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Effect of the comprehensive smoke-free law on time trends in smoking behaviour in primary healthcare patients in Spain: a longitudinal observational study

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ABSTRACT

Objective This study aimed to analyse the impact of comprehensive smoke-free legislation (SFL) on the prevalence and incidence of adult smoking in primary healthcare (PHC) patients from three Spanish regions, overall and stratified by sex.

Design Longitudinal observational study conducted between 2008 and 2013.

Setting 66 PHC teams in Catalonia, Navarre and the Balearic Islands (Spain).

Participants Population over 15 years of age assigned to PHC teams.

Primary and secondary outcomes measures Quarterly age-standardised prevalence of non-smoker, smoker and ex-smoker and incidence of new smoker, new ex-smoker and ex-smoker relapse rates were estimated with data retrieved from PHC electronic health records. Joinpoint analysis was used to analyse the trends of age-standardised prevalence and incidence rates. Trends were expressed as annual percentage change and average annual percent change.

Results The overall standardised smoker prevalence rate showed a significant downward trend (higher in men than women) and the overall standardised ex-smoker prevalence rate showed a significant increased trend (higher in women than men) in the three regions. Standardised smoker and ex-smoker prevalence rates were higher for men than women in all regions. With regard to overall trends of incidence rates, new smokers decreased significantly in Catalonia and Navarre and similarly in men and women, new ex-smokers decreased significantly and more in men in Catalonia and the Balearic Islands, and ex-smoker relapse increased in Catalonia (particularly in women) and decreased in Navarre.

Conclusions Trends in smoking behaviour in PHC patients remain unchanged after the implementation of comprehensive SFL. The impact of the comprehensive SFL might have been lessened by the effect of the preceding partial SFL.

Strengths and limitations of this study

► To our knowledge, no studies have been published on the impact of the Spanish comprehensive smoke-free legislation in all adult primary healthcare patients.
► Used as a research tool, electronic health records portray real life conditions and provide comprehensive, long-term health histories from a large population sample.
► The results of quarterly data by Joinpoint analysis provides more precise information than an analysis before-after the implementation of the law.
► This study only considered age and sex since other variables were not available for the adjusted analysis.
► The study period started later (shorter follow-up) in the Balearic Islands to ensure reliability of data.

is estimated that at least 30 million people may die prematurely from tobacco-related diseases.[2] Legislative measures have been adopted to protect people's health in public areas and workplaces. These include increasing the price of cigarettes, banning advertising, sponsorship and smoking in workplaces and public spaces, displaying warnings on tobacco packets and implementing prevention programmes.[3]

Some studies show a decrease in smoking prevalence since the introduction of smoke-free legislation (SFL).[4–9] A meta-analysis of 26 studies on the effect of the smoke-free workplace in various countries concluded in 2002 that smoke-free workplaces protect non-smokers from the dangers of passive smoking, and they encourage smokers to reduce tobacco consumption. The authors concluded that SFL is associated with a

INTRODUCTION

Smoking is the leading worldwide cause of preventable death.[1] According to WHO, it

3%–4% reduction in tobacco consumption.[10] In contrast, a Cochrane review published in 2016, which included 24 studies on smoking behaviour, showed inconsistencies regarding the impact of smoking bans on smoking prevalence and tobacco consumption.[11]

On 1 January 2006, the Spanish government introduced a partial SFL (Law 28/2005),[12] which included regulations on the sale, supply, consumption and advertising of tobacco products. Smoking was banned at all indoor public and private workplaces with the exception of the hospitality sector, where partial restrictions were established depending on the size of the establishment, that is, in bars or restaurants smaller than 100 m^2 the managers could decide whether to allow smoking in the premises (Law 28/2005). The mean concentration of nicotine subsequently decreased by 60% in public administration offices and by 97.4% in private workplaces, but in areas where smoking was permitted, including bars and nightclubs, no changes were found.[13–15] This prompted the enactment of comprehensive SFL (Law 42/2010),[16] which came into force in January 2011. This comprehensive law expanded smoking restriction to all hospitality venues of any size and, as a result, smoking was forbidden in all enclosed public places, including bars, restaurants and nightclubs, and in some open-air public places such as playgrounds.

Some studies have analysed the impact of these two Spanish laws on smoking prevalence. However, most have been based on health surveys[13 17–20] and surveys of hospitality workers.[21 22] Moreover, some studies evaluate only the partial law,[13 17 18] whereas others analyse the compound impact of both laws.[19 20 23 24] The results of these studies are often conflicting; while some conclude that the partial SFL does not have any effect on the downward trend in the prevalence of smokers,[13 19 23] other studies show a reduction in smoking prevalence,[24] an increase of the smoking quit ratio in the short term[18] and minor increases in the prevalence of active smoking.[20]

Only one study conducted in PHC patients evaluates the impact of the Spanish partial SFL, including smoking prevalence in active smoker workers that attended PHC visits; 1 month after the implementation of the law, a 9.5% decline of smokers was observed.[25] To our knowledge, no studies have been published on the impact of the Spanish comprehensive SFL in all adult PHC patients. In view of the pivotal role of PHC services in smoking habits, we consider that the information registered in PHC records is a good proxy to generate up-to-date evidence and to evaluate the impact of comprehensive SFL in the general population.

We hypothesised that Law 42/2010 does reduce exposure to environmental cigarette smoke and its harmful effects and crucially, it promotes smoking denormalisation in society, thus encouraging smokers to quit or reduce consumption and discouraging non-smokers from initiating this habit. Accordingly, the aim of this study was to examine the impact of the Spanish comprehensive SFL (Law 42/2010) on the prevalence and incidence of adult smoking in PHC patients in three regions (Catalonia, Navarre and Balearic Islands), during the 2008–2013 period, overall and stratified by sex.

METHODS
Design, study participants and information source
Longitudinal observational study of the adult population assigned to 66 PHC teams (PHCTs) in three Spanish regions: Catalonia, Navarre and the Balearic Islands (22 PHCTs per region). Inclusion criteria of the PHCTs were: (1) Computerisation of electronic health records (EHRs) by 1 January 2005 in Catalonia and Navarre, and 2008 in the Balearic Islands. (2) Agreement to participate in the study by over 80% healthcare professionals working in each PHCT. Random cluster sampling was stratified by region, with PHCT as randomisation unit.[26] In each PHCT, general practitioners (GPs) with a patient list between 400 and 3000 were selected. GPs with shorter patient lists were accepted if it was their first year in the PHCT.

The study period included from the first quarter of 2008 to the fourth quarter of 2013 in Catalonia and Navarre; and from the second quarter of 2010 to the fourth quarter of 2013 in the Balearic Islands. The study started in 2008 to obtain data from the 2 years prior analysis, a requirement to adequately construct the variable ex-smoker. In the case of the Balearic Islands, the study started later to ensure reliability of data.

Inclusion criteria for patients were: (1) Population allocated to the selected PHCT for the whole 2007–2013 period in Catalonia and Navarre; in the Balearic Islands, patients allocated to the selected PHCT in 2013 and evaluated retrospectively (no historical annual comprehensive register of allocation of patients was available). (2) Age ≥16 years and ≤100 years in 2007 in Catalonia and Navarre, and 2010 in the Balearic Islands. (3) In order to have data in the EHR collected during the study period, a minimum of one visit to their PHCT during the 2007–2013 period in Catalonia and Navarre and 2010–2013 in the Balearic Islands. (4) Information on smoking habit recorded in the EHR for the quarter prior to the onset of the study: last quarter of 2007 in Catalonia and Navarre and first quarter of 2010 in the Balearic Islands, to enable the adequate construction of the various variables. Since smoking is not an acute condition, this information was considered valid until new information was entered. Thus, closed cohorts (with fixed membership, where nobody is added nor excluded after the study begins) were constituted in the three regions. Figure 1 shows the flow chart of the study.

Data were retrieved from the Registry of Preventive Services in Primary Care (REGIPREV) database,[26] which contains encrypted and anonymised clinical information recorded in the EHR by these 66 PHCTs. An algorithm was applied to extract equivalent data from the health records software used in each region: 'ECAP' in Catalonia, 'Atenea' in Navarre and 'e-siap' in the Balearic Islands.
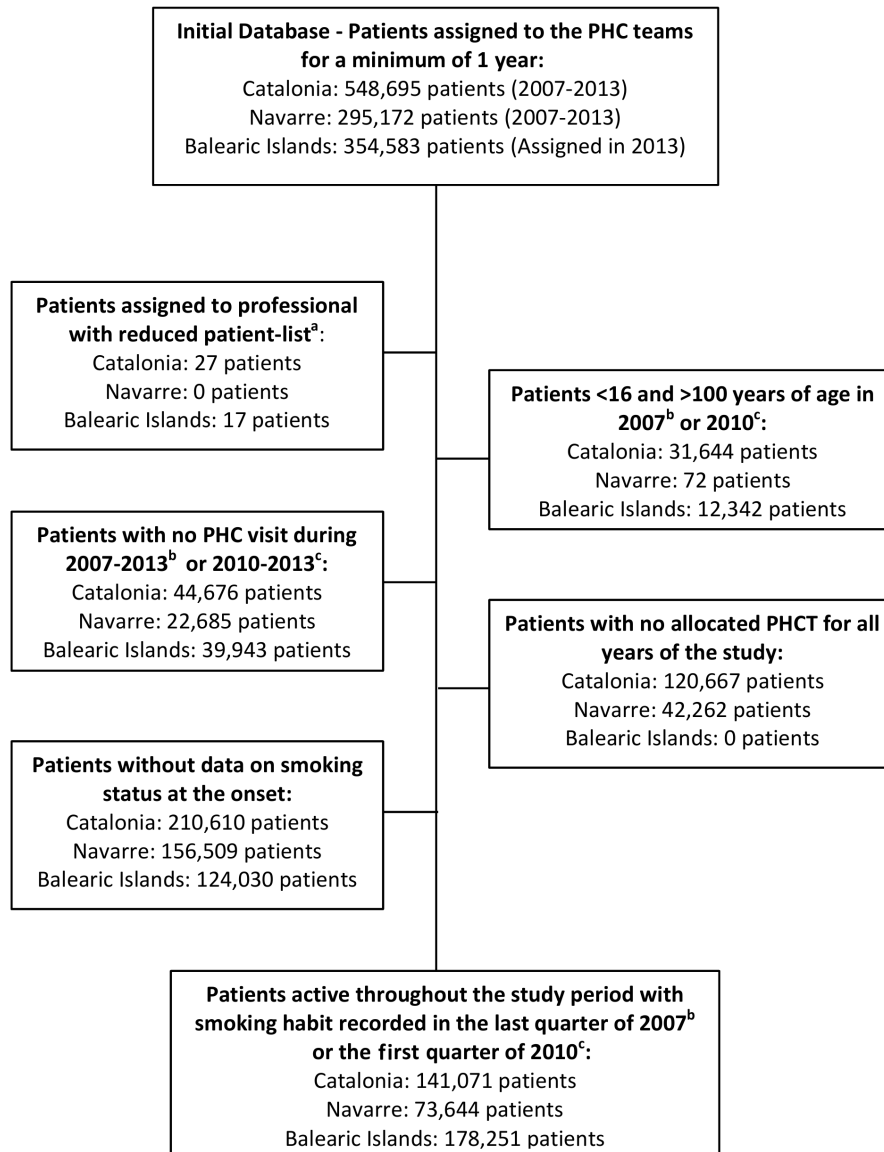
Figure 1 Flow chart of patients included in the study, by region.

Codes of the International Classification of Diseases, ninth revision in the Balearic Islands (ICD-9) and tenth in Catalonia (ICD tenth revision)[27] and the International Classification of Primary Care, second edition, in Navarre (ICPC-2)[28] were used.

Variables

Information on smoking is registered in the EHRs using diagnostic codes to classify diseases (codes F17.0 to F17.9 and Z72.0 of the ICD-10, 305.1 of the ICD-9 and P17 of the ICPC-2), and also clinical variables (number of cigarettes per day, history of smoking, history of advice for smoking cessation). This information is stored with the entry date (online supplementary file table S1). With the information on smoking status and entry date we created the following dependent variables at the end of each quarter of the study period:

Smoking status (three categories): (1) Non-smoker: patient that has never been a tobacco consumer. (2) Smoker: tobacco consumer or patient that has quit smoking for less than 12 months. (3) Ex-smoker: patient who used to smoke but has quit smoking for at least 12 continuous months. When the EHR did not

contain a new entry related to smoking status (diagnostic codes or clinical variables), we considered that no changes in smoking status had taken place and thus the last observation was still valid.

New smoker: patient non-smoker for the 12 months prior to the considered quarter that has started smoking during the said quarter.

New ex-smoker: the patient was a smoker 2 years before the considered quarter and has continuously abstained from tobacco for at least 12 months.

Ex-smoker relapse: patient ex-smoker during the 12 months prior to the considered quarter that has started smoking again during the said quarter.

For higher accuracy in prevalence and incidence changes, quarterly estimates were calculated.

The following variables of each patient were collected at baseline (2008 in Catalonia and Navarre; 2010 in the Balearic Islands): age, sex (male/female), annual number of health problems and annual number of PHC visits. The number of health problems was used as a morbidity indicator; it was calculated as the sum of the number of different active health problems (chronic and acute, coded by ICPC-2).

Data analyses

Descriptive statistics were used to summarise overall information. Categorical variables were expressed as percentage, and continuous variables as mean (SD) or median (IQR).

Because the three regions used different EHR systems (different standards and computer programs), have different socioeconomic characteristics, different complementary measures to the SFL and also due to the shorter study period in the Balearic Islands, we performed a stratified analysis per region, overall and by sex. Age-standardised prevalence (non-smokers, smokers and ex-smokers) and incidence (new smokers, new ex-smokers and ex-smoker relapse) rates were calculated for each quarter using the direct method, and based on the European standard population (rates per 10 000 inhabitants).

Joinpoint analysis was used to analyse the trends of age-standardised prevalence (smokers and ex-smokers) and incidence rates (new smokers, new ex-smokers and ex-smoker relapse) and to identify the best-fitting points (the 'joinpoints', in calendar quarters) where the rate changes significantly in the linear slope of the temporal trend. Significant changes include changes in direction or in the rate of increase or decrease.[29] Joinpoint analysis estimates the magnitude of the increase or the decrease observed in each specified time interval by estimating the annual percentage change (APC). In addition, temporal trends were expressed as the average annual percent change (AAPC), computed to summarise and compare these trends over the entire time period. Because the outcomes originate from repeated measurements, control for the autocorrelation errors was used; 95% CIs of APC and AAPC were calculated. The trend of

non-smoker prevalence rates was not calculated because the study consisted of a closed cohort where no new participants are recruited, and thus the prevalence of non-smokers can either remain the same or decrease, but never increase.

Analyses were performed using Stata/SE V.14.2 for Windows (Stata Corp, College Station, Texas, USA). The Joinpoint regression analysis was carried out using the Joinpoint software from the Surveillance Research Programme of the US National Cancer Institute (ref. Joinpoint Regression Program, V.4.6.0. April, 2018; Statistical Research and Applications Branch, National Cancer Institute) (https://surveillance.cancer.gov/branches/srab/).

Patient and public involvement

Study participants were not involved in the development of the research question or the outcome measures, nor in the design of the study. The results will be presented to citizens through informative activities and the media.

RESULTS

The study population was 392 966 patients: 141 071 in Catalonia, 73 644 in Navarre and 178 251 in the Balearic Islands (figure 1). At the onset of the study, the mean age was 50.4 years in Catalonia, 54.0 years in Navarre and 47.7 years in the Balearic Islands. In the three cohorts more than half were women (>51%). Catalonia presented the highest median number of visits (9, IQR: 3–16) and the Balearic Islands presented the highest number of recorded active health problems per patient (median 10, IQR: 6–16) (table 1).

The *overall standardised smoker prevalence rates* per 10 000 inhabitants were of similar magnitude in the three regions (ranges of 3579.2–4138.9 in Catalonia, 3719.8–4034.2 in Navarre and 3787.4–4029.7 in the Balearic Islands). The prevalence rate decreased in Navarre during the whole study period, decreased in the Balearic Islands in most quarters and also in Catalonia except for the last year. These rates were higher for men than for women in all regions (online supplementary file table S2–S7). A significant downward *overall trend of smoker prevalence rates* was found in Catalonia (AAPC=−2.18), Navarre (AAPC=−1.44) and the Balearic Islands (AAPC=−1.75); this downward trend was higher for men than for women in the three regions. In Catalonia, the most significant reduction occurred during the period 2010.3–2011.4 (APC=−6.75), similarly to the Balearic Islands (2010.2–2012.4; APC=−2.19), whereas in Navarre it occurred between 2008.1 and 2013.4 (APC=−1.44) (tables 2, 3 and 4, online supplementary file figure S1).

For the whole period, the *overall standardised ex-smoker prevalence rates* per 10 000 inhabitants increased in Navarre, in the Balearic Islands and in Catalonia except for the last year. The rates in Catalonia were higher (ranges of: 1168.5–1781.2 in Catalonia; 313.3–764.1 in Navarre; and 559.3–914.1 in the Balearic Islands). The standardised

Table 1 Characteristics of the cohort study population by region at the onset of the study (2008 in Catalonia and Navarre, 2010 in the Balearic Islands)

	Catalonia n = 141 071	Navarre n = 73 644	Balearic Islands n = 178 251
Age (years), SD	50.37 (17.23)	54.04 (18.26)	47.65 (17.56)
Sex (female), number (%)	72 340 (51.28)	37 898 (51.46)	94 164 (52.83)
Number of visits, mean (SD); median (IQR)	11.69 (12.19); 9.00 (3.00–16.00)	8.93 (9.30); 7.00 (3.00–12.00)	11.01 (13.25); 7.00 (3.00–15.00)
Number of health problems, mean (SD); median (IQR)	6.23 (4.58); 5.00 (3.00–8.00)	9.95 (5.39); 9.00 (6.00–13.00)	11.85 (7.74); 10.00 (6.00–16.00)

Patients belonged to 22 primary healthcare teams in each region.
Abbreviations: SD, standard deviation; IQR, interquartile range.

ex-smoker prevalence rates were higher for men than for women in all regions (online supplementary file table S2–S7). The *overall trend of ex-smoker prevalence rates* increased significantly in the three regions throughout the study period but was higher in Navarre (Navarre AAPC=16.67; Catalonia AAPC=7.19; Balearic Islands AAPC=14.96). The increase in the prevalence rate of ex-smokers was higher for the 2008.1–2008.2 period in Catalonia, 2008.1–2008.4 in Navarre and for 2010.2–2012.2 in the Balearic Islands, and higher in women in the three regions (women: Catalonia AAPC=10.87; Navarre AAPC=17.30 and Balearic Islands AAPC=19.51) (tables 2, 3 and 4, online supplementary file figure S1).

The *overall new smoker standardised incidence rates* per 10 000 inhabitants showed low values in the three regions (ranges of 7.9–26.8 in Catalonia; 9.5–30.9 in Navarre; 1.6–17.5 in the Balearic Islands) and higher for men than for women in Catalonia and Navarre (online supplementary file table S2–S7). The *overall trend of new smoker incidence rates* decreased significantly in Catalonia (AAPC=−10.39) and Navarre (AAPC=−9.49); additionally, the decline was similar for men and women. In contrast, the overall trend remained stable in the Balearic Islands despite a decrease until 2012.4 (APC=−46.20) and a considerable increase from 2012.4 to 2013.4 (APC=1054.2) (tables 2, 3 and 4, online supplementary file figure S2).

The *overall standardised new ex-smoker incidence rates* per 10 000 inhabitants showed higher values in Catalonia (range: 110.7–317.6) than in Navarre (range: 48.6–181.0) and the Balearic Islands (range: 93.7–188.1) (online supplementary file table S2–S7). The *overall trend of new ex-smoker incidence rates* showed a significant decrease in Catalonia (AAPC=−7.27) and especially in the Balearic Islands (AAPC=−11.24). This downward trend was higher for men than for women in Catalonia and the Balearic Islands (tables 2, 3 and 4, online supplementary file figure S2).

The *overall standardised ex-smoker relapse incidence rates* per 10 000 inhabitants presented higher values in the Balearic Islands (range: 103.9–576.6) than in Catalonia (range: 70.7–334.5) and Navarre (range: 58.6–230.3) (online supplementary file table S2–S7). The *overall trend of ex-smoker relapse incidence rates* showed significant

increases in Catalonia (AAPC=18.60), particularly in women (AAPC=14.56), although a decrease from 2008.1 to 2012.3 was observed (APC=−8.40). In contrast, Navarre showed significant decreases (AAPC=−11.42) (tables 2, 3 and 4, online supplementary file figure S2).

DISCUSSION

The previous implementation of the partial Spanish SFL could account for the low effectiveness of the comprehensive SFL observed in this study. A significant downward trend of smoker prevalence rates, higher in men than in women, was found in the three regions throughout the study period. Correspondingly, the trend of ex-smoker prevalence rates increased in the three regions, particularly in Navarre and during the period 2008.1–2008.2 in Catalonia, 2008.1–2008.4 in Navarre, and 2010.2–2012.2 in the Balearic Islands. Even though the standardised ex-smoker prevalence rate was higher for men, the increase in the trend of ex-smoker prevalence rate was higher in women in the three regions. The overall trends of new smoker incidence rates decreased significantly in Catalonia and Navarre and were similar for men and women. Also, the overall trends of new ex-smokers decreased significantly in Catalonia and the Balearic Islands, particularly for men. In addition, the overall trends of ex-smoker relapse increased in Catalonia and decreased in Navarre, more for women than for men in both cases.

The trends of smoker prevalence declined throughout the study and no changes were observed after the implementation of the comprehensive SFL. Indeed, the most significant decrease begins in 2010 in Catalonia (third quarter) and the Balearic Islands and in 2008 in Navarre, prior to the implementation of the comprehensive SFL (1 January 2011). However, the trend in Catalonia shows a drop in the prevalence rate of smokers around the time of the implementation of the law. In contrast, trends in Navarre and the Balearic Islands show a more progressive decline. Comparisons are difficult due to the lack of studies on smoking prevalence and incidence from a PHC perspective and because some studies evaluate the impact of SFL on smoking prevalence with surveys that

Table 2 Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse for age-standardised rates. Joinpoints overall and by sex in Catalonia; n=141 071 (2008–2013)

	Trend 1		Trend 2		Trend 3		Trend 4		Trend 5		AAPC (95% CI) 2008.1–2013.4
	Time	APC (95% CI)	Time	APC (95% CI)	Time	APC(95% CI)	Time	APC (95% CI)	Time	APC (95% CI)	
Smoker prevalence											
F	2008.1–2010.3	−0.72* (−1.51 to 0.09)	2010.3–2011.2	−9.85‡ (−16.24 to −2.98)	2011.2–2013.4	−0.53* (−1.29 to 0.24)					−1.88‡ (−2.85 to −0.90)
M	2008.1–2010.3	−2.12‡ (−2.52 to −1.71)	2010.3–2011.2	−8.17‡ (−11.24 to −4.99)	2011.2–2012.4	−2.93‡ (−3.88 to −1.98)	2012.4–2013.4	2.81‡ (1.47 to 4.17)			−2.31‡ (−2.83 to −1.79)
G	2008.1–2010.3	−1.71† (−2.88 to −0.53)	2010.3–2011.4	−6.75† (−10.46 to −2.89)	2011.4–2013.4	0.19* (−1.37 to 1.78)					−2.18‡ (−3.22 to −1.13)
Ex-smoker prevalence											
F	2008.1–2008.4	17.54‡ (12.88 to 22.40)	2008.4–2011.2	11.25‡ (10.17 to 12.34)	2011.2–2012.1	15.73‡ (9.03 to 22.85)	2012.1–2013.1	9.55‡ (5.91 to 13.31)	2013.1–2013.4	0.65* (−2.49 to 3.89)	10.87‡ (9.68 to 12.07)
M	2008.1–2012.4	6.64‡ (6.01 to 7.30)	2012.4–2013.4	4.45§ (−8.23 to −0.51)							4.63‡ (3.79 to 5.48)
G	2008.1–2008.2	16.70† (7.23 to 27.01)	2008.2–2011.1	7.63‡ (6.96 to 8.30)	2011.1–2012.4	9.68‡ (8.50 to 10.86)	2012.4–2013.4	−2.34§ (−4.21 to −0.42)			7.19‡ (6.31 to 8.07)
New smokers incidence											
F	2008.1–2013.4	−10.82§ (−19.17 to −1.59)									−10.82§ (−19.17 to −1.59)
M	2008.1–2013.4	−10.53† (−16.03 to −4.68)									−10.53† (−16.03 to −4.68)
G	2008.1–2013.4	−10.39† (−16.06 to −4.33)									−10.39† (−16.06 to −4.33)
New ex-smokers incidence											
F	2008.1–2013.4	−4.55* (−11.06 to 2.45)									−4.55* (−11.06 to 2.45)
M	2008.1–2013.4	−7.80§ (−13.44 to −1.79)									−7.80§ (−13.44 to −1.79)
G	2008.1–2013.4	−7.27§ (−12.89 to −1.29)									−7.27§ (−12.89 to −1.29)
Ex-smokers relapse incidence											
F	2008.1–2012.3	−9.20* (−18.05 to 1.03)	2012.3–2013.4	162.73‡ (67.31 to 312.56)							14.56§ (1.65 to 29.11)
M	2008.1–2009.3	−47.47* (−81.34 to 47.84)	2009.3–2013.4	115.64* (−100 to 1930603)	2010.2–2012.3	−27.20* (−44.70 to 1.35)	2012.3–2013.2	515.1* (−80.2 to 18963.4)	2013.2–2013.4	77.79* (−72.27 to 1040)	9.97* (−64.32 to 238.91)
G	2008.1–2012.3	−8.40§ (−15.98 to −0.13)	2012.3–2013.4	200.54‡ (120.8 to 309.0)							18.60‡ (8.50 to 29.64)

Note: 2008.1 represents the first trimester of the year 2008.
*p>0.05; †p≤0.01; ‡p≤0.001; §p≤0.05.
APC, annual percentage change; AAPC, average annual percent change estimated by Joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.

Table 3 Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse for age-standardised rates. Joinpoints overall and by sex in Navarre; n=73 644 (2008–2013)

	Trend 1		Trend 2		Trend 3		
	Time	APC (95% CI)	Time	APC (95% CI)	Time	APC (95% CI)	AAPC (95 % CI)
Smoker prevalence							
F	2008.1–2013.4	−0.93* (−1.11 to −0.75)					−0.93* (−1.11 to −0.75)
M	2008.1–2013.4	−1.95* (−2.09 to −1.81)					−1.95* (−2.09 to −1.81)
G	2008.1–2013.4	−1.44* (−1.59 to −1.28)					−1.44* (−1.59 to −1.28)
Ex-smoker prevalence							
F	2008.1–2008.4	35.81* (25.56 to 46.90)	2008.4–2012.2	16.50* (15.45 to 17.56)	2012.2–2013.4	10.66* (8.31 to 13.06)	17.30* (15.88 to 18.67)
M	2008.1–2009.2	25.93* (20.68 to 31.41)	2009.2–2012.4	13.90* (12.85 to 14.97)	2012.4–2013.4	9.32* (5.21 to 13.59)	15.59* (14.24 to 16.95)
G	2008.1–2008.4	34.30* (24.61 to 44.74)	2008.4–2012.2	15.80* (14.78 to 16.83)	2012.2–2013.4	10.68* (8.41 to 12.99)	16.67* (15.35 to 18.01)
New smokers incidence							
F	2008.1–2013.4	−9.43† (−15.95 to −2.75)					−9.43† (−15.95 to −2.75)
M	2008.1–2013.4	−9.40‡ (−14.96 to −3.48)					−9.40‡ (−14.96 to −3.48)
G	2008.1–2013.4	−9.49* (−14.31 to −4.40)					−9.49* (−14.31 to −4.40)
New ex-smokers incidence							
F	2008.1–2013.4	−9.67‡ (−15.05 to −3.96)					−9.67‡ (−15.05 to −3.96)
M	2008.1–2013.4	−2.83§ (−8.94 to 3.70)					−2.83§ (−8.94 to 3.70)
G	2008.1–2013.4	−5.01§ (−10.74 to 1.09)					−5.01§ (−10.74 to 1.09)
Ex-smoker relapse incidence							
F	2008.1–2013.4	−13.85‡ (−20.68 to −6.42)					−13.85‡ (−20.68 to −6.42)
M	2008.1–2013.4	−11.77† (−18.33 to −4.69)					−11.77† (−18.33 to −4.69)
G	2008.1–2013.4	−11.42* (−16.95 to −5.51)					−11.42* (−16.95 to −5.51)

*p≤0.001; †p≤0.05; ‡p≤0.01; §p>0.05

Note, 2008.1 represents the first trimester of the year 2008.

APC, annual percentage change; AAPC, average annual percent change estimated by Joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.

Table 4 Trends in prevalence of smoking status and incidence of new smokers, ex-smokers and ex-smoker relapse for age-standardised rates. Joinpoints overall and by sex in the Balearic Islands; n=178251 (2010–2013)

	Trend 1		Trend 2		Trend 3		
	Time	APC (95% CI)	Time	APC (95% CI)	Time	APC (95% CI)	AAPC (95 % CI)
Smoker prevalence							
F	2010.2–2013.4	−1.20* (−1.40 to −1.01)					−1.20* (−1.40 to −1.01)
M	2010.2–2012.4	−2.73* (−2.93 to −2.54)	2012.4–2013.4	−1.39† (−2.16 to −0.65)			−2.35.* (−2.58 to −2.12)
G	2010.2–2012.4	−2.19* (−2.33 to −1.89)	2012.4–2013.4	−0.86 ‡ (−1.90 to 0.18)			−1.75* (−2.05 to −1.46)
Ex-smoker prevalence							
F	2010.2–2012.1	26.19* (25.24 to 27.15)	2012.1–2013.4	13.18* (12.46 to 13.91)			19.51* (18.99 to 20.03)
M	2010.2–2012.1	15.82* (14.04 to 17.62)	2012.1–2013.4	7.44* (5.37 to 9.56)			12.15* (10.96 to 13.36)
G	2010.2–2012.2	19.29* (18.34 to 20.24)	2012.2–2013.4	9.43* (8.37 to 10.50)			14.96* (14.34 to 15.59)
New smokers incidence							
F	2010.2–2012.4	−46.09† (−60.51 to −26.40)	2012.4–2013.4	1370.6† (169.9 to 7913.0)			38.65‡ (−13.24 to 121.58)
M	2010.2–2012.4	−44.29§ (−64.78 to −11.87)	2012.4–2013.4	610.8† (98.1 to 2530.4)			15.32‡ (−25.52 to 78.56)
G	2010.2–2012.4	−46.20† (−60.28 to −27.12)	2012.4–2013.4	1054.2† (222.2 to 4034.8)			29.19‡ (−11.04 to 87.61)
New ex-smokers incidence							
F	2010.2–2013.4	−11.68§ (−19.32 to −3.31)					−11.68§ (−19.32 to −3.31)
M	2010.2–2013.4	−10.94§ (−20.39 to −0.38)					−10.94§ (−20.39 to −0.38)
G	2010.2–2013.4	−11.24† (−18.61 to −3.21)					−11.24† (−18.61 to −3.21)
Ex-smokers relapse incidence							
F	2010.2–2012.1	−33.75† (−47.83 to −15.88)	2012.1–2013.1	47.37‡ (−75.08 to 771.40)	2013.1–2013.4	−89.71‡ (−99.7 to 313)	−44.15‡ (−74.54 to 22.53)
M	2010.2–2013.4	−36.30* (−44.63 to −26.72)					−36.30* (−44.63 to −26.72)
G	2010.2–2013.2	−18.19* (−23.60 to −12.40)	2013.2–2013.4	−95.73‡ (−99.99 to 1380.5)			−46.35‡ (−74.32 to 12.09)

*p≤0.001; †p≤0.01; ‡p>0.05; §p>0.05.
Note, 2010.1 represents the first trimester of the year 2010.
APC, annual percentage change; AAPC, average annual percent change estimated by Joinpoint regression analysis; CI, confidence interval; F, female; G, global; M, male.

use different methodologies. Two studies that analysed data from surveys of the general population[19][20] did not find a significant decrease in the prevalence of smokers after the Spanish comprehensive law. In contrast, Lidón et al[24] showed that after the implementation of both Spanish SFLs, a significant decrease was observed in the smoking prevalence (from 34.5% to 26.1%, prevalence ratio=0.76, p<0.001) of people 16 years of age and older living in Barcelona surveyed in 2004–2005 and followed up in 2013–2014. In addition, National Health Survey data from the 1987–2005 period revealed an annual average absolute decline of 1.0% in the prevalence of male smokers, whereas women showed an annual average absolute increase in prevalence of 0.2%. Between 2006 and 2014, the prevalence of smokers declined annually by 0.7% in men and 0.5% in women.[23] Although the values of the current study are higher, the steeper decline in the prevalence of smokers in men agree with these data.[23] Also, one study that estimated the effect of the Spanish SFL for the 2012–2025 period predicted a decrease in smoking prevalence in all age groups and for both sexes, except for women aged 40–64 years.[30]

Concomitantly with the decline in the prevalence trends in smokers, a constant increase of prevalence trends in ex-smokers was observed in the three regions. Other studies failed to note a significant change in the prevalence of ex-smokers after the comprehensive SFL: a difference of only 0.3% between 2007 and 2011,[20] and a non-significant increase of 3.3% between 2006 and 2011.[19] In agreement with a recent evidence review,[23] we observed a higher increase in the trend of ex-smokers prevalence in women. This review showed that the rate of smoking cessation in men increased 0.9% annually during the 1987–2014 period, and 1.5% in women after the partial SFL came into force. The later incorporation of women to smoking might explain these gender differences. We should underscore that other studies that use health surveys as an information source have a higher prevalence of ex-smokers than the prevalence we obtained in this study, especially for Navarre and the Balearic Islands.[31] This discrepancy could be explained by the misclassification of long-term ex-smokers as non-smokers during the process of computerisation of medical records in the cases where the smoking habit was not sufficiently investigated.[32]

We observed a gradual decline in the new smoker incidence trends in Catalonia and Navarre throughout the study period, whereas incidence trends remained stable in the Balearic Islands (possibly due to the shorter study period or lower rates). A review by Wilson et al[33] of two studies that evaluated smoking initiation reported mixed results, while Guerrero et al[34] concluded that the Spanish partial SFL had no effect on new smokers in 2009. In contrast, Pinilla and Abásolo[35] observed a 6% decrease in the rate of smoking initiation among young people after the implementation of the same law, with a more positive impact in higher socioeconomic strata. We have not found studies that evaluate the impact of the comprehensive

SFL on the incidence of new smokers. However, our data show a continuation in the trend observed in Pinilla's study[35] on the impact of the partial law.

The incidence trend in new ex-smokers declined gradually throughout the study period in Catalonia and the Balearic Islands. While the literature to date lacks data on the effect of the SFL on the incidence of new ex-smokers, it provides some information on prevalence. In this respect, one study on the Spanish partial SFL observed an increase of 8% between 2006 and 2011 in the rate of cessation among adult smokers (age 21 years and older) according to data from the National Health Survey.[35] In Luxembourg, smoking cessation attributed to the SFL was higher among daily smokers with a higher socio-economic status.[8] In our cohort, we observed apparent random increases and declines in the adjusted rates in the three regions throughout the study.

The incidence trend in ex-smoker relapses increased in Catalonia and declined in Navarre constantly throughout the whole period, particularly for women, but the overall trend remained stable in the Balearic islands (most likely because of the shorter study period). However, the literature presents conflicting results regarding smoking relapse. One study on the partial Spanish SFL observed that most people who had succeeded in giving up smoking in 2006 had not relapsed by 2009.[34] On the other hand, a quasi-experimental study conducted in USA observed that relapse was similar between employees in workplaces with SFL and employees where smoking was permitted.[36] In contrast, Shang found that comprehensive SFL in bars significantly deters smoking relapse among people aged 21 years and older.[37] According to Buczkowski et al,[38] the main reasons for relapse are stress, missing the pleasure obtained from smoking and the smoking environment. Other factors not analysed in our study that might influence relapse rates could explain the variations between regions, for instance living with other smokers, being enrolled in work or clinics cessation programmes,[39] or the region-specific complementary measures to the SFL (for instance, Foral Law 6/2003,[40] of smoking prevention, protection from secondhand tobacco smoke and promotion of health with regard to smoking in Navarre). In addition, we should consider the impact of the financial crisis during the study period and the subsequent increase of anxiety and depression in the population.[41] In this respect, Navarre was the region with the lowest unemployment rate in Spain according to the 2010 Economically Active Population Survey (unemployment of 11.6% in Navarre, versus 18.0% in Catalonia and 22.2% in the Balearic Islands). According to the 2009 European Health Survey in Spain, these unemployment figures correlate with the prevalence of chronic depression, which was of 3.4% in Navarre versus 5.4% in Catalonia and 7.0% in the Balearic Islands.

The SFL is a keystone of the WHO Framework Convention on Tobacco Control and the MPOWER policy package (M=Monitor; P=Protect; O=Offer; W=Warm; E=Enforce; R=Raise).[42] The enforcement of Laws 28/2005

and 42/2010 have significantly advanced smoking control in Spain, in particular the 'Protect people from tobacco' strategy. However, the remaining MPOWER strategies have been patchily implemented and require further development.[23] On balance, a combination of specific, feasible, pragmatic, sufficiently funded policies and interventions aimed at populations and individuals is essential to achieve progress regarding smoking behaviour.

Limitations and strengths of the study

It is important to take into account that other than the law, the pattern of tobacco consumption is influenced by factors such as health interventions, level of education, age, civil status, having children and being unemployed.[43] However, this study only considered age, sex, number of health problems and number of PHC visits since other variables were not available. In addition, many patients were excluded from the study because of lack of baseline data on smoking (missing data are a common problem in studies based on EHR). In order to prevent bias caused by improved smoking records, we excluded the cases with no information at the beginning of the study. The selection criteria and the longitudinal design aimed to maximise the internal validity of the study. Moreover, young people might be under-represented due to their lower use of PHC services. On the other hand, 70% of the population attends PHC services at least once a year and smokers attend more frequently than no smokers.[44] In view of the limited length of the study period, particularly in the Balearic Islands, we consider these results a first approximation to be succeeded by follow-up research. We should underscore that rather than just comparing two different periods, Joinpoint analysis evaluates longitudinal trends, thus producing a more accurate assessment. The following characteristics of the study were taken into consideration: scarcity of data prior to the implementation of the SFL; delayed changes in smoking status; possibility of detecting more than one change in smoking trends; and influence of unanticipated factors. While other statistical models could have been used, we believe that Joinpoint is a suitable method to achieve the study objectives, as shown in previous studies.[45–47]

This study provides useful data on the impact of the Spanish comprehensive SFL on adult smoking behaviour in PHC patients. It is crucial to analyse the consequences of a public health law on PHC users. PHC has a pivotal role in smoking cessation because it is the gatekeeper of the health services; it is accessible and provides continuity of care to smokers.[48] We should also highlight that this study includes the evaluation of novel variables such as incidence of new smokers, new ex-smokers and ex-smoker relapse, which we consider of great relevance in relation to PHC interventions for smoking cessation. Used as a research tool, EHRs portray real life conditions and provide comprehensive, long-term health histories from a large population sample, ensure high representativeness and external validity, and minimise potential recall bias. The results are only generalisable to PHC users. To our knowledge, this study is among the first to show quarterly data from EHRs.

CONCLUSIONS

The introduction of the Spanish comprehensive SFL (Law 42/2010) does not significantly modify incidence and prevalence trends of smoking behaviour in PHC adult patients in Catalonia, Navarre and the Balearic Islands. The impact of the comprehensive SFL might have been lessened by the effect of the previous implementation of the partial SFL (Law 28/2005). The current article provides baseline data for future research into the effectiveness of this law. In addition to specific factors associated with smoking behaviour (such as the price of a pack of cigarettes or funding of smoking cessation services), future studies should consider socioeconomic status and age groups.

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