Effectiveness of e-cigarettes for smoking cessation in the German population - a comparison with nicotine replacement therapy and no use of evidence-based support (DEBRA study)

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DK, SJ and SK have nothing to declare. JB has received unrestricted research funding to study smoking cessation from Pfizer and J&J, who manufacture smoking cessation medications.

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SUMMARY

Background

Our primary aim was to assess – in the German population – the effectiveness of e-cigarettes (ECs, with or without nicotine), nicotine replacement therapy (NRT), and no use of evidence-based support in helping smokers quit smoking.

Methods

Cross-sectional analysis of data from a representative survey of the German population (age 14-96 years) collected in 2016-2021. We included all current and recent ex-smokers (quit smoking <12 months) who had made ≥1 quit attempt in the past 12 months (n=2740). They were asked about use of cessation aids in their most recent quit attempt and reported their current tobacco smoking status.

Results

239 respondents had used ECs, 168 NRT, and 2333 no aid. After adjustment for potential confounders, smokers who had tried to quit with ECs had 1.78 higher odds of abstinence (95%CI=1.09-2.92, p=.02) compared with the unaided group, and 1.46 (95%CI=0.68-3.13, p=.34, Bayes Factor=1.26) compared with the NRT group. Odds of abstinence were 2.34 times higher (95%CI=1.21-4.53, p=.01) in the subgroup using ECs with nicotine and 1.48 times higher (95%CI=0.68-3.26, p=.33) in the subgroup using ECs without nicotine, compared with the unaided group. Unadjusted abstinence rates in people who had started their quit attempt >6 months ago were 15.6% (95%CI=9.4-23.8) in the EC group and ~~,~~ 13.8%~~, and 20.2%, respectively~~ (95%CI=7.3-22.9) in the NRT group.

Conclusion

In Germany, use of ECs in an attempt to quit smoking tobacco is associated with a higher rate of successful cessation than attempting to quit unaided.

BACKGROUND

Guidelines recommend a range of evidence-based smoking cessation treatments,(1) but only a minority of smokers in Germany use these.(2) Electronic cigarettes (ECs) may be a useful alternative for quitting tobacco in smokers who do not want, or are not able, to use medically-licensed treatments. ECs are currently the most frequently used quitting aid in Germany,(2) which is remarkable because they are not formally promoted as a cessation aid, and their use is discouraged by medical associations.(3) ECs are not without risk but growing evidence suggests they are substantially less harmful than tobacco smoking.(4, 5) They are tobacco-free devices that typically heat a liquid into an aerosol containing nicotine that is inhaled by the user, offering a mechanism of action similar to nicotine replacement therapy (NRT).

A Cochrane review found moderate-certainty evidence that nicotine ECs are more effective in helping smokers quit than NRT and non-nicotine ECs.(6) Nevertheless, the recently updated German clinical guideline for smoking cessation does not recommend ECs but states the evidence on the efficacy and risks of ECs is inconsistent.(1)

Further evidence on the effectiveness of ECs is therefore needed, both from trials and from high-quality observational studies, particularly from studies conducted in Germany – a country with relatively high smoking prevalence (7), weak tobacco control (8), and critical attitude towards ECs. In this context, it is important to investigate long-term use of ECs in successful quitters (i.e., ongoing exposure to addictive and potential harmful ingredients) and dual use of ECs and tobacco in unsuccessful quitters (i.e., exposure to two sources of harm). In addition, there is a need for further evidence on the effectiveness of non-nicotine ECs for smoking cessation, as the current evidence is limited.(9)

The overall aim of this study was therefore to compare – in the German population – the effectiveness of ECs, NRT, and no use of evidence-based support (i.e., unaided quitting) in helping smokers quit smoking. We chose NRT as comparator because it is the most frequently used pharmacotherapy in Germany.(2) Other pharmacological treatments or behavioural counselling programs are used too infrequently to allow statistical comparisons with our current study data. Our primary research question was: among past-year smokers who reported making a quit attempt in the last 12 months, do the odds of cessation differ between those who used solely ECs (with and/or without nicotine), solely NRT and no cessation aid to support their quit attempt, after adjustment for confounders? A secondary research question was: do the results differ in the subgroup of those who reported using solely ECs with and without nicotine? A further secondary research question was: among past-year smokers who started their quit attempt between 6 and 12 months ago and who used ECs, does the prevalence of current EC use differ between successful (representing long-term exclusive EC use) and unsuccessful quitters (representing dual use of tobacco and EC)?

METHODS

We conducted a cross-sectional analysis using data from the German Study on Tobacco Use (DEBRA: "Deutsche Befragung zum Rauchverhalten"): an ongoing representative household survey on tobacco use in the German population (www.debra-study.info).(10) The study was registered at the German Clinical Trials Register (DRKS00011322, DRKS00017157) and approved by the medical ethics committee of the Heinrich-Heine-University Düsseldorf (HHU 5386R).

The DEBRA study collects data every other month from computer-assisted face-to-face household interviews of people aged 14+. From June/July 2016 to May/June 2021, respondents were selected through multi-stage, multi-stratified random probability sampling. Since January 2020, respondents have been selected by using a dual frame design: a composition of random stratified sampling and

quota sampling. This switch of the sampling design has been described in detail elsewhere (https://osf.io/e2nqr/).

Study population

We selected all past-year smokers from the DEBRA database who had made at least one serious attempt to quit smoking during past 12 months (see Appendix). We included all current and recent ex-smokers who reported at least one quit attempt and who had used ECs or NRT to aid their quit attempt or who had tried to quit with no evidence-base support (see below).

Measurement of effect: self-reported method of quitting

People were shown a list of 20 cessation methods (see Appendix). The following methods were considered evidence-based according to German guidelines:(1, 11) (a) brief advice by a physician; (b) behavioural counselling (one-to-one or group counselling); (c) telephone counselling; (d) NRT on prescription; (e) NRT without prescription (over-the-counter); (f) bupropion; and (g) varenicline. Furthermore, the list included (h) ECs with nicotine and (i) ECs without nicotine.

We defined the following groups according to method of quitting: solely ECs with and/or without nicotine (i.e., treatment h or i but not a-g); solely NRT on prescription or over-the-counter (i.e., treatment d or e but not a-c or f-i); and unaided quitting (i.e., any method from the list but not a-i). We sub-divided the ECs group into solely ECs with nicotine (i.e., treatment h but not a-g or i) and solely ECs without nicotine (i.e., treatment i but not a-h).

Measurement of outcome: self-reported non-smoking

Our primary outcome was cessation, defined as self-reported non-smoking up to the time of the survey in all current or recent ex-smokers who reported a quit attempt during the past 12 months (see Appendix for exact wording).

Measurement of potential confounding variables

We included the following variables in our adjusted analyses: age (continuous variable), sex (binary: female, male), monthly net household income per person in the household (continuous), educational qualification (categorical: low, middle, high), time since the most recent quit attempt started (categorical: ≤6 months, >6 months), time with urges to smoke during the past 24 hours (continuous: 1 to 6 = all the time),(12) strength of urges to smoke (continuous: 1 to 6 = extremely strong),(12) number of quit attempts in the past 12 months (categorical: 1, 2, ≥3), approach of quit attempt (binary: abrupt vs. gradual), planning of quit attempt (binary: planned vs. unplanned), and survey year (categorical: 2016 to 2020).

Statistical analyses

We pre-registered a study protocol and analysis plan prior to analysis (https://osf.io/z59m4/).

For the primary analysis, we used a multivariable logistic regression model with abstinence (i.e., non-smoking vs. smoking at the time of the survey) as the dependent variable and the method of quitting as independent variable (categorical: unaided, NRT and ECs with and/or without nicotine as reference), adjusted for confounders. In the event of non-significant results in the primary analyses, we had planned to calculate Bayes factors (see study protocol).

In our **secondary analysis 1**, we used multivariable logistic regression with abstinence (non-smoking vs. smoking) as the dependent variable and the method of quitting as the independent variable (categorical: ECs with nicotine, ECs without nicotine, NRT, and unaided as reference), adjusted for all potential confounders.

In our **secondary analysis 2**, we used a simple Chi-square test to compare the rate of current EC use (yes vs. no) between successful and unsuccessful quitters among users of ECs with and/or without nicotine who started their quit attempt >6 months ago.

We conducted a complete-case analysis in which cases with missing data on one or more of the potential confounding variables were excluded, as defined in our pre-registered study protocol. All analyses were conducted in IBM SPSS Statistics 25.

RESULTS

A total of 60998 people were interviewed, of whom 18217 had smoked during the past 12 months and 2991 had made at least one quit attempt during the past 12 months; 239 reported the use of ECs with and/or without nicotine to aid their most recent quit attempt, 168 reported the use of NRT, 2333 reported unaided quitting, and the remaining 251 reported the use of any other method of quitting. Among EC users, 117 had solely used ECs with nicotine, 94 had solely used ECs without nicotine, and the remaining 28 had used both.

Baseline characteristics are presented in Table 1. Approximately half had started their quit attempt >6 months and up to 12 months ago. People who had tried to quit with ECs and NRT reported stronger urges to smoke than people who had tried to quit unaided. The groups also differed on percentages quitting abruptly and planned quitting.

A total of 204 people (7.4% of 2740) had missing data on one or more of the confounding variables. The rate of missing data did not statistically differ between users of ECs (8.4%), NRT (5.4%), and unaided quitters (7.5%; p=.504). The complete case sample for the primary analysis was 2536 people. The adjusted OR of abstinence in the ECs group was 1.78 (95%CI=1.09-2.92, p=.022) compared with the unaided group, and 1.46 (95%CI=0.68-3.13, p=.336, Bayes Factor=1.26) compared with the NRT group (primary analysis, Table 2). These findings remained unchanged when restricting the analysis to people whose quit attempt started at least one week ago (see Appendix, Table E1).

Compared with unaided quitters, the adjusted OR of abstinence was 2.34 (95%CI=1.21-4.53, p=.011) for the ECs with nicotine subgroup and 1.48 (95%CI=0.68-3.23, p=.327) for the ECs without nicotine subgroup (secondary analysis 1, Table 2).

Among people who had started their quit attempt >6 months ago, 15.6% (95%CI=9.4-23.8) of users of ECs (17/109), 13.8% (95%CI=7.3-22.9) of users of NRT (12/87), and 20.2% (95%CI=17.9-22.6) of unaided quitters (238/1180) were still abstinent at the time of the survey (unadjusted abstinence rates). Eleven of the 17 abstainers in the ECs group (64.7%) and 21 of the 92 relapsers (22.8%) were current EC users (p<.001; secondary analysis 2). Among people who started their quit attempt >6 months earlier and used NRT or tried to quit unaided, none of the abstainers and only a small proportion of relapsers (5.3% and 3.7%, respectively) were current EC users.

DISCUSSION

In a large national household survey of the German population, people who tried to quit smoking with the use of ECs appeared more likely to report abstinence from smoking than those who tried to quit without any evidence-based support. Users of ECs with nicotine appeared more than twice as likely to report abstinence as those who tried to quit unaided, but the comparative effectiveness of ECs without nicotine was inconclusive. The comparison of ECs with NRT inconclusively favoured ECs.

Main findings in context

Approximately half of the people in our study who tried to quit smoking with the use of ECs reported the use of ECs with nicotine and the other half ECs without nicotine. Our effect estimate for the comparison of people who used ECs with nicotine with those who tried to quit without evidence-based support (OR=2.34) was close to the pooled estimate comparing ECs with nicotine and behavioural support only or no support from latest Cochrane review (RR=2.61).(6) Our estimate for the comparison of people who used ECs without nicotine and those who tried without evidence-based support (OR=1.48) was not statistically significant. It seems evident that ECs are more effective when used with nicotine than without because the nicotine from ECs can substitute the nicotine from cigarettes, thereby reducing withdrawals symptoms.(13)

The Cochrane review also found evidence that ECs with nicotine are more effective than NRT (RR=1.53).(6) Our effect estimate for the comparison of people who used ECs with and/or without nicotine was similar (OR=1.46) but inconclusive due to the smaller sample size for this comparison (N=219 in the EC group and N=159 in the NRT group).

We found that 65% (95%CI=38.2-85.8) of people who tried to quit with the use of ECs and achieved long-term abstinence (≥6 months) were still using ECs at the time of the survey. This estimate is not reliable as it was derived from a very small sample (N=17 long-term abstainers), but is consistent with results of a recent, large randomised controlled trial, in which 80% of people who achieved long-term abstinence with the use of ECs continued to use ECs.(14) There is currently a lack of evidence on the impact of extended EC use on long-term relapse to smoking. Extended use is inadvisable because, although safer than smoking, EC use is not without health risks.

Limitations and strengths

First, our cross-sectional design does not allow causal inferences and is prone to sources of bias, most importantly to confounding by indication. However, we adjusted our analyses for a range of confounding factors, including urges to smoke at the time of the survey which served as a proxy for the level of tobacco addiction at the time of starting the quit attempt. Furthermore, we tried to reduce the risk of measurement bias by using clear definitions of exposures and outcomes. A second limitation is that we relied on the self-report of quit attempts and use of quitting aids in the past 12 months (potential recall bias). Third, we did not have data on EC device and liquid (including nicotine concentration and flavour) or NRT product chosen, and how people actually used their EC or NRT product during the first weeks of their quit attempt. Fourth, our outcome measure was self-reported, included any duration up to 12 months, and was not biochemically verified. Finally, our sample size was too small to detect a difference between EC and NRT.

An important strength of our study is that it used a large, representative sample of the German population, and that we aggregated data over a period of almost five years, which increased the robustness of our analyses in times of potentially changing contextual factors. Our analyses were based on an established method of assessing the population effectiveness of smoking cessation aids by comparing the success rates of smokers trying to quit via different aids or quitting unaided and adjusting statistically for a range of factors that could bias the results, particularly tobacco dependence.(15-18)

Conclusion and recommendation

Our study adds further evidence that the use of ECs in a quit attempt, compared with unaided quitting, is associated with tobacco cessation, especially when containing nicotine. Experimental research on the effectiveness of ECs for smoking cessation in the German context is needed, both in the general population and in the context of patient care (e.g., smokers with chronic tobacco-related diseases).

Table 1: Characteristics of the study population

Characteristic		ECs with and/or without nicotine (N=239)	NRT (N=168)	Unaided (N=2333)	P
Years of age, mean (SD)		38.9 (15.0)	46.71 (14.8)	44.9 (17.0)	.108
Female sex (vs. male)		47.3 (113)	49.4 (83)	48.9 (1141)	
EUR/person income, mean (SD)		1367.4 (745.5)	1671.8 (801.6)	1365.6 (816.6)	.106
Education	low	27.8 (64)	29.9 (50)	31.7 (723)	.255
	middle	47.0 (108)	38.3 (64)	39.9 (910)	
	High	25.2 (58)	31.7 (53)	28.3 (645)	
Time since quitting	>6months (vs. ≤6 months)	45.8 (109)	52.1 (87)	51.0 (1180)	.286
Time spent with urges to smoke[a]		3.35 (1.21)	3.32 (1.05)	3.02 (1.20)	.020
Strength of urges to smoke[b]		2.11 (1.11)	2.14 (1.00)	1.84 (1.09)	.007
Quit attempts past 12 months	1	66.9 (160)	63.1 (106)	65.2 (1520)	.267
	2	18.8 (45)	22.0 (37)	20.6 (481)	
	≥3	14.2 (34)	14.9 (25)	7.8 (181)	
Quit abruptly (vs. gradually)		56.8 (134)	63.8 (104)	70.0 (1601)	<.001
Planned quitting (vs. unplanned)		42.7 (100)	52.1 (86)	39.5 (889)	.005

Data are presented as column percentage (N), unless stated otherwise. Cases with missing data were excluded. ECs = e-cigarettes. NRT = nicotine replacement therapy. SD = standard deviation. P = statistical significance level. [a]Time with urges to smoke during the past 24 hours (continuous: 1 to 6 = all the time).(12) [b]Strength of urges to smoke (continuous: 1 to 6 = extremely strong).(12)

Table 2: Associations between self-reported method of quitting during the last quit attempt and non-smoking at the time of the survey

	Odds Ratio[#]	95% Confidence Interval	P
Primary analysis			
ECs with and/or without nicotine (N=219) vs. unaided (N=2158)	1.78	1.09-2.92	.022
ECs with and/or without nicotine (N=219) vs. NRT (N=159)	1.46	0.68-3.13	.336
Secondary analysis 1 (N=2513)			
ECs with nicotine (N=108) vs. unaided (N=2158)	2.34	1.21-4.53	.011
ECs without nicotine (N=88) vs. unaided (N=2158)	1.48	0.68-3.23	.327

ECs = e-cigarettes. NRT = nicotine replacement therapy. P = statistical significance level. # Odds Ratio adjusted for age, sex, income, education, time since most recent quit attempt started, time with urges to smoke, strength of urges to smoke, number of quit attempts in the past 12 months, approach of quit attempt, planning of quit attempt, and survey year.

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APPENDIX

DEBRA questionnaire item on quit attempts during the past 12 months

"How many serious attempts to stop smoking have you made in the last 12 months? By serious attempt I mean you decided that you would try to make sure you never smoked again. Please include any attempt that you are currently making and please include any successful attempt made within the last year."

[Interviewer: if respondent has difficulty naming a whole number, please assist him in estimating a number.]

1. I have made no attempt
2. Yes, I have made XX attempts during the past year

[Interviewer: if the respondent cannot or does not want to give an exact answer (e.g., it is uncertain how many attempts there have been, the number cannot be estimated), please read out following answer options:]

3. Yes, I have made attempts in the last year (=at least one), but don't know exactly how many
   [Return value = 1]

DEBRA questionnaire item on use of quitting methods

[Interviewer: please show the laptop screen to the respondent]

"Which of the following did you try to help you stop smoking during the most recent quit attempt?"

[Interviewer: multiple choice question. Ask after response: "Is there anything else which you used during your most recent quit attempt?"]

a) Brief advice by a physician
b) Behavioural counselling for smoking cessation (one-to-one or group counselling)
c) Telephone counselling for smoking cessation
d) Nicotine replacement therapy (e.g., nicotine patch) on prescription by a physician
e) Nicotine replacement therapy (e.g., nicotine patch) without prescription
f) Zyban (bupropion)
g) Champix (varenicline)
h) E-cigarette with nicotine
i) E-cigarette without nicotine
j) Brief advice by a pharmacist
k) App for smoking cessation on a smartphone or tablet PC
l) A website for smoking cessation
m) Allen Carr's book "Easy way to stop smoking"
n) A different book for smoking cessation
o) Hypnotherapy
p) Acupuncture
q) Alternative healer (German: Heilpraktiker)
r) Own willpower
s) Social environment (family, friends, colleagues)
t) Other
u) N/A

DEBRA questionnaire items on self-reported non-smoking

"How long did your most recent serious quit attempt last before you went back to smoking?"

1. I am still not smoking
2. Less than a day
3. Less than a week
4. Less than a month
5. Less than 2 months
6. Less than 3 months
7. Less than 6 months
8. Less than a year
9. N/A

Those who responded (1) "I am still not smoking" were defined as non-smoking whereas all others were defined as smoking. Those with no response on this question but with the response "I have stopped smoking completely in the last year" to the entry question of the survey defining current smoking status were also defined as non-smoking.

Table E1: Associations between self-reported method of quitting during the last quit attempt and non-smoking at the time of the survey, in the subsample of people who started their quit attempt longer than one week ago

	Odds Ratio[#]	95% Confidence Interval	P
Primary analysis			
ECs with and/or without nicotine (N=214) vs. unaided (N=2091)	1.92	1.17-3.17	.010
ECs with and/or without nicotine (N=214) vs. NRT (N=157)	1.56	0.71-3.41	.265
Secondary analysis 1 (N=2513)			
ECs with nicotine (N=106) vs. unaided (N=2091)	2.49	1.28-4.84	.007
ECs without nicotine (N=86) vs. unaided (N=2091)	1.63	0.74-3.60	.230

ECs = e-cigarettes. NRT = nicotine replacement therapy. P = statistical significance level. # Odds Ratio adjusted for age, sex, income, education, time since most recent quit attempt started, time with urges to smoke, strength of urges to smoke, number of quit attempts in the past 12 months, approach of quit attempt, planning of quit attempt, and survey year.