XIX Convegno Nazionale Tabagismo e Servizio Sanitario Nazionale

Tabacco - una minaccia per lo sviluppo

Contributi dei relatori

Le e-cig nella disassuefazione: la revisione Cochrane

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Background

Le sigarette elettroniche (EC) sono dispositivi elettronici che riscaldano un liquido in un aerosol per inalazione.

Il liquido comprende solitamente glicole propilenico e glicerolo, con o senza nicotina e sapori e conservanti in cartucce monouso o ricaricabili o in un serbatoio.

Dal momento che le EC sono apparse sul mercato nel 2006, si è registrata una crescita costante delle vendite. I fumatori affermano di utilizzare le EC per ridurre i rischi del fumo, ma alcune organizzazioni sanitarie, i gruppi di difesa del controllo del tabacco e i responsabili politici sono stati riluttanti a incoraggiare i fumatori a passare alle EC, citando la mancanza di prove di efficacia e sicurezza.

I fumatori, il personale sanitario e le autorità di regolamentazione sono interessati a sapere se questi dispositivi possono aiutare i fumatori a smettere e se sono sicuri da utilizzare.

Obiettivo

E' efficace per smettere di fumare?
E' sicura?
Rispetto agli altri interventi disponibili, quali sono i vantaggi? E quali gli svantaggi?

Cochrane Library
Cochrane Database of Systematic Reviews

Electronic cigarettes for smoking cessation (Review)

Hartmann-Boyce J, McRobbie H, Bullen C, Begh R, Stead LF, Hajek P

Hartmann-Boyce J, McRobbie H, Bullen C, Begh R, Stead LF, Hajek P.
Electronic cigarettes for smoking cessation.
Cochrane Database of Systematic Reviews 2016, Issue 9. Art. No.: CD010216.
DOI: 10.1002/14651858.CD010216.pub3.

www.cochranelibrary.com

WILEY

Obiettivi

Valutare la sicurezza e l’efficacia dell'utilizzo delle EC per aiutare le persone che fumano a raggiungere l'astinenza del fumo a lungo termine.

PICOS

P	**Fumatori motivati o non motivati a smettere.**
I	**Sigaretta Elettronica (EC)**
C	**placebo EC, altri aiuti per smettere di fumare quali NRT, nessun intervento, EC in aggiunta a trattamenti standard (comportamentali o farmacologici o entrambi) verso trattamenti standard da soli**
O	**Cessazione al più lungo periodo di follow-up, (almeno sei mesi dall'inizio dell'intervento) misurato utilizzando la definizione più rigorosa dell'astinenza, preferendo i risultati convalidati biochimicamente quando riportati.**

RCT e Studi osservazioali

D/EPI Lazio

Strategie di ricerca

We searched the following databases in January 2016:

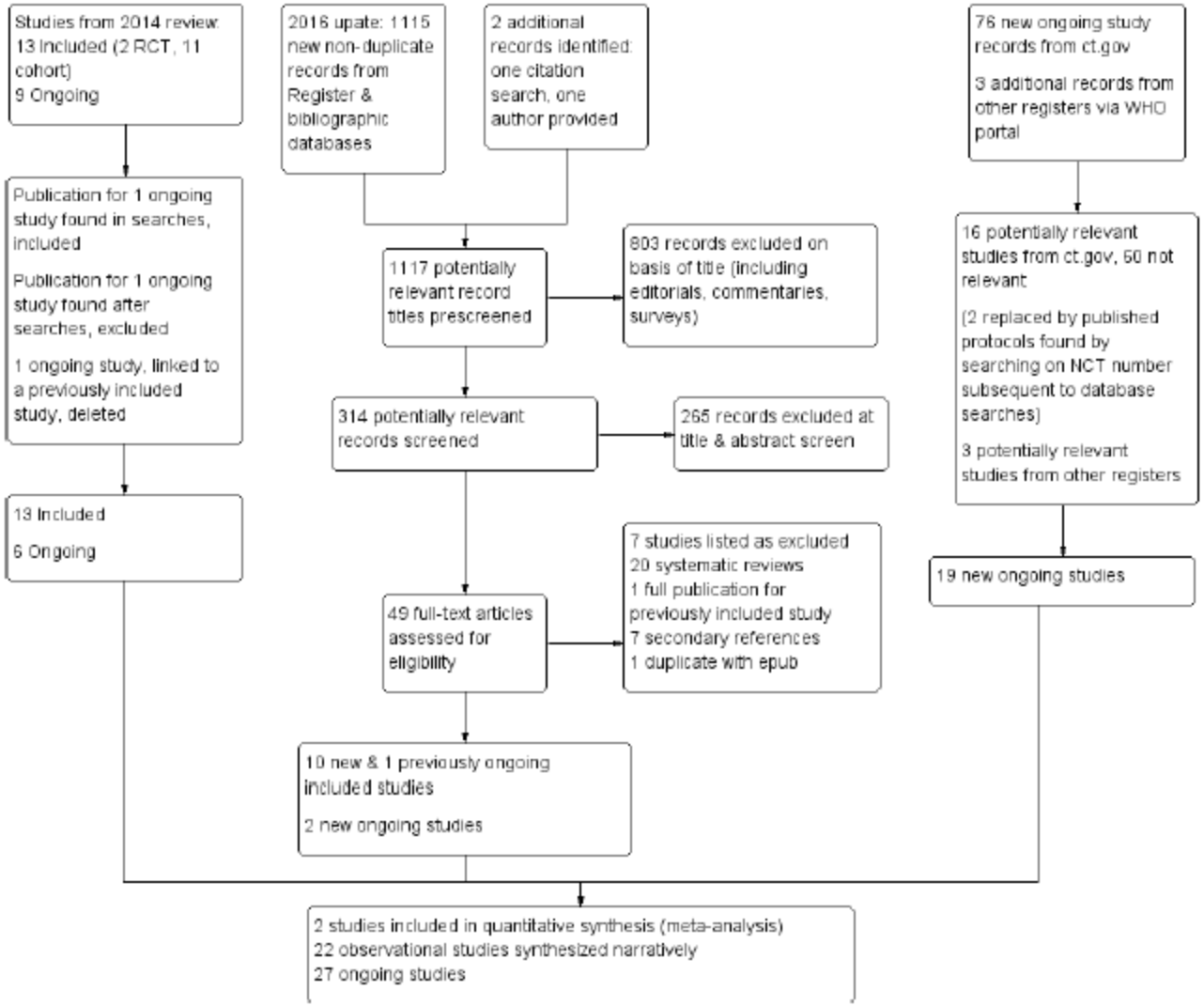
- Cochrane Tobacco Addiction Group Specialized Register
- Cochrane Central Register of Controlled Trials (CENTRAL) (the Cochrane Library, 2016, Issue 1)
- MEDLINE (OVID SP) (2004 to 2016 January week 2, & MEDLINE in process/In data review Feb 1 2016)
- Embase (OVID SP) (2004 to 2016 week 5)PsycINFO (OVID SP) (2004 to 2016 January week 4)

For the first version of the review we also searched CINAHL (EBSCO Host) (2004 to July 2014). We did not search this database for this review update as it did not contribute additional search results to the first version of the review.

The search terms were broad and included e-cig$ OR elect$ cigar$ OR electronic nicotine. The search for the 2016 update added the terms vape or vaper or vapers or vaping.

The search date parameters are limited to 2004 to the present, due to the fact that ECs were not available before 2004.

Figure 1. Study flow diagram for review update 2016

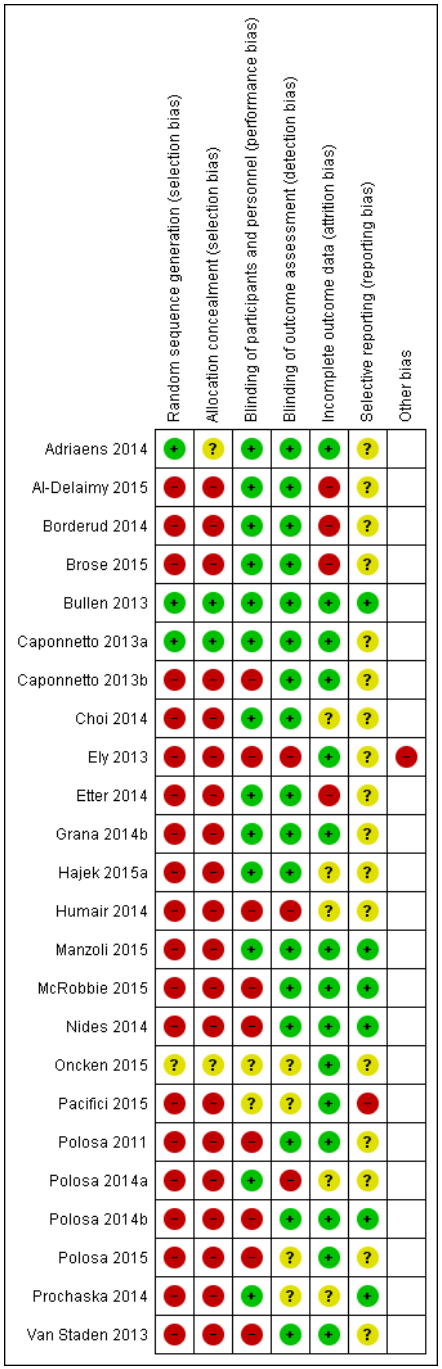


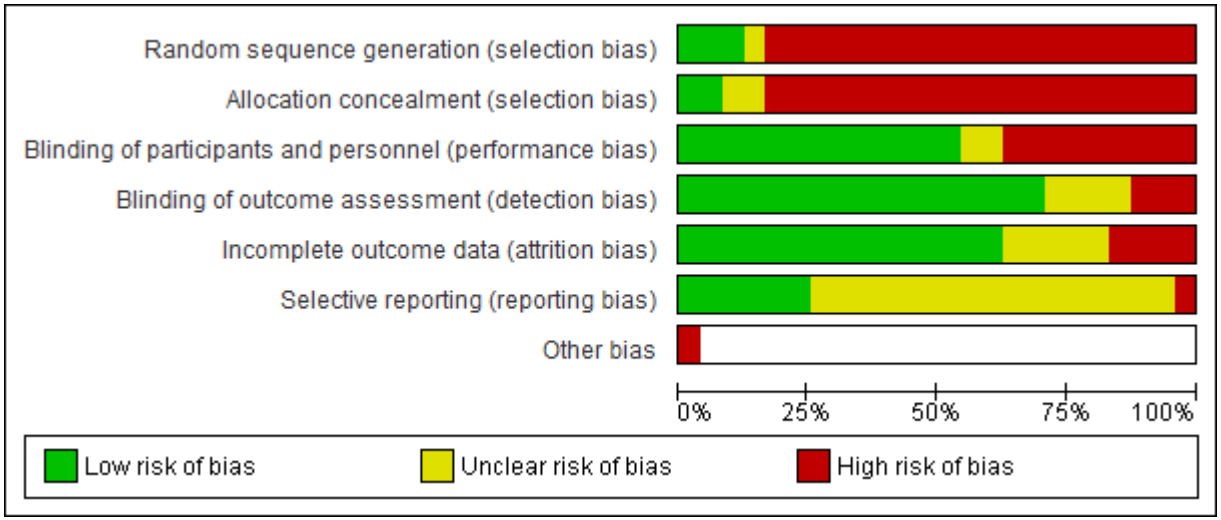
La strategia di ricerca ha identificato più di 1700 record

24 studi sono stati inclusi (3 RCT, due dei quali inseriti nella metaanalisi sulla cessazione, e 21 studi di coorte).

Sono stati inoltre identificati 27 studi ongoing

2 RCT confrontavano EC con EC placebo (senza nicotina) includendo complessivamente 662 partecipanti.





Ely: Other bias:
No definition of abstinence provided
Not clear if 'completed programme' was at 6 months.

Risultati da RCT

Rispetto al placebo, le persone che utilizzavano la EC, avevano più probabilità di essere astinenti dal fumo per almeno sei mesi (RR 2.29, 95% IC da 1.05 a 4.96; placebo 4% verso EC 9%; 2 studi; 662 partecipanti. GRADE: low).

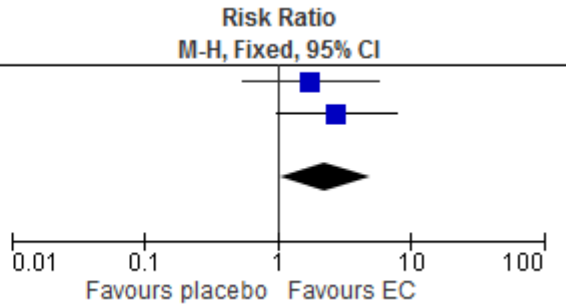
L'unico studio che confrontava la EC con il cerotto a base di nicotina, non ha evidenziato differenze significative rispetto al numero di persone astinenti a 6 mesi, ma gli intervalli di confidenza non escludono una differenza clinicamente importante(RR 1.26, 95% IC da 0.68 a 2.34; 584 partecipanti. GRADE: very low).

Smoking cessation: Nicotine EC versus placebo EC.

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bullen 2013	21	289	3	73	47.3%	1.77 [0.54, 5.77]
Caponnetto 2013a	22	200	4	100	52.7%	2.75 [0.97, 7.76]
Total (95% CI)		**489**		**173**	**100.0%**	**2.29 [1.05, 4.96]**
Total events	43		7			

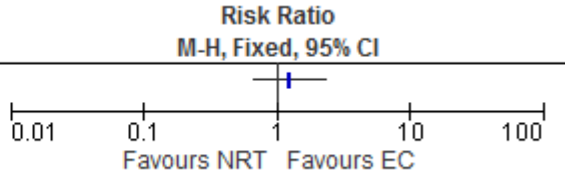
Heterogeneity: Chi² = 0.30, df = 1 (P = 0.58); I² = 0%

Test for overall effect: Z = 2.09 (P = 0.04)



Smoking cessation: Nicotine EC versus nicotine replacement therapy

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Risk Ratio M-H, Fixed, 95% CI
Bullen 2013	21	289	17	295	1.26 [0.68, 2.34]



SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Electronic cigarettes (EC) for smoking cessation

Patient or population: people defined as current smokers at enrolment into trials, motivated or unmotivated to quit
Intervention: nicotine-containing electronic cigarettes
Comparison: placebo electronic cigarettes or nicotine replacement therapy (or for adverse events, uncontrolled)

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk[1]	Corresponding risk				
	Control	Electronic cigarettes				
Cessation: Nicotine EC versus placebo EC[2] assessed with exhaled CO Follow-up: 6 - 12 months	**40 per 1000**	**93 per 1000** (42 to 201)	**RR 2.29** (1.05 to 4.96)	662 (2 studies)	⊕⊕◯◯ **low**[3,4]	Only RCTs reported here. Some cohort data also available (see full review) but only RCTs provide efficacy data
Cessation: Nicotine EC versus nicotine replacement therapy assessed with exhaled CO Follow-up: 6 months	**58 per 1000**	**73 per 1000** (39 to 135)	**RR 1.26** (0.68 to 2.34)	584 (1 study)	⊕◯◯◯ **very low**[3,5]	As above
Adverse events (AEs) Follow-up: 6 - 24 months	Summary data not available. No studies reported serious AEs considered related to EC use. One RCT provided data on the proportion of participants experiencing any adverse events. The proportion of participants in the study arms experiencing adverse events was similar (ECs vs placebo EC: RR 0.97, 95% CI 0.71 to 1.34 (298 participants); ECs vs patch: RR 0.99, 95% CI 0.81 to 1.22 (456 participants)). The second 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. Cohort studies found mouth and throat irritation, dissipating over time, to be the most			1201 (11 studies (2 RCTs, 9 cohort))	⊕⊕◯◯ **low**[6,7]	

Cessation: Nicotine EC versus placebo EC[2] assessed with exhaled CO Follow-up: 6 - 12 months	**40 per 1000**	**93 per 1000** (42 to 201)	**RR 2.29** (1.05 to 4.96)	662 (2 studies)	⊕⊕◯◯ **low**[3,4]	Only RCTs reported here. Some cohort data also available (see full review) but only RCTs provide efficacy data

3:Downgraded one level due to indirectness. The electronic cigarette used in Bullen 2013 was not very effective at delivering nicotine.
4: Downgraded one level due to imprecision. Only two included studies, small number of events (< 300) in each arm.

Cessation: Nicotine EC versus nicotine re-placement therapy assessed with exhaled CO Follow-up: 6 months	**58 per 1000**	**73 per 1000** (39 to 135)	**RR 1.26** (0.68 to 2.34)	584 (1 study)	⊕◯◯◯ **very low**[3,5]	As above

3:Downgraded one level due to indirectness. The electronic cigarette used in Bullen 2013 was not very effective at delivering nicotine.
5: Downgraded two levels due to imprecision. Only one included study, with small number of events in each arm.

Adverse events (AEs) Follow-up: 6 - 24 months	Summary data not available. No studies reported serious AEs considered related to EC use. One RCT provided data on the proportion of participants experiencing any adverse events. The proportion of participants in the study arms experiencing adverse events was similar (ECs vs placebo EC: RR 0.97, 95% CI 0.71 to 1.34 (298 participants); ECs vs patch: RR 0.99, 95% CI 0.81 to 1.22 (456 participants)). The second 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. Cohort studies found mouth and throat irritation, dissipating over time, to be the most	1201 (11 studies (2 RCTs, 9 cohort))	⊕⊕◯◯ **low**[6,7]

6: Downgraded due to risk of bias. 11/13 included studies (cohort studies) judged to be at high risk of bias.

7: Downgraded due to imprecision. Only one trial provided data for nicotine EC versus nicotine replacement therapy

La qualità complessiva delle prove utilizzando il metodo GRADE è stata giudicata bassa o molto bassa a causa della imprecisione dovuta all'esiguo numero di studi.

Qualità delle prove bassa significa che ulteriori ricerche sono necessarie e potrebbero modificare sostanzialmente i risultati sulla stima dell'effetto.

Qualità delle prove molto bassa significa che la stima dell'effetto è molto incerta

Study	Smokers motivated or unmotivated to quit?	Intervention vs relevant Control	% abstinent			
Cohort studies			**6-month**	**12-month**	**18-month**	**24-month**
Adriaens 2014[1]	Unmotivated to quit	Nicotine EC	19.6% (10/51)			
Al-Delaimy 2015	Not defined. 43% intended to quit in next 6m	Had ever used nicotine EC at baseline		5% (12/236)		
Borderud 2014	Motivated to quit	Used EC in past 30 days at baseline		14.5%		
Caponnetto 2013b	Unmotivated to quit	Nicotine EC		14% (2/14)		
Ely 2013	Motivated to quit	Nicotine EC[2]	44% (21/48)			
Manzoli 2015	Not defined	Nicotine EC		16% (51/319)		
Pacifici 2015	Unmotivated to quit	Nicotine EC		53% (18/34)		
Polosa 2011	Unmotivated to quit	Nicotine EC	23% (9/40)		15% (6/40)	13% (5/40)
Polosa 2014b	Unmotivated to quit	Nicotine EC	36% (18/50)			
Polosa 2015	Not defined	Nicotine EC	42% (30/71)	41% (29/71)		
Cohort studies not allowing inclusion of non-responders						
Brose 2015	Not defined. 46% attempted to quit in past 1 yr	Daily EC users at baseline		8% (7/86)		
Etter 2014	Not defined	Daily EC users at baseline		46% (16/35)		
Grana 2014b	Not defined	Used EC in the past 30 days (even once) at baseline		10% (9/88)		
Choi 2014	Not defined	Used EC for ≥ 1 day in the past 30 days at baseline		11%		
Prochaska 2014[1]	Not defined. 24% intended to quit smoking in next month	EC use at baseline via open-ended question		21%		

Eventi avversi

Nessuno degli studi (RCT o di coorte) ha riportato gravi eventi avversi (SAE) ritenuti plausibilmente correlati all'uso della CE.

Uno degli studi inclusi ha rilevato un evento avverso eventualmente correlato all'uso della CE: gola pruriginosa e tosse in un partecipante con una storia di asma infantile.
I sintomi si sono risolti una volta che l'uso della CE è stato interrotto (Oncken 2015).

Gli Eventi avversi più comunemente riportati erano irritazione locale della gola e della bocca.
Uno dei RCT (Caponnetto 2013a) ha misurato gli EA al baseline e poi durante la durata dello studio e ha mostrato che la frequenza dei sintomi respiratori (ad es. Tosse e mancanza di respiro) è diminuita nel tempo, probabilmente a causa dei cambiamenti relativi al fumo di sigaretta .
Questa constatazione è stata sostenuta dai dati degli studi di coorte

Conclusioni

Gli studi randomizzati disponibili sono molto pochi e quindi la certezza circa la stima degli effetti è bassa. Per rafforzare questi dati sono necessari ulteriori studi.

I due RCT disponibili evidenziano l'efficacia delle EC con nicotina rispetto al placebo quale aiuto per smettere di fumare a lungo termine.
Questi risultati confermano le prove evidenziate in un'altra RS Cochrane (Stead 2012) che valutava l'efficacia della NRT rispetto al placebo.

Un unico studio evidenzia che, a 6 mesi, i tassi di interruzione ottenuti con le EC sono simili a quelli che si ottengono con la NRT, ma l'intervallo di confidenza è ampio.

Le EC sono una tecnologia in continua evoluzione e non sono noti gli effetti dei nuovi dispositivi che hanno migliorato le modalità di somministrazione della nicotina.

Conclusioni

Gli Eventi avversi più comunemente riportati erano irritazione locale della gola e della bocca.

Nessuno degli studi inclusi ha rilevato gravi eventi avversi ritenuti eventualmente correlati all'uso della EC (da breve a metà termine, fino a due anni) .

La sicurezza a lungo termine delle EC non è nota. In alcuni studi, sono state osservate riduzioni dei biomarcatori nei fumatori che sono passati alle EC e tali riduzioni corrispondono a quelle osservate nelle persone che smettono di fumare.

AMERICAN JOURNAL OF
Preventive Medicine

REVIEW ARTICLE

Overview of Electronic Nicotine Delivery Systems: A Systematic Review

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Context: Rapid developments in e-cigarettes, or electronic nicotine delivery systems (ENDS), and the evolution of the overall tobacco product marketplace warrant frequent evaluation of the published literature. The purpose of this article is to report updated findings from a comprehensive review of the published scientific literature on ENDS.

Evidence acquisition: The authors conducted a systematic review of published empirical research literature on ENDS through May 31, 2016, using a detailed search strategy in the PubMed electronic database, expert review, and additional targeted searches. Included studies presented empirical findings and were coded to at least one of nine topics: (1) Product Features; (2) Health Effects; (3) Consumer Perceptions; (4) Patterns of Use; (5) Potential to Induce Dependence; (6) Smoking Cessation; (7) Marketing and Communication; (8) Sales; and (9) Policies; reviews and commentaries were excluded. Data from included studies were extracted by multiple coders (October 2015 to August 2016) into a standardized form and synthesized qualitatively by topic.

Evidence synthesis: There were 687 articles included in this systematic review. The majority of studies assessed patterns of ENDS use and consumer perceptions of ENDS, followed by studies examining health effects of vaping and product features.

Conclusions: Studies indicate that ENDS are increasing in use, particularly among current smokers, pose substantially less harm to smokers than cigarettes, are being used to reduce/quit smoking, and are widely available. More longitudinal studies and controlled trials are needed to evaluate the impact of ENDS on population-level tobacco use and determine the health effects of longer-term vaping.

(Am J Prev Med 2017;52(2):e33–e66)

Heterogeneity in the measurement and reporting of outcomes in studies of electronic cigarette use in adolescents: a systematic analysis of observational studies

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ABSTRACT

Objective To examine consistency between cross-sectional studies of conventional and electronic cigarette use among adolescents in terms of the measurement, analysis and reporting of parameters.

Design A systematic analysis of cross-sectional studies of conventional and electronic cigarette use in adolescents, to identify measured and reported parameters.

Data sources Studies examining use of electronic and conventional cigarette use in adolescents were identified by searching the SCOPUS database in August 2015.

Study selection The selection criteria for studies were: cross-sectional studies, in English, on e-cigarette use in adolescents. Two reviewers independently selected relevant studies from the search. 60 abstracts were identified, from which 31 papers were eligible for review (23 unique studies).

Data extraction Measured and reported parameters were identified and tabulated. These included the prevalence of cigarette and/ or electronic cigarette use, and the definitions of terms. Data were extracted independently by two reviewers.

Data synthesis With regards basic parameters of 'ever' or 'current' use of electronic or conventional cigarettes, there were 31 unique measured parameters across 23 studies. Of 16/23 studies in which authors collected information on dual current use, prevalence was reported in 11/16, with six different definitions of 'dual use'.

Conclusions There are substantial differences in measurement and reporting of parameters across observational studies of electronic and conventional cigarette use in adolescents. These studies are at risk of reporting bias, and results are difficult to interpret. A core outcome set that should be measured and reported in all observational studies is required, using structured consensus techniques.

BACKGROUND

There is debate, worldwide, around the benefits and harms of electronic cigarettes (e-cigarettes).[1–5] One uncertainty is whether e-cigarette use among adolescents results in conventional cigarette use.[6]

Observational studies may be the most appropriate study design to explore this issue, as randomised controlled trials face ethical and legal obstacles. Three longitudinal cohort studies and numerous cross-sectional studies, from various countries, have examined the use of e-cigarettes and conventional cigarettes in adolescents. One longitudinal cohort study in 694 people aged 16–24 years reported that in smoking-naïve individuals, those that used e-cigarettes were more likely to progress to cigarette smoking, although absolute numbers were small (11/16, 68.8% vs 128/678, 18.9%).[7]

A second longitudinal study of 2530 tobacco-naïve 14-year-olds showed similar findings: at 6 months the proportion of those who had tried combustible tobacco was 182/ 2247 (8.1%) in never e-cigarettes users compared to 67/218 (30.7%) in ever e-cigarette users. Combustible tobacco was defined as the ever use of conventional cigarettes, cigars, and/ or hookah at any time. Numbers were smaller for conventional cigarette use: 68/2267 (3.0%) vs 21/217 (9.7%).[8] This would be consistent with a 'gateway effect' towards conventional cigarette use, but the authors correctly state that this does not show causation. For example, 'ever use' may be a surrogate measure of experimentation which could account for the risk of future cigarette ever use. A third longitudinal survey of 2338 adolescents from Hawaii showed that transition from never-use to smoking was associated with e-cigarette use, even when other covariates such as age, ethnicity and rebelliousness were included in the multivariate model.[9]

There are many more cross-sectional studies than longitudinal studies, and it seems likely this trend will continue. Although they also cannot prove causation, multiple cross-sectional studies may provide useful information on associations and trends in e-cigarette and conventional cigarette use. For example, an increase in the number of e-cigarette users and conventional cigarette smokers with time would be consistent with the gateway effect; an increase in e-cigarette use with a reduction in conventional cigarette smoking would be inconsistent with this phenomenon. Currently, the interpretation of these studies appears to vary. Some feel that the results reassure against a gateway effect,[10] but others urge caution in light of the results.[2 8] Therefore, these observational studies require transparent and consistent reporting to aid their interpretation.

However, within these studies, researchers can measure various parameters, and analyse and present them in different ways (box 1). There is currently no guidance around these methodological decisions, and no core set of results that should be reported in all studies. This may lead to reporting

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Review Article

Potential health effects of electronic cigarettes: A systematic review of case reports

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ABSTRACT

The health risks associated with electronic cigarettes (ECs) are largely unknown. The purpose of this systematic review was to evaluate published case reports that deal with health effects attributed to EC use. An Internet search was conducted to identify case reports dealing with the effects of EC use on health. Twenty-six case reports representing 27 individuals (one study contained reports for two individuals) were published between April 2012 and January 2016, and these were grouped into categories of effect according to their health outcomes. Of the 27 individuals, 25 had negative effects subsequent to use or exposure to ECs and their refill fluids, while two reported improvement in chronic immune and gastrointestinal conditions. Three categories of negative health effects were identified: systemic effects, nicotine poisoning, and mechanical injury. Thirteen cases reported EC effects on different systems including: respiratory (6), gastrointestinal or developing intestine of an infant (3), cardiovascular (2), neurological (1), and immune (1). Twelve cases involved nicotine poisoning resulting from accidental ($N = 3$), misuse/abuse ($N = 1$), or suicidal/intentional ingestion ($N = 8$); four of these involved children and three resulted in adult fatalities. Two cases reported mechanical injury caused by an EC battery explosion. Most case reports show that the health of children and adults can be negatively affected by EC products and that if death does not occur, negative effects can be reversed. Data further indicate that EC use can cause negative health effects in previously healthy individuals and exacerbate pre-existing conditions.

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E-cigarettes and smoking cessation in real-world and clinical settings: a systematic review and meta-analysis

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Department of Medicine, (S Kalkhoran MD, Prof S A Glantz PhD) and Center for Tobacco Control Research and Education, Cardiovascular Research Institute (Prof S A Glantz), University of California San Francisco, San Francisco, CA, USA

Summary

Background—Smokers increasingly use e-cigarettes for many reasons, including attempts to quit combustible cigarettes and to use nicotine where smoking is prohibited. We aimed to assess the association between e-cigarette use and cigarette smoking cessation among adult cigarette smokers, irrespective of their motivation for using e-cigarettes.

Methods—PubMed and Web of Science were searched between April 27, 2015, and June 17, 2015. Data extracted included study location, design, population, definition and prevalence of e-cigarette use, comparison group (if applicable), cigarette consumption, level of nicotine dependence, other confounders, definition of quitting smoking, and odds of quitting smoking. The primary endpoint was cigarette smoking cessation. Odds of smoking cessation among smokers using e-cigarettes compared with smokers not using e-cigarettes were assessed using a random effects meta-analysis. A modification of the ACROBAT-NRSI tool and the Cochrane Risk of Bias Tool were used to assess bias. This meta-analysis is registered with PROSPERO (number CRD42015020382).

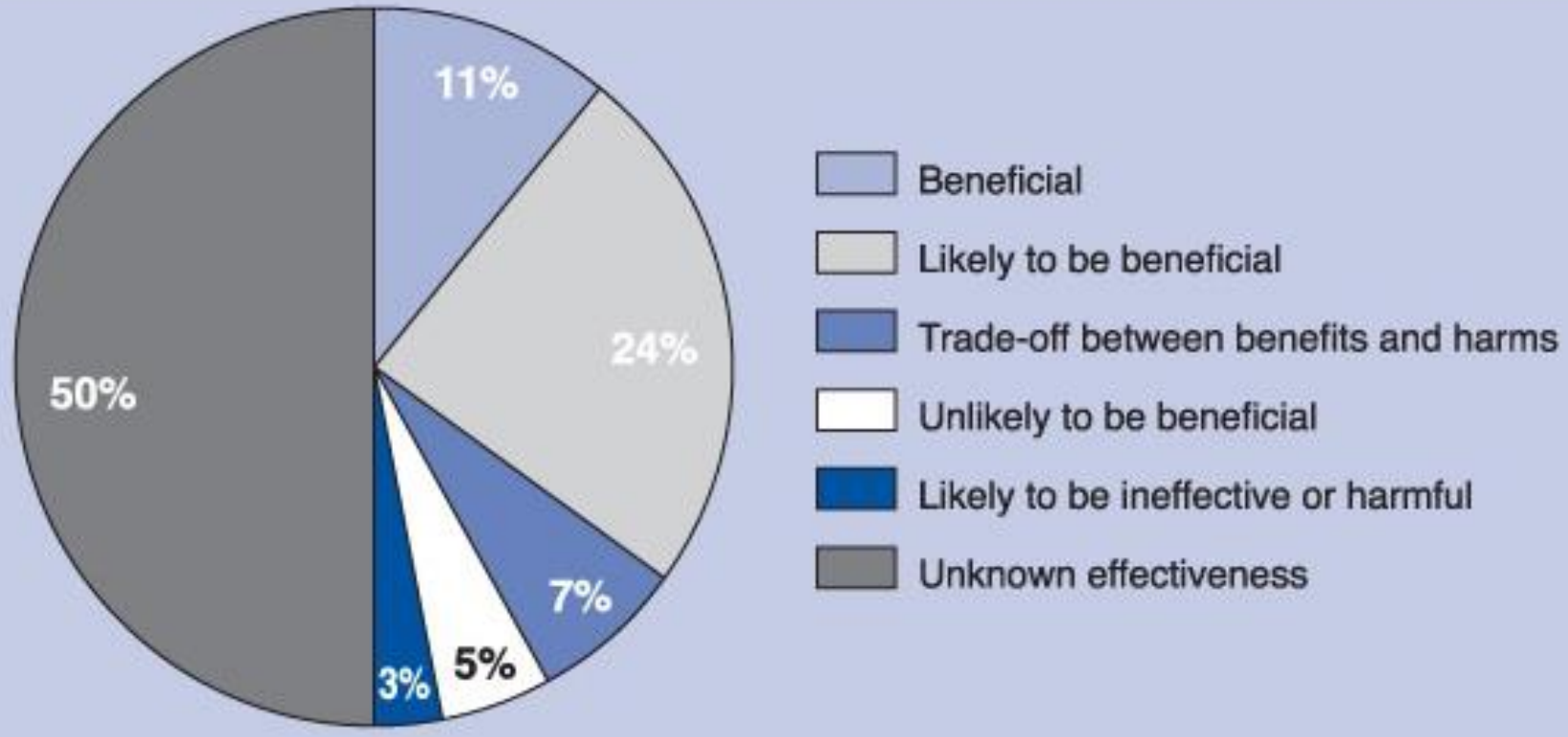
Findings—38 studies (of 577 studies identified) were included in the systematic review; all 20 studies with control groups (15 cohort studies, three cross-sectional studies, and two clinical trials) were included in random effects meta-analysis and sensitivity analyses. Odds of quitting cigarettes were 28% lower in those who used e-cigarettes compared with those who did not use e-cigarettes (odds ratio [OR] 0·72, 95% CI 0·57–0·91). Association of e-cigarette use with quitting did not significantly differ among studies of all smokers using e-cigarettes (irrespective of interest in quitting cigarettes) compared with studies of only smokers interested in cigarette cessation (OR 0·63, 95% CI 0·45–0·86 *vs* 0·86, 0·60–1·23; p=0·94). Other study characteristics (design, population, comparison group, control variables, time of exposure assessment, biochemical

Likelihood of and confidence in an effect

I figure there is a 20% reduction in risk with this intervention and low certainty we know what we are talking about

60 milioni. 36 attivi in Rete.
28 sui social media. 22 dallo smartphone.


facebook
16% 22% 19% 18% 15% 10%
Google+
16% 25% 22% 18% 13% 7%
LinkedIn
14% 21% 22% 18% 16% 9%
Instagram
19% 22% 21% 18% 13% 7%
Pinterest
23% 26% 19% 15% 12% 4%
tumblr.
15% 26% 21% 17% 15% 7%
Vine
28% 25% 18% 13% 11% 6%
snapchat
28% 23% 17% 15% 10% 7%
45% 26% 13% 10% 6% 1%
Age 18-24
Age 25-34
Age 35-44
Age 45-54
Age 55-64
Age 65+



Effectiveness of 3000 treatments as reported in randomised controlled trials selected by Clinical Evidence. This does **not** indicate how oftentreatments are used in healthcare settings or their effectiveness in individual patients.

http://evidence.Bmj.Com; *accessed February 5, 2015*

Grazie

Laura, Marina, Silvia, Simona, Zuzana
in nome della Cochrane e della EBM italiana