

ASHES, Vol. 9(13) - Do e-cigarettes deliver? A randomized control trial of nicotine delivery systems

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As awareness about and use of e-cigarettes has grown across the globe ([ASHES Vol. 9\(6\)](#)), these devices have come under more scrutiny from researchers and public policy experts. E-cigarettes are gaining popularity because like nicotine patches, they provide a low dose of nicotine, contain fewer toxins than cigarettes, and simulate behavioral and sensory dimensions of smoking. However, because e-cigarettes are a relatively new technology, there is a paucity of research to inform discussions about safety and efficacy. This week's ASHES reviews a recent randomized control trial examining the efficacy of e-cigarettes compared to placebo and nicotine patches for smoking cessation (Bullen et al., 2013).

Methods

- Researchers recruited a sample of 657 New Zealand adult smokers who wanted to quit smoking cigarettes.
 - Participants were randomized into 3 groups:
 - 289 received e-cigarettes;
 - 295 received nicotine replacement patches; and
 - 73 received placebo e-cigarettes (i.e., a vaporized solution with no nicotine)
- Participants completed telephone interviews at baseline, and follow-up surveys at 1, 3, and 6 months.
- Outcomes of interest included cigarette smoking abstinence, number of cigarettes per day, and adverse events related to e-cigarette or nicotine patch use (e.g., persistent or significant disability, admission to hospital).
- Researchers used intent to treat analysis and compared groups using Chi square and multivariate regressions.

Results

- As Figure 1 shows, e-cigarette users initially had better success maintaining continuous abstinence at one month than patch users. This difference is no longer significant at 3 months and 6 months. There was not enough [statistical power](#) to detect differences in continuous abstinence between e-cigarettes and placebos.
- Among those who relapsed (i.e., began smoking cigarettes again), the median time to relapse was 35 days among the e-cigarette group, 2.5 times longer than the nicotine patch group, and nearly 3 times longer than the placebo group.
- At all time points, e-cigarette users who did relapse reported smoking significantly fewer cigarettes per day than patch users who relapsed.
- There was no significant difference in the rate of serious adverse events between groups (i.e., 19.7% for e-cigarette group; 11.8% for nicotine patch group; and 13.9% for placebo e-cigarette group).

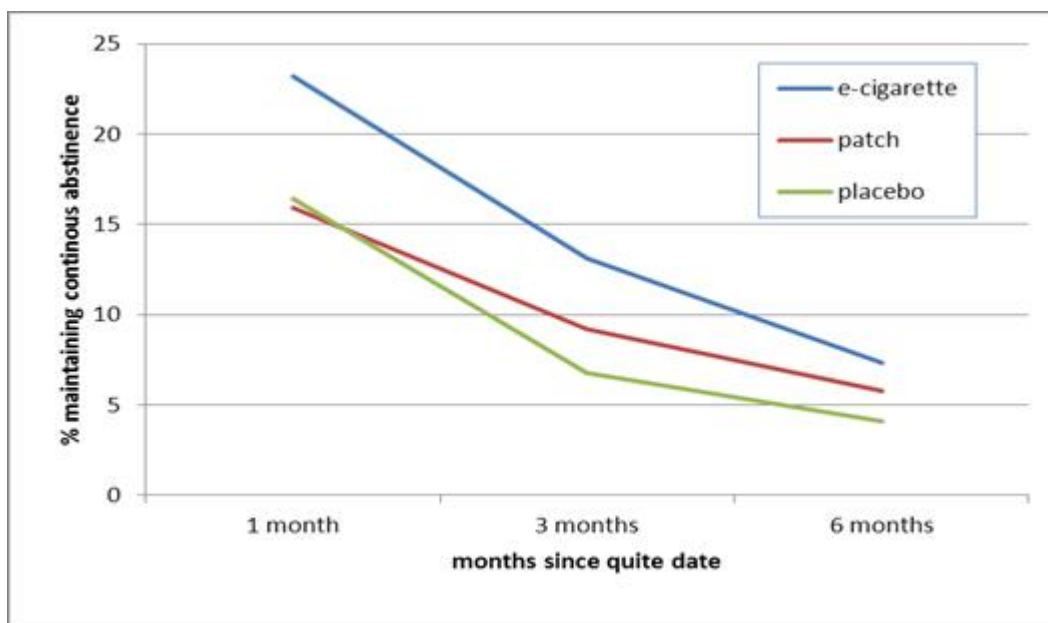


Figure. Percent maintaining continuous cigarette smoking abstinence by time and treatment group. Click image to enlarge.

Limitations

- Rates of smoking abstinence at 6-month follow-up were much lower than anticipated, leading to insufficient power to detect differences between groups, particularly between the placebo group and other groups.
- Most of the outcomes assessed (e.g., cigarettes per day, continuous abstinence) relied on [self-report](#) and are therefore subject to memory errors and other limitations.

Conclusion

The efficacy of e-cigarettes to help individuals quit smoking remains unresolved. This study suggests that e-cigarettes are as effective as the patch in terms of abstinence at 6-months, and appear to be more effective initially. Researchers also found some promising results including a longer time to relapse and larger reductions in the number of cigarettes smoked per day among e-cigarette users compared to patch users. In addition, e-cigarette users reported adverse events at similar rates compared to the other two groups. Future research should attempt to replicate the study with larger samples and varying nicotine doses.

-John Kleschinsky

References

Bullen, C., Howe, C., Laugesen, M., McRobbie, H., Parag, V., Williman, J., & Walker, N. (2013). Electronic cigarettes for smoking cessation: a randomised controlled trial. *Lancet*, 382(9905), 1629-1637. doi: 10.1016/S0140-6736(13)61842-5

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