Qualität der Forschung zu E-Zigaretten – Bestandsaufnahme und Verbesserungsvorschläge

Ute Mons | Universität zu Köln, Medizinische Fakultät & Universitätsklinikum Köln

Transparenz-Erklärung

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 - Keinerlei finanzielle oder sonstige Zuwendungen von pharmazeutischen, E-Zigaretten- oder Tabakunternehmen oder deren Stiftungen und keinerlei kommerzielle Beziehungen zu solchen Unternehmen oder Stiftungen
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 - Gehalt von der Universität zu Köln und dem Deutschen Krebsforschungszentrum, vereinzelt Honorare für Fortbildungsvorträge von medizinischen Fachgesellschaften
- **Bezüglich sonstiger potentiellen Einflüsse auf meine Einstellungen und Haltung:**
 - Mitautorin der S3-Leitlinie Tabakentwöhnung (2021) und Mitarbeit an der Strategie für ein tabakfreies Deutschland 2040 (2021)
 - Vorstandsmitglied im Wissenschaftlichen Arbeitskreis Tabakentwöhnung (WAT) und der Society for Research on Nicotine and Tobacco Europe (SRNT-E)
 - Mitglied mehrerer wissenschaftlicher Fachgesellschaften, wie der Deutschen Gesellschaft für Epidemiologie (DGEpi), Deutsche Gesellschaft für Medizinische Soziologie (DGMS), Deutsche Krebsgesellschaft (DKG)
 - (Passives) Mitglied bei Bündnis 90/Die Grünen

Bestandsaufnahme

Bandbreite wissenschaftlichen Fehlverhaltens

The Retraction Watch Leaderboard

Who has the most retractions? Here's our unofficial list (see notes on methodology), which we'll update as more information comes to light:

1. [Yoshitaka Fujii](#) (total retractions: 183) See also: [Final report of investigating committee](#), [our reporting](#), [additional coverage](#)
2. [Joachim Boldt](#) (159) See also: [Editors-in-chief statement](#), [our coverage](#)
3. [Yoshihiro Sato](#) (106) See also: [our coverage](#)
4. [Jun Iwamoto](#) (82) See also: [our coverage](#)
5. [Ali Nazari](#) (77) See also: [our coverage](#)
6. [Diederik Stapel](#) (58) See also: [our coverage](#)
7. [Yuhji Saitoh](#) (53) See also: [our coverage](#)
8. [Adrian Maxim](#) (48) See also: [our coverage](#)
9. [Chen-Yuan \(Peter\) Chen](#) (43) See also: [SAGE](#), [our coverage](#)
10. [Fazlul Sarkar](#) (41) See also: [our coverage](#)

Schlechte
wissenschaftliche
Praxis

Betrug und
Fälschung

■ Fehlerquellen

- Bias (Selektionsbias, Informationsbias)
- Confounding (durch Störfaktoren)
- Umgekehrte Kausalität

■ Probleme in der Interpretation und Präsentation

- Überinterpretation: Kausale Schlussfolgerungen ziehen, obwohl es plausible alternative Erklärungen (→ Fehlerquellen) gibt
- Überbewertung: Irreführende Eindrücke hinsichtlich der Größe oder Bedeutung von Effekten erzeugen
- Überverallgemeinerung: Unberechtigte Verallgemeinerung der Studienergebnisse über die Grundgesamtheit, Studienbedingungen und -instrumente hinaus
- „Cherry Picking“: Selektives Berichten oder Hervorheben von Ergebnissen, die eine bestimmte Sichtweise unterstützen

Ein großes Interesse seitens Öffentlichkeit und Politik zu bestimmten Forschungsthemen kann sich negativ auf die Studienqualität auswirken. Der hohe Publikationsdruck veranlasst Autoren genau wie auch Fachzeitschriften dazu, Ergebnisse vor allem schnell zu veröffentlichen.

U In gesundheitspolitische Bewegungen zur Regulierung von E-Zigaretten zu entwickeln, muss man die Auswirkungen von E-Zigaretten für die öffentliche Gesundheit verstehen. Dafür ist epidemiologische Forschung unverzichtbar. Ein Problem dabei: Ausgewählte Studienergebnisse wie Korrelationsstudien sind aufwendig und benötigen lange Beobachtungszeiten – Politik und Öffentlichkeit brauchen aber schnelle Antworten. Weniger aufwendige Studien und kürzere Beobachtungsperioden liefern wiederum methodische Probleme mit sich. Sie gibt es oftmals alternative plausible Erklärungen für Befunde, wie umgekehrte Kausalität, Verzerrungen oder Überschätzung von Ergebnissen, die in der Interpretation der Studienergebnisse angemessen berücksichtigt werden müssen. Dies geschieht jedoch

Beispiel 1: Eine Querschnittsstudie (1) untersucht den Zusammenhang zwischen Konsum von E-Zigaretten und herkömmlichen Zigarettenkonsum und höhere Nicotinkonzentrationen wurden gleichzeitig in einem Fragebogen abgefragt. Im multivariaten Analysemodell zeigte sich, dass die Chance eines Heroinmissbrauchs zu haben, bei höheren E-Zigarettenkonsum um 10 Prozent größer war als bei denjenigen, die von E-Zigaretten konsumieren (Odds Ratio (OR): 1,10, 95-Prozent-Konfidenzintervall (KI): 1,00–1,20). Beobachtungsstudien des Konsums, 74 Prozent E-Zigarettenkonsum ... ist mit einem erhöhten Risiko für Heroinmissbrauch assoziiert (siehe hier). Eine zentral methodische – Verzerrung – ist, dass E-Zigarettenkonsum, mindestens genauso wahrscheinlich wäre daher eine Interpretation in umgekehrter Kausalrichtung. Eine negative Studie zu hören, kann bei Rauchern zum Umstieg auf E-Zigaretten.

Wo treten häufig Probleme auf?

- Beim Studiendesign
 - Unzureichende Vorkehrungen zur Minimierung von Bias und/oder Confounding
 - Ungeeignete Analysemethoden
 - Nutzung von für Fragestellung ungeeigneten Daten/Instrumenten
- Bei der Datenanalyse
 - p-hacking
 - HARKing
- Im Manuskript von Originalarbeiten/Übersichtsarbeiten
 - Bei der Interpretation und Diskussion der Ergebnisse
 - Im Abstract

Methodische Mängel im Studiendesign

Studien zu E-Zigaretten und Gateway

Methodische Mängel im Studiendesign Studien zu E-Zigaretten und Gateway

ADDICTION SSA SOCIETY FOR THE STUDY OF ADDICTION
REVIEW doi:10.1111/add.15246

Gateway or common liability? A systematic review and meta-analysis of studies of adolescent e-cigarette use and future smoking initiation

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ABSTRACT

Background and Aims Studies have consistently found cigarette smoking. Many have interpreted such associations as evidence of a causal interpretation by (1) estimating study quality characteristics, (2) evaluating the sufficient model (SDM) and the social ecological model (SEM) publication bias. **Methods** Systematic review and meta-analysis of e-cigarette use at baseline and smoking at follow-up. **Results** Meta-analysis of 11 studies showed a significant association (aOR) = 2.93, 95% confidence interval (CI) = 2.22, 3.87]. Studies with sample sizes < 1000 had a significantly higher odds ratio (OR = 6.68, 95% CI = 3.63, 12.31) than studies with sample sizes > 1000 (OR = 2.49, 95% CI = 1.97, 3.15). Overall, the attrition rate was very high (median = 30%). All but one study reported results from complete sample analysis, despite those dropping out having higher risk profiles. Only two studies comprehensively adjusted for confounding. The median E-value was 2.90, indicating that the estimates were not robust against unmeasured confounding. **Conclusions** There is a longitudinal association between adolescent vaping and smoking initiation; however, the evidence is limited by publication bias, high sample attrition and inadequate adjustment for potential confounders.

Keywords Adolescent, cigarette, e-cigarette, smoking

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INTRODUCTION

Tobacco smoking kills more than 8 million people prematurely each year [1]. The main public health approaches to reduce the tobacco-related disease burden have been to assist smokers to quit and prevent uptake among youth through demand and supply reduction policies. The introduction of nicotine vaping products (NVP), including electronic cigarettes (e-cigarettes), has provided a potential harm reduction alternative to cigarettes. There is high consumer acceptability of NVPs, but there is ongoing debate about whether these products increase smoking cessation rates and divert youth from taking up smoking [2] or whether they deter smokers from completely quitting and act as a gateway to smoking for youth [3].

A systematic review of NVPs found a positive association between vaping and quitting smoking, but noted that the quality of the evidence was low [4]. Most recently a large pragmatic multi-centre randomised controlled trial reported an 80% increase in successful quitting, with patients using NVPs over standard nicotine-replacement therapy [5]. However, the rapid uptake of NVPs among young people in some countries has raised concerns that the potential benefits of NVPs for smokers seeking to quit may be offset by adverse impacts on youth. In the United States the prevalence of youth vaping in the past 30 days

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Addiction

Results Meta-analysis of 11 studies showed a significant longitudinal association between vaping and smoking [adjusted odds ratio (aOR) = 2.93, 95% confidence interval (CI) = 2.22, 3.87]. Studies with sample sizes < 1000 had a significantly higher odds ratio (OR = 6.68, 95% CI = 3.63, 12.31) than studies with sample sizes > 1000 (OR = 2.49, 95% CI = 1.97, 3.15). Overall, the attrition rate was very high (median = 30%). All but one study reported results from complete sample analysis, despite those dropping out having higher risk profiles. Only two studies comprehensively adjusted for confounding. The median E-value was 2.90, indicating that the estimates were not robust against unmeasured confounding.

Conclusions There is a longitudinal association between adolescent vaping and smoking initiation; however, the evidence is limited by publication bias, high sample attrition and inadequate adjustment for potential confounders.

Methodische Mängel im Studiendesign

Studien zu E-Zigaretten und Rauchstopp

Methodische Mängel im Studiendesign

Studien zu E-Zigaretten und Gesundheitsrisiken

Beispiel Herzinfarkt-Studie

This Article was Retracted in February 2020

ORIGINAL RESEARCH

Electronic Cigarette Use and Myocardial Infarction Among Adults in the US Population Assessment of Tobacco and Health

Dharma N. Bhatta, PhD, MPH; Stanton A. Glantz, PhD

Background—E-cigarettes are popular for smoking cessation and as an alternative to combustible cigarettes. We assess the association between e-cigarette use and having had a myocardial infarction (MI) and whether reverse causality can explain the observed cross-sectional association between e-cigarette use and MI.

Methods and Results—Cross-sectional analysis of the Population Assessment of Tobacco and Health Wave 1 for association between e-cigarette use and having had MI. Longitudinal analysis of Population Assessment of Tobacco and Health Waves 1 and 2 for reverse causality analysis. Logistic regression was performed to determine the associations between e-cigarette initiation and MI, adjusting for cigarette smoking, demographic and clinical variables. Every-day (adjusted odds ratio, 2.25, 95% CI: 1.23–4.11) and some-day (1.99, 95% CI: 1.11–3.58) e-cigarette use were independently associated with increased odds of having had an MI with a significant dose-response ($P < 0.0005$). Odds ratio for daily dual use of both products was 6.64 compared with a never cigarette smoker who never used e-cigarettes. Having had a myocardial infarction at Wave 1 did not predict e-cigarette use at Wave 2 ($P > 0.67$), suggesting that reverse causality cannot explain the cross-sectional association between e-cigarette use and MI observed at Wave 1.

Conclusions—Some-day and every-day e-cigarette use are associated with increased risk of having had a myocardial infarction, adjusted for combustible cigarette smoking. Effect of e-cigarettes are similar as conventional cigarette and dual use of e-cigarettes and conventional cigarettes at the same time is riskier than using either product alone. (*J Am Heart Assoc.* 2019;8:e012317. DOI: 10.1161/JAHA.119.012317.)

Key Words: e-cigarettes • epidemiology • myocardial infarction • smoking

Cardiovascular disease is the leading cause of death in the United States¹ and tobacco smoking is a major modifiable risk factor for cardiovascular disease, including myocardial infarction.² The risk of myocardial infarction is 2- to 5-fold higher among young men,^{2,3} with a non-linear relationship between low levels of exposure and risk. E-cigarette use is associated with increased risk of having had a myocardial infarction, adjusted for combustible cigarette smoking.⁴ E-cigarettes are promoted as a smoking cessation device and less dangerous way to self-administer nicotine than

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Beispiel Herzinfarkt-Studie

ARTICLE IN PRESS

American Journal of
Preventive Medicine

RESEARCH ARTICLE

Re-examining the Association Between E-Cigarette Use and Myocardial Infarction: A Cautionary Tale

Clayton R. Critcher, PhD,¹ Michael Siegel, MD, MPH²

Introduction: Cross-sectional analyses have suggested that e-cigarette use, independent of combustible cigarette use, elevates the risk of myocardial infarction. Previous researchers confused their own models' assumptions that these risks were independent with the idea that their analyses validated the presence of independent risks. This study avoids this pitfall.

Methods: Cross-sectional analyses of the 2014–2019 National Health Interview Surveys (N=175,546) were conducted in 2020.

Results: Logistic regressions found that e-cigarette use was associated with having had a myocardial infarction, but this association significantly varied on the basis of one's smoking history. With a host of demographic and clinical variables controlled, e-cigarette use was associated with lifetime myocardial infarction occurrence only among current smokers. A counterfactual analysis first removed all (current or former) e-cigarette-using respondents who had suffered a myocardial infarction without a history of smoking. The independent-effects model used in previous research misleadingly indicated that daily vaping increases never smokers' odds of having had a myocardial infarction by 1.55 (95% CI=1.11, 2.15), even though no such myocardial infarction sufferers remained in the analyzed data. The association between myocardial infarction and vaping daily has shown a significant annual decline (AOR=0.81, 95% CI=0.67, 0.98).

Conclusions: There is no reliable evidence that e-cigarette use is associated with ever having had a myocardial infarction among never smokers. Contrary to concerns that the harms associated with e-cigarettes are only now emerging after more years of possible product use, the only evidence of time-dependent variation in the association between e-cigarette use and myocardial infarction ran counter to this possibility. The scientific community must insist that researchers engage in accurate public communication of peer-reviewed findings.

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INTRODUCTION

E-cigarettes have been heralded as effective tools for smoking cessation.¹ Cross-sectional analyses² and RCTs³ show that e-cigarettes both are associated with and lead to superior smoking-cessation outcomes. That said, public health organizations and policymakers vary in whether they have embraced or resisted these products, due, in part, to uncertainties about the consequences of prolonged use. Although e-cigarettes are widely considered safer than combustible tobacco cigarettes,⁴ some have claimed that vaping increases the risk of various

negative health events, including myocardial infarction (MI).^{5–7} A better understanding of whether vaping indeed poses risks to cardiovascular health is critical for formulating and evaluating public policy as well as for informing clinical recommendations.

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Beispiel COPD-Studie

Research Paper

Tobacco Induced Diseases

Electronic cigarette use and its association with asthma, chronic obstructive pulmonary disease (COPD) and asthma-COPD overlap syndrome among never cigarette smokers

Emine Bircan¹, Ummugul Bezirhan², Austin Porter^{3,4}, Pebbles Fagan^{5,6}, Mohammed S. Orloff^{1,7}

ABSTRACT

INTRODUCTION Although smoking is a strong risk factor for lung diseases including asthma, COPD, and asthma-COPD overlap syndrome (ACOS), studies are needed to examine the association between e-cigarettes and asthma, COPD, and ACOS. This study evaluated the association between e-cigarette use and self-reported diagnosis of asthma, COPD, and ACOS using a large nationally representative sample of adults aged ≥ 18 years in the United States.

METHODS Cross-sectional data from the Behavioral Risk Factor Surveillance System (BRFSS) from 2016 to 2018 was used to examine self-reported information on current e-cigarette use, demographic variables, and asthma and COPD status among never cigarette smokers ($n=8736$). Asthma and COPD were measured by self-reported diagnosis, and respondents who reported having both diagnoses were then classified as having ACOS. Of the 46079 never cigarette smokers, 4368 non-e-cigarette smokers were 1:1 propensity score-matched to e-cigarette smokers on age, sex, race/ethnicity and education level. We used multinomial logistic regression to examine association between current e-cigarette use and self-report asthma, COPD and ACOS while controlling for marital status and employment in addition to matching variables.

RESULTS Compared with never e-cigarette smokers, e-cigarette smokers had increased odds of self-reported ACOS (OR=2.27; 95% CI: 2.23–2.31), asthma (OR=1.26; 95% CI: 1.25–1.27) and COPD (OR=1.44; 95% CI: 1.42–1.46).

CONCLUSIONS Data from this large nationally representative sample suggest that e-cigarette use is associated with increased odds of self-reported asthma, COPD, and ACOS among never combustible cigarette smokers. The odds of ACOS were twice as high among e-cigarette users compared with never smokers of conventional cigarettes. The findings from this study suggest the need to further investigate the long-term and short-term health effects of e-cigarette use, since the age of those at risk in our study was 18–24 years.

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COPD, e-cigarettes, combustible cigarettes, asthma, asthma-COPD overlap syndrome (ACOS)

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INTRODUCTION

Overall tobacco use has declined in the United States over the past 50 years, but the prevalence of electronic cigarette (e-cigarette) use has increased rapidly in United States since their introduction in 2007¹. E-cigarettes are battery-powered devices that

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RESULTS Compared with never e-cigarette smokers, current e-cigarette use was associated with increased odds of self-reported ACOS (OR=1.26; 95% CI: 1.25-1.27) and asthma (OR=1.26; 95% CI: 1.25-1.27) among never cigarette smokers (OR=1.42-1.46).

CONCLUSIONS Data from this large nationally representative study suggest that e-cigarette use is associated with increased odds of asthma, COPD, and ACOS among never cigarette smokers. The odds of ACOS were twice as high among never smokers of conventional cigarettes. These findings suggest the need to further investigate the health effects of e-cigarette use, since the prevalence of e-cigarette use was 18-24 years.

AFFILIATION

¹Department of Epidemiology

Characteristics	E-cigarette use status		p
	Smokers (N=4368) n (%)	Never smokers (N=4368) n (%)	
Age (years)	18-24	18-24	-
Women	1504 (34.40)	1504 (34.40)	-
Race			-
Pulmonary disease			<0.001
Asthma	430 (9.80)	314 (7.20)	
COPD	90 (2.10)	58 (1.30)	
ACOS	66 (1.50)	31 (0.70)	

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AFFILIATION

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The odds of ACOS were twice as high among e-cigarette users compared with never smokers of conventional cigarettes. The findings from this study suggest the need to further investigate the long-term and short-term health effects of e-cigarette use, since the age of those at risk in our study was 18–24 years.

Wo treten häufig Probleme auf?

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 - Im Abstract
- In Pressemitteilungen zu Fachartikeln

Beispiel einer Biomarker-Studie

Circulation

RESEARCH LETTER

Association of Cigarette and Electronic Cigarette Patterns With Levels of Inflammatory and Oxidative Stress Biomarkers Among US Adults Population Assessment of Tobacco and Health Study

The cardiovascular toxicity of electronic cigarettes (e-cigarettes) is not well understood, and population data assessing the cardiovascular effects of e-cigarette use are sparse. In the present study, we used nationally representative data to examine the association of cigarette and e-cigarette use behaviors with biomarkers of inflammation and oxidative stress. Inflammation and oxidative stress are key contributors of smoking-induced cardiovascular disease, and related biomarkers have been studied as predictive factors for cardiovascular events.^{1,2}

The PATH study (Population Assessment of Tobacco and Health) is a nationally representative longitudinal cohort in the United States. The Wave 1 survey was administered from 2013 to 2014 and included the collection of blood and urine samples. Additional information on PATH biospecimen procedures is given elsewhere.³ Our analysis was restricted to Wave 1 adults ≥18 years of age with nonmissing data on biomarkers and cigarette/e-cigarette use. Analytic sample sizes were dependent on the respective biomarker considered.

We classified participants into 4 categories based on cigarette/e-cigarette use behaviors in the past 30 days to assess product exposure: (1) Nonuse included respondents with no cigarette or e-cigarette use; (2) exclusive e-cigarette included individuals with no cigarette use but e-cigarette use; (3) exclusive cigarette included individuals with cigarette use but no e-cigarette use; and (4) dual use included individuals with e-cigarette and cigarette use.

We selected biomarkers of inflammation (high-sensitivity C-reactive protein, interleukin-6, fibrinogen, soluble intercellular adhesion molecule) and oxidative stress (urinary 8-isoprostane) as dependent variables. We used the PATH imputed biomarker variables in which observations under the limit of detection were replaced by limit of detection/√2. All biomarkers were right skewed and thus log transformed for analyses.

We adjusted for covariates that may be associated with smoking behaviors or biomarkers of interest. Data on race and ethnicity were combined to classify respondents as non-Hispanic White, non-Hispanic Black, Hispanic, and non-Hispanic other. Additional self-reported measures included sex (male, female); age (18–24, 25–34, 35–44, 45–54, 55–64, ≥65 years); education (less than high school, high school diploma, some college, college or higher); poverty status based on household income (<100%, 100%–199%, ≥200% of poverty level); body mass index (<18.5, 18.5–24.9, 25–29.9, ≥30 kg/m²); diabetes (yes, no); heart attack (yes, no); heart failure (yes, no); stroke (yes, no); use of other tobacco products, including traditional cigar, filtered cigar, cigarillo, pipe, hookah, snus, dissolvable, smokeless (never, former, current), and marijuana/blunt (never, former, current); recreational drug (never, former, current); prescription drug (never, former, current); second-hand smoke exposure at home or at work (yes, no); and pack-year of cigarette smoking and its squared term.

Andrew C. S. Wubin Xie, Anna E. Wills Hanqi Yang, Olusola A. O. MBBS, MPH Alyssa E. Har Jessica L. Fet PhD Andrew P. D. MSc Emella J. Ben Rose Marie R. MD Aruni Bhatn Naomi M. Ha MD, MSc Michael J. Bl MPH

Key Words: electronic nicotine delivery systems • inflammation • oxidative stress

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Indicators	Compared with nonuse				Compared with exclusive smoking	
	Nonuse (n=2191, 58.6%)	Exclusive e-cigarette use (n=261, 1.9%)	Exclusive smoking (n=3261, 29.6%)	Dual use n=1417, 9.9%)	Exclusive e-cigarette use	Dual use
IL-6 (n=6915)						
Adjusted geometric mean†	1.4 (1.3–1.4)	1.4 (1.3–1.6)	1.6 (1.6–1.7)	1.6 (1.5–1.7)		
Age-, sex-, race/ethnicity-adjusted GMR (95% CI)‡	Ref.	1.10 (0.98–1.24)	1.28 (1.20–1.37)*	1.24 (1.16–1.33)*	0.86 (0.73–0.83)*	0.97 (0.91–1.03)
Multivariable-adjusted GMR (95% CI)§	Ref.	1.00 (0.89–1.12)	1.15 (1.07–1.23)*	1.11 (1.03–1.19)*	0.87 (0.78–0.98)*	0.97 (0.91–1.03)
Urinary 8-isoprostane (n=7076)						
Adjusted geometric mean†	401.0 (380.2–421.4)	418.2 (366.4–470.0)	514.9 (489.1–540.7)	519.2 (485.6–552.8)		
Age-, sex-, race/ethnicity-adjusted GMR (95% CI)‡	Ref.	1.11 (0.97–1.26)	1.41 (1.31–1.51)*	1.41 (1.31–1.53)*	0.78 (0.66–0.76)*	1.00 (0.93–1.08)
Multivariable-adjusted GMR (95% CI)§	Ref.	1.02 (0.89–1.17)	1.24 (1.15–1.34)*	1.26 (1.15–1.37)*	0.82 (0.72–0.93)*	1.01 (0.94–1.08)

Beispiel einer Biomarker-Studie

Circulation

RESEARCH LETTER

Association of Cigarette and Electronic Cigarette Use Patterns With Levels of Inflammatory and Oxidative Stress Biomarkers Among US Adults

Population Assessment of Tobacco and Health Study

The cardiovascular toxicity of electronic cigarettes (e-cigarettes) is not well understood, and population data assessing the cardiovascular effects of e-cigarette use are sparse. In the present study, we used nationally representative data to examine the association of cigarette and e-cigarette use behaviors with biomarkers of inflammation and oxidative stress. Inflammation and oxidative stress are key contributors of smoking-induced cardiovascular disease, and related biomarkers have been studied as predictive factors for cardiovascular events.^{1,2}

The PATH study (Population Assessment of Tobacco and Health) is a nationally representative longitudinal cohort in the United States. The Wave 1 survey was administered from 2013 to 2014 and included the collection of blood and urine samples. Additional information on PATH biospecimen procedures is given elsewhere.³ Our analysis was restricted to Wave 1 adults ≥ 18 years of age with nonmissing data on biomarkers and cigarette/e-cigarette use. Analytic sample sizes were dependent on the respective biomarker considered.

We classified participants into 4 categories based on cigarette/e-cigarette use behaviors in the past 30 days to assess product exposure: (1) Nonuse included respondents with no cigarette or e-cigarette use; (2) exclusive e-cigarette included individuals with no cigarette use but e-cigarette use; (3) exclusive cigarette included individuals with cigarette use but no e-cigarette use; and (4) dual use included individuals with e-cigarette and cigarette use.

We selected biomarkers of inflammation (high-sensitivity C-reactive protein, interleukin-6, fibrinogen, soluble intercellular adhesion molecule) and oxidative stress (urinary 8-isoprostane) as dependent variables. We used the PATH imputed biomarker variables in which observations under the limit of detection were replaced by limit of detection $\sqrt{2}$. All biomarkers were right skewed and thus log transformed for analyses.

We adjusted for covariates that may be associated with smoking behaviors or biomarkers of interest. Data on race and ethnicity were combined to classify respondents as non-Hispanic White, non-Hispanic Black, Hispanic, and non-Hispanic other. Additional self-reported measures included sex (male, female); age (18–24, 25–34, 35–44, 45–54, 55–64, ≥ 65 years); education (less than high school, high school diploma, some college, college or higher); poverty status based on household income (<100%, 100%–199%, $\geq 200\%$ of poverty level); body mass index (<18.5, 18.5–24.9, 25–29.9, ≥ 30 kg/m²); diabetes (yes, no); heart attack (yes, no); heart failure (yes, no); stroke (yes, no); use of other tobacco products, including traditional cigar, filtered cigar, cigarillo, pipe, hookah, snus, dissolvable, smokeless (never, former, current); and marijuana/blunt (never, former, current); recreational drug (never, former, current); prescription drug (never, former, current); second-hand smoke exposure at home or at work (yes, no); and pack-year of cigarette smoking and its squared term.

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Vaping combined with smoking is likely as harmful as smoking cigarettes alone

Circulation Journal Report

Research Highlights:

- People who smoked traditional cigarettes in addition to using e-cigarettes experienced health effects as harmful as those who smoked cigarettes exclusively; those effects are associated with a higher risk for cardiovascular disease and death.
- In a large data analysis of more than 7,100 U.S. adults, researchers examined the association of cigarette and e-cigarette use with inflammation and oxidative stress as biomarkers predicting cardiovascular disease.
- This is among the first nationally representative studies of e-cigarettes to include these kinds of measurable early indicators of the health impacts of nicotine products.

Wo treten häufig Probleme auf?

- Beim Studiendesign
 - Unzureichende Vorkehrungen zur Minimierung von Bias und/oder Confounding
 - Ungeeignete Analysemethoden
 - Nutzung von eigentlich ungeeigneten Daten/Instrumenten
- Bei der Datenanalyse
 - p-hacking
 - HARKing
- Im Manuskript von Originalarbeiten/Übersichtsarbeiten
 - Bei der Interpretation und Diskussion der Ergebnisse
 - Im Abstract
- In Pressemitteilungen zu Fachartikeln
- In Stellungnahmen/Positionspapieren

DHS-Stellungnahme zu E-Zigaretten (2021)

Stellungnahme der Deutschen Hauptstelle für Suchtfragen e.V. (DHS) zu E-Zigaretten

Die E-Zigarette ist seit ihrer Einführung auf dem Markt in den Jahren 2007/2008 einer Kontroverse unter Wissenschaftlern und Wissenschaftlerinnen, Medizinerinnen, Suchttherapeuten und -therapeutinnen sowie weiteren Expertinnen und Gesundheitswesens. Wissenschaftliche Erkenntnisse und gesundheitspolitische Vorarbeiten der letzten fünf Jahre veranlassen die DHS als Fachgesellschaft für Suchtfragen, die Grundlagen und Fakten zu prüfen, nachdem sie bereits im Jahr 2017 eine Stellungnahme zur Thematik veröffentlicht hatte (Deutsche Hauptstelle für Suchtfragen 2017).

Inzwischen liegen Studien vor, die belegen, dass E-Zigaretten-Konsumierende Schadstoffe inhalieren, die schädigend auf Lunge, Herz-Kreislauf- und Immunsystem und im Verdacht stehen, Krebs zu fördern (Palamidis et al., 2017; Meo et al., 2016; Tsai et al., 2019; Biondi-Zoccai et al., 2019; Fettermann et al., 2020; Kerr et al., 2019; Putzhammer et al., 2016; Scott et al., 2018). Die typischen Schadstoffe einer Tabakzigarette sind wegen der anderen Zusammensetzung des Aerosols und der unterschiedlichen, beim Konsumvorgang erreichten Temperaturen in der Zigarette nicht nachweisbar. Dafür kann das Aerosol neben den Vernebelungsmitteln Propylen glykol und Glycerin, je nach technischer Umsetzung der Vernebelung, variable Mengen an kanzerogenen Formaldehyd, Acrolein und Acrylamid oder Schwermetalle wie Chrom, Nickel und Cadmium enthalten (Aherrera et al., 2017; National Academies of Sciences, Engineering and Medicine, 2018; Schick et al., 2017; Schober et al., 2019; Canistro et al., 2017). Diese Schadstoffe machen die E-Zigarette zu einem gesundheitlich riskanten Produkt, auch wenn die Risiken für den einzelnen Nutzenden bzw. die einzelnen Nutzende nach derzeitigem Stand der Wissenschaft im direkten Vergleich zur Tabakzigarette als geringer einzuschätzen sein dürften. Ein Gesundheitsproblem stellt bei der E-Zigarette die Entwicklung oder Verlängerung der Nikotinsucht dar. Denn die Nikotinaufnahme entspricht bei den Geräten neuerer Typen der Inhalation der von Tabakzigaretten.

¹ Von der Arbeitsgruppe des Wissenschaftlichen Kuratoriums der DHS, Dr. Martina Pöhlmann (Leitung), Prof. Dr. Volker Auwärter, Dr. Gallus Bischof, Prof. Dr. Reiner Hanewinkel, Prof. Dr. John, Prof. Dr. Thomas Redecker, PD Dr. Hans-Jürgen Rumpf und Christina Rummel vom Vorstand der DHS am 11. März 2021 diskutiert und verabschiedet. Es handelt sich um ein Promisspapier, welches nicht in allen Punkten die wissenschaftliche Einschätzung sämtlicher Autorinnen und Autoren darstellt.

- E-Zigaretten sind in der Tabakentwöhnung umstritten. Obwohl sie seit über zehn Jahren angeboten werden, gibt es nur wenige klinische, kontrollierte Studien. Ein kürzlich veröffentlichtes Cochrane Review (Hartmann-Boyce et al., 2020) identifiziert 20 Studien, die Ergebnisse zum Rauchstopp berichten. Von diesen wurden 4 als methodisch unproblematisch eingestuft. Die übrigen Studien leiden an einer geringen Anzahl von Studienteilnehmern und -teilnehmerinnen und hohen Verzerrungstendenzen (Pisinger, Vestbo, 2020). Obwohl E-Zigaretten in den methodisch hochwertigen Studien gegenüber herkömmlichen Nikotinersatztherapien höhere Raten an Tabakabstinenz erzielten, war die Wirksamkeit von E-Zigaretten für den Rauchstopp insgesamt gering: Von 100 Raucherinnen und Rauchern, die die E-Zigarette zum Rauchstopp nutzten, blieben 90 beim Rauchen. Das Cochrane-Review berichtet nicht, wie viele Raucherinnen und Raucher nach dem Rauchstopp weiterhin E-Zigaretten konsumieren. In einer methodisch hochwertigen klinischen Studie waren ein Jahr nach Einsatz der E-Zigarette als Rauchstopphilfe nur 3 % der Raucherinnen und Raucher komplett tabak- und nikotinfrei (Hajek et al., 2019; persönliche Mitteilung).

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Inzwischen liegen Studien vor, die belegen, dass E-Zigaretten-Konsumierende Aerosolpartikel und Nikotin einatmen, die schädigend auf Lunge, Herz-Kreislauf- und Immunsystem sind und im Verdacht stehen, Krebs zu fördern (Palamidis et al., 2017; Meo et al., 2016; Tsai et al., 2019; Biondi-Zoccai et al., 2019; Fettermann et al., 2020; Ip et al., 2019; Putzhammer et al., 2016; Scott et al., 2018). Die typischen Bestandteile einer Tabakzigarette sind wegen der anderen Zusammensetzung des Aerosols und der unterschiedlichen, beim Konsumvorgang erreichten Temperaturen bei E-Zigaretten nicht nachweisbar. Dafür kann das Aerosol neben den Vernebelungsmitteln Propylen- und Glycerin, je nach technischer Umsetzung der Vernebelung, variable Mengen an Karbonmonoxid, formaldehyd, Acrolein und Acrylamid oder Schwermetalle wie Chrom, Nickel und Cadmium (Aherrera et al., 2017; National Academies of Sciences, Engineering and Medicine, 2018; Schick et al., 2017; Schober et al., 2019; Canistro et al., 2017). Diese Stoffe machen die E-Zigarette zu einem gesundheitlich riskanten Produkt, auch wenn die Risiken für den einzelnen Nutzenden bzw. die einzelnen Nutzende nach derzeitigem Kenntnisstand im direkten Vergleich zur Tabakzigarette als geringer einzuschätzen sein dürften. Ein weiteres Gesundheitsproblem stellt bei der E-Zigarette die Entwicklung oder Verlängerung der Nikotinsucht dar. Denn die Nikotinaufnahme entspricht bei den Geräten neueren Typs bei entsprechender Inhalation der von Tabakzigaretten.

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- Auch in Bevölkerungsstudien konnte kein Nutzen von E-Zigaretten für einen erfolgreichen Rauchstopp belegt werden (Glantz, Bareham, 2018; Weaver et al., 2018; Beard et al., 2019; Johnson et al., 2019). Sowohl Bevölkerungsstudien als auch klinische Studien zeigen zudem, dass Raucher und Raucherinnen, die mittels der E-Zigarette das Rauchen aufgehört hatten, mehrheitlich zu dauerhaften E-Zigarettenkonsumentinnen und -konsumenten wurden und somit keine Nikotinabstinenz erreichten (Chen et al., 2020; Pisinger, Vesbo, 2020).

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Inzwischen liegen Studien vor, die belegen, dass E-Zigaretten-Konsumierende toxische Inhaltsstoffe inhalieren, die schädigend auf Lunge, Herz-Kreislauf- und Immunsystem wirken und im Verdacht stehen, Krebs zu fördern (Palamidis et al., 2017; Meo et al., 2018; Martin et al., 2016; Tsai et al., 2019; Biondi-Zoccai et al., 2019; Fettermann et al., 2020; Ip et al., 2020; Kerr et al., 2019; Putzhammer et al., 2016; Scott et al., 2018). Die typischen Verbrennungsstoffe einer Tabakzigarette sind wegen der anderen Zusammensetzung des Ausgangsmaterials und der unterschiedlichen, beim Konsumvorgang erreichten Temperaturen bei einer E-Zigarette nicht nachweisbar. Dafür kann das Aerosol neben den Vernebelungsmitteln Propylen glykol und Glycerin, je nach technischer Umsetzung der Vernebelung, variable Mengen der Kanzerogene Formaldehyd, Acrolein und Acrylamid oder Schwermetalle wie Chrom, Blei und Nickel enthalten (Aherrera et al., 2017; National Academies of Sciences, Engineering and Medicine, 2018; Schick et al., 2017; Schober et al., 2019; Canistro et al., 2017). Diese Schadstoffe machen die E-Zigarette zu einem gesundheitlich riskanten Produkt, auch wenn die Risiken für den einzelnen Nutzenden bzw. die einzelnen Nutzende nach derzeitigem Kenntnisstand im direkten Vergleich zur Tabakzigarette als geringer einzuschätzen sein dürften. Ein weiteres Gesundheitsproblem stellt bei der E-Zigarette die Entwicklung oder Verlängerung der Nikotinsucht dar. Denn die Nikotinaufnahme entspricht bei den Geräten neueren Typs bei entsprechender Inhalation der von Tabakzigaretten.

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- Auch in England, wo die E-Zigarette zur Tabakentwöhnung propagiert wird, ist man von einem Erfolg weit entfernt: Vielmehr stellte eine britische Arbeitsgruppe um den Suchtforscher Robert West fest, dass die gestiegene Prävalenz von E-Zigaretten unter Rauchern und Raucherinnen in England mit keiner spürbaren Veränderung des täglichen Zigarettenkonsums einhergeht (Beard et al., 2018).

Verbesserungsvorschläge

Vorschläge zur Förderung einer besseren wissenschaftlichen Praxis

Es braucht eine bessere Ausbildung

Problem: In der wissenschaftlichen Lehre und Ausbildung wird (wenn überhaupt...) wissenschaftliches Arbeiten vermittelt, aber nicht notwendigerweise gute wissenschaftliche Praxis

Lösung: Gute wissenschaftliche Praxis muss schon in der wissenschaftlichen Lehre/Ausbildung vermittelt und bei Forschungsprojekten/Abschlussarbeiten eingefordert werden

Vorschläge zur Förderung einer besseren wissenschaftlichen Praxis

Es braucht bessere Anreizsysteme und Evaluations-Metriken

Problem: Aktuelles Wissenschafts- und Publikationssystem begünstigt hohe Zahl an Publikationen („publish or perish“) und Publikation in renommierten Fachzeitschriften, die bevorzugt Publikationen mit hohem Neuigkeitswert publizieren → Sorgfalt bleibt auf der Strecke, auch zweifelhafte Ergebnisse werden veröffentlicht

Lösung: Evaluations-Metriken sollten Qualität und/oder Impact von Publikationen honorieren statt Quantität (Bsp. Top10-Angabe bei DFG-Anträgen, Berücksichtigung der tatsächlichen Zitationen statt Journal Impact Factor...)

Vorschläge zur Förderung einer besseren wissenschaftlichen Praxis

Es braucht bessere Mechanismen der Selbstkontrolle

Problem: Intransparente (einseitig verblindete) Begutachtungssysteme begünstigen verzerrte Publikations-Entscheidungen

Lösung: Unverblindete und offene Begutachtungssysteme mit Veröffentlichung sämtlicher Gutachten und Autorenrepliken erhöhen Transparenz des Peer-Review-Systems und ermöglichen kritische Überprüfung

Vorschläge zur Förderung einer besseren wissenschaftlichen Praxis

Es braucht offenere und transparentere Wissenschaft

Problem: Auswertungsfehler, unwissenschaftliche Praktiken wie p-hacking und HARKing sowie Betrug sind im Rahmen des Peer Review schwer zu erkennen

Lösung: „Open Science“-Praxis, in deren Rahmen Analyseprotokolle vor Durchführung der Studie registriert werden und Daten und Analyseskripte öffentlich zugänglich gemacht werden, erschweren Betrug und unwissenschaftliche Praktiken und ermöglichen Identifikation von Fehlern

Umfassendes Verständnis von Interessenskonflikten und
Einforderung von Transparenz notwendig

Abschließende Überlegungen

- Fragwürdige Studien und Positionspapiere schaden der Glaubwürdigkeit der Tabakkontrolle → Zweck heiligt nicht die Mittel
- Wir bleiben alle mal hinter dem wissenschaftlichen Anspruch zurück → Gute Wissenschaft erfordert ein ständiges Hinterfragen der eigenen Arbeit und der Arbeit anderer → wissenschaftliche Selbstkontrolle

Abschließende Überlegungen

PLASTIC FANTASTIC: HOW THE BIGGEST FRAUD IN PH...

And which scientists did the most to contribute to the resolution of the case? Paradoxically, it wasn't those who acted as if they were confident that science was self-correcting, but those who acted as if they were worried that it wasn't. Somewhere, they figured, science was going wrong. Something had been miscommunicated or misunderstood. There was missing information. There hadn't been enough cross-checks. There were problems in the experimental method or the data analysis. People who reasoned in this way were more likely to find themselves pulling on, or uncovering, or pointing out, problems in Schön's work that it appeared might have arisen through clerical errors or experimental artifacts, but that eventually turned out to be the thin ends of wedges supporting an elaborately constructed fraud. Even when they failed to expose fraud, researchers acting in this way were most likely to contribute to the momentum of the eventual whistleblowers, and to begin the task of setting the scientific record straight. In contrast, those who did the most to prolong and sustain the fraud were those who acted as if the self-correcting nature of science could be trusted to come to the rescue, who were confident that future research would fill the gaps. This way of thinking provided a rationalization for publishing papers at journals; both at *Science* magazine, where editors expedited at least one of Schön's papers into print without always following their own review policy, and at *Nature*, where, on at least one occasion, technical questions about Schön's method were less of a priority than accessibility. Bell Labs managers reasoned similarly, taking the decision to put the reputation of a renowned research institution behind research that was known to be puzzling, and so crossed the line between open-mindedness to new results, leading others astray.

Abschließende Überlegungen

- Fragwürdige Studien und Positionspapiere schaden der Glaubwürdigkeit der Tabakkontrolle → Zweck heiligt nicht die Mittel
- Wir bleiben alle mal hinter dem wissenschaftlichen Anspruch zurück → Gute Wissenschaft erfordert ein ständiges Hinterfragen der eigenen Arbeit und der Arbeit anderer → wissenschaftliche Selbstkontrolle
- Alle Akteure im Wissenschaftssystem (Drittmittelgeber, Hochschulen, Fachzeitschriften, Lehrende, Forschende...) sind aufgefordert, zur Umsetzung struktureller Änderungen beizutragen:
 - Bessere Ausbildung
 - Bessere Anreizsysteme und Evaluations-Metriken
 - Bessere Mechanismen der Selbstkontrolle
 - Offenere und transparentere Wissenschaft

A portrait of Prof. Doug Altman, an older man with grey hair and a beard, wearing a light blue button-down shirt. The background is a plain, light grey color.

Prof. Doug Altman
1948-2018

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**„We need less research,
better research and
research done for the
right reasons.“**