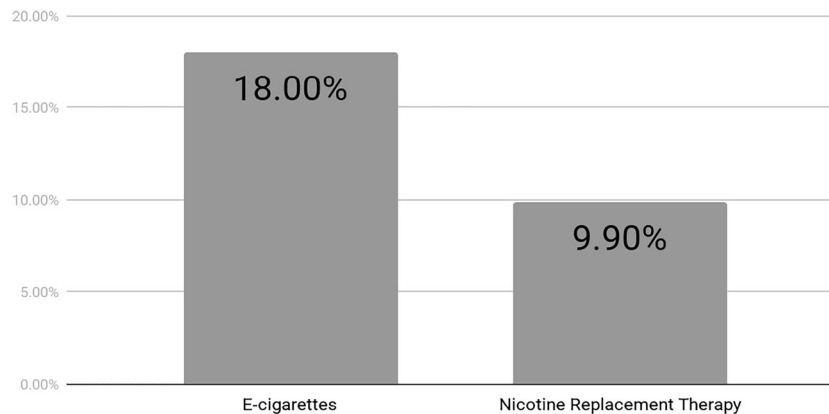


Figure 1 One-year abstinence rates among patients trying to quit smoking using e-cigarettes versus nicotine replacement therapy. *The relative risk for abstinence at 1 year with EC versus NRT was 1.83 (95% CI 1.30–2.58).

- **Primary results:** The trial randomized 886 adult patients who smoke and sought smoking cessation services at local community health centers to use of e-cigarettes or nicotine replacement therapy and followed them for 1 year³. The study found an 8.1 absolute difference in 1-year abstinence rates in those who use e-cigarettes compared to nicotine replacement therapy (see Fig. 1). The study found an 83% relative risk of abstinence at 12 months with the use of EC as compared to NRT (see Fig. 1).
- **Secondary outcomes:** EC were associated with increased abstinence rates in each of the secondary outcomes compared to NRT.
- **Adverse events:** There were no significant increases in adverse events except for 12% higher incidence of throat or mouth irritation in the EC group ($p < 0.05$)
- Emerging data on the safety of e-cigarette use is notable for 2170 cases of e-cigarette or vaping product use–associated lung injury (EVALI) and over 40 deaths^{3,4}.
- It is worth noting that 80% of patients in the EC group were still using EC at 1 year, suggesting that e-cigarettes may be a replacement for cigarettes instead of a strategy to quit using cigarettes.
- Given the modest increase in abstinence rates and the growing concern about EVALI and death^{3,4}, more data are needed on the relative harms of EC or vaping before it can be routinely recommended for smoking cessation.

STUDY QUALITY AND APPLICABILITY

Only 43% (886/2045) of people screened for eligibility met criteria to be enrolled in the study. Thus, the study results may only apply to a select group of highly motivated individuals who want to stop smoking. The production of the Aspire One Kit was discontinued during the study, creating an internal validity issue since all the participants did not receive the same type of EC product. The lack of blinding for patients, clinicians, and study personnel to treatment assignments could introduce bias in reporting and adjudication of outcomes. The health system in the UK facilitated free smoking cessation resources and intensive face-to-face behavioral counseling, which could limit its generalizability to patients who are not in health systems that can facilitate these resources.

TIPS FOR DISCUSSION OF RESULTS WITH PATIENTS

- Among adult patients who smoke, using EC, as compared to NRT, resulted in a 8% increase in 1-year abstinence rates with intensive behavioral counseling.
- EC users in this study experienced more throat and mouth irritation than NRT users.

Compliance with Ethical Standards:

Conflict of Interest: The authors declare that they do not have a conflict of interest.

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The Bottom Line summaries reflect the expertise and opinions of the SGIM EBM Task Force as of the date of release of this summary.

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