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Impact of the Spanish smoke-free legislation on prematurity and low birth weight

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Abbreviations: CI: confidence interval; SGA (small-for-gestational age); SHS (second hand smoke)

What's known on this subject: Second hand smoke exposure during pregnancy is associated with health complications affecting perinatal and neonatal outcomes. However, previous studies fail to provide uniform evidence on the impact of smoke-free policies on low birth weight and prematurity. Further research is needed.

What this study adds: The implementation of two Spanish smoking bans (partial and comprehensive) was associated with a risk reduction regarding preterm births and low birth weight infants. This health benefit was especially evident with the introduction of the more restrictive ban.

Contributors' statement:

Lorena Simón and Iñaki Galán: Drs. Simón and Galán conceptualized and designed the study, carried out the initial analyses, and drafted the initial manuscript.

Roberto Pastor-Barriuso: Dr. Pastor-Barriuso supervised the analyses and reviewed and revised the manuscript.

Elena Boldo, Cristina Linares, Rafael Fernández-Cuenca, María José Medrano, and Cristina Ortiz: Drs. Boldo, Linares, Fernández-Cuenca, Medrano, and Ms. Ortiz designed the data collection instruments and critically reviewed the manuscript.

All authors approved the final manuscript as submitted and agreed to be accountable for all aspects of the work.

ABSTRACT

Background: Spain implemented a partial smoking ban in 2006 followed by a comprehensive ban in 2011. The aim was to examine the association between these smoke-free policies and different perinatal complications.

Methods: Cross-sectional study including all live births between 2000-2013. Selected adverse birth outcomes were: preterm births (<37 gestational weeks), small-for-gestational age (SGA) (<10th weight percentile according to Spanish reference tables), and low birth weight (<2,500gr). We estimated immediate and gradual rate changes following smoking bans by using overdispersed Poisson models with different linear trends for 2000-2005 (pre-ban), 2006-2010 (partial ban), and 2011-2013 (comprehensive ban). Models were adjusted for maternal socio-demographics, delivery healthcare, and smoking prevalence during pregnancy.

Results: The comprehensive ban was associated with preterm birth rate reductions of 4.5% (95% confidence interval [CI]: 2.9 to 6.1) and 4.1% (95% CI: 2.5 to 5.6) immediately and one year after implementation, respectively. Low birthweight rates also dropped immediately (2.3%, 95% CI: 0.7 to 3.8) and one year after the comprehensive ban implementation (3.5%, 95% CI: 2.1 to 5.0). Rates for SGA experienced an immediate reduction at the onset of the partial ban (4.9%, 95% CI: 3.5 to 6.2), which was sustained one year post-implementation. Although not associated with the comprehensive ban at the onset, SGA declined by 1.7% (95% CI: 0.3 to 3.1) one year post-implementation.

Conclusions: The implementation of the Spanish smoke-free policies was associated with a risk reduction regarding preterm births and low birthweight infants, especially with the introduction of the more restrictive ban.

INTRODUCTION

Worldwide, second hand smoke (SHS) is responsible for close to 600,000 annual deaths. The very young are particularly affected as the greatest SHS prevalence and SHS-related disease burden are found in children under 5 years of age.¹ Solid evidence supports that SHS exposure during pregnancy is associated with a diverse array of complications during gestation as well as perinatal and neonatal periods. Specifically, there is a high risk for preterm, low birth weight, small-for-gestational age (SGA) babies, as well as for sudden infant death syndrome.^{2,3}

In Spain, the prevalence of fetal SHS exposure is high. It is estimated that between 2004 and 2008 one of every two non-smoking women was exposed to SHS during the third trimester of her pregnancy,⁴ and one in five pregnant women smoked during pregnancy in 2013.⁵

Smoking bans designed to protect non-smokers from involuntary SHS exposure is the main preventive and tobacco control measure. Many countries, in compliance with the 2003 WHO Framework Convention on Tobacco Control,⁶ have implemented laws regulating tobacco consumption in public places. The Spanish law on Health Measures Against Smoking took effect on January 1st, 2006,⁷ which banned smoking in the workplace except in the hospitality sector where a partial ban was implemented. The law substantially reduced SHS exposure in the workplace but had little impact on reducing this environmental risk in hospitality establishments.^{8,9} To further reduce SHS exposure, a reform of the original law¹⁰ took effect on January 2nd, 2011. This reform banned tobacco consumption in almost the totality of public places, a measure vastly successful in reducing SHS exposure in bars and restaurants (over a 90% reduction in

vapor-phase nicotine and particulate matter 2.5 micrometers or less in diameter (PM_{2.5}) in hospitality venues).¹¹

Several studies have evaluated the impact of smoke-free policies on perinatal complications such as low birth weight and prematurity.¹² Published evidence to date has failed to provide uniform evidence on the impact of smoke-free policies on low birth weight and prematurity¹² with articles reporting favorable results,¹³⁻¹⁶ others reporting no change,¹⁷⁻¹⁹ and others reaching different conclusions depending on the health indicator examined.²⁰⁻²⁴

Spain is one of few countries with a 2-stage smoking ban legislation, high compliance, and a 5-year gap between a less restrictive to a complete ban. The main objective of this study was to examine whether the two Spanish smoking bans put in place to reduce SHS exposure, were associated with reductions in the rates of preterm, low birth weight, and SGA births.

METHODS

Study design and participants

In this population-based study we analyzed cross-sectional data from the Spanish Birth Registry (Spanish National Statistics Institute, INE for its Spanish acronym) from January 2000 to December 2013. Data from 5,293,700 records included clinical information on all live births occurring between week 22 and 44 of gestation in Spain. SGA analyses included only infants born in the period 26-42 weeks of pregnancy because weight reference tables to define this indicator are based on that gestational time.

Variables

Outcome variables included preterm birth (<37 weeks gestational age), low birth weight (< 2,500 grams), and SGA births (<10th weight percentile according to Carrascosa et al.²⁵). Based on the existing literature we included those relevant covariates available in the data. These included mother's age grouped in 5-year intervals and socioeconomic status based on mother's and father's occupation, separately. Occupational status was categorized as follows: Groups I and II (managerial positions, technical staff, and professionals), Group III (administrative staff), Groups IV and V (manual workers). Other variables adjusted for included: birth location (health center, private home, or another location), health professional-assisted birth or not, singleton or multiple birth, and the region where the mother resided. Preliminary analyses showed that these variables were significantly related to the outcomes under study (statistically significant p-value) and they could vary between time periods: pre-ban (2000-2005), partial-ban (2006-2010) and full-ban (2011-2013). Finally, we included the annual prevalence of tobacco consumption during pregnancy using information of controls participating in the Spanish Collaborative Study on Congenital Malformations by the Research Center for Birth Defects (CIAC-ECEMC for its acronym in Spanish)^{5,26}.

Statistical analyses

Poisson models allowing for overdispersion were used to assess rate changes in the three adverse birth outcomes over time. The segmented models allowed for different log-linear rate trends during the 2000–2005 pre-ban period, the 2006–2010 partial ban period, and the 2011–2013 comprehensive ban period, while adjusting for maternal socio-demographics, delivery healthcare, and smoking prevalence during pregnancy. From these models, we estimated the percent changes in perinatal complication rates at the partial ban's implementation and one year after by comparing the estimated rates at

these time points with the projected rates from the pre-ban period.²⁷ Similarly, the percent rate changes at the comprehensive ban's implementation and one year after were calculated by relating the estimated rates at these time points to the projected rates from the previous partial ban period.

Sensitivity analyses were performed. To determine the robustness of the models we reran the models varying the specifications and compared the association estimates. First, we excluded multiple births. Second, we evaluated the association estimates by building 3-, 6-, and 9-month lags between birth and bans' implementation into the model.

Additional analyses were performed to estimate differences in coefficients by newborn's sex, whether the mother worked outside the home, and parent's socioeconomic position based on occupation, evaluating the statistical significance of the interaction. We performed analyses with Stata version 14 (StataCorp) and R version R3.3.1 (R Foundation).

RESULTS

Table 1 shows participants' sociodemographic characteristics and healthcare services. Mother's average age was 31 years, and although occupation varied, the most common reported occupation was "other" which captured those who have not held a paying job before. Father's most common occupation was manual labor. The vast majority of births were singleton, took place in healthcare centers, and were assisted by health professionals.

Preterm birth rate was 7.9%, 9.2% were SGA births, and 7.8% of newborns had low birth weight in the period 2000-2013 (Table 1). Figure 1 presents how the three outcomes under study evolved throughout time, displaying the annual gross rates and the segmented linear trends for 2000-2005 (pre-ban), 2006-2010 (partial ban) and 2011-2013 (comprehensive ban). Corresponding changes in rate ratios (crude rates) are summarized in Table 2. SGA birth is the variable with greater stability through time with a slight decreasing trend. In contrast, the rate for low birth weight increases during the pre-ban period only to remain constant for the last 4 years of the study. The trend for preterm births also increased until peaking in 2007-2009 and decreased moderately thereafter.

Table 2 shows the changes in perinatal complications over the three periods under study: pre-ban, partial ban, and comprehensive ban. The comprehensive ban was associated with an immediate reduction (percent change of adjusted rates) in preterm births from -4.5% (95% Confidence Interval (CI): -6.1 to -2.9) which was sustained at -4.1% (95% CI: -5.6 to -2.5) one year after implementation. Similarly, the rate of low birth weight infants also experienced an immediate reduction (-2.3%; 95% CI: -3.8 to -0.7) with the comprehensive ban and decreased slightly further one year after implementation (-3.5%; 95% CI: -5.0 to -2.1).

Finally, the implementation of the partial ban was associated with an immediate reduction in SGA birth rates (-4.9%, 95% CI: -6.2 to -3.5). The rate continued dropping throughout the first year but at a more modest pace (-4.2%, 95% CI: -5.7 to -2.7).

Although we did not observe changes in SGA birth rates at the time of the onset of the 2011 comprehensive ban, rates fell by -1.7% (95% CI: -3.1 to -0.3) one year later.

Results from sensitivity analyses were similar to those from the general models after excluding multiple births from the analysis. Estimate changes were not observed either when models included the 3-, 6-, and 9-month lags between the delivery and the implementation of the ban.

The associations described above were not modified by the newborn's sex, having a mother working outside the home or not, or parental socioeconomic position based on occupation. Tested interactions failed to reach statistical significance.

DISCUSSION

The onset of the partial ban was associated with a reduction in the SGA rate and the reduction was maintained throughout the first year after ban was put in place. The expansion of this law into a comprehensive ban was associated with an immediate reduction in the preterm and low birth weight rates, both of which sustained the reduction one year after implementation.

Despite the existing evidence of the harmful effects of tobacco consumption during pregnancy, as well as of the role of SHS exposure in pregnancy complications and perinatal health,^{2;28-30} research on the impact of local and national smoking bans is scarce and findings are inconsistent depending on type of ban and health indicators examined.³¹ Half of the studies on smoking bans and prematurity report a reduction in births earlier than 37 gestational weeks once the ban is implemented,^{15;16;22-24} the other half fail to detect an association.¹⁷⁻²¹

Four studies detected a protective association between smoking bans and low birth weight,^{13;15;16;21} however, seven articles failed to find any benefits.^{17-20;22-24} Finally, of the five studies evaluating the effect of bans on SGA rates, most report a protective

effect¹⁴⁻¹⁶ versus those failing to detect an association.^{19;22} Overall, findings are highly inconsistent; however, studies based on proximate countries, with similar smoking regulations to Spain, and high levels of compliance—as is the case of Ireland,^{14;23} Scotland,¹⁵ and England¹³—have also observed falling rates in perinatal complications.

The mechanisms through which smoke-free legislation works to improve perinatal health include maternal tobacco consumption, changes in SHS exposure, or both if the mother smokes. Only a few studies evaluating the impact of smoking bans have differentiated between these mechanisms. In Norway, Bharadwaj and colleagues²¹ reported that most of the benefit stemmed from changes in maternal tobacco consumption and only a reduced portion of the benefit came from changes in SHS exposure. However, MacKay and colleagues¹⁵, in Scotland, reported improvements in prematurity and SGA indicators in mothers whether they smoked or not.

The fact that the associations between the two smoking bans and birth outcomes differed is worth elaborating upon. Based on a meta-analysis on the effects of smoke-free regulations on cardiovascular and respiratory diseases, Tan and Glantz³² reported a dose-response relationship where benefits increased as regulations grew more restrictive. Few countries have introduced smoke-free legislation in stages from a less restrictive to a broader legislation, from only affecting the workplace to designating bars, restaurants, and other public places as “smoke-free space.” Amaral²⁰ in California (U.S.) and Cox and colleagues²² in Flanders (Belgium) reported conflicting results. The former study links a decrease in newborns’ average birth weight with the less restrictive ban, whereas the latter study associates a reduction in preterm birth rates with the gradual increase of public spaces designated “smoke-free.”

In our study we observed a stronger beneficial association between the comprehensive smoking ban and preterm and low birth weight birth rates but not SGA rates; however, we found a beneficial association between the preceding partial ban and SGA rates.

Future studies should explore these findings further.

It is also noteworthy that the association between smoking bans and perinatal outcomes did not vary by mothers' socioeconomic position given that these types of complications are more prevalent in mothers from low socioeconomic groups.^{33,34}

Similarly, SHS exposure in adults tends to be higher among the lowest educational or socioeconomic groups.³⁵ These findings imply a broadening of existing socioeconomic disparities regarding a wide variety of health outcomes. Nonetheless, our results are consistent with those reported by McKinnon and colleagues in Quebec,¹⁶ where they found no evidence of effect modification by mother's educational level either.

Our results should be interpreted in the context of the study's limitations. First, given the cross-sectional design no causal inference can be drawn. Second, although the birth registry includes sociodemographic information about the mother, it does not collect tobacco consumption habits during pregnancy. However, we used CIAC-ECHEMC data on smoking prevalence among pregnant women as an ecological control. Third, we could not differentiate between spontaneous and provider-initiated preterm deliveries due to data limitations. This matters since tobacco addiction is a risk factor for spontaneous preterm births. MacKay and colleagues, able to examine spontaneous preterm births only, detected a statistically significant association between Scottish smoking bans and preterm births only slightly lessened after adjusting for pre-eclampsia.¹⁵ Fourth, variables not taken into account may contribute to residual

confounding, for instance, cesarean rates (25% in Spain) which are related to gestational time and newborn's weight. However, cesarean rates do not seem to be related to the smoking bans since cesarean incidence grew gradually, peaking in 2006, only to stabilize thereafter. Also, the use of tocolytic drugs for suppression of premature labor could modify the association under study. But, again, there seems to be no temporal relationship between the bans and the use of this family of drugs, or more specifically oxytocine receptors antagonists (Atosiban), which may reduce birth weight.³⁶

Finally, other changes in fetal medicine practice over the study period could have confounded the association (e.g., recognition and earlier treatment of blood pressure leading to better placental function, or aspirin administration in early pregnancy to prevent preeclampsia). However, in this period Clinical Practice Guidelines for Care in Pregnancy and Puerperium in the Spanish National Health System,³⁷ did not change their recommendations of blood pressure monitoring (to prevent hypertension complicating pregnancies) or the use of low-dose aspirin in early pregnancy. However, between 2000 and 2013, Spanish hospitals have experienced steady negative linear trends in admission rates for hypertension complicating pregnancy (ICDM-9-CM, code 642) and for preeclampsia (ICDM-9-CM, codes 642.4 and 642.5). Coincidentally, these trends stabilized starting in 2010 for hypertension complicating pregnancy and starting in 2008 for preeclampsia, time periods including the post-comprehensive ban years under study (2011-2013) and during which we observed the more substantial effects of the smoking-free policies on our outcomes of interest. This suggests the independence of our findings from the improved management of those clinical conditions. Likewise, the guideline did not change the recommendations on the management of growth restriction with the addition of doppler assessment.³⁷

Although we are not aware of any changes in obstetric practices coinciding with the implementation of the two smoking bans, we cannot rule out the risk of unknown bias due to unaccounted variation of factors potentially related to outcomes.

Our study also has important strengths. First, this large population-based study analyzed data from a comprehensive and highly relevant nationwide dataset. Second, Spain is one of few countries with a 2-stage smoking ban legislation and a 5-year gap between a partial and a comprehensive ban. Third, this smoke-free regulation was effective in reducing exposure to SHS in workplace and hospitality venues.^{8,9,11} Fourth, the substantial follow-up period, starting six years before the implementation of the first policy and terminating 2 years after the implementation of the second one, allowed for the separate evaluation of the two phases of smoke-free legislation.

CONCLUSIONS

Our results show a risk reduction for preterm births and low birth weight newborns coinciding with the implementation of the smoke-free regulations in Spain. This is especially true with the second regulation, a comprehensive ban prohibiting smoking in most enclosed public spaces. This association strongly suggests the benefits of implementing smoke-free legislation in the prevention of pregnancy complications and brings to the forefront the importance of developing comprehensive regulations preventing or minimizing maternal and fetal exposure to this key environmental risk factor.

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