

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	OPPOSITE TRENDS IN THE CONSUMPTION OF MANUFACTURED AND ROLL-YOUR-OWN CIGARETTES IN SPAIN (1991-2020)
AUTHORS	Jose; Fu, Martínez-Sánchez, Marcela; Cleries, Ramón; Villalbí, Joan; Daynard, Richard; Connolly, Gregory; Fernandez, Esteve

VERSION 1 - REVIEW

REVIEWER	Tait, Peter Lincoln University, Agribusiness and Economics Research Unit
REVIEW RETURNED	27-May-2014

GENERAL COMMENTS	<ul style="list-style-type: none">- The contribution of the paper is unclear.- How were the number joinpoints determined?- I think the authors should offer some reasoning for their AR model specification given the alternative methods available; and provide some estimation reporting that facilitates a degree of assessment of model performance.- What data exactly is the model fitted to? Is it monthly? Sales are often found to increase over holiday periods particularly over the Xmas period; has any seasonal effect been unidentified and/or treated? Is it the 2008 -2012 period?- Can you provide a within-sample prediction test?- The usefulness of the methodological approach towards policy development should be made clear.
-------------------------	--

REVIEWER	Young, David Cancer Council Victoria, Knowledge Building, VCTC
REVIEW RETURNED	04-Jun-2014

GENERAL COMMENTS	<p>This is a useful study which should be published after a minor revision. While the authors rightfully note the limitations generated by the heterogeneous data, and the use of product sales information, I believe they make their case for a relative increase in RYO use convincingly. This is important information because it is consistent with results from other countries which indicate that the Global Financial Crisis has probably helped generate an increase in RYO use relative to the use of manufactured cigarettes. In addition to the tax advantages, one of the constraints identified (i.e. that the amount of tobacco used in a RYO cigarette is variable) is also one of the attributes that attracts use by financially stressed smokers. I am also pleased to see the use of Bayesian statistics in a paper aimed</p>
-------------------------	--

	<p>at mainstream publication</p> <p>The only change I would recommend is a table indicating the effect of the constraints on the relative rate of RYO use; those that would lead to an overestimate, and those that lead to an underestimate (my reading is that the constraints lead to a net underestimate of RYO use).</p>
--	---

REVIEWER	<i>anonymous</i>
REVIEW RETURNED	15-Jun-2014

GENERAL COMMENTS	<p>This paper is intended to provide data regarding trends in consumption of factory-made (“manufactured”) and roll-your-own (RYO) cigarettes in Spain over the period 1991 through 2012, and projected consumption trends through 2020. The paper is generally well written, but I have several concerns:</p> <ol style="list-style-type: none"> 1. The authors do not provide sufficient evidence that their calculation of the basic unit of analysis (per capita units of cigarettes) is valid or reliable for the RYO category. They rely on 2008 RYO surveillance data to convert bags/cans/packs sold into a common weight unit (kg of product), then use a sensitivity approach for estimation of the analytic unit (number of RYO cigarettes). Give the much more highly standardized weight of tobacco in manufactured cigarettes, why not covert manufactured cigarettes sales into per capita weight units and analyze trends on that measure, obviating the need to estimate the yield of RYO cigarettes from a weight value? The authors state that they were “able to estimate the sales of rolling tobacco in kg of product for all the studied period” (p. 4, line 41), so why wasn’t this used as the basis for the unit of analysis without converting to cigarette units? 2. Estimation of the common weight of 50g per unit is described but please provide documentation that a “package” = a “bag” = a “can” (p. 4). 3. The authors do not account for the consumption of pipe tobacco, which for many years was used in RYO cigarettes as the low-cost alternative to manufactured cigarettes. How do trends in pipe tobacco consumption affect the reported RYO trends? 4. Other than acknowledging this as a limitation, the authors do not attempt to quantify the impact of illicit trade on these trends, especially regarding the reported downward slope of manufactured cigarette sales. If possible, please add illicit sales estimates to the models. 5. The statement, “a revision of studies providing data on the weight of roll-your-won cigarettes indicated median estimates ranging between 0.48 abd 1.1 [25]” (p. 8-9) is not supported by reference #25, which is a duplicate of #24 in the reference list.
-------------------------	---

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

1. The contribution of the paper is unclear.

Our first objective was to describe trends in the consumption of manufactured and RYO cigarettes in Spain, with the available information on sales from 1991 up to date. This information had been provided only for specific periods of time, but not with all the available information, because it is not easily extracted from the registries. Thus, this is the first time this information is provided in a systematic way for a long period of time.

Once we observed the trend in sales between 1991 and 2012, our second objective was to project this trend up to 2020 by means of a time-series methodology. We provide these novel results and think this information is relevant, given the expected increase in the consumption of RYO cigarettes.

As this type of tobacco has had an increase in the market share, we consider useful projection to quantify the magnitude of the situation and to help the politicians and the public health community to take the opportune measures.

We have added a sentence at the beginning of the Discussion section to highlight the contribution of the paper.

2. How were the number joinpoints determined?

Making use of the program developed by Kim et al. in 2000, we started with the minimum number of joinpoints and tested whether more joinpoints were statistically significant and should be added to the model (up to that maximum number). Based on the shape of the time trend of the daily cigarette consumption per capita (Figure 1), we assumed a maximum number of 4 joinpoints (note that 0 joinpoints leads to estimate a straight line). We also tested the presence of 5 joinpoints, but the regression confirmed a maximum of 4 joinpoints.

We added more detail on this procedure in the Methods section, on page 6:

“In order to assess changing trends during 1991-2012, we used joinpoint regression. According to the procedure developed by Kim et al., [18] and based on the shape of the time trend of the daily cigarette consumption per capita, we assumed a maximum number of 4 joinpoints. (...)”

REF: Kim HJ, Fay MP, Feuer EJ, Midthune DN. Permutation tests for joinpoint regression with applications to cancer rates. *Stat Med* 2000;19:335-51.

3. I think the authors should offer some reasoning for their AR model specification given the alternative methods available; and provide some estimation reporting that facilitates a degree of assessment of model performance.

We thank the reviewer for pointing this out. Since the mean of the daily units of cigarettes per capita every year (CCt) used were based on small numbers, a Bayesian approach was applied to obtain a smoothed estimate of the time trend of these units through a log-linear Poisson model. A Bayesian modelling imposing a temporal structure on model parameters might improve precision in these estimates in situations where other Poisson models may fail, as it has been shown in other epidemiological studies (Clèries et al., 2014). These temporal structures could be based on autoregressive smoothing of first order or second order, which are known as random walks, RW1 and RW2, respectively. The RW1 prior assumes a constant trend over the time scale, whereas the RW2 prior assumes moving average (Clayton, 1996). Therefore the order of the random walk should be chosen depending on whether a constant or a linear time trend can be assumed. The autoregressive model specifies that the output variable, CCt in our case, depends linearly on its own previous values, CCt-1, CCt-2, CCt-3, and so on. The choice of RW1 or RW2 depends on the shape of the time trend of the CCt. The RW1 assumes a constant rate K of increase or decrease of CC, therefore $CC_t \sim K * CC_{t-1}$. But this hypothesis does not hold in this study, since there were changing trends in CCt throughout the period of analysis (as the joinpoint analysis showed) and a constant K value makes no

sense. On the other hand, the RW2 assumes a constant absolute change per unit of time that depends linearly only in two predecessors, $C_t - 2 * C_{t-1} - C_{t-2}$, therefore $C_{t-1} \sim (C_t + C_{t-2}) / 2$. In this line, this is a moving average that changes in time and allows for smoothing of the trend. Extending this assumption into the future makes possible to perform the prediction of CC into the future. In addition, we compared within sample predictions using both assumptions and we found that RW2 model performed better than RW1 model. Please see below the response to question #5 of reviewer 1.

We added an explanation justifying the choice of the RW2 model on page 6:

“(…) To predict trends, we fitted an autoregressive Bayesian log-linear Poisson model to the observed data in 1991-2012. This model allows better predictions in situations where other models may fail[18] and gives more weight to data from recent periods, especially when changing trends arise through the study period.[19] In this line, the temporal trend was modelled through a random walk (RW). We assessed the performance of the model comparing a RW of order 1, which assumes constant rate of changes, with a RW of order 2, which is a moving average that changes in time and allows for smoothing of the trend.[19] We found that model with RW of order 2 showed less variability in the within sample prediction of the observed cigarettes per capita in 1991-2012, and then the RW of order 2 assumption was used. (…)”

REFS:

Clèries R, Martínez JM, Moreno V, et al. Predicting the change in breast cancer deaths in Spain by 2019: a Bayesian approach. *Epidemiology*. 2013;24:454–60.

Clayton DG. Generalized Linear Mixed Models. In: Gilks WR, Richardson S, Spiegelhalter DJ, eds. *Markov chain Monte Carlo in Practice*. London: Chapman & Hall, 1996. p. 275-301.

4. What data exactly is the model fitted to? Is it monthly? Sales are often found to increase over holiday periods particularly over the Xmas period; has any seasonal effect been unidentified and/or treated? Is it the 2008 -2012 period?

The model was fitted with the annual information on sales. We think this is a good approximation, which avoids seasonal effects. The Commission collects the data in a monthly basis and report it in its website both in a monthly and annual basis. We have clarified we used the annual sales at the beginning of the Methods section.

Related to the period used to fit the model, more exactly, it was the 1991-2012 period. However, due to the autoregressive modelling used (please see the response to the comment #3), future rates depend on the last trends observed; therefore, the last time period where the analysis found a changing trend, 2009-2012, influenced more than data from early periods.

We now provide a better explanation in the main text:

“(…) To predict trends, we fitted an autoregressive Bayesian log-linear Poisson model to the observed data in 1991-2012. This model allows better predictions in situations where other models may fail[20] and gives more weight to data from recent periods, especially when changing trends arise through the study period.[21] (…)

5. Can you provide a within-sample prediction test?

We assessed the performance of assumptions RW1 and RW2 as follows. To test between models is preferred to calculate the Deviance Information Criterion (DIC) and the effective number of parameters (pD) (Spiegelhalter et al., 2002), where the model with lower DIC is preferred. We found no huge differences in DIC values between the RW1 and RW2 assumption when fitting the models to Factory-Made and to Combined Unit Cigarettes per capita (CC). However, we compared the differences between observed and predicted CC during the period 1991-2012 using the RW1 and

RW2 assumption. We found that differences due to RW1 prediction were larger than those found using RW2 model (please see the Supplementary Figure S1 below).

If the Editor considers appropriate to include the figure in the manuscript, we propose to mention it at the end of the new sentences proposed on page 6:

“(…) We found that model with RW of order 2 showed less variability in the within sample prediction of the observed cigarettes per capita in 1991-2012, and then the RW of order 2 assumption was used (See Supplementary Figure S1). (…)”

REF:

Spiegelhalter D, Best N, Carlin B, van der Linde A. Bayesian measures of model complexity and fit (with discussion). *J Royal Statistical Society (series B)*. 2002; 64(4): 583–639.

6. The usefulness of the methodological approach towards policy development should be made clear. Since our first objective was to describe and to predict trends in the consumption of manufactured and RYO cigarettes in Spain, with the available information on annual sales from 1991 up to date, a well-established time-series methodology should be used to assess the burden of cigarette consumption.

The long-run relationship between manufactured and RYO must be extrapolated using the most reliable hypothesis on the time trend. This hypothesis can be implemented in the statistical modelling through Bayesian autoregressive assumption. Combining this statistical modelling with the hypothesis generated through the observed trends, more attention could be paid to develop concrete strategies in the line of the results presented: higher taxation and information on the health effects, with emphasis in specific populations.

We have expanded with two sentences at the end of the Discussion section:

“(…) We have used a well-established time-series methodology to assess cigarette consumption over time. The statistical modelling through Bayesian autoregressive assumption appears a useful method to assess the long-run relationship between manufactured and RYO cigarettes. (…)”

Reviewer: 2

1. The only change I would recommend is a table indicating the effect of the constraints on relative rate of RYO use; those that would lead to an overestimate, and those that lead to an underestimate (my reading is that the constraints lead to a net underestimate of RYO use).

We have drawn the suggested table. Data indicate that the net RYO and conventional cigarettes estimated according to the constraints of the Bayesian model per each year (1991-2012) were similar to the figures observed (please see the supplementary table S1 below). We are inclined not to include the table but add a sentence in the Discussion section (page 11 of the new version) as follows:

“(…) Moreover, the net estimations of manufactured and RYO cigarettes according to the constraints of the Bayesian model were similar to the data observed per each year (data not shown).”

Table S1. Manufactured cigarettes and RYO cigarettes observed and estimated according to the constraints of the Bayesian model.

Year	Observed data	Estimated data*	Observed data	Estimated data*
	Manufactured cigarettes RYO			
	cigarettes % of RYO			
	from overall Manufactured cigarettes RYO			
	cigarettes % of RYO			
	from overall			
1991	7.55	0.07	0.88	7.55
1992	7.09	0.07	0.95	7.09
1993	6.49	0.07	1.09	6.45
1994	6.92	0.09	1.27	6.89
1995	6.43	0.10	1.54	6.41
1996	6.09	0.10	1.64	6.02
1997	6.55	0.12	1.81	6.51
1998	7.22	0.13	1.76	7.21
1999	7.07	0.16	2.15	7.01
2000	7.14	0.18	2.47	7.09
2001	7.23	0.26	3.46	7.15
2002	7.19	0.25	3.30	7.12
2003	7.19	0.29	3.94	7.12
2004	7.15	0.36	4.85	7.12
2005	6.99	0.44	5.92	6.91
2006	6.68	0.41	5.80	6.61
2007	6.50	0.47	6.80	6.45
2008	6.47	0.59	8.38	6.51
2009	5.77	0.78	11.87	5.68
2010	5.13	0.76	12.98	5.14
2011	4.26	0.71	14.35	4.27
2012	3.78	0.92	19.62	3.71

*Expected figures estimated through simulation from RW2 model fit.

Reviewer: 3

1. The authors do not provide sufficient evidence that their calculation of the basic unit of analysis (per capita units of cigarettes) is valid or reliable for the RYO category. They rely on 2008 RYO surveillance data to convert bags/cans/packs sold into a common weight unit (kg of product), then use a sensitivity approach for estimation of the analytic unit (number of RYO cigarettes). Give the much more highly standardized weight of tobacco in manufactured cigarettes, why not convert manufactured cigarettes sales into per capita weight units and analyze trends on that measure, obviating the need to estimate the yield of RYO cigarettes from a weight value? The authors state that they were “able to estimate the sales of rolling tobacco in kg of product for all the studied period” (p. 4, line 41), so why wasn’t this used as the basis for the unit of analysis without converting to cigarette units?

We appreciate the reviewer’s comment. Nevertheless, it is also true that previous studies in this topic have used cigarette units (as referenced in the manuscript). Thus, the use of cigarettes per capita allows the comparison across studies. Moreover, the more common form to smoke is using cigarettes, and hence the results in this way are more practical for its use and application for tobacco control.

Thus, we are inclined to maintain the analysis in cigarette units.

2. Estimation of the common weight of 50g per unit is described but please provide documentation that a “package” = a “bag” = a “can” (p. 4).

No systematic information on the weight of the packages, bags and cans are provided in the registries for each year. We based our assumption in the data from 2008, because for that year the

Commission provided the figures both in kg and in bags/cans (http://www.cmtabacos.es/wwwcmt/verEstadistica.php?a=2009&f=2009_comun-u and http://www.cmtabacos.es/wwwcmt/verEstadistica.php?a=2008&f=2008_comun-u). This was already explained in the Methods section but no source was referenced, which now we have included. Please see page 5 of the new version of the Manuscript and the list of references (#15 & #16).

3. The authors do not account for the consumption of pipe tobacco, which for many years was used in RYO cigarettes as the low-cost alternative to manufactured cigarettes. How do trends in pipe tobacco consumption affect the reported RYO trends?

We thank the reviewer for this comment. We had already recognised a possible underestimation of RYO trends in the limitations' section due to no consideration of pipe tobacco in our estimations. Although there is no way to know how much of the tobacco pipe were used to make RYO cigarettes, we do know that the use of pipe tobacco in Spain is almost marginal: less than 1% of the Spanish smoking population uses pipes, according to repeated National Health Interview Surveys (Bilal et al., 2009) and correspondingly the sales are very low.

In addition, the market share of pipe tobacco supports it. Pipe tobacco have had a low market share, being approximately a quarter of the sales of fine-cut tobacco by 1991-1993, and going down until 2009 (3.6% of sales of fine-cut tobacco in 2009); then it started to go up in 2010, being 7% of sales of fine-cut tobacco that year, reaching a peak in 2011, with 27.7% of sales of fine-cut tobacco that year, and then going down again, being 13.6% of sales observed for fine-cut tobacco in 2012, and 7.7% of fine-cut tobacco sales in 2013.

We think that the contribution of pipe tobacco to RYO cigarette consumption may have been greater in 2011-2012, when this increase of sales occurred, by presumably more use of this kind of tobacco by RYO cigarette users. These data coincide with the economical crisis in Spain. But, as mentioned before, it is not possible to know which proportion of this tobacco was used to make RYO cigarettes and in any case appears to be marginal.

We now provided information on the prevalence of pipe users in the Discussion section and the corresponding reference:

“(…) Fourth, pipe tobacco can be also used to make roll-your-own cigarettes, so their unitary estimations may be slightly underestimated, although less than 1% of the Spanish population smoked pipes.[30](…)”

REF: Bilal U, Fernández E, Beltran P, Navas-Acien A, Bolumar F, Franco M. Validation of a method for reconstructing historical rates of smoking prevalence. *Am J Epidemiol.* 2014;179:15-9.

4. Other than acknowledging this as a limitation, the authors do not attempt to quantify the impact of illicit trade on these trends, especially regarding the reported downward slope of manufactured cigarette sales. If possible, please add illicit sales estimates to the models.

Unfortunately, it is not possible to add illicit sales to our analyses, because we do not have reliable information about it. However, illicit trade of tobacco had hugely decreased in the last decades (Joossens & Raw, 2008) and in a European survey conducted in 2010 only 3.4% of Spanish smokers self-reported purchase from illicit source (Joossens et al. 2014). We have added a sentence to clarify this point in the Discussion section (page 10 of the new version):

“(…) On the other hand, official sales do not include smuggling and therefore a variable portion of the consumption is not being considered. However, smuggling had hugely decreased in the last decades[27] and in a European survey conducted in 2010 only 3.4% of Spanish smokers self-reported purchase from illicit source.[28](…)”

REFS:

Joossens L, Raw M. Progress in combating cigarette smuggling: controlling the supply chain. *Tob Control* 2008;17:399-404.

Joossens L, Lugo A, La Vecchia C, et al. Illicit cigarettes and hand-rolled tobacco in 18 European countries: a cross-sectional survey. *Tob Control* 2014;23:e17-23.

5. The statement, “a revision of studies providing data on the weight of roll-your-won cigarettes indicated median estimates ranging between 0.48 and 1.1 [25]” (p. 8-9) is not supported by reference #25, which is a duplicate of #24 in the reference list.

We are sorry for the mistake. We referred to another reference (an error in handling the references). We deleted the duplicate reference and put in its place the correct one for this statement, and further clarified it within the text. The correct reference is:

Gallus S, Lugo A, Ghislandi S, et al. Roll-your-own cigarettes in Europe: use, weight and implications for fiscal policies. *Eur J Cancer Prev* 2014;23:186–92. doi:10.1097/CEJ.000000000000010

VERSION 2 – REVIEW

REVIEWER	Tait, Peter Lincoln University, Agribusiness and Economics Research Unit
REVIEW RETURNED	30-Oct-2014

GENERAL COMMENTS	My concerns and recommendations for this manuscript have not expanded upon re-examination since originally reviewed. I consider that the authors have satisfactorily addressed those concerns and incorporated recommendations appropriately, and of those presented by the other reviewers. Therefore, I support publication of this manuscript to BMJ Open.
-------------------------	---