Characteristics of patients seeking outpatient smoking cessation treatment before and after the implementation of a smoke-free law in Valencia (Spain): a cross-sectional study

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ABSTRACT

Objective Explore potential changes in the characteristics of patients seeking smoking cessation treatment at an outpatient setting in Spain before and after Law 42/2010 was enacted.

Design This is a cross-sectional study with convenience sampling. The information was obtained from the medical records of patients receiving smoking cessation treatment from January 2008 to December 2014.

Setting Hospital Clínico Universitario de Valencia.

Participants 423 patients who sought smoking cessation treatment 36 months before or 48 months after the enactment of the law.

Results After the enactment of a comprehensive smoke-free law in Spain, the patients seeking smoking cessation treatment were older (p=0.003), had lower values of exhaled CO (p<0.0001), lower number of previous attempts to quit (p=0.027) and more history of medical problems related to smoking (p=0.002).

Conclusion Our findings support the idea that society–nation level interventions could have an impact at the individual level, reflected by the change of patients’ characteristics. It seems that the Law 42/2010 mobilised certain group of patients to seek treatment.

INTRODUCTION

As a clinical risk factor, tobacco use causes cancer, cardiovascular disease and respiratory diseases, among others, accounting for over 8 million deaths worldwide every year. It also represents a public health threat given its impact on society and the economy. For example, every year around 1.2 million non-smokers lose their lives due to exposure to secondhand smoke and about 100 million people live in poverty due to tobacco-related health expenditures. During 2006 in Spain, 27% of individuals aged 15 or older were smokers and one in every seven deaths among people over 35 years of age were caused by tobacco consumption. Furthermore, the additional annual cost for a company if an employee uses tobacco is around €1700.

George Engel developed the biopsychosocial model in the 1980s. It is not only a philosophy of clinical care for understanding how suffering, disease and illness are affected by multiple levels of organisation, but also a practical clinical guide for understanding the patient and expanding the domain of medical knowledge to address the needs of each patient. Its development formed the foundation of the integration theory in healthcare, and leads to the integration of primary care and public health to improve population health. This model enables the understanding of smoking cessation interventions from a new perspective involving eight levels: organ/organs systems, nervous system, person (experience and behaviour), two-person, family, community, culture–subculture and society–nation. The model also takes into account patients’ preferences, objectives and values making it...
‘patient-centred medicine’. Based on the systematic and integrative theory, the society–nation level interventions could have an impact at the individual level. Therefore, patients could display different characteristics after their implementation.

In the current practice of smoking cessation interventions, only two effective approaches are frequently used. The first one is a multicomponent treatment of clinical interventions combining pharmacotherapy and behavioural therapy. It helps smokers receiving treatment in clinical settings quit using tobacco and has been proven to improve patients’ health. The second method includes society–nation level interventions, which take effect through the implementation of public health policy. The WHO has introduced the MPOWER package of six proven policies (monitor tobacco use and prevention policies, protect people from tobacco smoke, offer help to quit tobacco use, warn smokers about the dangers of tobacco, enforce bans on tobacco advertising, promotion and sponsorship, and raise taxes on tobacco). In Europe, the tobacco control policy development is not uniform, nevertheless all countries have experienced improvements, making smoke-free laws one of the most developed interventions.

Spain has implemented two smoke-free laws to date. The laws limit the tobacco retailer network, enforce the publication of information on the harmful effect of tobacco, limit the spread of tobacco products, restrict illegal trade, aim to protect vulnerable populations and encourage the development of public education actions and programmes to help smokers quit. Compared to the 2006 law, the 2011 law (Law 42/2010) expands the smoking ban to closed and some collective public spaces, such as institutes, playgrounds and hospitals. It was considered that minors and workers in the hospitality sector could especially benefit from the new regulations.

Recent studies have shown that after the implementation of the new law the prevalence of tobacco consumption has decreased in the country. Studying the individual characteristics of the patients seeking treatment after the implementation of the law can help the public health authorities and the clinical services better tailor their interventions.

Many cross-sectional studies of the Spanish population have evaluated the characteristics of patients seeking tobacco cessation treatment in the country. Those studies explored the role of motivation to quit and different sociodemographic and tobacco use characteristics as potential predictors of seeking tobacco cessation treatment. One study examined the characteristics of patients seeking treatment before and after the implementation of the 2006 smoke-free law in Spain. The study found that after the enactment of the law the patients were older, with lower cigarette consumption and lower motivation to quit. To our knowledge, there has not been a study evaluating patients’ characteristics after the implementation of the comprehensive law in 2011.

Considering the above, we conducted this study aiming to explore potential changes in the sociodemographic, medical and tobacco use characteristics of patients requesting smoking cessation treatment at Hospital Clínico Universitario de Valencia before and after Law 42/2010 was enacted. Understanding the potential changes in the characteristics of patients seeking treatment can help clinicians and public health authorities develop a more comprehensive insight of the patients in order to adapt to their needs and provide more effective care.

METHODS
Design and data source
This is a cross-sectional study. The information was obtained from medical records. The target population was active smokers aged 18 or older living in the Valencian Community of Spain who received smoking cessation treatment at Hospital Clínico Universitario de Valencia. Data were collected from smokers receiving treatment in the Service of Preventive Medicine and Quality Care of the hospital during a period of 7 years from January 2008 to December 2014 (36 months before Law 42/2010 and 48 months after Law 42/2010). This hospital is one of the two hospitals providing services to 343,497 patients, representing about 38% of the registered patients in Valencia. About 84.96% of the patient registered in the hospital were 15 years or older. Given the prevalence of smoking in Spain, the approximate number of local smokers was 88,655 individuals. Six hundred and twenty-two medical records were selected through a convenience sampling method. Of those, 199 were excluded due to incomplete information or invalid records, resulting in the 423 medical records that were analysed for this study. The enrolment rate was 68.0%.

Data collection
Based on guidelines and the methods used by previous studies published about smoking cessation research, two researchers, with experience in multicomponent treatment and quantitative research, collected data from the medical records and organised it into four groups of variables generally considered as predictors of multicomponent treatment outcomes. The first group included sociodemographic variables, such as gender (male and female), age (years) and occupation. Based on the standards of the Spanish National Institute of Statistics and the principle of statistics, the occupations were separated into nine types (retired or unemployed, directors and managers, scientific and intellectual technicians and professionals, healthcare professionals and public health technicians, college students, accounting, administrative and other office employees, waiter, security and sales personnel, skilled workers in agricultural, livestock, forestry and fisheries sector and other occupations). The second group of characteristics included medical history and smoking history, such as having a disease related to smoking (yes or
no), age of first tobacco use (years), number of cigarettes smoked per day, number of years smoking, pack-years, values of exhaled CO, number of previous attempts to quit, duration of previous unassisted attempts to quit (months), family history of tobacco use (yes or no) and tobacco-related deaths in the family (yes or no). The third group of variables included information about tobacco dependence and motivation to quit based on the scores and levels of the Fagerström test (low, middle and high) and the Richmond test (low, middle and high). Additionally, the records were divided into two groups, before January 2011 and after January 2011 when the new law was enacted.

### Data analysis

We used descriptive statistics to provide indicators of the distribution of data. χ² and t-tests, one-way analysis of variance (ANOVA) and Kruskal-Wallis analysis were conducted to compare the possible differences between the before and after enactment groups. All the variables considered and measured in this study were coded and analysed using the software SPSS V.24.0 for Windows (IBM Software Group). The level of significance was p≤0.05.

### Patient and public involvement

Our data were obtained from medical records. There was no direct contact with patients.

### RESULT

A total of 423 medical records were reviewed for this study. Among them, 44.2% (187 patients) sought smoking cessation treatment before 2011. The mean (±SD) age was 50.21±22.55 years, and 59.8% of the patients were women. Most of the participants were retired (25.3%), healthcare technicians and professionals (22.5%) and administrative employees (8.5%). 79.7% of the patients had a history of a tobacco use-related disease.

The sociodemographic characteristics of patients requesting treatment before and after 2011 are summarised in table 1. After 2011, participants older than 50 years old (p=0.003), those unemployed or retired (p=0.028) and those with a tobacco use-related disorder (p=0.002) were more likely to seek tobacco cessation treatment.

The groups did not show significant differences in most of the smoking history variables. However, patients who started treatment after 2011 showed lower values of exhaled CO (p<0.0001), and had lower number of previous quit attempts (p=0.027) (table 2). Additionally, the mean score was 5.58 for the Fagerström test and 7.64 for the Richmond test. The differences in terms of the levels of dependence and the motivation to quit were not statistically significant. More people chose the group intervention (p=0.011) and received varenicline (p=0.018) after 2011 (table 3).

### DISCUSSION

Despite its importance for developing effective smoking cessation interventions, little is known about the change in the characteristics of patients seeking treatment in Spain after the implementation of smoke-free laws. In order to fill that gap in knowledge, we assessed the characteristics...
of patients seeking smoking cessation treatment before and after the enactment of the comprehensive 42/2010 smoke-free law in Spain. When compared with patients before the implementation of the law, after 2011 patients were older, had lower level of cigarette consumption, lower number of previous attempts to quit and more history of medical problems related to smoking.

Given the correlation between cigarette consumption and CO levels measured by cooximetry and its higher objectivity, our study shows that patients who came to the clinic after 2011 have a lower level of cigarette consumption. Furthermore, patients seeking treatment after the enactment of the law had fewer attempts to quit. Those changes were considered as positive by some national reports. Those findings were consistent with previous reports evaluating the changes in patients’ characteristics after the enactment of the 2006 law. This suggests that the implementation of the smoke-free laws in Spain may have mobilised patients with lower severity of tobacco use to seek treatment. As it has been suggested by other authors, this could be secondary to increased social pressure and increased barriers to obtaining and using tobacco after the enactment of the law.

After the enactment of the 2011 law older patients were more likely to seek treatment than before. Our findings are consistent with the study assessing patients’ characteristics after the enactment of the 2006 law. Additionally, they could be considered a confirmation of the trend previously described. As it has been suggested in previous studies, it is possible that the barriers to obtain and use tobacco and the education provided after the implementation of the 2006 and 2011 law prevented younger generations to start using tobacco, therefore modifying the sociodemographic characteristics of the patients seeking treatment. Furthermore, in recent years there is more knowledge and public awareness about the negative consequences of tobacco use. Also, the incidence of smoking has been decreasing steadily worldwide.

In our study, patients with a history of medical problems related to smoking were more likely to seek treatment after 2011. This is consistent with a study from the USA that reported that patients with more medical problems were more willing to quit smoking. It is possible that the enactment of the law prompted sicker patients to translate their ideas about quitting into action. It is important to consider that the underlying factors and mechanisms that influence smokers to quit are quite complex, including knowledge and contextual factors.

One of the focuses of the Law 42/2010 was to protect children, adolescents and workers in the hospitality sector by improving air quality and reducing exposure to secondhand smoke in public places. In our study, the proportion of waiters, security and sales personnel seeking treatment did not increase after 2011. This finding indirectly supports the conclusions of previous studies proposing that legislations to ban smoking in public places have a greater impact on passive smoking than on active smoking.

For most of the indicators, there were no significant differences before and after the enactment of the law. The cessation support systems available in Spain include a quitline, reimbursement and subsidies for smoking cessation medications, and the use and dissemination of national guidelines for the treatment of tobacco use disorders.

### Table 2 The comparison of the variables about personal pathological and smoking history before and after January 2011

| Groups                          | Before 2011.1 | After 2011.1 | P value |
|--------------------------------|--------------|--------------|---------|
| Age of the first smoke         |              |              |         |
| Before 2011.1                  | 18.99        | 19.53        | 0.314*  |
| After 2011.1                   |              |              |         |
| Number of cigarettes per smoker per day |              |              |         |
| Before 2011.1                  | 21.76        | 20.37        | 0.121†  |
| After 2011.1                   |              |              |         |
| Number of years of smoking     |              |              |         |
| Before 2011.1                  | 29.71        | 31.33        | 0.133*  |
| After 2011.1                   |              |              |         |
| Pack-years                     |              |              |         |
| Before 2011.1                  | 32.91        | 32.41        | 0.796*  |
| After 2011.1                   |              |              |         |
| Values of exhaled CO           |              |              |         |
| Before 2011.1                  | 14.31        | 10.29        | <0.0001†|
| After 2011.1                   |              |              |         |
| Number of previous quit attempts |              |              |         |
| Before 2011.1                  | 1.35         | 1.12         | 0.027†  |
| After 2011.1                   |              |              |         |
| Maximum duration (months) of previous unassisted quit attempts |              |              |         |
| Before 2011.1                  | 11.6         | 10.91        | 0.082†  |
| After 2011.1                   |              |              |         |

*Differences tested by independent Student’s t-tests, p<0.05.
†Differences tested by Mann-Whitney U test, p<0.05.

### Table 3 The comparison of patient’s dependence and motivation level before and after January 2011

| Groups                          | Before 2011.1 | After 2011.1 | P value* |
|--------------------------------|--------------|--------------|---------|
| Levels of the Fagestrom test    |              |              |         |
| Low                            | 54 (28.9)    | 68 (28.8)    | 0.004   | 0.998  |
| Middle                         | 67 (35.8)    | 84 (35.6)    |         |        |
| High                           | 66 (35.3)    | 84 (35.6)    |         |        |
| Levels of the Richmond test    |              |              |         |
| Low                            | 40 (21.4)    | 60 (25.4)    | 3.121   | 0.21   |
| Middle                         | 121 (64.7)   | 133 (56.4)   |         |        |
| High                           | 26 (13.9)    | 43 (18.2)    |         |        |

*Differences between categories tested by Pearson χ² test, p<0.05.
However, the use of the quitline and internet resources is extremely low and only 2.2% of participants used smoking cessation service. Using the Engel's 'systems hierarchy' model suggests a gap in the transmission from public policy to clinical practice.

**Strengths and limitations**

This is an exploratory study trying to assess potential effects of the 2011 smoke-free law in the characteristics of patients seeking treatment in a hospital in Spain. This is a valuable attempt from a local clinical service to understand the potential impact of the regulations in the service to improve public policy and the design of services. Additionally, we used a systematic and integrative approach when conceptualising smoking cessation interventions. However, the precision and external validity of this study is limited given the sample size and sampling method. Additionally, being a cross-sectional study causality cannot be established. Future research in the area should ideally be qualitative and use a mixed method research.

**CONCLUSION**

After the enactment of a comprehensive smoke-free law in Spain, the patients seeking smoking cessation treatment were older, had lower level of cigarette consumption, lower number of previous attempts to quit and more history of medical problems related to smoking. Our findings support the idea that society–nation level interventions could have an impact at the person level, reflected by the change of patients’ characteristics. It seems that Law 42/2010 mobilised certain groups of patients to seek treatment.

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