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News Release

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Session B102: Novel Approaches to Understand and Improve Health Outcomes Monday, May 18, 2015, 2:15 p.m. – 4:15 p.m. Location: Colorado Convention Center

Evidence that Electronic Cigarettes Are Effective for Smoking Cessation Long-Term is Lacking

ATS 2015, DENVER — There is little reliable evidence that electronic cigarettes are effective for long-term smoking cessation, according to a new analysis of the currently available research which was presented at the 2015 American Thoracic Society International Conference.

"While e-cigarettes have been shown to significantly improve abstinence at 1 month compared with placebo, no such evidence is available supporting their effectiveness for longer periods," said lead author Riyad al-Lehebi, MBBS, of the University of Toronto. "Until such data are available, there are a number of other smoking cessation aids available that have a more robust evidence base supporting their efficacy and safety."

The meta-analysis included four studies of the efficacy and safety of e-cigarettes for promoting smoking cessation in 1011 patients and an additional 18 studies of the safety of e-cigarettes reporting adverse effects that occurred in 1212 patients.

At 1 month, e-cigarettes significantly improved the prevalence of abstinence among study subjects, but this effect was no longer observed at 3- or 6-month follow-ups. In one study, no significant difference in 6-month abstinence rates were observed between e-cigarettes and placebo or between e-cigarettes and the nicotine patch.

Adverse effects of e-cigarette use noted in the studies included dry cough, throat irritation, and shortness of breath. The incidence of serious adverse events did not differ between e-cigarettes and placebo e-cigarettes, but e-cigarette use was associated with a higher rate of adverse effects than the nicotine patch.

"Although e-cigarettes are widely promoted and used as a smoking cessation tool, we found no data supporting their long-term efficacy and safety," said al-Lehebi. "Given the potential health risks of using these unproven and unregulated devices, individuals seeking help with smoking cessation should consider other more well-established options until more research is performed."

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* Please note that numbers in this release may differ slightly from those in the abstract. Many of these investigations are ongoing; the release represents the most up-to-date data available at press time.

Abstract 65842

Efficacy and Safety of Electronic Cigarettes for Smoking Cessation: A Systematic Review Type: Scientific Abstract Category: 06.14 - Smoking: Prevention/Education/Cessation (NUR/BSHSR) Authors: <u>R.O. Allehebi</u>, M.H. Khan, M.B. Stanbrook; Division of Respiraology, Department of Medicine, University of Toronto - Toronto, ON/CA

Abstract Body

Rationale: Electronic-cigarettes (e-cigarettes) are battery-powered electronic nicotine delivery devices designed to deliver nicotine in a similar manner to tobacco without tobacco's other harmful constituents. We systematically reviewed the evidence to date regarding the efficacy and safety of e-cigarettes.

Methods: We searched MEDLINE and EMBASE from 1946 to May 2014. Studies of efficacy were included if they enrolled current smokers and compared e-cigarettes to placebo, active control or no therapy. Studies of safety were included regardless of design if they reported any adverse events associated with e-cigarette use.

Results: Of 4569 abstracts identified, 297 articles underwent full-text review. For efficacy, 4 studies (2 randomized trials, 2 uncontrolled before-and-after studies) met inclusion criteria. For safety, 22 articles met inclusion criteria. Meta-analysis showed that point prevalence abstinence was significantly better for e-cigarettes vs. placebo at 1 month (RR 1.71, 95% CI 1.08-2.72, $I^2 = 0\%$). However, differences for point prevalence abstinence did not reach statistical significance at 3 months (RR 1.95, 95% CI 0.74-5.13, $I^2 = 65\%$) or 6 months (RR 1.32, 95% CI 0.59-2.93, $I^2 = 59\%$), with large heterogeneity between studies rendering the validity of these pooled estimates uncertain. The only study to evaluate continuous abstinence found low rates at 6 months, with no significant differences seen between e-cigarettes compared with placebo (7.3% vs. 4.1%, RR 1.77, 95% CI 0.54-5.77) or open-label nicotine patch (7.3% vs. 5.8%, RR 1.26, 95% CI 0.68-2.34). Respiratory adverse effects among e-cigarette users included dry cough

(incidence range 26-32%), throat irritation (7-32%), and shortness of breath (2- 20%), although incidence of these events tended to decrease over time. Case reports have documented serious adverse events in e-cigarette users including death, lipoid pneumonia, and recurrent atrial fibrillation. In comparative studies, incidence of serious adverse events did not differ between e-cigarettes and placebo e-cigarettes (19.7% vs. 13.9%, RR 1.36, 95% CI 0.54-3.42), but were more frequent with e-cigarettes than open-label nicotine patch (19.7% vs. 11.8%, RR 1.97, 95% CI 1.05-3.68).

Conclusions: Electronic cigarettes achieve higher rates of smoking cessation at 1 month than placebo, but limited available data suggest that this effect may not be sustained over longer time periods. E-cigarettes are associated with frequent short-term respiratory adverse events and may pose a higher risk of serious adverse events than nicotine patch. Given the paucity of existing data, long-term studies of the efficacy and safety of e-cigarettes are needed to determine their possible role in smoking cessation.