Electronic cigarettes in Italy: a tool for harm reduction or a gateway to smoking tobacco?

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ABSTRACT

Introduction More than a decade after electronic cigarettes (e-cigarette) hit the European market, we are still debating whether they may help or hinder tobacco control. It is therefore useful to explore the potential net effect of e-cigarette use in the general population.

Methods We annually conduct a face-to-face survey on smoking in Italy on a representative sample of the general population aged 15 years or over (52.4 million). A total of 15,406 subjects were interviewed in 2014–2018. We investigated the consequences of using e-cigarettes on tobacco smoking behaviour among ever and regular e-cigarette users.

Results In all, 5.7% of our sample reported ever e-cigarette use. Multivariate analyses showed more use by men, ex-smokers and current smokers. E-cigarette use decreased with age and increased with education and calendar year. Only 1.1% of subjects were regular e-cigarette users. This prevalence rose from 0.4% in 2014–2015 to 1.8% in 2016–2017 and was 1.3% in 2018. Among 522 ever users, 13.2% stopped smoking after trying e-cigarettes and 22.2% started smoking or relapsed after using e-cigarettes. The corresponding estimates among regular users were 24.7% and 28.0%, respectively.

Conclusions Among Italian e-cigarette users, those (re)starting smoking after using e-cigarettes outnumber those who stop smoking after using e-cigarettes. From a public health point of view, e-cigarettes may have an unfavourable net effect. Consequently, if we are not able to prevent sales of e-cigarettes to non-smokers, this product will more likely stimulate smoking tobacco than reduce harm.

INTRODUCTION

The electronic cigarette (e-cigarette) is a battery-powered device that heats a liquid containing propylene glycol, glycerin and/or water with flavours, to generate an inhalable aerosol containing nicotine or not. E-cigarettes were marketed in most high-income countries around 2010, and its popularity and use soon spread widely.1 Some public and private organisations, including Public Health England, have endorsed e-cigarette use, on the basis of the widely accepted standpoint that they could be beneficial for heavy smokers who are not able to quit with standard support.2,3 This endorsement, conflicting with the conclusions of the WHO4 and the US National Academies of Sciences, Engineering, and Medicine,5 has provoked much debate and concern over the spread and use of e-cigarettes.6–8

The debate is mainly due to uncertainty about the harmful effects of e-cigarettes and their effectiveness as a smoking cessation tool.8 Indeed, the safety of e-cigarette use, particularly its long-term effects, remains unclear.7,10 while these e-cigarettes emit less toxicants and carcinogens than conventional cigarettes, they are still measurable and vary widely with individual puffing topography and puff duration,11 and from study to study.12–15 Although some studies showed that e-cigarettes may help smokers cut down or stop smoking conventional cigarettes,14–16 others found e-cigarettes even stop cessation or give low cessation rates, similar to those of smokers who have tried to quit without aid.10–17–19 There is also concern that e-cigarettes may undermine efforts to ‘denormalise’ smoking.20 Finally, non-smokers trying e-cigarettes can succumb to nicotine addiction, particularly young people.1,21,22

To get a better picture of the potential net benefit of e-cigarette use in reducing tobacco consumption at a population level, we analysed data from our annual population-based surveys conducted in Italy from 2014 to 2018, where a specific section was devoted to e-cigarette use.

METHODS

Surveys were conducted by DOXA, the Italian branch of the Worldwide Independent Network/ G Gallup International Association, in collaboration with the Italian National Institute of Health and the Mario Negri Institute for Pharmacological Research. Each year, the survey is based on around 3000 subjects, representative of the general Italian population aged 15 years and over (52.4 million inhabitants in 2018), in terms of sex, age, area of residence and socioeconomic characteristics.21 For the present analysis, the sample comprised 15,406 individuals aged 15 years or more (7393 men and 8013 women), enrolled in the survey conducted in 2014–2018.

Participants were selected by a representative multistage sampling. The first stage involved the selection of municipalities in all the 20 Italian regions, based on the region and the size of the municipality. We selected 116 municipalities in 2014, 110 in 2015, 2016 and 2017 and 119 in 2018 as representative of the regions sampled. In the second stage, an adequate number of electoral wards was randomly extracted in each municipality, so that the more or less affluent areas of the municipality were represented in the right proportions. In the third stage, individuals were randomly sampled from electoral rolls, within strata defined by sex and age. Adolescents aged 15–17 years, who were not included in the electoral lists, were randomly selected by a ‘quota’ method based on the sex and age.
age proportions among them. A statistical weight was generated for each subject to ensure the representativeness of the Italian population aged 15 years or more.

Ad hoc trained interviewers conducted the survey using a structured questionnaire in a computer-assisted personal interview. Besides general information on sociodemographic characteristics, smoking status (never smoker, ex-smoker and current smoker) and other tobacco-related data were collected. Ever smokers (current smokers and ex-smokers) were participants who had smoked 100 or more cigarettes in their lifetime. Ex-smokers were participants who had quit smoking for at least 1 year, and current smokers were individuals smoking at the time of the interview or having stopped for less than 1 year. Participants were asked about their use of e-cigarettes, using the question: ‘Do you use electronic cigarettes or other electronic devices for vaping (disposable or prefilled or refillable cartridges with liquid), even only occasionally?’ (1) Yes, occasionally; (2) Yes, usually; (3) I used it in the past; (4) No. We define herewith as occasional e-cigarette users reporting the first answer, regular users the second answer, past users the third answer, current users first and second answers combined, and ever users first, second and third answers combined. Occasional and regular e-cigarette users (and past e-cigarette users in 2017 and 2018) were further investigated about the consequences of e-cigarette use on their tobacco smoking habits with the following question: ‘Which of the following best describes the consequence of using electronic cigarettes on your current cigarette smoking consumption? (1) I started smoking conventional cigarettes (I did not smoke before, and now I smoke); (2) I re-started smoking conventional cigarettes (I was an ex-smoker, and now I relapsed); (3) I haven’t changed my smoking habits (I smoke the same number of conventional cigarettes as before); (4) I slightly reduced the number of conventional cigarettes per day; (5) I substantially reduced the number of conventional cigarettes per day; (6) I increased the number of conventional cigarettes per day; (7) I quit smoking; (8) I did not smoke conventional cigarettes before and I do not smoke now’. Almost all e-cigarette users (97%) provided a valid response to this question. In 2017–2018, a single-choice question to current e-cigarette users only investigated the type of e-cigarette used (with or without nicotine).

Descriptive statistics were used for the main results, including prevalence and the corresponding 95% confidence interval (CI) by categorical variables. In view of the small numbers, we grouped the survey year as 2014–2015, 2016–2017 and 2018. Statistical weights were used to reassure the representativeness of our sample in terms of age, sex, area of residence and socioeconomic characteristics. Odds ratios (OR) and the 95% CIs for ever—and regular—e-cigarette use were calculated using multivariate logistic regression models, adjusting for sex, age, level of education, smoking status, area of residence and survey year. A sensitivity analysis limited to data from 2017 and 2018 was done to explore whether the answers on the consequence of e-cigarette use differed between current and past users. Another sensitivity analysis was done on nicotine-containing e-cigarette users, that is, current users in 2014–2015, 2017–2018, to assess the consequence of their use of e-cigarettes on tobacco smoking. All analyses were done with SAS V.9.4 statistical package.

RESULTS

The distribution of 15 406 Italians aged 15 years or more according to their use of e-cigarettes is shown in table 1. Only 1.1% of Italian adults (95% CI: 1.0% to 1.3%) reported regular e-cigarette use, 1.1% (95% CI: 0.9% to 1.2%) occasional use and 3.5% (95% CI: 3.2% to 3.8%) past use (table 1). Among regular and occasional users, 62% were dual users (ie, current smokers and e-cigarette users): 81% in 2014–2015, 53% in 2016–2017 and 66% in 2018. Ever (ie, occasional, regular or

### Table 1

Prevalence (per cent) of occasional, regular and past use of electronic cigarettes in a total sample of 15 406 Italians aged at least 15 years, overall and according to selected characteristics (Italy, 2014–2018)

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Electronic cigarette use (%)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Never use</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>7393</td>
<td>92.9</td>
</tr>
<tr>
<td>Women</td>
<td>8013</td>
<td>95.6</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
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</tr>
<tr>
<td>15–24</td>
<td>1751</td>
<td>93.7</td>
</tr>
<tr>
<td>25–45</td>
<td>4786</td>
<td>92.6</td>
</tr>
<tr>
<td>45–65</td>
<td>5034</td>
<td>93.4</td>
</tr>
<tr>
<td>≥65</td>
<td>3835</td>
<td>97.9</td>
</tr>
<tr>
<td>Level of education</td>
<td></td>
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</tr>
<tr>
<td>Low</td>
<td>5569</td>
<td>96.1</td>
</tr>
<tr>
<td>Intermediate</td>
<td>7370</td>
<td>92.6</td>
</tr>
<tr>
<td>High</td>
<td>2467</td>
<td>95.1</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never smoker</td>
<td>10 046</td>
<td>98.6</td>
</tr>
<tr>
<td>Current smoker</td>
<td>3395</td>
<td>82.2</td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>1965</td>
<td>93.2</td>
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<tr>
<td>Survey year</td>
<td></td>
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</tr>
<tr>
<td>2014–2015</td>
<td>6098</td>
<td>95.3</td>
</tr>
<tr>
<td>2016–2017</td>
<td>6086</td>
<td>93.1</td>
</tr>
<tr>
<td>2018</td>
<td>3222</td>
<td>94.9</td>
</tr>
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</table>
past) e-cigarette users were 5.7% with fewer women (4.4%) than men (7.1%; multivariate OR: 0.80; 95% CI: 0.68 to 0.91), inversely related to age (p for trend <0.001) and directly related to education (p for trend 0.021). Compared with never cigarette smokers (1.4%), ever e-cigarette use was more frequent among current smokers (17.8%; multivariate OR: 14.3; 95% CI: 11.8 to 17.3) and ex-smokers (6.8%; OR: 5.80; 95% CI: 4.51 to 7.45). The prevalence of ever e-cigarette use rose from 4.7% in 2014–2015, to 6.9% in 2016–2017 (OR: 1.52; 95% CI: 1.29 to 1.78) and was 5.2% in 2018 (OR: 1.01; 95% CI: 0.82 to 1.23). Fewer women than men were regular e-cigarette users (OR: 0.66; 95% CI: 0.49 to 0.91) and the rate decreased with increasing age (p for trend 0.008). No specific pattern was found for level of education (p for trend 0.121). Compared with never smokers, regular e-cigarette users were more frequent among current smokers (4.87; 95% CI: 3.33 to 7.12) and ex-smokers (7.23; 95% CI: 4.75 to 11.00). Compared with 2014–2015 (0.4%), Italians were more frequently regular e-cigarette users in 2016–2017 (1.8%; OR: 4.70; 95% CI: 3.01 to 7.33) and in 2018 (1.3%; OR: 3.10; 95% CI: 1.87 to 5.15; p for trend <0.001).

Among the 522 ever users (including 182 regular users), 13.2% (95% CI: 10.3% to 16.1%; n=69) reported having stopped smoking, therefore changing their smoking status from current to ex-smoker; 64.6% (95% CI: 60.5% to 68.7%; n=337) did not substantially change their smoking behaviour (including 139 who cut down the numbers of cigarettes smoked per day); and 22.2% (95% CI: 18.7% to 25.8%; n=116) reported they had started smoking or relapsed as a consequence of e-cigarette use, therefore changing their smoking status from non-smoker (ie, never or ex-smokers) to current smoker (table 2). The corresponding proportions among regular users were 24.7% (95% CI: 18.5% to 31.0%; n=45) who stopped smoking, 47.3% (95% CI: 40.0% to 54.5%; n=86) who did not substantially change their smoking behaviour and 28.0% (95% CI: 21.5% to 34.5%; n=51) who started smoking or relapsed. Sensitivity analysis using data from 2017 and 2018 showed that the rates of e-cigarette users (re)starting smoking were similar among current (22.0%) and past users (21.4%), while those quitting smoking were more frequent among regular/occasional e-cigarette users (20.0%) than past users (8.9%, only).

Among younger subjects (under 35 years), 7.1% were ever e-cigarette users. Among these, 5.5% reported having stopped smoking and 16.4% had (re)started smoking as a consequence of their e-cigarette experience. Among the 86 current users reporting in 2017 and 2018 that they used nicotine-containing e-cigarettes, 24 (27.9%) started/restarted smoking and 14 (16.3%) quit smoking (data not shown).

**DISCUSSION**

The prevalence of regular e-cigarette use in Italy is still relatively low, but it rose significantly from 0.4% in 2014–2015 to 1.3% in 2018. We explicitly asked ever users about the consequence of e-cigarette use on their smoking status. Among ever, regular, young e-cigarette users and subjects vaping nicotine-containing e-cigarettes, the number of those (re)starting smoking due to e-cigarette use systematically exceeded those quitting smoking with e-cigarette use. This indicates that only a small proportion of ever e-cigarette users in Italy potentially benefit from these e-cigarettes (only 13% quit smoking), and e-cigarette use seems to act as a gateway to smoking tobacco in a larger proportion (22%).

Our findings are in broad agreement with those by Soneji and colleagues, who, using a Monte Carlo simulation model applied to data from different national surveys from the USA, concluded that e-cigarette use causes more population-level harm than benefit. A large proportion of e-cigarette users (27%) reported having (slightly or substantially) reduced their smoking intensity. This, however, cannot be considered an achievement from a public health perspective, given the growing evidence that (1) dual users are more likely to transition to exclusive combustible use than to remain in their dual-use category and (2) there is no safe level of smoking for cardiovascular disease and overall mortality.
meta-analysis, success in quitting smoking was 28% less in those who used e-cigarettes than in those who did not use them.\textsuperscript{10} The most recent and comprehensive review gave conflicting results. The only two randomised controlled trials suggested a possible increase in smoking cessation using e-cigarettes with nicotine compared with e-cigarettes with no nicotine, but cohort studies suggested possibly lower rates of quitting using e-cigarettes than with other smoking cessation methods.\textsuperscript{28, 29}

We can confirm that most of the smokers who had started e-cigarette use (more than 80%) continued to smoke tobacco.\textsuperscript{1, 19} Several studies showed that many smokers transition to dual use, vaping in order to have nicotine intake in places where they cannot smoke combustible cigarettes, or so as to bother other people less.\textsuperscript{30–33}

Pharmacological support for smoking cessation in Italy includes nicotine patches, chewing gums and nasal/oral sprays, approved by the Italian Medicines Agency after proof of safety and efficacy through the publication of clinical trials. These products can only be purchased in pharmacies and are promoted only to smokers. In contrast, e-cigarettes were marketed without any official approval and are available to anyone, including never smokers. Indeed, we found that 1.3% of never smokers had tried e-cigarettes, and 0.4% were regular e-cigarette users. Findings have been similar in the USA, where 4.1% of adult never smokers had tried e-cigarettes.\textsuperscript{34} In agreement with the USA results,\textsuperscript{35} we also found that 16% of ever (and 22% of regular) e-cigarette users had never smoked before using e-cigarettes. The potential risk of nicotine addiction among never smokers cannot be overlooked, since the majority of never smokers trying e-cigarettes started smoking afterwards.

The tobacco control environment is hard put to explain these transitions. In fact, in Italy over the period there was only a marginal improvement in selective tobacco regulations,\textsuperscript{36} mainly aimed at children and which did not affect tobacco prices, adopted in 2016.\textsuperscript{21} In the meantime, e-cigarettes enjoy 50% lower tax than conventional cigarettes. Although in 2017, excise taxes were introduced for e-cigarettes, the fiscal benefit for this product results in a substantially lower price as compared with cigarette tobacco. There are no national regulations against e-cigarette use in public places, except in schools,\textsuperscript{37} and the social desirability of e-cigarette is neutral.

A large prospective study conducted in the UK recently confirmed findings from a meta-analysis on adolescents and young adults,\textsuperscript{38} showing that baseline ever use of e-cigarettes was strongly associated with subsequent starting and escalation of conventional cigarette use among teenagers.\textsuperscript{39} Our data too show 16% of young e-cigarette users started smoking as a consequence of their e-cigarette use.

In the current tobacco market, there are also heated tobacco products (HTPs) that heat disposable tobacco sticks, without reaching combustion, to generate a sort of ‘cold smoke’ containing nicotine.\textsuperscript{40} Independent toxicological studies showed that these HTPs release relatively high nicotine levels—similar to those released by conventional cigarettes—and non-negligible amounts of harmful substances, including various carcinogens.\textsuperscript{41–43} However, given the belief that they are less harmful, hence the fiscal and regulatory favours, HTP rapidly spread after 2016 in the Italian tobacco market.\textsuperscript{40, 44} This growth may be responsible, at least partially, for the lower number of Italian e-cigarette consumers in 2018 compared with 2016–2017.

Our study is limited by its cross-sectional design, which meant we could not observe the time sequence of the causal effects of e-cigarette use on smoking cessation. Therefore, the findings need to be confirmed by large longitudinal studies. In addition, the survey collected self-reported data, which is likely to suffer recall bias and imprecise responses. To reduce these limitations as far as possible, we explicitly explained the purpose of the questions, clearly asking ever e-cigarette users how their use had affected their smoking habits and providing all the mutually exclusive responses.

Another limitation is that the question on the consequences of e-cigarette use on their smoking habits was not put to past e-cigarette users in 2014–2016. However, this may, if anything, have led to underestimation of quitting smoking as the consequence of e-cigarette use. In a sensitivity analysis limited to data from 2017 and 2018, the number of e-cigarette users (re)starting smoking were similar among current and past users (around 22%), while those quitting smoking were more frequent among regular/occasional e-cigarette users (20%) than past users (only 9%). Thus, including past users in 2014–2016 may well have lowered the percentage of subjects quitting smoking with e-cigarette use.

Our classification of e-cigarette users as never, past, occasional and regular did not allow us to record the intensity of use (eg, daily use, number of puffs per day), so we could not identify intensive e-cigarette use, which has been shown to be directly related to quitting smoking.\textsuperscript{15} Our study is also limited by the sample size, focusing on e-cigarette users only. For this reason, we merged data from the annual surveys conducted over the last 5 years.

In conclusion, the number of regular e-cigarette users increased in Italy from 2014 to 2018. Our data indicate that around 680,000 Italians regularly use e-cigarettes today. Among them, 170,000 stopped smoking after using e-cigarettes, while 190,000 (re)started smoking conventional cigarettes with e-cigarette use.

Given the limitations inherent to the cross-sectional study design and the fact that recall and social desirability biases could not be ruled out in self-reported data, our main findings need to be confirmed by longitudinal studies. Nevertheless, they do suggest that, from a public health point of view, e-cigarette commerce in Italy has had an unfavourable net effect. Consequently, if we are not able to regulate the sales, taxation, advertising and places of use, this product is more likely to act as an incentive for smoking rather than a strategy for reducing harm.

What this paper adds

- The popularity and use of electronic cigarettes (e-cigarette) worldwide has substantially spread in recent years.
- The scientific community is still debating whether e-cigarettes help or hinder tobacco control. The debate is mainly caused by the uncertainty on their effectiveness as a tool for smoking cessation.
- We found that in Italy the number of e-cigarette users (re)starting smoking after using e-cigarettes exceeded that of users quitting smoking by using these e-cigarettes.
- The spread of e-cigarettes may have an unfavourable net effect from the public health point of view.

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Competing interests None declared.

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