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Individual and environmental factors associated with death on cyclists involved in road crashes in Spain

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ABSTRACT

Objective: To quantify the magnitude of associations between cyclist fatalities and both cyclist- and environment-related characteristics in Spain during the first 24 hours after a crash.

Methods: We designed a case series study to analyze data for all 65,977 cyclists recorded between 1993 and 2013 in the Spanish Register of Road Crashes with Victims. To mitigate the effect of missing values, we used a multiple imputation procedure. Differences between regions were assumed and managed with a multilevel approach including cyclist and province levels. Incidence density ratios (IDR) with 95% confidence intervals (95%CI) were calculated with a multivariate Poisson model.

Results: Lack of helmet use was directly associated with death (IDR 1.43, 95%CI 1.25–1.64). Among other cyclist´s characteristics, age after the third decade of life was also directly associated with death, especially in older cyclists ("over 74" category, IDR 4.61, 95%CI 3.49–6.08). Work-related cyclists showed no differences compared to other types of cyclists. There was a direct association with death for crashes on rural roads and highways. Any adverse meteorological condition also showed a direct association but altered road surfaces were associated inversely. Crashes during night-time were directly associated with death, with its peak between 3:00 to 5:00 am (IDR 1.58, 95%CI 1.03–2.41).

Conclusions: We found strong associations between several cyclist- and environment-related variables and death, either directly or inversely. These variables should be considered in efforts to prioritize public health measures aimed at reducing the number of cycling-related fatalities.

Keywords: cyclist; risk factor; road crash; fatality

Word count: 2933

ARTICLE SUMMARY

Strengths and limitations of this study

- We used a nationwide database which contains information of nearly 66,000 cyclists.
- The database compiles huge information on the characteristics of the people involved, their vehicles and the environment.
- As the database is a police-based registry, it can be assumed that less serious crashes are underrepresented
- We had to cope with missing data, so information biases cannot be discarded even if we used a multiple imputation procedure.

BACKGROUND

Cycling is increasing as an alternative to private cars.[1] But it can also be harmful: there are about 5.5 times more traffic deaths per kilometer traveled by bicycle than by car.[2] In Spain, the number of people who use bicycles daily or almost daily has nearly doubled since the mid-2000s.[3] Although the annual number of cyclist deaths decreased from 75 to 58 between 2006 and 2015,[4] there are still peaks in certain years, highlighting the importance of cycling as a cause of death. Nevertheless, relatively few studies have aimed to quantify the association between different factors and cycling fatalities, given that most previous studies were based mainly on non-fatal injuries, and their results are far from consistent. Furthermore, for factors that have shown a clear association in one direction (for example, the protective effect of helmets) there is no consensus regarding the magnitude of effect.[5] The present study was designed to quantify the magnitude of the associations between cyclist- and environment-related characteristics and the likelihood of cyclist fatality within the first 24 hours post-crash in Spain between 1993 and 2013.

METHODS

We analyzed the case series comprising all 65,977 cyclists involved in road crashes recorded in the Spanish National Registry of Road Crashes with Victims between 1993 and 2013. Crashes in the autonomous cities of Ceuta and Melilla were excluded because of their specific characteristics and low mortality: both cities are located in northern Africa, and all road crashes involving cyclists occurred in urban areas. The aforementioned nationwide database, maintained and anonymized by the Spanish National Directorate of Traffic, contains information recorded by national police agents at the crash scene, and compiles information on the characteristics of the persons involved (e.g. age, sex), their vehicles (e.g. type, condition), and the environment (e.g. type of crash, road characteristics).[6] A detailed description of this database can be consulted in a previous publication.[7]

From this Registry we collected information about a subset of variables which, according to previous studies and based on univariate analysis, could be associated (directly or indirectly) with injury severity (see the list below). The categories used in our analysis of each variable are shown in parentheses, along with their original categories from the database (see Appendices A.1 and A.2 for frequencies).

Study variables

- Death within the first 24 hours after the crash (Yes/No)
- Helmet use (Yes/No)
- Age (3 to 94 years, stratified in 5-year subgroups except in the categories "under 10" and "75 and older")
- Sex (Male/Female)
- Psychophysical circumstances (No/Yes – including alcohol consumption with breath test, alcohol consumption without breath test, drug consumption, sudden illness, sleepiness or drowsiness, tiredness, or appearing worried, as perceived by the police officer –)
- Nationality (Spanish/Other – including French, Moroccan, German, British, Italian, Swiss, Belgian, Dutch, American, other Magreb countries, other countries –)
- Commission of infraction (None/Distraction/Incorrect use of lighting/Wrong way/Crossing into opposite lane/Incorrect turning/Illegal passing/Disregarding safety distance/Failure to yield right of way/Disregarding traffic lights/Disregarding stop

lights/Disregarding crossing signals/Disregarding other signals/Not signaling a maneuver/Entering traffic flow without caution/Cycling while standing/Cycling in parallel/Cycling off traffic lanes/Other)

- Reason for cycling (To or From work, Other work-related/Other reasons – leaving for or returning from vacation, leaving for or returning from holiday or long weekend, emergency, leisure –)

- Type of crash (Collision with moving vehicle/Other – collision with an obstacle including stopped vehicles, collision with a pedestrian, collision with an animal, overturning, running off the road, other type of crash –)

- Traffic lane characteristics (Intersection – T or Y configuration, X or + configuration, entrance ramp, exit ramp, traffic circle, other intersection – /Other – straightaway, gentle curve, unmarked sharp curve, marked sharp curve without posted speed limit, marked sharp curve with posted speed limit –)

- Area (Highway/Urban area/Community road)

- Meteorological conditions (Good weather/Any adverse circumstances – heavy fog, light fog, light rain, heavy rain, hail, snow, strong winds, other –)

- Road surface (Normal/Altered – shaded, wet, ice, snow, slick formed from water + dirt + oil, loose gravel, oil, other –)

- Time (stratified in 3-hour subgroups from 0:00–2:59 to 21:00–23:59 in the 24-h clock)

- Year (stratified backwards triennially from 2011–2013 until 1993–1995)

- Province (see below)

Statistical analysis

We built a fixed-effect multivariate Poisson regression model (a generalized linear model which uses log [rate] as the link function) to obtain adjusted incidence density ratios (IDR) of death for each category of every variable, to assess the magnitude of associations with cyclist death rates. IDR is a good estimate of the relative risk (RR) of death across categories of independent variables when, as in this analysis, the risk of death yields exactly the same value as the death rate for a fixed amount of persons-time (i.e., the number of cyclists involved in road crashes multiplied by the same follow-up period for all of them). For each IDR, its corresponding 95% confidence interval (95%CI) was also calculated.

Spain is divided in 50 provinces, which differ markedly regarding cycling density, cycler-friendly environment, socioeconomic conditions and health care facilities, among other important factors potentially related with cyclists' risk of death. Therefore, we first tested the hypothesis that the province level would explain a significant part on the total variance in the outcome variable (cyclist fatalities). For this purpose, we constructed both unilevel (Appendices A.3 and A.4) and multilevel (province level) empty models, and compared the variances explained by each. Significant differences ($P<0.001$ for the likelihood ratio test) between the two models were obtained, thus confirming our hypothesis. This led us to choose a multilevel multivariate model for the main results.

More than 25% of the data were missing for some variables (e.g. helmet use) (see Appendices A.1 and A.2 for details). The overall amount of these missing values may be explained by missing at random (MAR) and missing not at random (MNAR) mechanisms. Although we cannot compensate for MNAR values, we can control MAR values through a multiple imputation procedure. Therefore, we initially assumed that some missing values might be explained by the combination of the values observed for some of the remaining variables in the database. To test this assumption, for each variable with missing values we constructed a multivariate regression model with the existence or not of missing values as the dependent variable, and the observed values for the remaining variables as independent terms. In all cases we observed parameters of association significantly away from the null. These results supported our initial hypothesis and led us to build 50 files in which missing data were represented as stabilized variances estimated from different variables, according to the chained equations method described by van Buuren[8] and implemented with the ice command in Stata.[9] This is a community-contributed Stata command focused on simplifying the imputation of categorical variables. However, this procedure was unable to provide missing values for many categorical variables with more than two strata when the frequency of responses in different categories was low, and we thus opted to dichotomize these variables. Age was imputed based on its logarithm to maintain positive values, and its antilogarithm was then used to transform it into a categorical variable. We therefore built a multilevel (including cyclist-level and province-level) fixed-effect multivariate Poisson regression model for each of our 50 complete datasets to obtain adjusted incidence density ratios (IDR). We then used the community-contributed mim command for Stata[10] to combine the estimates obtained for each imputed file according to the Rubin method.[11]

All analyses were performed with Stata software (v. 14).[12]

RESULTS

Appendices A.1 and A.2 summarize descriptive information on cyclist- and crash/environment-related characteristics. Fatality was a rare event (2.49%). The male-to-female ratio was greater than 8:1. The main mechanism for crashes was collision with another vehicle (69.40%), and most crashes occurred in urban areas (60.71%) followed by highways (35.71%)

and community roads (3.58%). Although most crashes occurred during the day (83.44% between 9:00 and just before 21:00), many of them (47.48%) occurred shortly after the end of the morning and afternoon work shifts, i.e. from 12:00 to just before 15:00, and from 18:00 to just before 21:00.

Table 1 shows the IDR for the association between cyclist characteristics and the risk of death. A direct association was found with cyclists' age from the 30-to-34 years old group onward, and was greatest in the "over 74 years" category (IDR 4.61, 95%CI 3.49–6.08). Non-use of a helmet was associated with a 43.45% higher chance of death (IDR 1.43, 95%CI 1.25–1.64). Male gender, psychophysical circumstances, nationality other than Spanish, and committing an infraction (except for "distraction" and "disregarding safety distance") showed also a direct association with death. Work-related cyclists showed no differences compared to other types of cyclists (i.e., those who cycled as a leisure activity or for other reasons).

Table 1. Adjusted incidence-density ratios (IDR) for the association between cyclist-related variables and the risk of death in the first 24 hours after a road crash. Spain, 1993–2013.

Variable	Category	IDR	95% CI		P value	FMI**
Sex	Male*	1	-	-	-	-
	Female	0.82	0.68	1.00	0.047	0.019
Age	< 10	0.95	0.60	1.50	0.813	0.020
	10 a 14	1.02	0.75	1.38	0.906	0.038
	15 a 19	1.12	0.85	1.49	0.416	0.036
	20 a 24	0.97	0.70	1.33	0.832	0.047
	25 a 29*	1	-	-	-	-
	30 a 34	1.26	0.93	1.71	0.134	0.057
	35 a 39	1.79	1.35	2.39	0.000	0.035
	40 a 44	1.67	1.24	2.25	0.001	0.039
	45 a 49	1.85	1.37	2.48	0.000	0.035
	50 a 54	2.15	1.59	2.90	0.000	0.029

	55 a 59	2.91	2.17	3.90	0.000	0.033
	60 a 64	3.59	2.70	4.77	0.000	0.034
	65 a 69	4.49	3.43	5.89	0.000	0.034
	70 a 74	3.67	2.62	5.13	0.000	0.028
	> 74	4.61	3.49	6.08	0.000	0.038
Helmet use	Yes*	1	-	-	-	-
	No	1.43	1.25	1.64	0.000	0.091
Psychophysical circumstances	Normal*	1	-	-	-	-
	Altered	1.43	1.08	1.89	0.011	0.305
Nationality	Spaniard*	1	-	-	-	-
	Other nationality	1.39	1.18	1.62	0.000	0.016
Commision of infraction	None*	1	-	-	-	-
	Distracting conduction	0.73	0.58	0.90	0.004	0.004
	Incorrect use of lighting	1.54	0.96	2.45	0.072	0.007
	Wrong way driving	1.21	0.79	1.84	0.386	0.004
	Invading the opposite lane	2.04	1.57	2.66	0.000	0.004
	Incorrect turning	1.58	1.30	1.92	0.000	0.004
	Anti-regulation overtaking manoeuvers	2.15	1.30	3.54	0.003	0.001
	Close driving	0.45	0.20	1.01	0.052	0.003
	Not respecting priority	1.84	1.43	2.37	0.000	0.005
	Not respecting the signal of the traffic lights	1.47	0.88	2.43	0.140	0.016
	Not respecting the stop lights	2.61	2.09	3.26	0.000	0.003
	Not respecting crossing signals	1.70	1.05	2.74	0.031	0.001
	Not respecting other signals	2.95	1.39	6.24	0.005	0.017
	Not indicating a manoeuver	1.23	0.55	2.76	0.613	0.000
	Entering to traffic flow without precaution	1.96	1.39	2.76	0.000	0.004
	Driving stand up in a dangerous way	2.08	0.29	14.87	0.465	0.000
	Driving in parallel	1.95	1.07	3.56	0.030	0.002
	Driving off the traffic lanes	2.16	1.70	2.74	0.000	0.004
	Other	1.92	1.66	2.22	0.000	0.014
Reason for cycling	Work-related*	1	-	-	-	-
	Other reason	1.12	0.93	1.34	0.249	0.081

* Reference category

** Fraction of missing information

Table 2 shows the IDR for the association between environmental characteristics and the risk of death. There were no conclusive trends according to the type of crash (IDR 0.89, 95%CI

200 0.78–1.00), but cyclists traveling through an intersection, on rural roads (i.e., roads outside urban
201 areas) and on highways had a direct association with death. This association was also found with
202 adverse meteorological conditions. Nevertheless, when the road surface was altered, the
203 association was inverse. Direct association with death was found after midnight, with a peak
204 between 3:00 and 5:00 (IDR 1.58, 95%CI 1.03–2.41), whereas it was an inverse association at
205 midday between 12:00 and 14:00 (IDR 0.40, 95%CI 0.29–0.56). In the 10-year period analyzed
206 here, there was a trend toward higher chance of death in the earlier years.
207

208 **Table 2.** Adjusted incidence-density ratios (IDR) for the association between crash/environment-
209 related variables and the risk of death in the first 24 hours after a road crash. Spain, 1993–2013.

Variable	Category	IDR	95% CI		P value	FMI**
Type of crash	Collision*	1	-	-	-	-
	Other	0.89	0.78	1.00	0.056	0.013
Traffic lane characteristics	Intersection*	1	-	-	-	-
	Other	1.65	1.46	1.87	0.000	0.007
Area	Highway*	1	-	-	-	-
	Urban area	0.18	0.16	0.21	0.000	0.016
	Community road	0.61	0.48	0.76	0.000	0.002
Meteorological conditions	Good weather*	1	-	-	-	-
	Any adverse circumstances	1.36	1.07	1.72	0.011	0.005
Traffic lane surface	Normal*	1	-	-	-	-
	Altered	0.75	0.59	0.96	0.022	0.006
Time of the day (hours)	0:00-2:59*	1	-	-	-	-
	3:00-5:59	1.58	1.03	2.41	0.036	0.010
	6:00-8:59	0.78	0.54	1.11	0.165	0.013
	9:00-11:59	0.46	0.33	0.64	0.000	0.015
	12:00-14:59	0.40	0.29	0.56	0.000	0.015
	15:00-17:59	0.45	0.32	0.63	0.000	0.013
	18:00-20:59	0.49	0.35	0.68	0.000	0.013
	21:00-23:59	0.61	0.43	0.87	0.006	0.013
Years	2011 - 2013*	1	-	-	-	-

	2008 - 2010	1.34	1.07	1.68	0.011	0.012
	2005 - 2007	2.11	1.71	2.61	0.000	0.015
	2002 - 2004	2.16	1.75	2.67	0.000	0.012
	1999 - 2001	2.42	1.97	2.99	0.000	0.011
	1996 - 1998	2.30	1.86	2.84	0.000	0.012
	1993 - 1995	2.67	2.17	3.28	0.000	0.015
* Reference category						
** Fraction of missing information						

DISCUSSION

Our results are generally in agreement with those of previous studies regarding the direction and magnitude of the associations between cyclist- and environment-related factors and the severity of crashes involving cyclists.[5,13-25] Perhaps our most important finding is the association between non-use of a helmet and a higher chance of death. Although the protective effect of helmet use on the risk of head trauma is widely accepted,[13,22] this effect has not been shown for risk of death given that relatively few studies to date have focused on this association, and their results are inconsistent.[5] Although our study is observational and causality cannot be demonstrated, it is unlikely that residual confounding could entirely explain an association of the magnitude we observed. We are confident that our approach to the analysis was robust given that it included appropriate management of missing values, controlling for between-province-level variance, and multivariate adjustment for most well-known confounders of the association between helmet use and death. Therefore, taking into account that helmet use is the most easily modifiable cyclist-dependent risk factor, our results suggest that a non-negligible amount of cyclist deaths might be prevented by increasing helmet use in our population of cyclists.

Regarding other cyclist-related variables, the association we found between age and risk of death is consistent with previous studies.[14,18,19,25] This association is usually explained on the basis of mechanisms such as greater fragility, loss of physical agility, decreased visual acuity and concomitant diseases. In contrast to other authors,[23,26] we found no association between young age and death.

In relation to gender, we found that hazard of death was higher for males, as it was reported previously.[17,25,26] This association has been explained as a result of either physical differences or safer behaviors in females,[16] which may be associated with the severity of the crash itself. However, some authors have not observed this association[18,19] or have found an association in the opposite direction.[14]

We identified a direct association between alcohol consumption, along with other psychophysical circumstances, and death, which was also noted previously.[19,24] According to some authors, alcohol consumption is associated with risky behaviors[15,21] when cycling and driving other types of vehicles. However, the association found in our study should be viewed with caution because of potential shortcomings in the validity of our data source. The low number of cyclists in the original categories for this variable forced us to combine alcohol consumption, drug consumption, tiredness, sleepiness and other psychophysical circumstances into the single category "altered", obscuring the true association between each type of psychophysical circumstance and death. Non-Spanish nationality also showed a higher probability of death, but this should likewise be interpreted with care. We could not obtain information about cyclists' expertise, and for non-Spanish cyclists, we did not know how long they had been living in Spain, or whether they had changed their cycling patterns while living abroad. Furthermore, all non-Spanish cyclists were clustered in a single subgroup which included people from countries which may differ widely in a large variety of aspects such as social and cultural characteristics as well as cycling infrastructure in their country of origin. This subgroup

251 was thus too heterogeneous for informative comparisons. Consequently, the association found in
252 our study undoubtedly deserves further research designed to address its underlying factors.

253 Like Kim and colleagues,[20] we observed that committing an infraction was directly
254 associated with death, except for the "distraction" and "disregarding safety distance" categories.
255 In relation with the reason for cycling, we found no associations with chance of death. However,
256 previous studies showed a lower risk of fatalities in work-related cyclists associated with their
257 expertise, their choice of safer routes and their helmet use, [17] and a higher risk was associated
258 with higher exposure in terms of kilometers traveled.[14] Although most authors have reported
259 different risks of injury depending on the type of crash,[14,17-19,23] in the present study the direct
260 association with death observed for collisions was not significantly different than for other types
261 of crashes (IDR 0.89, 95%CI 0.78–1.00). Nevertheless, because type of crash was a binary
262 variable in our analysis (see section 2.2 Analysis), all other types of collisions were included in a
263 single category and compared to other types of crashes (such as running over or overturning),
264 hence the two groups were heterogeneous. Furthermore, unless the cyclist is fatally injured,
265 cyclists are probably more likely to receive police assistance when they collide with another
266 vehicle. Therefore cyclists who sustained minor injuries in the "other crashes" category were
267 likely to be underrepresented in our sample.

268 Regarding environment-related variables, in accordance with some findings[14,19] we
269 identified an inverse association between intersections and death compared to other places
270 (straight roads or curves). But again, our two categories were heterogeneous, and there may be
271 very different risks for different types of intersections.[27]

272 The location of the crash showed a close relationship with fatalities. As in previous
273 studies,[14,19,23] there was a direct association between rural roads and highways, and death. This

association is probably related with the speeds reached by cyclists or the other vehicles involved in crashes.

Adverse meteorological conditions were directly associated with death, as reported by other authors.[20] This association is probably due to lower cyclist conspicuity under adverse weather conditions. On the other hand, altered road surfaces were inversely associated with risk of death, which may be a result of cycling or driving at lower speeds. More research is needed to characterize the influence of weather and road conditions on risk of death among cyclists, given that our findings differ from previous studies.[19]

Although the frequency of crashes was much greater during daylight hours, there was a direct association between night hours and death, with a peak in the early morning hours.[14] Apart from lack of conspicuity,[28] factors such as alcohol consumption, speed and exhaustion may play major roles in this association.[29] Finally, the lower risk of death in crashes recorded in more recent years may be explained by improvements in cycling infrastructure,[28] improved health care for injured cyclists,[1] and increased reporting of less serious road crashes by the police.

Limitations

A main limitation of our study is its observational nature, which prevents us from suggesting causal interpretations of the associations we found. Given that our analysis is based on information from a police-based registry designed to collect information on all types of road traffic crashes, as noted in the Methods section, selection bias is an important issue because it can be assumed that less serious crashes were underrepresented.[30-33] Although we used a multiple imputation procedure to address missing information, this method only partially resolves issues related with missing data; therefore our results may still be affected by biases of an undetermined magnitude. Information bias is also a potential limitation, due to the subjective nature of some variables recorded by police officers at the scene of the crash.

Finally, the lack of information regarding vehicle speed is an important limitation in our study. Although this is probably the most important factor affecting the severity of cyclists' injuries, no direct information was available for vehicle speed when the crash occurred.

CONCLUSIONS

We found strong associations between several cyclist- and environment-related variables and the probability of death, and suggest that these associations should be taken into account in efforts to prioritize public health measures aimed at reducing the number of cycling-related fatalities. In particular, we believe helmet use by cyclists needs to be encouraged. Although we are aware that the magnitude of the association between non-helmet use and death is not entirely causal, it supports the hypothesis that helmet use may significantly reduce the risk of death among cyclists involved in road crashes. Although using a helmet is now mandatory for all cyclists on open roads in Spain, our data show that even in recent years, the proportion of non-helmet-use has been non-negligible. Another topic which deserves attention is the risk in older cyclists, considering that this subgroup of cyclists will very likely grow in the coming years. Finally, the reasons for the higher risk of death during nighttime cycling merit further investigation in order to manage factors which are potentially modifiable by, for example, encouraging measures to improve the conspicuity of cyclists.

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Author Contributions: All authors meet the conditions for authorship. PLC conceived and designed the study, helped to redact the manuscript and performed a critical revision. DMS and VMR executed the revision of the literature and redacted the first draft of the manuscript. JPM, EMR and LMMR helped with the revision of the literature and critically reviewed the manuscript. EJM did a critical revision of the original manuscript, proposed corrections and did methodological contributions. All authors have approved the final version of this manuscript. The present article is part of the doctoral thesis of Daniel Molina-Soberanes at the University of Granada.

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KEY MESSAGES

What is already know on this subject

- Cycling is increasing but it can be harmful
- Helmets are intended to protect against injury severity, but its effect on death remains unclear.

What this study adds

- Helmet non-use is associated directly with death in cyclists, especially on highways
- Work-related cyclists showed no difference in their association with death than other cyclists
- As age increases, direct association with death increases, especially after the third decade of life.

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APPENDICES

Appendix A.1. Distribution of cyclist-related variables. Spain, 1993–2013.

Variable	Category: For analysis	Category: Original*	N	% Total	N	% Excluding missing values
Death	Yes		1,643	2.49	1,643	2.54
	No		62,969	95.44	62,969	97.46
	Unknown		1,365	2.07	-	-
	Total		65,977	100	64,612	100
Helmet use	Yes		17,183	26.04	17,183	35.38
	No		31,378	47.56	31,378	64.62
	Unknown		17,416	26.40	-	-
	Total		65,977	100	48,561	100
Age (years)	< 10		1,596	2.42	1,596	2.60
	10 - 14		6,073	9.20	6,073	9.89
	15 - 19		9,065	13.74	9,065	14.76
	20 - 24		6,130	9.29	6,130	9.98
	25 - 29		5,963	9.04	5,963	9.71
	30 - 34		5,797	8.79	5,797	9.44
	35 - 39		5,244	7.95	5,244	8.54
	40 - 44		4,632	7.02	4,632	7.54
	45 - 49		4,119	6.24	4,119	6.71
	50 - 54		3,357	5.09	3,357	5.46
	55 - 59		2,555	3.87	2,555	4.16
	60 - 64		2,256	3.42	2,256	3.67
	65 - 69		1,804	2.73	1,804	2.94
	70 - 74		1,361	2.06	1,361	2.22
	> 74		1,477	2.24	1,477	2.40
	Unknown		4,548	6.89	-	-
	Total		65,977	100	61,429	100
Sex	Male		55,901	84.73	55,901	87.13
	Female		8,259	12.52	8,259	12.87
	Unknown		1,817	2.75	-	-
	Total		65,977	100	64,160	100
Psychophysical circumstances	Normal		53,622	81.27	53,622	98.32
	Altered		915	1.39	915	1.68
		Alcohol consumption without breath test	*207*	*0.31*	*207*	*0.38*
		Alcohol	*190*	*0.29*	*190*	*0.35*

		consumption with breath test				
		Drug consumption	*32*	*0.05*	*32*	*0.06*
		Sudden illness	*137*	*0.21*	*137*	*0.25*
		Sleepiness or drowsiness	*36*	*0.05*	*36*	*0.07*
		Tired	*194*	*0.29*	*194*	*0.36*
		Worried	*119*	*0.18*	*119*	*0.22*
	Unknown		11,440	17.34	-	-
	Total		65,977	100	54,537	100
Nationality	Spanish		57,208	86.71	57,208	91.69
	Other		5,184	7.86	5,184	8.31
		French	*199*	*0.30*	*199*	*0.32*
		Moroccan	*632*	*0.96*	*632*	*1.01*
		German	*731*	*1.11*	*731*	*1.17*
		British	*298*	*0.45*	*298*	*0.48*
		Italian	*125*	*0.19*	*125*	*0.20*
		Swiss	*75*	*0.11*	*75*	*0.12*
		Belgian	*130*	*0.20*	*130*	*0.21*
		Dutch	*115*	*0.17*	*115*	*0.18*
		USA	*50*	*0.08*	*50*	*0.08*
		From other Maghreb countries	*91*	*0.14*	*91*	*0.15*
		From other countries	*2,738*	*4.15*	*2,738*	*4.39*
	Unknown		3,585	5.43	-	-
	Total		65,977	100	62,392	100
Commission of infraction	None		34,607	52.45	34,607	52.45
	Distraction		6,851	10.38	6,851	10.38
	Incorrect use of lighting		296	0.45	296	0.45
	Wrong way		1,335	2.02	1,335	2.02
	Crossing into opposite lane		1,200	1.82	1,200	1.82
	Incorrect turning		1,879	2.85	1,879	2.85
	Illegal passing		489	0.74	489	0.74
	Disregarding safety distance		676	1.02	676	1.02
	Not yielding right of way		1,595	2.42	1,595	2.42
	Disregarding traffic lights		1,558	2.36	1,558	2.36
	Disregarding stop lights		1,639	2.48	1,639	2.48
	Disregarding crossing signals		937	1.42	937	1.42
	Disregarding other signals		214	0.32	214	0.32
	Failure to signal a maneuver		157	0.24	157	0.24
	Careless merging		1,112	1.69	1,112	1.69
	Cycling while standing		22	0.03	22	0.03
	Cycling in parallel		213	0.32	213	0.32

	Cycling outside traffic lanes		914	1.39	914	1.39
	Other		10,283	15.59	10,283	15.59
	Total		65,977	100	65,977	100
Reason for cycling	Work-related		6,770	10.26	6,770	12.49
		To or from work	*2,395*	*3.63*	*2,395*	*4.42*
		Other work-related	*4,375*	*6.63*	*4,375*	*8.07*
	Other reason		47,450	71.92	47,450	87.51
		Leaving for or returning from vacation	*70*	*0.11*	*70*	*0.13*
		Leaving for or returning from holiday or long weekend	*606*	*0.92*	*606*	*1.12*
		Emergency	*156*	*0.24*	*156*	*0.29*
		Leisure	*34,396*	*52.13*	*34,396*	*63.44*
		Other	*12,222*	*18.52*	*12,222*	*22.54*
	Unknown		11,757	17.82	-	-
	Total		65,977	100	54,220	100

* Original categories are shown in italics, and their frequencies are included in the categories in the For analysis column.

4

Appendix A.2. Distribution of crash- and environment-related variables. Spain, 1993-2013

Variable	Category: For analysis	Category: Original*	N	% Total	N	% Excluding missing values
Type of crash	Collision with moving vehicle		45,791	69.40	45,791	69.90
	Other		19,722	29.89	19,722	30.10
		Collision with an obstacle (including stopped vehicles)	*2,127*	*3.22*	*2,127*	*3.25*
		Collision with a pedestrian	*4,404*	*6.68*	*4,404*	*6.72*
		Collision with an animal	*197*	*0.30*	*197*	*0.30*
		Overturning	*2,993*	*4.54*	*2,993*	*4.57*
		Running off the road	*2,753*	*4.17*	*2,753*	*4.20*
		Other	*7,248*	*10.99*	*7,248*	*11.06*
	Unknown		464	0.70	-	-
	Total		65,977	100	65,513	100
Traffic lane characteristics	Intersection		28,283	42.87	28,283	43.23
		T or Y configuration	*11,263*	*17.07*	*11,263*	*17.22*
		X or + configuration	*11,332*	*17.18*	*11,332*	*17.32*
		Entrance ramp	*603*	*0.91*	*603*	*0.92*
		Exit ramp	*377*	*0.57*	*377*	*0.58*
		Traffic circle	*3,792*	*5.75*	*3,792*	*5.80*

		Other intersection	*916*	*1.39*	*916*	*1.40*
	Other		37,139	56.29	37,139	56.77
		Straightaway	*30,220*	*45.80*	*30,220*	*46.19*
		Gentle curve	*3,945*	*5.98*	*3,945*	*6.03*
		Unmarked sharp curve	*1,533*	*2.32*	*1,533*	*2.34*
		Marked sharp curve without posted speed limit	*696*	*1.05*	*696*	*1.06*
		Marked sharp curve with posted speed limit	*745*	*1.13*	*745*	*1.14*
	Unknown		555	0.84	-	-
	Total		65,977	100	65,422	100
Area	Highway		23,561	35.71	23,561	35.71
	Urban area		40,056	60.71	40,056	60.71
	Community road		2,360	3.58	2,360	3.58
	Total		65,977	100	65,977	100
Meteorological conditions	Good weather		61,972	93.93	61,972	93.95
	Any adverse circumstances		3,991	6.05	3,991	6.05
		Heavy fog	*69*	*0.10*	*69*	*0.10*
		Light fog	*176*	*0.27*	*176*	*0.27*
		Light rain	*1,849*	*2.80*	*1,849*	*2.80*
		Heavy rain	*271*	*0.41*	*271*	*0.41*
		Hail	*5*	*0.01*	*5*	*0.01*
		Snow	*14*	*0.02*	*14*	*0.02*
		Strong winds	*385*	*0.58*	*385*	*0.58*
		Other	*1,222*	*1.85*	*1,222*	*1.85*
	Unknown		14	0.02	-	-

	Total		65,977	100	65,963	100
Road surface	Normal		60,835	92.21	60,835	92.58
	Altered		4,876	7.39	4,876	7.42
		Shaded	*283*	*0.43*	*283*	*0.43*
		Wet	*2,780*	*4.21*	*2,780*	*4.23*
		Ice	*65*	*0.10*	*65*	*0.10*
		Snow	*34*	*0.05*	*34*	*0.05*
		Slick formed from water + dirt + oil	*62*	*0.09*	*62*	*0.09*
		Loose gravel	*654*	*0.99*	*654*	*1.00*
		Oil	*289*	*0.44*	*289*	*0.44*
		Other	*709*	*1.07*	*709*	*1.08*
	Unknown		266	0.40	-	-
	Total		65,977	100	65,711	100
Time of day (hours)	0:00 - 2:59		972	1.47	972	1.47
		0:00 - 0:59	*419*	*0.64*	*419*	*0.64*
		1:00 - 1:59	*351*	*0.53*	*351*	*0.53*
		2:00 - 2:59	*202*	*0.31*	*202*	*0.31*
	3:00 - 5:59		401	0.61	401	0.61
		3:00 - 3:59	*144*	*0.22*	*144*	*0.22*
		4:00 - 4:59	*123*	*0.19*	*123*	*0.19*
		5:00 – 5:59	*134*	*0.20*	*134*	*0.20*
	6:00 - 8:59		3,580	5.43	3,580	5.43
		6:00 – 6:59	*328*	*0.50*	*328*	*0.50*
		7:00 – 7:59	*1,020*	*1.55*	*1,020*	*1.55*
		8:00 – 8:59	*2,232*	*3.38*	*2,232*	*3.38*
	9:00 - 11:59		12,582	19.07	12,582	19.07
		9:00 – 9:59	*3,180*	*4.82*	*3,180*	*4.82*
		10:00 – 10:59	*3,985*	*6.04*	*3,985*	*6.04*
		11:00 – 11:59	*5,417*	*8.21*	*5,417*	*8.21*
	12:00 - 14:59		15,753	23.88	15,753	23.88
		12:00 – 12:59	*6,059*	*9.18*	*6,059*	*9.18*

		13:00 – 13:59	*5,413*	*8.20*	*5,413*	*8.20*
		14:0 – 14:59	*4,281*	*6.49*	*4,281*	*6.49*
	15:00 - 17:59		11,144	16.89	11,144	16.89
		15:00 – 15:59	*3,232*	*4.90*	*3,232*	*4.90*
		16:00 – 16:59	*3,536*	*5.36*	*3,536*	*5.36*
		17:00 – 17:59	*4,376*	*6.63*	*4,376*	*6.63*
	18:00 - 20:59		15,572	23.60	15,572	23.60
		18:00 – 18:59	*5,134*	*7.78*	*5,134*	*7.78*
		19:00 – 19:59	*5,421*	*8.22*	*5,421*	*8.22*
		20:00 – 20:59	*5,017*	*7.60*	*5,017*	*7.60*
	21:00 - 23:59		5,973	9.05	5,973	9.05
		21:00 – 21:59	*3,304*	*5.01*	*3,304*	*5.01*
		22:00 – 22:59	*1,774*	*2.69*	*1,774*	*2.69*
		23:00 – 23:59	*895*	*1.36*	*895*	*1.36*
	Total		65,977	100	65,977	100
Years	2011 - 2013		16,315	24.73	16,315	24.73
		2013	*6,134*	*9.30*	*6,134*	*9.30*
		2012	*5,444*	*8.25*	*5,444*	*8.25*
		2011	*4,737*	*7.18*	*4,737*	*7.18*
	2008 - 2010		10,468	15.87	10,468	15.87
		2010	*3,766*	*5.71*	*3,766*	*5.71*
		2009	*3,618*	*5.48*	*3,618*	*5.48*
		2008	*3,084*	*4.67*	*3,084*	*4.67*
	2005 - 2007		7,826	11.86	7,826	11.86
		2007	*2,808*	*4.26*	*2,808*	*4.26*
		2006	*2,594*	*3.93*	*2,594*	*3.93*
		2005	*2,424*	*3.67*	*2,424*	*3.67*
	2002 - 2004		7,229	10.96	7,229	10.96
		2004	*2,576*	*3.90*	*2,576*	*3.90*

	2003	*2,340*	*3.55*	*2,340*	*3.55*
	2002	*2,313*	*3.51*	*2,313*	*3.51*
1999 - 2001		6,628	10.05	6,628	10.05
	2001	*2,239*	*3.39*	*2,239*	*3.39*
	2000	*2,038*	*3.09*	*2,038*	*3.09*
	1999	*2,351*	*3.56*	*2,351*	*3.56*
1996 - 1998		8,154	12.36	8,154	12.36
	1998	*2,543*	*3.85*	*2,543*	*3.85*
	1997	*2,817*	*4.27*	*2,817*	*4.27*
	1996	*2,794*	*4.23*	*2,794*	*4.23*
1993 - 1995		9,357	14.18	9,357	14.18
	1995	*3,149*	*4.77*	*3,149*	*4.77*
	1994	*3,206*	*4.86*	*3,206*	*4.86*
	1993	*3,002*	*4.55*	*3,002*	*4.55*
Total		65,977	100	65,977	100

* Original categories are shown in italics, and their frequencies are included in the categories in the For analysis column.

7

Appendix A.3. Adjusted incidence-density ratios (IDR) in a multivariate unilevel model for the imputed associations between cyclist-related variables and the risk of death in the first 24 hours after a road crash. Spain, 1993-2013.

Variable	Category	IDR	95% CI		P value	FMI**
Helmet use	Yes*	1	-	-	-	-
	No	1.41	1.23	1.62	0.000	0.091
Age	< 10	0.93	0.58	1.47	0.744	0.020
	10 a 14	1.02	0.75	1.38	0.904	0.038
	15 a 19	1.13	0.85	1.50	0.389	0.036
	20 a 24	0.98	0.71	1.34	0.879	0.046
	25 a 29*	1	-	-	-	-
	30 a 34	1.27	0.94	1.73	0.124	0.057
	35 a 39	1.81	1.36	2.41	0.000	0.035
	40 a 44	1.68	1.25	2.26	0.001	0.039
	45 a 49	1.85	1.37	2.49	0.000	0.036
	50 a 54	2.15	1.59	2.90	0.000	0.029
	55 a 59	2.92	2.18	3.91	0.000	0.033
	60 a 64	3.55	2.67	4.72	0.000	0.034
	65 a 69	4.43	3.38	5.81	0.000	0.034
	70 a 74	3.57	2.55	4.99	0.000	0.028
	> 74	4.48	3.39	5.91	0.000	0.038
Sex	Male*	1	-	-	-	-
	Female	0.82	0.68	1.00	0.045	0.019
Psychophysical circumstances	Normal*	1	-	-	-	-
	Altered	1.44	1.09	1.90	0.011	0.309
Nationality	Spaniard*	1	REF	REF	REF	REF
	Other nationality	1.37	1.16	1.61	0.000	0.017
Commission of infraction	None*	1	-	-	-	-
	Distraction	0.71	0.57	0.89	0.002	0.005
	Incorrect use of lighting	1.48	0.93	2.37	0.097	0.007
	Wrong way	1.19	0.78	1.82	0.423	0.004
	Crossing into opposite lane	2.00	1.53	2.60	0.000	0.004
	Incorrect turning	1.52	1.25	1.85	0.000	0.004
	Illegal passing	2.12	1.28	3.49	0.003	0.001

	Disregarding safety distance	0.44	0.20	0.99	0.047	0.003
	Failure to yield	1.77	1.38	2.28	0.000	0.005
	Disregarding traffic lights	1.44	0.87	2.39	0.161	0.016
	Disregarding stop lights	2.53	2.02	3.15	0.000	0.003
	Disregarding crossing signals	1.65	1.02	2.66	0.041	0.001
	Disregarding other signals	2.94	1.39	6.24	0.005	0.017
	Failure to signal a maneuver	1.19	0.53	2.66	0.679	0.000
	Careless merging	1.94	1.37	2.74	0.000	0.004
	Cycling while standing	2.01	0.28	14.39	0.487	0.000
	Cycling in parallel	1.89	1.04	3.46	0.038	0.002
	Cycling outside traffic lanes	2.09	1.64	2.66	0.000	0.004
	Other	1.89	1.63	2.19	0.000	0.014
Reason for cycling	Work-related*	1	-	-	-	-
	Other reason	1.13	0.94	1.36	0.204	0.081

* Reference category
** Fraction of missing information

11

12 **Appendix A.4.** Adjusted incidence-density ratios (IDR) in a multivariate unilevel model for the
13 imputed associations between crash- and environment-related variables and the risk of death in
14 the first 24 hours after a road crash. Spain, 1993-2013.

Variable	Category	IDR	95% CI		P value	FMI**
Type of crash	Collision*	1	-	-	-	-
	Other	0.89	0.78	1.00	0.058	0.014
Road characteristics	Intersection*	1	-	-	-	-
	Other	1.64	1.45	1.86	0.000	0.007
Area	Highway*	1	-	-	-	-
	Urban area	0.18	0.16	0.21	0.000	0.015
	Community road	0.59	0.47	0.74	0.000	0.003
Meteorological conditions	Good weather*	1	-	-	-	-
	Any adverse circumstances	1.37	1.08	1.73	0.009	0.005
Road surface	Normal*	1	-	-	-	-
	Altered	0.76	0.59	0.97	0.030	0.006
Time of day (hours)	0:00-2:59*	1	-	-	-	-
	3:00-5:59	1.55	1.01	2.38	0.043	0.009
	6:00-8:59	0.77	0.54	1.09	0.141	0.012
	9:00-11:59	0.45	0.33	0.64	0.000	0.014
	12:00-14:59	0.40	0.28	0.55	0.000	0.014
	15:00-17:59	0.45	0.32	0.63	0.000	0.012
	18:00-20:59	0.48	0.35	0.67	0.000	0.012
	21:00-23:59	0.60	0.43	0.85	0.004	0.012
Years	2011 - 2013*	1	-	-	-	-
	2008 - 2010	1.34	1.07	1.69	0.010	0.012
	2005 - 2007	2.10	1.70	2.60	0.000	0.015
	2002 - 2004	2.16	1.75	2.68	0.000	0.012
	1999 - 2001	2.42	1.96	2.98	0.000	0.010
	1996 - 1998	2.31	1.87	2.85	0.000	0.012
	1993 - 1995	2.67	2.17	3.29	0.000	0.015
Province	Alava	1	-	-	-	-
	Albacete	1.51	0.80	2.87	0.206	0.004
	Alicante	1.02	0.61	1.71	0.928	0.004
	Almería	1.61	0.92	2.83	0.095	0.006
	Ávila	0.29	0.07	1.25	0.097	0.001
	Badajoz	1.96	1.06	3.62	0.032	0.007
	Baleares	1.25	0.76	2.07	0.373	0.005

Barcelona	1.01	0.62	1.64	0.974	0.009
Burgos	1.35	0.76	2.43	0.308	0.003
Cáceres	1.48	0.64	3.39	0.360	0.002
Cádiz	1.04	0.56	1.91	0.907	0.007
Castellón	1.08	0.61	1.91	0.798	0.005
Ciudad Real	1.28	0.71	2.31	0.417	0.005
Córdoba	1.12	0.60	2.10	0.715	0.003
Coruña, La	1.12	0.62	2.02	0.714	0.003
Cuenca	2.95	1.45	6.02	0.003	0.003
Girona	1.07	0.62	1.85	0.799	0.006
Granada	1.18	0.66	2.10	0.584	0.005
Guadalajara	1.91	0.76	4.80	0.169	0.001
Guipúzcoa	0.65	0.36	1.18	0.157	0.003
Huelva	0.89	0.41	1.93	0.774	0.002
Huesca	1.36	0.70	2.66	0.365	0.003
Jaen	1.41	0.65	3.04	0.386	0.003
León	1.49	0.88	2.54	0.140	0.004
Lleida	1.38	0.75	2.57	0.302	0.003
La Rioja	2.15	1.18	3.92	0.013	0.003
Lugo	1.16	0.60	2.25	0.654	0.003
Madrid	1.10	0.66	1.82	0.725	0.006
Málaga	1.24	0.69	2.21	0.474	0.004
Murcia	1.76	1.05	2.94	0.031	0.005
Navarra	1.91	1.08	3.41	0.027	0.005
Orense	1.96	1.04	3.67	0.037	0.003
Asturias	0.76	0.43	1.33	0.335	0.004
Palencia	1.24	0.63	2.42	0.537	0.004
Palmas, Las	1.70	0.93	3.08	0.084	0.003
Pontevedra	0.96	0.52	1.75	0.886	0.003
Salamanca	1.49	0.74	2.99	0.261	0.003
Santa Cruz	1.43	0.76	2.73	0.270	0.003
Cantabria	0.97	0.53	1.75	0.909	0.004
Segovia	1.53	0.69	3.41	0.298	0.006
Sevilla	1.38	0.82	2.35	0.230	0.003
Soria	1.81	0.72	4.56	0.207	0.002
Tarragona	1.52	0.91	2.54	0.111	0.005
Teruel	1.77	0.74	4.24	0.201	0.002
Toledo	2.37	1.36	4.12	0.002	0.003
Valencia	1.28	0.78	2.10	0.324	0.005
Valladolid	1.58	0.87	2.86	0.134	0.004

Vizcaya	0.68	0.37	1.22	0.193	0.003
Zamora	2.54	1.36	4.73	0.003	0.004
Zaragoza	1.71	0.99	2.95	0.056	0.005

* Reference category
** Fraction of missing information

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*4*
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	N/A
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	7
		(*c*) Explain how missing data were addressed	7
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Supplementary tables
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8

		(b) Indicate number of participants with missing data for each variable of interest	Supplementary tables
Outcome data	15*	Report numbers of outcome events or summary measures	8
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9
		(*b*) Report category boundaries when continuous variables were categorized	Supplementary tables
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	12
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Individual and environmental factors associated with death of cyclists involved in road crashes in Spain: a cohort study

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ABSTRACT

Objective: To quantify the magnitude of associations between cyclist fatalities and both cyclist- and environment-related characteristics in Spain during the first 24 hours after a crash.

Design: Cohort study

Setting: Spain

Participants: 65,977 cyclists injured in road crashes recorded between 1993 and 2013 in the Spanish Register of Road Crashes with Victims

Main outcome: Death within the first 24 hours after the crash

Methods: A multiple imputation procedure was used to mitigate the effect of missing values. Differences between regions were assumed and managed with multilevel analysis at the cyclist and province levels. Incidence density ratios (IDR) with 95% confidence intervals (95%CI) were calculated with a multivariate Poisson model.

Results: Non-use of a helmet use was directly associated with death (IDR 1.43, 95%CI 1.25–1.64). Among other cyclist characteristics, age after the third decade of life was also directly associated with death, especially in older cyclists ("over 74" category, IDR 4.61, 95%CI 3.49–

6.08). The association with death did not differ between work-related cycling and other reasons for cycling.

There was an inverse association with death for crashes in urban areas and on community roads. Any adverse meteorological condition also showed a direct association with death, whereas altered road surfaces showed an inverse association. Crashes during nighttime were directly associated with death, with a peak between 3:00 and 5:59 am (IDR 1.58, 95%CI 1.03–2.41).

Conclusions: We found strong direct and inverse associations between several cyclist- and environment-related variables and death. These variables should be considered in efforts to prioritize public health measures aimed at reducing the number of cycling-related fatalities.

Keywords: cyclist; bicycling; injuries; fatality; risk factor; road crash

Word count: 4142

ARTICLE SUMMARY

Strengths and limitations of this study

- We used a nationwide database with information on 65,977 cyclists.
- The database compiles abundant information on the characteristics of the people involved, their vehicles and the environment.
- Because the database is a police-based registry, it can be assumed that less serious crashes are underrepresented.
- Because of missing data, information biases cannot be ruled out despite the multiple imputation procedure used.

INTRODUCTION

Cycling is considered a healthy alternative to private cars because it helps increase physical activity and reduce carbon emissions.[1] But it can also be harmful: there are about 5.5 times more traffic deaths per kilometer traveled by bicycle than by car.[2] In fact, cyclists along with pedestrians are the most vulnerable road users because of their lack of protection and comparatively greater likelihood of suffering severe injuries or dying after a crash.[3] These outcomes can be caused mainly by factors related to the cyclist (as in single-vehicle crashes) or related to other road users (as in collisions with other vehicles), or even by environment-related factors. Understanding the factors involved in cyclist injuries and deaths is necessary in order to design and promote better public policies worldwide to encourage safe cycling. The current transition in commuting patterns in Spain merits attention, because the number of people who use bicycles daily or almost daily has nearly doubled since the mid-2000s.[4] Public policies in this country promote cycling not only as a leisure activity, but as a regular mode of transport. Although the annual number of cyclist deaths decreased from 75 to 58 between 2006 and 2015,[5] this tendency is expected to revert in the absence of interventions aimed at making cycling a safer activity.

Many previous studies have identified individual and/or environmental factors associated with injury severity or fatalities among cyclists.[6-17] However, there is no consensus regarding the magnitude or even the direction of some observed associations. Death is sometimes considered the most severe injury category along with other serious injuries, rather than as a specific category itself.[6–8,10,15] Because death of one or more cyclists after a crash is uncommon, some studies found no statistically significant associations between this outcome and a number of variables,[6] and multivariate analysis was not possible in some studies because of the small numbers involved.[15] In studies that did report significant associations, the findings may still be debatable: recent metaanalyses have consistently shown an inverse association between helmet use and head injury severity, although these studies focused mainly on non-fatal injuries.[18,19] Olivier and Creighton[18] found only two studies that reported effect sizes for fatalities, and Høye[19] was obliged to merge fatalities with serious injuries in a single category for most of her analyses.

Regarding age and gender differences, the biological effect of aging is a plausible cause for the association between cyclist involvement in a road crash and greater injury severity,[7–11,13,15,17] but the relationship between age and death in some age groups (e.g. children or adolescents) awaits clarification.[8,12,13,15,17] Both males[12,15,17] and females[11] have been reported to be at increased risk of more severe injuries. Physical and behavioral aspects related to gender have been argued to explain differences in injury severity,[20–22] but there is no consensus.

Although alcohol consumption is known to be associated with risky behavior while cycling,[23,24] studies focusing on the association between this factor and injury severity or fatality are inconclusive.[9,11,13,16,17] The commission of infractions is reportedly associated with injury severity or death, but only in bicycle collisions with a motor vehicle, not on other types of crashes.[9]

Environmental factors can also play a major role as independent variables in fatal outcomes. Traffic lane characteristics, e.g. intersections as opposed to open roadways, are usually related to an increased risk of collision but not necessarily with more severe injuries [10,11,13] except in unsignalized intersections.[8] Road surface and adverse weather circumstances appear to be related to the likelihood of crashes, but their association with injury severity or death also requires clarification, given that previous studies have found both a direct association with injuries or death[8,9,13] and no association.[6,10–12] Time of day is related to conspicuity, and has been linked to crash rates. However, the association found for injury severity has not shown a clear direction: a direct association with severity has been reported during daytime[6,9,13] and during nighttime,[8,10] with some analyses finding no association at all.[11,12]

It seems obvious that cycling speed would be related to death after a crash. Because it is almost impossible to measure speed at the time of the crash, proxy variables such as speed limit at the site of the crash,[9,10,12,13] or the area of the crash[6,10,13] have been widely used. In fact, speed may be the main reason for the greater severity of cyclists' injuries in crashes involving a motor vehicle compared to single crashes, as reported in previous studies.[11,12,15]

Previous research in Spain has focused on impacts on cyclists' health,[25,26] their behavior and other correlates with crash involvement,[20,21,27,28] and the causal chain of events related to death after a crash.[29] However, to our knowledge there have been no attempts to analyze personal and environmental characteristics and their relationship with the risk of death.

To help fill the gaps in our current knowledge, we designed a large nationwide study to quantify the magnitude of the associations between cyclist- and environment-related characteristics and the likelihood of cyclist fatality within the first 24 hours post-crash in Spain between 1993 and 2013.

METHODS

Data source and study population

139 We analyzed the cohort comprising all 65,977 cyclists involved in road crashes recorded in the Spanish National Registry of Road Crashes with Victims between 1993 and 2013 once the crashes in the autonomous cities of Ceuta and Melilla were excluded because of their specific characteristics and low mortality: both cities are located in northern Africa, and all road crashes involving cyclists occurred in urban areas.

144 The aforementioned registry is a nationwide electronic database maintained by the Spanish General Directorate of Traffic. It has high security standards to protect anonymity, and was developed to support the design and evaluation of public policies concerning road safety. Researchers can use this data upon specific request, after a motivation letter is accepted by the Directorate authorities. This database contains information from the Statistical Questionnaire of the Accident documents submitted for every crash resulting in injury or death and involving at least one moving vehicle in areas subject to traffic laws. Information in the registry includes the characteristics of the persons involved (e.g. age, sex), their vehicles (e.g. type, condition), and the environment (e.g. type of crash, geographic coordinates, road characteristics). It does not include information that may lead to personal identification. Victims are categorized as injured if they are seen by a health care service, or as dead if they die at the crash scene or within the first 30 days. This questionnaire is completed by national police agents at the crash scene, and filed within the first 24 hours for crashes that result in death or severe injury (needing hospitalization), or within the next 10 days after the crash. All data must be submitted within the first 30 days post-event, including follow-up information from health care services. Amendments to the infrastructure data recorded at the crash scene can be made within the next 30 days by the appropriate authorities.[30]

Patient and public involvement

This study relies on data collected by the Spanish General Directorate of Traffic; no patients or participants interacted with the study authors.

Variables

We collected information about a subset of variables which, according to previous studies and based on univariate analysis, may be associated directly or indirectly with injury severity. Our dependent variable was death within the first 24 hours after the crash as our main outcome, and the independent variables were cyclist-related (age, sex, helmet use, psychophysical circumstances, nationality, commission of infraction and reason for cycling) and crash- or environment-related (type of crash, traffic lane characteristics, area, meteorological conditions, road surface, time of day, year and province). Original categories and dichotomized categories (see "Statistical analysis") can be viewed in the frequency distribution tables (Table 1 and Table 2).

Statistical analysis

Univariate analysis was first done for each variable included as an independent variable and for death as the dependent variable. Then we built a Poisson regression model (a generalized linear model which uses log [rate] as the link function). Spain is divided in 50 provinces which differ markedly regarding cycling density, cycler-friendly environment, socioeconomic conditions and health care facilities, among other important factors potentially related with cyclists' risk of death. Therefore, we first tested the hypothesis that the province level would explain a significant part on the total variance in the outcome variable (cyclist fatalities). For this purpose, we constructed both unilevel (Appendices 1 and 2) and multilevel empty models (including cyclist-level and province-level), and compared the variances explained by each. Significant differences (P<0.001 for the likelihood ratio test) between the two models were obtained, thus confirming our hypothesis. This led us to choose a multilevel multivariate model for the main results.

More than 25% of the data were missing for some variables (e.g. helmet use) (see Tables 1 and 2 for details). The overall amount of these missing values may be explained by missing at random (MAR) and missing not at random (MNAR) mechanisms. Although we cannot compensate for MNAR values, we can control MAR values through a multiple imputation procedure. Therefore, we initially assumed that some missing values might be explained by the combination of the values observed for some of the remaining variables in the database. To test this assumption, for each variable with missing values we constructed a multivariate regression model with the existence or not of missing values as the dependent variable, and the observed values for the remaining variables as independent terms. In all cases we observed parameters of association significantly away from the null. These results supported our initial hypothesis and led us to build 50 files in which missing data were represented as stabilized variances estimated from different variables, according to the chained equations method described by van Buuren[31] and implemented with the "ice" command in Stata.[32] This is a community-contributed Stata command focused on simplifying the imputation of categorical variables. However, this procedure was unable to provide missing values for many categorical variables with more than two strata when the frequency of responses in different categories was low, and we thus opted to dichotomize these variables. The dichotomization process considered theoretical similarities between original categories (e.g. any adverse weather circumstances such as rain, snow and hail were grouped in the category "any adverse circumstances") and tried to keep the most important category for analysis unaltered (e.g. intersections). Age was imputed based on its logarithm to maintain positive values, and its antilogarithm was then used to transform it into a categorical variable. We used this approach to build a multilevel fixed-effect multivariate Poisson regression model for each of our 50 complete datasets. Thus we obtain adjusted incidence density ratios (IDR) for death for each category of every variable, to assess the magnitude of associations with cyclist death rates. IDR is a good estimate of the relative risk (RR) of death across categories of independent variables when, as in this analysis, the risk of death yields exactly the same value as the death rate for a fixed amount of persons-time (i.e., the number of cyclists involved in road crashes multiplied by the same follow-up period for all of them). For each IDR, its corresponding 95% confidence interval (95%CI) was also calculated. We then used the community-contributed "mim" command for Stata[33] to combine the estimates obtained for each imputed file according to the Rubin method.[34]

All analyses were done with Stata software (v. 14).[35]

RESULTS

Table 1 and Table 2 summarize descriptive information on cyclist- and crash/environment-related characteristics. Fatality was a rare event (2.49%). The male-to-female ratio was almost 8:1. The main mechanism for crashes was collision with another vehicle (69.40%), and most crashes occurred in urban areas (60.71%), followed by highways (35.71%) and community roads (3.58%). Although most crashes occurred during the day (83.44% between 9:00 and just before 21:00), many of them (47.48%) occurred shortly after the end of the morning and afternoon work shifts, i.e. from 12:00 to just before 15:00, and from 18:00 to just before 21:00.

Table 1. Distribution of cyclist-related variables. Spain, 1993–2013.

Variable	Category	N	% Total	N	% Excluding missing values
Death	Yes	1,643	2.49	1,643	2.54
	No	62,969	95.44	62,969	97.46
	Unknown	1,365	2.07	-	-
	Total	*65,977*	*100*	*64,612*	*100*
Sex	Male	55,901	84.73	55,901	87.13
	Female	8,259	12.52	8,259	12.87
	Unknown	1,817	2.75	-	-
	Total	*65,977*	*100*	*64,160*	*100*
Age (years)	< 10	1,596	2.42	1,596	2.60
	10 - 14	6,073	9.20	6,073	9.89
	15 - 19	9,065	13.74	9,065	14.76
	20 - 24	6,130	9.29	6,130	9.98
	25 - 29	5,963	9.04	5,963	9.71
	30 - 34	5,797	8.79	5,797	9.44
	35 - 39	5,244	7.95	5,244	8.54
	40 - 44	4,632	7.02	4,632	7.54
	45 - 49	4,119	6.24	4,119	6.71
	50 - 54	3,357	5.09	3,357	5.46
	55 - 59	2,555	3.87	2,555	4.16
	60 - 64	2,256	3.42	2,256	3.67
	65 - 69	1,804	2.73	1,804	2.94
	70 - 74	1,361	2.06	1,361	2.22
	> 74	1,477	2.24	1,477	2.40
	Unknown	4,548	6.89	-	-
	Total	*65,977*	*100*	*61,429*	*100*
Helmet use	Yes	17,183	26.04	17,183	35.38
	No	31,378	47.56	31,378	64.62
	Unknown	17,416	26.40	-	-
	Total	*65,977*	*100*	*48,561*	*100*
Psychophysical circumstances	Normal	53,622	81.27	53,622	98.32
	Altered(1)	915	1.39	915	1.68
	Unknown	11,440	17.34	-	-
	Total	*65,977*	*100*	*54,537*	*100*
Nationality	Spanish	57,208	86.71	57,208	91.69

	Other nationality(2)	5,184	7.86	5,184	8.31
	Unknown	3,585	5.43	-	-
	Total	*65,977*	*100*	*62,392*	*100*
Commission of infraction	None	34,607	52.45	34,607	52.45
	Distraction	6,851	10.38	6,851	10.38
	Incorrect use of lighting	296	0.45	296	0.45
	Wrong way	1,335	2.02	1,335	2.02
	Invading the opposite lane	1,200	1.82	1,200	1.82
	Incorrect turning	1,879	2.85	1,879	2.85
	Illegal passing	489	0.74	489	0.74
	Disregarding safety distance	676	1.02	676	1.02
	Failure to yield right of way	1,595	2.42	1,595	2.42
	Disregarding traffic lights	1,558	2.36	1,558	2.36
	Disregarding stop lights	1,639	2.48	1,639	2.48
	Disregarding crossing signals	937	1.42	937	1.42
	Disregarding other signals	214	0.32	214	0.32
	Not indicating a maneuver	157	0.24	157	0.24
	Entering traffic flow without precaution	1,112	1.69	1,112	1.69
	Cycling while standing	22	0.03	22	0.03
	Cycling in parallel	213	0.32	213	0.32
	Cycling outside traffic lanes	914	1.39	914	1.39
	Other	10,283	15.59	10,283	15.59
	Total	*65,977*	*100*	*65,977*	*100*
Reason for cycling	Work-related	6,770	10.26	6,770	12.49
	Other reason(3)	47,450	71.92	47,450	87.51
	Unknown	11,757	17.82	-	-
	Total	*65,977*	*100*	*54,220*	*100*

(1) Including alcohol consumption with breath test, alcohol consumption without breath test, drug consumption, sudden illness, sleepiness or drowsiness, tiredness, or appearing worried, as perceived by the police officer

(2) Including French, Moroccan, German, British, Italian, Swiss, Belgian, Dutch, American, other Magreb countries, and other countries

(3) Including leaving for or returning from vacation, leaving for or returning from a holiday or long weekend, emergency, and leisure

Table 2. Distribution of crash- and environment-related variables. Spain, 1993–2013

Variable	Category	N	% Total	N	% Excluding missing values
Type of crash	Collision with moving vehicle	45,791	69.40	45,791	69.90
	Other(1)	19,722	29.89	19,722	30.10
	Unknown	464	0.70	-	-

	Total	*65,977*	*100*	*65,513*	*100*
Traffic lane characteristics	Intersection(2)	28,283	42.87	28,283	43.23
	Other(3)	37,139	56.29	37,139	56.77
	Unknown	555	0.84	-	-
	Total	*65,977*	*100*	*65,422*	*100*
Area	Highway	23,561	35.71	23,561	35.71
	Urban area	40,056	60.71	40,056	60.71
	Community road	2,360	3.58	2,360	3.58
	Total	*65,977*	*100*	*65,977*	*100*
Meteorological conditions	Good weather	61,972	93.93	61,972	93.95
	Any adverse circumstances(4)	3,991	6.05	3,991	6.05
	Unknown	14	0.02	-	-
	Total	*65,977*	*100*	*65,963*	*100*
Road surface	Normal	60,835	92.21	60,835	92.58
	Altered(5)	4,876	7.39	4,876	7.42
	Unknown	266	0.40	-	-
	Total	*65,977*	*100*	*65,711*	*100*
Time of day (24-hour clock)	0:00 - 2:59	972	1.47	972	1.47
	3:00 - 5:59	401	0.61	401	0.61
	6:00 - 8:59	3,580	5.43	3,580	5.43
	9:00 - 11:59	12,582	19.07	12,582	19.07
	12:00 - 14:59	15,753	23.88	15,753	23.88
	15:00 - 17:59	11,144	16.89	11,144	16.89
	18:00 - 20:59	15,572	23.60	15,572	23.60
	21:00 - 23:59	5,973	9.05	5,973	9.05
	Total	*65,977*	*100*	*65,977*	*100*
Years	2011 - 2013	16,315	24.73	16,315	24.73
	2008 - 2010	10,468	15.87	10,468	15.87
	2005 - 2007	7,826	11.86	7,826	11.86
	2002 - 2004	7,229	10.96	7,229	10.96
	1999 - 2001	6,628	10.05	6,628	10.05
	1996 - 1998	8,154	12.36	8,154	12.36
	1993 - 1995	9,357	14.18	9,357	14.18
	Total	*65,977*	*100*	*65,977*	*100*

(1) Including collision with an obstacle (e.g. stopped vehicles, pedestrians or animals), overturning, running off the road, or other types of crash
(2) Including T or Y configuration, X or + configuration, entrance ramp, exit ramp, traffic circle, or other intersections
(3) Including straightaway, gentle curve, unmarked sharp curve, marked sharp curve without posted speed limit, marked sharp curve with posted speed limit, or others

(4) Including heavy fog, light fog, light rain, heavy rain, hail, snow, strong winds, or other adverse meteorological conditions
(5) Including shaded, wet, ice, snow, slick formed from water + dirt + oil, loose gravel, oil, or other altered surfaces

Table 3 shows the IDR for the association between cyclist characteristics and the risk of death. A tendency towards a direct association between cyclists' age and death was observed from the third decade of life; the association was statistically significant (P<0.05) in categories from 35-to-39 years and older, and was greatest in the "over 74 years" category (IDR 4.61, 95%CI 3.49–6.08). Non-use of a helmet was associated with a 43.45% higher chance of death (IDR 1.43, 95%CI 1.25–1.64). Male gender, psychophysical circumstances, and nationality other than Spanish showed a direct association with death. Committing an infraction was, in general, directly associated with death. "Disregarding safety distance" and "distraction" were inversely associated with death, but this association was statistically significant only for the latter (P<0.05). The association for work-related cycling did not differ compared to other motives for cycling (i.e., for leisure or for other reasons).

Table 3. Adjusted incidence-density ratios (IDR) for the association between cyclist-related variables and the risk of death in the first 24 hours after a road crash. Spain, 1993–2013.

Variable	Category	IDR	95% CI		P value	FMI(2)
Sex	Male(1)	1	-	-	-	-
	Female	0.82	0.68	0.99	0.047	0.019
Age (years)	< 10	0.95	0.60	1.50	0.813	0.020
	10 - 14	1.02	0.75	1.38	0.906	0.038
	15 - 19	1.12	0.85	1.49	0.416	0.036
	20 - 24	0.97	0.70	1.33	0.832	0.047
	25 - 29(1)	1	-	-	-	-
	30 - 34	1.26	0.93	1.71	0.134	0.057

	35 - 39	1.79	1.35	2.39	< 0.001	0.035
	40 - 44	1.67	1.24	2.25	0.001	0.039
	45 - 49	1.85	1.37	2.48	< 0.001	0.035
	50 - 54	2.15	1.59	2.90	< 0.001	0.029
	55 - 59	2.91	2.17	3.90	< 0.001	0.033
	60 - 64	3.59	2.70	4.77	< 0.001	0.034
	65 - 69	4.49	3.43	5.89	< 0.001	0.034
	70 - 74	3.67	2.62	5.13	< 0.001	0.028
	> 74	4.61	3.49	6.08	< 0.001	0.038
Helmet use	Yes(1)	1	-	-	-	-
	No	1.43	1.25	1.64	< 0.001	0.091
Psychophysical circumstances	Normal(1)	1	-	-	-	-
	Altered	1.43	1.08	1.89	0.011	0.305
Nationality	Spanish(1)	1	-	-	-	-
	Other nationality	1.39	1.18	1.62	< 0.001	0.016
Commission of infraction	None(1)	1	-	-	-	-
	Distraction	0.73	0.58	0.90	0.004	0.004
	Incorrect use of lighting	1.54	0.96	2.45	0.072	0.007
	Wrong way	1.21	0.79	1.84	0.386	0.004
	Invading the opposite lane	2.04	1.57	2.66	< 0.001	0.004
	Incorrect turning	1.58	1.30	1.92	< 0.001	0.004
	Illegal passing	2.15	1.30	3.54	0.003	0.001
	Disregarding safety distance	0.45	0.20	1.01	0.052	0.003
	Failure to yield right of way	1.84	1.43	2.37	< 0.001	0.005
	Disregarding traffic lights	1.47	0.88	2.43	0.140	0.016
	Disregarding stop lights	2.61	2.09	3.26	< 0.001	0.003
	Disregarding crossing signals	1.70	1.05	2.74	0.031	0.001
	Disregarding other signals	2.95	1.39	6.24	0.005	0.017
	Not indicating a maneuver	1.23	0.55	2.76	0.613	< 0.001
	Entering traffic flow without precaution	1.96	1.39	2.76	< 0.001	0.004
	Cycling while standing	2.08	0.29	14.87	0.465	< 0.001
	Cycling in parallel	1.95	1.07	3.56	0.030	0.002
	Cycling outside traffic lanes	2.16	1.70	2.74	< 0.001	0.004
	Other	1.92	1.66	2.22	< 0.001	0.014
Reason for cycling	Work-related(1)	1	-	-	-	-
	Other reason	1.12	0.93	1.34	0.249	0.081

(1) Reference category
(2) Fraction of missing information

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Table 4 shows the IDR for the association between environmental characteristics and the risk of death. There were no conclusive trends according to the type of crash (IDR 0.89, 95%CI 0.78–1.00), but cycling through an intersection (IDR 1.65 for "other", 95%IC 1.46–1.87), in urban areas, and on community roads were inversely association with death. This association was also found for adverse meteorological conditions. However, when the road surface was altered, the association was inverse. A direct association with death was found after midnight, in the category "03:00-05:59" (IDR 1.58, 95%CI 1.03–2.41), whereas an inverse association was found during the day, with a peak at midday between 12:00 and 14:59 (IDR 0.40, 95%CI 0.29–0.56). Over the 10-year period analyzed here, there was a trend toward a higher likelihood of death in the earlier years.

Table 4. Adjusted incidence-density ratios (IDR) for the association between crash- and environment-related variables and the risk of death in the first 24 hours after a road crash. Spain, 1993–2013.

Variable	Category	IDR	95% CI		P value	FMI(2)
Type of crash	Collision with moving vehicle(1)	1	-	-	-	-
	Other	0.89	0.78	1.00	0.056	0.013
Traffic lane characteristics	Intersection(1)	1	-	-	-	-
	Other	1.65	1.46	1.87	< 0.001	0.007
Area	Highway(1)	1	-	-	-	-
	Urban area	0.18	0.16	0.21	< 0.001	0.016
	Community road	0.61	0.48	0.76	< 0.001	0.002
Meteorological conditions	Good weather(1)	1	-	-	-	-
	Any adverse circumstances	1.36	1.07	1.72	0.011	0.005
Road surface	Normal(1)	1	-	-	-	-
	Any adverse circumstances	0.75	0.59	0.96	0.022	0.006
Time of day (24-hour clock)	0:00 - 2:59(1)	1	-	-	-	-
	3:00 - 5:59	1.58	1.03	2.41	0.036	0.010

	6:00 - 8:59	0.78	0.54	1.11	0.165	0.013
	9:00 - 11:59	0.46	0.33	0.64	< 0.001	0.015
	12:00 - 14:59	0.40	0.29	0.56	< 0.001	0.015
	15:00 - 17:59	0.45	0.32	0.63	< 0.001	0.013
	18:00 - 20:59	0.49	0.35	0.68	< 0.001	0.013
	21:00 - 23:59	0.61	0.43	0.87	0.006	0.013
Years	2011 - 2013(1)	1	-	-	-	-
	2008 - 2010	1.34	1.07	1.68	0.011	0.012
	2005 - 2007	2.11	1.71	2.61	< 0.001	0.015
	2002 - 2004	2.16	1.75	2.67	< 0.001	0.012
	1999 - 2001	2.42	1.97	2.99	< 0.001	0.011
	1996 - 1998	2.30	1.86	2.84	< 0.001	0.012
	1993 - 1995	2.67	2.17	3.28	< 0.001	0.015

(1) Reference category

(2) Fraction of missing information

DISCUSSION

Our results are generally in agreement with those of previous studies regarding the direction and magnitude of the associations between cyclist- and environment-related factors and the severity of crashes involving cyclists.[6–17] Perhaps our most important finding is the association between non-use of a helmet and a higher chance of death. Although the protective effect of helmet use on the risk of head trauma is widely accepted,[7–10,12–15] its association with injury severity has been addressed mostly for non-fatal injuries given that relatively few studies to date have focused on its association with death.[18,19] Although our study is observational and causality cannot be demonstrated, it is unlikely that residual confounding could entirely explain an association of the magnitude we observed. We are confident that our approach to the analysis was robust given that it included appropriate management of missing values, controlling for between-province-level variance, and multivariate adjustment for most well-known confounders of the association between helmet use and death. Therefore, taking into account that helmet use is the most easily modifiable cyclist-dependent risk factor, our results suggest that a non-negligible amount of cyclist deaths might be prevented by increasing helmet use in our population of cyclists.

Regarding other cyclist-related variables, the association we found between age and risk of death is consistent with previous studies.[7,9,10] This association is usually explained on the basis of mechanisms such as greater fragility, loss of physical agility, decreased visual acuity and concomitant diseases. In contrast to other authors,[8,13,17] we found no association between younger age and death.

In relation to gender, we found that the risk of death was higher for males, as reported previously.[15,17] This association has been explained as a result of either physical differences or safer behaviors in females,[22] which may be associated with the severity of the crash itself. Other explanations have been based on the presumably riskier behavior in males when failing to stop for red lights[36] and when their risk perception is lower.[20] On the other hand, female gender has been associated with higher rates of reporting road crashes.[37] Because we considered only injured cyclists or death as our main outcomes, and assuming there was no difference between genders in deaths recorded in our database, differences in reporting non-fatal road crashes could lead to overestimation of the association with death (if any) in the underreported category. In fact, some authors did not observe this association,[7] or found female gender to be related with injury severity.[11]

According to some authors, alcohol consumption is associated with risky behaviors[23,24] when cycling and driving other types of vehicles, and is directly associated with injury severity.[9,11,13,16] This condition could not be investigated in our study because of the dichotomization process used to account for missing values. The low number of cyclists in the original categories for the “psychophysical circumstances” variable forced us to combine alcohol consumption, drug consumption, tiredness, sleepiness and other psychophysical circumstances into a single "altered" category, obscuring the true association between each type of psychophysical circumstance and death. Nevertheless, alcohol consumption with and without a breath test was the most prevalent condition included in the "altered" category, and showed a direct association with death. However, this association should be viewed with caution because of potential shortcomings in the validity of our data source.

Non-Spanish nationality also showed a stronger association with death, but this should likewise be interpreted with care. We could not obtain information about cyclists' expertise, and for non-Spanish cyclists, we did not know how long they had been living in Spain, or whether they had changed their cycling patterns while living abroad. Furthermore, all non-Spanish cyclists were clustered in a single subgroup which included people from countries which may differ widely in a large variety of aspects such as social and cultural characteristics as well as cycling infrastructure in their country of origin. This subgroup was thus too heterogeneous for informative comparisons. Consequently, the association found in our study undoubtedly deserves further research designed to address its underlying factors.

Like Kim and colleagues,[9] we observed that most traffic infractions (11 out of 18) were directly associated with death. "Distraction" was the only infraction inversely associated with death, perhaps because it may be inversely associated with speed, an unobserved variable. In relation with the reason for cycling, we found no associations with the likelihood of death. However, previous studies showed that work-related or utilitarian cycling was associated with less severe injuries because of cyclists' expertise, choice of safer routes and helmet use,[12] although greater injury severity was also associated with more experience and more frequent cycling.[11] Although some authors have reported different injury severity depending on the type of crash, especially when a motor vehicle was involved,[11,12,15,38] in the present study the direct association between death and collisions with moving vehicles did not differ significantly in comparison to other types of crashes (IDR 0.89, 95%CI 0.78–1.00). Nevertheless, because type of crash was a binary variable in our analysis (see Statistical analysis), all other types of collisions with moving vehicles were included in a single category and compared to other types of crashes (such as collisions with an obstacle, overturning or running off the road), hence the two groups were heterogeneous. Furthermore, unless the cyclist is fatally injured, cyclists are probably more likely to receive police assistance when they collide with another vehicle. Therefore cyclists who sustained minor injuries in the “other crashes” category were likely to be underrepresented in our sample.

Regarding environment-related variables, although some authors found no clear association with traffic lane characteristics or road geometry,[10,11] we identified an inverse association between intersections and death compared to other road configurations (straight roads or curves), in accordance with previous findings for injury severity.[13] But again, our two categories were heterogeneous, and the risks may differ among for different types of intersection.[8,39]

The location of the crash showed a close relationship with fatalities. Previous studies have reported less severe injuries in dense urban settings, and more severe injuries on rural or community roads. We found an inverse association with death for crashes in urban areas and community roads compared to highways. This association is probably related to the higher speeds reached on highways by cyclists or the other vehicles involved in crashes. In fact, speed has been previously associated with injury severity.[9,10,12,13,15]

Adverse meteorological conditions were directly associated with death, as reported by other authors.[8,9] This association is probably due to lower cyclist conspicuity under adverse weather conditions, although other authors found no clear association.[6,11,12] On the other hand, altered road surfaces were inversely associated with risk of death, which may be the result of cycling or driving at lower speeds. Nevertheless, other authors have reported more severe injuries on altered surfaces,[8,13] or found no association at all.[6,10] More research is needed to characterize the influence of weather and road conditions on risk of death among cyclists, given the discrepancies among findings from different studies.

Although the frequency of crashes was much greater during daylight hours, there was a direct association between crashes that occurred at night and death, as also found by Boufous et al.[10] and Wang et al.,[8] with a peak in the early morning hours, as reported by Asgarzadeh et al.[6] Other authors, however, found no association between time of the crash and injury severity or death, although one Danish study reported an association with daylight hours, probably because of the high standard of nighttime roadway lighting in Denmark[13]. Apart from the lack of conspicuity,[40] factors such as alcohol consumption, speed and exhaustion may play major roles in this association.[6,41] Finally, the lower risk of death in crashes recorded in more recent years in Spain may be explained by improvements in cycling infrastructure,[42] improved health care for injured cyclists,[1] and increased reporting of less serious road crashes by the police.

Strengths and limitations

Our data source for this analysis was the Spanish National Registry of Road Crashes with Victims. This registry contains information recorded over many years by police officers on a standard form. Our large sample size and total number of cyclist deaths made it possible for us to precisely estimate the magnitude of the associations between each variable in the model and fatal injuries. Our choice of main outcome categories reduced the possible effect of misrepresentation for certain independent variables in this police-based registry. Furthermore, the statistical approach used here considered variability in the outcome variable across provinces in Spain, and was intended to decrease the effect of missing values that could be explained by the remaining variables.

Nevertheless, a main limitation of our study is its observational nature, which prevents us from suggesting causal interpretations for the associations we found. Given that our analysis is based on information from a police-based registry designed to collect information on all types of road traffic crashes, as noted in the Methods section, selection bias is an important issue given the assumption that less serious crashes were underrepresented, because of a direct association between injury severity and reporting rates to the police.[43–45] Behavioral differences and differences in representation rates related to the categories for specific variables (e.g. gender) could not be measured with the available data, and this may have led to over- or underestimation of some of the observed associations. Regarding helmet use, we do not have information on the characteristics of the helmets, and cannot confirm that they were being worn correctly at the moment of the crash. Although we used a multiple imputation procedure to compensate for missing information, this method only partially resolves issues related with missing data; therefore our results may still be affected by biases of an undetermined magnitude. Furthermore, the dichotomization used for our multiple imputation procedure forced us to combine heterogeneous categories for some of the variables (e.g. psychophysical circumstances), so the results for these variables should be considered with due caution. Bias is also a potential limitation, because of the subjective nature of some variables recorded by police officers at the crash scene.

Finally, the lack of information regarding vehicle speed is an important limitation in our study. Although this is probably the most important factor affecting the severity of cyclists' injuries, no direct information was available for vehicle speed when the crash occurred.

CONCLUSIONS

We found strong associations between several cyclist- and environment-related variables and the probability of death, and suggest that these associations should be taken into account in efforts to prioritize public health measures aimed at reducing the number of cycling-related fatalities. In particular, we believe helmet use by cyclists needs to be encouraged. Although we are aware that the magnitude of the association between non-helmet use and death is not entirely causal, it supports the hypothesis that helmet use may significantly reduce the risk of death among cyclists involved in road crashes. Although using a helmet is now mandatory for all cyclists on open roads in Spain, our data show that even in recent years, the proportion of non-helmet-use has been non-negligible. Another topic which deserves attention is the risk in older cyclists, considering that this subgroup of cyclists will very likely grow in the coming years. Finally, the reasons for the higher risk of death during nighttime cycling merit further investigation in order to manage factors which are potentially modifiable by, for example, encouraging measures to improve cyclist conspicuity.

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Author Contributions: All authors meet the conditions for authorship. PLC conceived and designed the study, helped to draft the manuscript and critically revised it. DMS and VMR carried out the literature review and prepared the first draft of the manuscript. JPM, EMR and LMMR helped with the literature review and critically reviewed the manuscript. EJM critically reviewed the first draft of the manuscript, proposed corrections, and provided methodological advice. All authors approved the final version of this manuscript. The present article is part of the doctoral thesis of Daniel Molina-Soberanes at the University of Granada.

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Data sharing statement: All data relevant to the study are included in the article or uploaded as supplementary information.

KEY MESSAGES

What is already know on this subject

- Cycling is increasing but is associated with risks.
- Helmets are intended to protect against severe injury, but their effect on the risk of death remains unclear.

What this study adds

- Helmet non-use is directly associated with cyclist deaths, especially on highways.
- Work-related and non-work-related cycling did not differ in their association with the risk of death.
- Increasing age was directly associated with increasing risk of death, especially after the third decade of life.

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Appendix 1. Adjusted incidence-density ratios (IDR) in a multivariate unilevel model for the imputed associations between cyclist-related variables and the risk of death in the first 24 hours after a road crash. Spain, 1993-2013.

Variable	Category	IDR	95% CI		P value	FMI(2)
Helmet use	Yes(1)	1	-	-	-	-
	No	1.41	1.23	1.62	<0.001	0.091
Age (years)	< 10	0.93	0.58	1.47	0.744	0.020
	10 a 14	1.02	0.75	1.38	0.904	0.038
	15 a 19	1.13	0.85	1.50	0.389	0.036
	20 a 24	0.98	0.71	1.34	0.879	0.046
	25 a 29(1)	1	-	-	-	-
	30 a 34	1.27	0.94	1.73	0.124	0.057
	35 a 39	1.81	1.36	2.41	<0.001	0.035
	40 a 44	1.68	1.25	2.26	0.001	0.039
	45 a 49	1.85	1.37	2.49	<0.001	0.036
	50 a 54	2.15	1.59	2.90	<0.001	0.029
	55 a 59	2.92	2.18	3.91	<0.001	0.033
	60 a 64	3.55	2.67	4.72	<0.001	0.034
	65 a 69	4.43	3.38	5.81	<0.001	0.034
	70 a 74	3.57	2.55	4.99	<0.001	0.028
	> 74	4.48	3.39	5.91	<0.001	0.038
Sex	Male(1)	1	-	-	-	-
	Female	0.82	0.68	1.00	0.045	0.019
Psychophysical circumstances	Normal(1)	1	-	-	-	-
	Altered	1.44	1.09	1.90	0.011	0.309
Nationality	Spanish(1)	1	REF	REF	REF	REF
	Other nationality	1.37	1.16	1.61	<0.001	0.017
Commission of infraction	None(1)	1	-	-	-	-
	Distraction	0.71	0.57	0.89	0.002	0.005
	Incorrect use of lighting	1.48	0.93	2.37	0.097	0.007
	Wrong way	1.19	0.78	1.82	0.423	0.004
	Invading the opposite lane	2.00	1.53	2.60	<0.001	0.004
	Incorrect turning	1.52	1.25	1.85	<0.001	0.004
	Illegal passing	2.12	1.28	3.49	0.003	0.001

	Disregarding safety distance	0.44	0.20	0.99	0.047	0.003
	Failure to yield right of way	1.77	1.38	2.28	<0.001	0.005
	Disregarding traffic lights	1.44	0.87	2.39	0.161	0.016
	Disregarding stop lights	2.53	2.02	3.15	<0.001	0.003
	Disregarding crossing signals	1.65	1.02	2.66	0.041	0.001
	Disregarding other signals	2.94	1.39	6.24	0.005	0.017
	Not indicating a maneuver	1.19	0.53	2.66	0.679	<0.001
	Entering traffic flow without precaution	1.94	1.37	2.74	<0.001	0.004
	Cycling while standing	2.01	0.28	14.39	0.487	<0.001
	Cycling in parallel	1.89	1.04	3.46	0.038	0.002
	Cycling outside traffic lanes	2.09	1.64	2.66	<0.001	0.004
	Other	1.89	1.63	2.19	<0.001	0.014
Reason for cycling	Work-related(1)	1	-	-	-	-
	Other reason	1.13	0.94	1.36	0.204	0.081

(1) Reference category

(2) Fraction of missing information

4

Appendix 2. Adjusted incidence-density ratios (IDR) in a multivariate unilevel model for the imputed associations between crash- and environment-related variables and the risk of death in the first 24 hours after a road crash. Spain, 1993-2013.

Variable	Category	IDR	95% CI		P value	FMI(2)
Type of crash	Collision with moving vehicle(1)	1	-	-	-	-
	Other	0.89	0.78	1.00	0.058	0.014
Traffic lane characteristics	Intersection(1)	1	-	-	-	-
	Other	1.64	1.45	1.86	<0.001	0.007
Area	Highway(1)	1	-	-	-	-
	Urban area	0.18	0.16	0.21	<0.001	0.015
	Community road	0.59	0.47	0.74	<0.001	0.003
Meteorological conditions	Good weather(1)	1	-	-	-	-
	Any adverse circumstances	1.37	1.08	1.73	0.009	0.005
Road surface	Normal(1)	1	-	-	-	-
	Altered	0.76	0.59	0.97	0.030	0.006
Time of day (24-hour clock)	0:00-2:59(1)	1	-	-	-	-
	3:00-5:59	1.55	1.01	2.38	0.043	0.009
	6:00-8:59	0.77	0.54	1.09	0.141	0.012
	9:00-11:59	0.45	0.33	0.64	<0.001	0.014
	12:00-14:59	0.40	0.28	0.55	<0.001	0.014
	15:00-17:59	0.45	0.32	0.63	<0.001	0.012
	18:00-20:59	0.48	0.35	0.67	<0.001	0.012
	21:00-23:59	0.60	0.43	0.85	0.004	0.012
Years	2011 - 2013(1)	1	-	-	-	-
	2008 - 2010	1.34	1.07	1.69	0.010	0.012
	2005 - 2007	2.10	1.70	2.60	<0.001	0.015
	2002 - 2004	2.16	1.75	2.68	<0.001	0.012
	1999 - 2001	2.42	1.96	2.98	<0.001	0.010
	1996 - 1998	2.31	1.87	2.85	<0.001	0.012
	1993 - 1995	2.67	2.17	3.29	<0.001	0.015
Province	Alava	1	-	-	-	-
	Albacete	1.51	0.80	2.87	0.206	0.004
	Alicante	1.02	0.61	1.71	0.928	0.004
	Almería	1.61	0.92	2.83	0.095	0.006
	Ávila	0.29	0.07	1.25	0.097	0.001

Badajoz	1.96	1.06	3.62	0.032	0.007
Baleares	1.25	0.76	2.07	0.373	0.005
Barcelona	1.01	0.62	1.64	0.974	0.009
Burgos	1.35	0.76	2.43	0.308	0.003
Cáceres	1.48	0.64	3.39	0.360	0.002
Cádiz	1.04	0.56	1.91	0.907	0.007
Castellón	1.08	0.61	1.91	0.798	0.005
Ciudad Real	1.28	0.71	2.31	0.417	0.005
Córdoba	1.12	0.60	2.10	0.715	0.003
Coruña, La	1.12	0.62	2.02	0.714	0.003
Cuenca	2.95	1.45	6.02	0.003	0.003
Girona	1.07	0.62	1.85	0.799	0.006
Granada	1.18	0.66	2.10	0.584	0.005
Guadalajara	1.91	0.76	4.80	0.169	0.001
Guipúzcoa	0.65	0.36	1.18	0.157	0.003
Huelva	0.89	0.41	1.93	0.774	0.002
Huesca	1.36	0.70	2.66	0.365	0.003
Jaen	1.41	0.65	3.04	0.386	0.003
León	1.49	0.88	2.54	0.140	0.004
Lleida	1.38	0.75	2.57	0.302	0.003
La Rioja	2.15	1.18	3.92	0.013	0.003
Lugo	1.16	0.60	2.25	0.654	0.003
Madrid	1.10	0.66	1.82	0.725	0.006
Málaga	1.24	0.69	2.21	0.474	0.004
Murcia	1.76	1.05	2.94	0.031	0.005
Navarra	1.91	1.08	3.41	0.027	0.005
Orense	1.96	1.04	3.67	0.037	0.003
Asturias	0.76	0.43	1.33	0.335	0.004
Palencia	1.24	0.63	2.42	0.537	0.004
Palmas, Las	1.70	0.93	3.08	0.084	0.003
Pontevedra	0.96	0.52	1.75	0.886	0.003
Salamanca	1.49	0.74	2.99	0.261	0.003
Santa Cruz	1.43	0.76	2.73	0.270	0.003
Cantabria	0.97	0.53	1.75	0.909	0.004
Segovia	1.53	0.69	3.41	0.298	0.006
Sevilla	1.38	0.82	2.35	0.230	0.003
Soria	1.81	0.72	4.56	0.207	0.002
Tarragona	1.52	0.91	2.54	0.111	0.005
Teruel	1.77	0.74	4.24	0.201	0.002
Toledo	2.37	1.36	4.12	0.002	0.003

Valencia	1.28	0.78	2.10	0.324	0.005
Valladolid	1.58	0.87	2.86	0.134	0.004
Vizcaya	0.68	0.37	1.22	0.193	0.003
Zamora	2.54	1.36	4.73	0.003	0.004
Zaragoza	1.71	0.99	2.95	0.056	0.005

(1) Reference category
(2) Fraction of missing information

4

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*8*
Bias	9	Describe any efforts to address potential sources of bias	9
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	N/A
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	8
		(*c*) Explain how missing data were addressed	9
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Table 1 and Table 2
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10
		(b) Indicate number of participants with missing data for each variable of interest	Table1 and Table 2
Outcome data	15*	Report numbers of outcome events or summary measures	10
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear	14

		which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	Table 1 and Table 2
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	17
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	21
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	23
Generalisability	21	Discuss the generalisability (external validity) of the study results	23
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	24

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Individual and environmental factors associated with death of cyclists involved in road crashes in Spain: a cohort study

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ABSTRACT

Objective: To quantify the magnitude of associations between cyclist fatalities and both cyclist- and environment-related characteristics in Spain during the first 24 hours after a crash.

Design: Cohort study

Setting: Spain

Participants: 65,977 cyclists injured in road crashes recorded between 1993 and 2013 in the Spanish Register of Road Crashes with Victims

Main outcome: Death within the first 24 hours after the crash

Methods: A multiple imputation procedure was used to mitigate the effect of missing values. Differences between regions were assumed and managed with multilevel analysis at the cyclist and province levels. Incidence density ratios (IDR) with 95% confidence intervals (95%CI) were calculated with a multivariate Poisson model.

Results: Non-use of a helmet use was directly associated with death (IDR 1.43, 95%CI 1.25–1.64). Among other cyclist characteristics, age after the third decade of life was also directly associated with death, especially in older cyclists ("over 74" category, IDR 4.61, 95%CI 3.49–

6.08). The association with death did not differ between work-related cycling and other reasons for cycling.

There was an inverse association with death for crashes in urban areas and on community roads. Any adverse meteorological condition also showed a direct association with death, whereas altered road surfaces showed an inverse association. Crashes during nighttime were directly associated with death, with a peak between 3:00 and 5:59 am (IDR 1.58, 95%CI 1.03–2.41).

Conclusions: We found strong direct and inverse associations between several cyclist- and environment-related variables and death. These variables should be considered in efforts to prioritize public health measures aimed at reducing the number of cycling-related fatalities.

Keywords: cyclist; bicycling; injuries; fatality; risk factor; road crash

Word count: 4325

ARTICLE SUMMARY

Strengths and limitations of this study

- We used a nationwide database with information on 65,977 cyclists.
- The database compiles abundant information on the characteristics of the people involved, their vehicles and the environment.
- Because the database is a police-based registry, it can be assumed that less serious crashes are underrepresented.
- Because of missing data, information biases cannot be ruled out despite the multiple imputation procedure used.

INTRODUCTION

Cycling is considered a healthy alternative to private cars because it helps increase physical activity and reduce carbon emissions.[1] But it can also be harmful: there are about 5.5 times more traffic deaths per kilometer traveled by bicycle than by car.[2] In fact, cyclists along with pedestrians are the most vulnerable road users because of their lack of protection and comparatively greater likelihood of suffering severe injuries or dying after a crash.[3] These outcomes can be caused mainly by factors related to the cyclist (as in single-vehicle crashes) or related to other road users (as in collisions with other vehicles), or even by environment-related factors. Understanding the factors involved in cyclist injuries and deaths is necessary in order to design and promote better public policies worldwide to encourage safe cycling. The current transition in commuting patterns in Spain merits attention, because the number of people who use bicycles daily or almost daily has nearly doubled since the mid-2000s.[4] Public policies in this country promote cycling not only as a leisure activity, but as a regular mode of transport. Although the annual number of cyclist deaths decreased from 75 to 58 between 2006 and 2015,[5] this tendency is reverting, and interventions aimed at making cycling a safer activity are needed.[6]

Many previous studies have identified individual and/or environmental factors associated with injury severity or fatalities among cyclists.[7 -18] However, there is no consensus regarding the magnitude or even the direction of some observed associations. Death is sometimes considered the most severe injury category along with other serious injuries, rather than as a specific category itself.[7–9,11,16] Because death of one or more cyclists after a crash is uncommon, some studies found no statistically significant associations between this outcome and a number of variables,[7] and multivariate analysis was not possible in some studies because of the small numbers involved.[16] In studies that did report significant associations, the findings may still be debatable: recent meta-analyses have consistently shown an inverse association between helmet use and head injury severity, although these studies focused mainly on non-fatal injuries.[19,20] Olivier and Creighton[19] found only two studies that reported effect sizes for fatalities, and Høye[20] was obliged to merge fatalities with serious injuries in a single category for most of her analyses.

Regarding age and gender differences, the biological effect of aging is a plausible cause for the association between cyclist involvement in a road crash and greater injury severity,[8–12,14,16,18] but the relationship between age and death in some age groups (e.g. children or adolescents) awaits clarification.[9,13,14,16,18] Both males[13,16,18] and females[12] have been reported to be at increased risk of more severe injuries. Physical and behavioral aspects related to gender have been argued to explain differences in injury severity,[21–23] but there is no consensus.

Although alcohol consumption is known to be associated with risky behavior while cycling,[24,25] studies focusing on the association between this factor and injury severity or fatality are inconclusive.[10,12,14,17,18] The commission of infractions is reportedly associated with injury severity or death, but only in bicycle collisions with a motor vehicle, not on other types of crashes.[10]

Environmental factors can also play a major role as independent variables in fatal outcomes. Traffic lane characteristics, e.g. intersections as opposed to open roadways, are usually related to an increased risk of collision but not necessarily with more severe injuries [11,12,14] except in unsignalized intersections.[9] Road surface and adverse weather circumstances appear to be related to the likelihood of crashes, but their association with injury severity or death also requires clarification, given that previous studies have found both a direct association with injuries or death[9,10,14] and no association.[7,11–13] Time of day is related to conspicuity, and has been linked to crash rates. However, the association found for injury severity has not shown a clear direction: a direct association with severity has been reported during daytime[7,10,14] and during nighttime,[9,11] with some analyses finding no association at all.[12,13]

It seems obvious that cycling speed would be related to death after a crash. Although the speed at the time of the crash can be estimated with ad hoc studies using accident reconstruction techniques,[26] proxy variables such as speed limit at the site of the crash,[10,11,13,14] or the area of the crash[7,11,14] have been widely used. In fact, speed may be the main reason for the greater severity of cyclists' injuries in crashes involving a motor vehicle compared to single crashes, as reported in previous studies.[12,13,16]

Previous research in Spain has focused on impacts on cyclists' health,[27,28] their behavior and other correlates with crash involvement,[21,22,29,30] and the causal chain of events related to death after a crash.[31] However, to our knowledge there have been no attempts to analyze personal and environmental characteristics and their relationship with the risk of death.

To help fill the gaps in our current knowledge, we designed a large nationwide study to quantify the magnitude of the associations between cyclist- and environment-related characteristics and the likelihood of cyclist fatality within the first 24 hours post-crash in Spain between 1993 and 2013.

METHODS

Data source and study population

We analyzed the cohort comprising all 65,977 cyclists involved in road crashes recorded in the Spanish National Registry of Road Crashes with Victims between 1993 and 2013 once the crashes in the autonomous cities of Ceuta and Melilla were excluded because of their specific characteristics and low mortality: both cities are located in northern Africa, and all road crashes involving cyclists occurred in urban areas.

The aforementioned registry is a nationwide electronic database maintained by the Spanish General Directorate of Traffic. It has high security standards to protect anonymity, and was developed to support the design and evaluation of public policies concerning road safety. Researchers can use this data upon specific request, after a motivation letter is accepted by the Directorate authorities. This database contains information from the Statistical Questionnaire of the Accident documents submitted for every crash resulting in injury or death and involving at least one moving vehicle in areas subject to traffic laws. Information in the registry includes the characteristics of the persons involved (e.g. age, sex), their vehicles (e.g. type, condition), and the environment (e.g. type of crash, geographic coordinates, road characteristics). It does not include information that may lead to personal identification. Victims are categorized as injured if they are seen by a health care service, or as dead if they die at the crash scene or within the first 30 days. This questionnaire is completed by national police agents at the crash scene, and filed within the first 24 hours for crashes that result in death or severe injury (needing hospitalization), or within the next 10 days after the crash. All data must be submitted within the first 30 days post-event, including follow-up information from health care services. Amendments to the infrastructure data recorded at the crash scene can be made within the next 30 days by the appropriate authorities.[32]

Patient and public involvement

This study relies on data collected by the Spanish General Directorate of Traffic; no patients or participants interacted with the study authors.

Variables

We collected information about a subset of variables which, according to previous studies and based on univariate analysis, may be associated directly or indirectly with injury severity. Our dependent variable was death within the first 24 hours after the crash, and the independent variables were cyclist-related (age, sex, helmet use, psychophysical circumstances, nationality, commission of infraction and reason for cycling) and crash- or environment-related (type of crash, traffic lane characteristics, area, meteorological conditions, road surface, time of day, year and province). Original categories and dichotomized categories (see "Statistical analysis") can be viewed in the frequency distribution tables (Table 1 and Table 2).

Statistical analysis

Univariate analysis was first done for each variable included as an independent variable and for death as the dependent variable. Then we built a Poisson regression model (a generalized linear model which uses log [rate] as the link function). Spain is divided in 50 provinces which differ markedly regarding cycling density, cycler-friendly environment, socioeconomic conditions and health care facilities, among other important factors potentially related with cyclists' risk of death. Therefore, we first tested the hypothesis that the province level would explain a significant part on the total variance in the outcome variable (cyclist fatalities). For this purpose, we constructed both unilevel (Appendices 1 and 2) and multilevel empty models (including cyclist-level and province-level), and compared the variances explained by each. Significant differences (P<0.001 for the likelihood ratio test) between the two models were obtained, thus confirming our hypothesis. This led us to choose a multilevel multivariate model for the main results.

More than 25% of the data were missing for some variables (e.g. helmet use) (see Tables 1 and 2 for details). The overall amount of these missing values may be explained by missing at random (MAR) and missing not at random (MNAR) mechanisms. Although we cannot compensate for MNAR values, we can control MAR values through a multiple imputation procedure. Therefore, we initially assumed that some missing values might be explained by the combination of the values observed for some of the remaining variables in the database. To test this assumption, for each variable with missing values we constructed a multivariate regression model with the existence or not of missing values as the dependent variable, and the observed values for the remaining variables as independent terms. In all cases we observed parameters of association significantly away from the null. These results supported our initial hypothesis and led us to build 50 files in which missing data were represented as stabilized variances estimated from different variables, according to the chained equations method described by van Buuren[33] and implemented with the “ice” command in Stata.[34] This is a community-contributed Stata command focused on simplifying the imputation of categorical variables. However, this procedure was unable to provide missing values for many categorical variables with more than two strata when the frequency of responses in different categories was low, and we thus opted to dichotomize these variables. The dichotomization process considered theoretical similarities between original categories (e.g. any adverse weather circumstances such as rain, snow and hail were grouped in the category "any adverse circumstances") and tried to keep the most important category for analysis unaltered (e.g. intersections). Age was imputed based on its logarithm to maintain positive values, and its antilogarithm was then used to transform it into a categorical variable. We used this approach to build a multilevel fixed-effect multivariate Poisson regression model for each of our 50 complete datasets. Thus we obtain adjusted incidence density ratios (IDR) for death for each category of every variable, to assess the magnitude of associations with cyclist death rates. IDR is a good estimate of the relative risk (RR) of death across categories of independent variables when, as in this analysis, the risk of death yields exactly the same value as the death rate for a fixed amount of persons-time (i.e., the number of cyclists involved in road crashes multiplied by the same follow-up period for all of them). For each IDR, its corresponding 95% confidence interval (95%CI) was also calculated. We then used the community-contributed "mim" command for Stata[35] to combine the estimates obtained for each imputed file according to the Rubin method.[36]

All analyses were done with Stata software (v. 14).[37]

RESULTS

Table 1 and Table 2 summarize descriptive information on cyclist- and crash/environment-related characteristics. Fatality was a rare event (2.49%). The male-to-female ratio was almost 8:1. The main mechanism for crashes was collision with another vehicle (69.40%), and most crashes occurred in urban areas (60.71%), followed by highways (35.71%) and community roads (3.58%). Although most crashes occurred during the day (83.44% between 9:00 and just before 21:00), many of them (47.48%) occurred shortly after the end of the

230 morning and afternoon work shifts, i.e. from 12:00 to just before 15:00, and from 18:00 to just
231 before 21:00.
232

233 **Table 1.** Distribution of cyclist-related variables. Spain, 1993–2013.
234

Variable	Category	N	% Total	N	% Excluding missing values
Death	Yes	1,643	2.49	1,643	2.54
	No	62,969	95.44	62,969	97.46
	Unknown	1,365	2.07	-	-
	Total	*65,977*	*100*	*64,612*	*100*
Sex	Male	55,901	84.73	55,901	87.13
	Female	8,259	12.52	8,259	12.87
	Unknown	1,817	2.75	-	-
	Total	*65,977*	*100*	*64,160*	*100*
Age (years)	< 10	1,596	2.42	1,596	2.60
	10 - 14	6,073	9.20	6,073	9.89
	15 - 19	9,065	13.74	9,065	14.76
	20 - 24	6,130	9.29	6,130	9.98
	25 - 29	5,963	9.04	5,963	9.71
	30 - 34	5,797	8.79	5,797	9.44
	35 - 39	5,244	7.95	5,244	8.54
	40 - 44	4,632	7.02	4,632	7.54
	45 - 49	4,119	6.24	4,119	6.71
	50 - 54	3,357	5.09	3,357	5.46
	55 - 59	2,555	3.87	2,555	4.16
	60 - 64	2,256	3.42	2,256	3.67
	65 - 69	1,804	2.73	1,804	2.94
	70 - 74	1,361	2.06	1,361	2.22
	> 74	1,477	2.24	1,477	2.40
	Unknown	4,548	6.89	-	-
	Total	*65,977*	*100*	*61,429*	*100*
Helmet use	Yes	17,183	26.04	17,183	35.38
	No	31,378	47.56	31,378	64.62
	Unknown	17,416	26.40	-	-
	Total	*65,977*	*100*	*48,561*	*100*
Psychophysical circumstances	Normal	53,622	81.27	53,622	98.32
	Altered(1)	915	1.39	915	1.68
	Unknown	11,440	17.34	-	-
	Total	*65,977*	*100*	*54,537*	*100*
Nationality	Spanish	57,208	86.71	57,208	91.69

	Other nationality(2)	5,184	7.86	5,184	8.31
	Unknown	3,585	5.43	-	-
	Total	*65,977*	*100*	*62,392*	*100*
Commission of infraction	None	34,607	52.45	34,607	52.45
	Distraction	6,851	10.38	6,851	10.38
	Incorrect use of lighting	296	0.45	296	0.45
	Wrong way	1,335	2.02	1,335	2.02
	Invading the opposite lane	1,200	1.82	1,200	1.82
	Incorrect turning	1,879	2.85	1,879	2.85
	Illegal passing	489	0.74	489	0.74
	Disregarding safety distance	676	1.02	676	1.02
	Failure to yield right of way	1,595	2.42	1,595	2.42
	Disregarding traffic lights	1,558	2.36	1,558	2.36
	Disregarding stop lights	1,639	2.48	1,639	2.48
	Disregarding crossing signals	937	1.42	937	1.42
	Disregarding other signals	214	0.32	214	0.32
	Not indicating a maneuver	157	0.24	157	0.24
	Entering traffic flow without precaution	1,112	1.69	1,112	1.69
	Cycling while standing	22	0.03	22	0.03
	Cycling in parallel	213	0.32	213	0.32
	Cycling outside traffic lanes	914	1.39	914	1.39
	Other	10,283	15.59	10,283	15.59
	Total	*65,977*	*100*	*65,977*	*100*
Reason for cycling	Work-related	6,770	10.26	6,770	12.49
	Other reason(3)	47,450	71.92	47,450	87.51
	Unknown	11,757	17.82	-	-
	Total	*65,977*	*100*	*54,220*	*100*

(1) Including alcohol consumption with breath test, alcohol consumption without breath test, drug consumption, sudden illness, sleepiness or drowsiness, tiredness, or appearing worried, as perceived by the police officer
(2) Including French, Moroccan, German, British, Italian, Swiss, Belgian, Dutch, American, other Magreb countries, and other countries
(3) Including leaving for or returning from vacation, leaving for or returning from a holiday or long weekend, emergency, and leisure

Table 2. Distribution of crash- and environment-related variables. Spain, 1993–2013

Variable	Category	N	% Total	N	% Excluding missing values
Type of crash	Collision with moving vehicle	45,791	69.40	45,791	69.90
	Other(1)	19,722	29.89	19,722	30.10
	Unknown	464	0.70	-	-

	Total	*65,977*	*100*	*65,513*	*100*
Traffic lane characteristics	Intersection(2)	28,283	42.87	28,283	43.23
	Other(3)	37,139	56.29	37,139	56.77
	Unknown	555	0.84	-	-
	Total	*65,977*	*100*	*65,422*	*100*
Area	Highway	23,561	35.71	23,561	35.71
	Urban area	40,056	60.71	40,056	60.71
	Community road	2,360	3.58	2,360	3.58
	Total	*65,977*	*100*	*65,977*	*100*
Meteorological conditions	Good weather	61,972	93.93	61,972	93.95
	Any adverse circumstances(4)	3,991	6.05	3,991	6.05
	Unknown	14	0.02	-	-
	Total	*65,977*	*100*	*65,963*	*100*
Road surface	Normal	60,835	92.21	60,835	92.58
	Altered(5)	4,876	7.39	4,876	7.42
	Unknown	266	0.40	-	-
	Total	*65,977*	*100*	*65,711*	*100*
Time of day (24-hour clock)	0:00 - 2:59	972	1.47	972	1.47
	3:00 - 5:59	401	0.61	401	0.61
	6:00 - 8:59	3,580	5.43	3,580	5.43
	9:00 - 11:59	12,582	19.07	12,582	19.07
	12:00 - 14:59	15,753	23.88	15,753	23.88
	15:00 - 17:59	11,144	16.89	11,144	16.89
	18:00 - 20:59	15,572	23.60	15,572	23.60
	21:00 - 23:59	5,973	9.05	5,973	9.05
	Total	*65,977*	*100*	*65,977*	*100*
Years	2011 - 2013	16,315	24.73	16,315	24.73
	2008 - 2010	10,468	15.87	10,468	15.87
	2005 - 2007	7,826	11.86	7,826	11.86
	2002 - 2004	7,229	10.96	7,229	10.96
	1999 - 2001	6,628	10.05	6,628	10.05
	1996 - 1998	8,154	12.36	8,154	12.36
	1993 - 1995	9,357	14.18	9,357	14.18
	Total	*65,977*	*100*	*65,977*	*100*

(1) Including collision with an obstacle (e.g. stopped vehicles, pedestrians or animals), overturning, running off the road, or other types of crash
(2) Including T or Y configuration, X or + configuration, entrance ramp, exit ramp, traffic circle, or other intersections
(3) Including straightaway, gentle curve, unmarked sharp curve, marked sharp curve without posted speed limit, marked sharp curve with posted speed limit, or others

(4) Including heavy fog, light fog, light rain, heavy rain, hail, snow, strong winds, or other adverse meteorological conditions
(5) Including shaded, wet, ice, snow, slick formed from water + dirt + oil, loose gravel, oil, or other altered surfaces

Table 3 shows the IDR for the association between cyclist characteristics and the risk of death. A tendency towards a direct association between cyclists' age and death was observed from the third decade of life; the association was statistically significant (P<0.05) in categories from 35-to-39 years and older, and was greatest in the "over 74 years" category (IDR 4.61, 95%CI 3.49–6.08). Non-use of a helmet was associated with a 43.45% higher chance of death (IDR 1.43, 95%CI 1.25–1.64). Male gender, psychophysical circumstances, and nationality other than Spanish showed a direct association with death. Many recorded cyclist infractions were directly associated with death, with IDR higher than 2 for infractions such as disregarding stop lights or other signals, cycling while standing, illegal passing, invading the opposite lane and cycling outside traffic lanes. However, "Disregarding safety distance" and "distraction" were inversely associated with death, but this association was statistically significant only for the latter (P<0.05). The association for work-related cycling did not differ compared to other motives for cycling (i.e., for leisure or for other reasons).

Table 3. Adjusted incidence-density ratios (IDR) for the association between cyclist-related variables and the risk of death in the first 24 hours after a road crash. Spain, 1993–2013.

Variable	Category	IDR	95% CI		P value	FMI(2)
Sex	Male(1)	1	-	-	-	-
	Female	0.82	0.68	0.99	0.047	0.019
Age (years)	< 10	0.95	0.60	1.50	0.813	0.020
	10 - 14	1.02	0.75	1.38	0.906	0.038
	15 - 19	1.12	0.85	1.49	0.416	0.036

	20 - 24	0.97	0.70	1.33	0.832	0.047
	25 - 29(1)	1	-	-	-	-
	30 - 34	1.26	0.93	1.71	0.134	0.057
	35 - 39	1.79	1.35	2.39	< 0.001	0.035
	40 - 44	1.67	1.24	2.25	0.001	0.039
	45 - 49	1.85	1.37	2.48	< 0.001	0.035
	50 - 54	2.15	1.59	2.90	< 0.001	0.029
	55 - 59	2.91	2.17	3.90	< 0.001	0.033
	60 - 64	3.59	2.70	4.77	< 0.001	0.034
	65 - 69	4.49	3.43	5.89	< 0.001	0.034
	70 - 74	3.67	2.62	5.13	< 0.001	0.028
	> 74	4.61	3.49	6.08	< 0.001	0.038
Helmet use	Yes(1)	1	-	-	-	-
	No	1.43	1.25	1.64	< 0.001	0.091
Psychophysical circumstances	Normal(1)	1	-	-	-	-
	Altered	1.43	1.08	1.89	0.011	0.305
Nationality	Spanish(1)	1	-	-	-	-
	Other nationality	1.39	1.18	1.62	< 0.001	0.016
Commission of infraction	None(1)	1	-	-	-	-
	Distraction	0.73	0.58	0.90	0.004	0.004
	Incorrect use of lighting	1.54	0.96	2.45	0.072	0.007
	Wrong way	1.21	0.79	1.84	0.386	0.004
	Invading the opposite lane	2.04	1.57	2.66	< 0.001	0.004
	Incorrect turning	1.58	1.30	1.92	< 0.001	0.004
	Illegal passing	2.15	1.30	3.54	0.003	0.001
	Disregarding safety distance	0.45	0.20	1.01	0.052	0.003
	Failure to yield right of way	1.84	1.43	2.37	< 0.001	0.005
	Disregarding traffic lights	1.47	0.88	2.43	0.140	0.016
	Disregarding stop lights	2.61	2.09	3.26	< 0.001	0.003
	Disregarding crossing signals	1.70	1.05	2.74	0.031	0.001
	Disregarding other signals	2.95	1.39	6.24	0.005	0.017
	Not indicating a maneuver	1.23	0.55	2.76	0.613	< 0.001
	Entering traffic flow without precaution	1.96	1.39	2.76	< 0.001	0.004
	Cycling while standing	2.08	0.29	14.87	0.465	< 0.001
	Cycling in parallel	1.95	1.07	3.56	0.030	0.002
	Cycling outside traffic lanes	2.16	1.70	2.74	< 0.001	0.004
	Other	1.92	1.66	2.22	< 0.001	0.014
Reason for cycling	Work-related(1)	1	-	-	-	-
	Other reason	1.12	0.93	1.34	0.249	0.081

(1) Reference category
(2) Fraction of missing information

Table 4 shows the IDR for the association between environmental characteristics and the risk of death. There were no conclusive trends according to the type of crash (IDR 0.89, 95%CI 0.78–1.00), but cycling through an intersection (IDR 1.65 for "other", 95%IC 1.46–1.87), in urban areas, and on community roads were inversely associated with death. This association was also found when the road surface was altered. However, for adverse meteorological conditions the association was direct. A direct association with death was also found after midnight, in the category "03:00-05:59" (IDR 1.58, 95%CI 1.03–2.41), whereas an inverse association was found during the day, with a peak at midday between 12:00 and 14:59 (IDR 0.40, 95%CI 0.29–0.56). Over the 10-year period analyzed here, there was a trend toward a higher likelihood of death in the earlier years.

Table 4. Adjusted incidence-density ratios (IDR) for the association between crash- and environment-related variables and the risk of death in the first 24 hours after a road crash. Spain, 1993–2013.

Variable	Category	IDR	95% CI		P value	FMI(2)
Type of crash	Collision with moving vehicle(1)	1	-	-	-	-
	Other	0.89	0.78	1.00	0.056	0.013
Traffic lane characteristics	Intersection(1)	1	-	-	-	-
	Other	1.65	1.46	1.87	< 0.001	0.007
Area	Highway(1)	1	-	-	-	-
	Urban area	0.18	0.16	0.21	< 0.001	0.016
	Community road	0.61	0.48	0.76	< 0.001	0.002
Meteorological conditions	Good weather(1)	1	-	-	-	-
	Any adverse circumstances	1.36	1.07	1.72	0.011	0.005

Road surface	Normal(1)	1	-	-	-	-
	Any adverse circumstances	0.75	0.59	0.96	0.022	0.006
Time of day (24-hour clock)	0:00 - 2:59(1)	1	-	-	-	-
	3:00 - 5:59	1.58	1.03	2.41	0.036	0.010
	6:00 - 8:59	0.78	0.54	1.11	0.165	0.013
	9:00 - 11:59	0.46	0.33	0.64	< 0.001	0.015
	12:00 - 14:59	0.40	0.29	0.56	< 0.001	0.015
	15:00 - 17:59	0.45	0.32	0.63	< 0.001	0.013
	18:00 - 20:59	0.49	0.35	0.68	< 0.001	0.013
	21:00 - 23:59	0.61	0.43	0.87	0.006	0.013
Years	2011 - 2013(1)	1	-	-	-	-
	2008 - 2010	1.34	1.07	1.68	0.011	0.012
	2005 - 2007	2.11	1.71	2.61	< 0.001	0.015
	2002 - 2004	2.16	1.75	2.67	< 0.001	0.012
	1999 - 2001	2.42	1.97	2.99	< 0.001	0.011
	1996 - 1998	2.30	1.86	2.84	< 0.001	0.012
	1993 - 1995	2.67	2.17	3.28	< 0.001	0.015

(1) Reference category

(2) Fraction of missing information

DISCUSSION

Our results are generally in agreement with those of previous studies regarding the direction and magnitude of the associations between cyclist- and environment-related factors and the severity of crashes involving cyclists.[7–18] Perhaps our most important finding is the association between non-use of a helmet and a higher chance of death. Although the protective effect of helmet use on the risk of head trauma is widely accepted,[8–11,13–16] its association with injury severity has been addressed mostly for non-fatal injuries given that relatively few studies to date have focused on its association with death.[19,20] Although our study is observational and causality cannot be demonstrated, it is unlikely that residual confounding could entirely explain an association of the magnitude we observed. We are confident that our approach to the analysis was robust given that it included appropriate management of missing values, controlling for between-province-level variance, and multivariate adjustment for most well-known confounders of the association between helmet use and death. Therefore, taking into account that helmet use is the most easily modifiable cyclist-dependent risk factor, our results suggest that a non-negligible amount of cyclist deaths might be prevented by increasing helmet use in our population of cyclists.

Regarding other cyclist-related variables, the association we found between age and risk of death is consistent with previous studies.[8,10,11] This association may be explained on the basis of mechanisms such as greater fragility, loss of physical agility, decreased visual acuity and concomitant diseases[38]. In contrast to other authors,[9,14,18] we found no association between younger age and death.

In relation to gender, we found that the risk of death was higher for males, as reported previously.[16,18] This association has been explained as a result of either physical differences or safer behaviors in females,[23] which may be associated with the severity of the crash itself. Other explanations have been based on the presumably riskier behavior in males when failing to stop for red lights[39] and when their risk perception is lower.[21] On the other hand, female gender has been associated with higher rates of reporting road crashes.[40] Because we considered only injured cyclists or death as our main outcomes, and assuming there was no difference between genders in deaths recorded in our database, differences in reporting non-fatal road crashes could lead to overestimation of the association with death (if any) in the underreported category. In fact, some authors did not observe this association,[8] or found female gender to be related with injury severity.[12]

According to some authors, alcohol consumption is associated with risky behaviors[24,25] when cycling and driving other types of vehicles, and is directly associated with injury severity.[10,12,14,17] This condition could not be investigated in our study because of the dichotomization process used to account for missing values. The low number of cyclists in the original categories for the "psychophysical circumstances" variable forced us to combine alcohol consumption, drug consumption, tiredness, sleepiness and other psychophysical circumstances into a single "altered" category, obscuring the true association between each type of psychophysical circumstance and death. Nevertheless, alcohol consumption with and without a breath test was the most prevalent condition included in the "altered" category, and showed a direct association with death. However, this association should be viewed with caution because of potential shortcomings in the validity of our data source.

Non-Spanish nationality also showed a stronger association with death, but this should likewise be interpreted with care. We could not obtain information about cyclists' expertise, and for non-Spanish cyclists, we did not know how long they had been living in Spain, or whether they had changed their cycling patterns while living abroad. Furthermore, all non-Spanish cyclists were clustered in a single subgroup which included people from countries which may differ widely in a large variety of aspects such as social and cultural characteristics as well as cycling infrastructure in their country of origin. This subgroup was thus too heterogeneous for informative comparisons. Consequently, the association found in our study undoubtedly deserves further research designed to address its underlying factors.

Like Kim and colleagues,[10] we observed that most traffic infractions (11 out of 18) were directly associated with death. Distraction while walking or driving has been deeply explored, but it is not the case while bicycling.[41] There are inherent limitations to record distractions when the cyclist died at the crash scene. In our study, "Distraction" was unexpectedly the only infraction inversely associated with death and statistically significant, but this category included a wide range of sources of distraction, such as involuntary risky behaviors and intentionally committed behaviors (e.g. use of technological devices). Although other authors have found distraction to be associated with a higher risk of crash [22], to our knowledge the association between distractions and the severity of the crash has not been previously assessed. A possible explanation for this inverse association with death could be the lower speed (an unobserved variable) while cycling distracted.[41] In relation with the reason for cycling, we found no associations with the likelihood of death. However, previous studies showed that work-related or utilitarian cycling was associated with less severe injuries because of cyclists' expertise, choice of safer routes and helmet use,[13] although greater injury severity was also associated with more experience and more frequent cycling.[12] Although some authors have reported different injury severity depending on the type of crash, especially when a motor vehicle was involved,[12,13,16,42] in the present study the direct association between death and collisions with moving vehicles did not differ significantly in comparison to other types of crashes (IDR 0.89, 95%CI 0.78–1.00). Nevertheless, because type of crash was a binary variable in our analysis (see Statistical analysis), all other types of collisions with moving vehicles were included in a single category and compared to other types of crashes (such as collisions with an obstacle, overturning or running off the road), hence the two groups were heterogeneous. Furthermore, unless the cyclist is fatally injured, cyclists are probably more likely to receive police assistance when they collide with another vehicle. Therefore cyclists who sustained minor injuries in the "other crashes" category were likely to be underrepresented in our sample.

Regarding environment-related variables, although some authors found no clear association with traffic lane characteristics or road geometry,[11,12] we identified an inverse association between intersections and death compared to other road configurations (straight roads or curves), in accordance with previous findings for injury severity.[14] But again, our two categories were heterogeneous, and the risks may differ among for different types of intersection.[9,43]

The location of the crash showed a close relationship with fatalities. Previous studies have reported less severe injuries in dense urban settings, and more severe injuries on rural or community roads. We found an inverse association with death for crashes in urban areas and community roads compared to highways. This association is probably related to the higher speeds reached on highways by cyclists or the other vehicles involved in crashes. In fact, speed has been previously associated with injury severity.[10,11,13,14,16]

Adverse meteorological conditions were directly associated with death, as reported by other authors.[9,10] This association is probably due to lower cyclist conspicuity under adverse weather conditions, although other authors found no clear association.[7,12,13] On the other hand, altered road surfaces were inversely associated with risk of death, which may be the result of cycling or driving at lower speeds. Nevertheless, other authors have reported more severe injuries on altered surfaces,[9,14] or found no association at all.[7,11] More research is needed to characterize the influence of weather and road conditions on risk of death among cyclists, given the discrepancies among findings from different studies.

Although the frequency of crashes was much greater during daylight hours, there was a direct association between crashes that occurred at night and death, as also found by Boufous et al.[11] and Wang et al.,[9] with a peak in the early morning hours, as reported by Asgarzadeh et al.[7] Other authors, however, found no association between time of the crash and injury severity or death, although one Danish study reported an association with daylight hours, probably because of the high standard of nighttime roadway lighting in Denmark[14]. Apart from the lack of conspicuity,[44] factors such as alcohol consumption, speed and exhaustion may play major roles in this association.[7,45] Finally, the lower risk of death in crashes recorded in more recent years in Spain may be explained by improvements in cycling infrastructure,[46] improved health care for injured cyclists,[1] and increased reporting of less serious road crashes by the police.

Strengths and limitations

Our data source for this analysis was the Spanish National Registry of Road Crashes with Victims. This registry contains information recorded over many years by police officers on a standard form. Our large sample size and total number of cyclist deaths made it possible for us to precisely estimate the magnitude of the associations between each variable in the model and fatal injuries. Our choice of main outcome categories reduced the possible effect of misrepresentation for certain independent variables in this police-based registry. Furthermore, the statistical approach used here considered variability in the outcome variable across provinces in Spain, and was intended to decrease the effect of missing values that could be explained by the remaining variables.

Nevertheless, a main limitation of our study is its observational nature, which prevents us from suggesting causal interpretations for the associations we found. Given that our analysis is based on information from a police-based registry designed to collect information on all types of road traffic crashes, as noted in the Methods section, selection bias is an important issue given the assumption that less serious crashes were underrepresented, because of a direct association between injury severity and reporting rates to the police.[47–49] Behavioral differences and differences in representation rates related to the categories for specific variables (e.g. gender) could not be measured with the available data, and this may have led to over- or underestimation of some of the observed associations. Regarding helmet use, we do not have information on the characteristics of the helmets, and cannot confirm that they were being worn correctly at the moment of the crash. Although we used a multiple imputation procedure to compensate for missing information, this method only partially resolves issues related with missing data; therefore our results may still be affected by biases of an undetermined magnitude. Furthermore, the dichotomization used for our multiple imputation procedure forced us to combine heterogeneous categories for some of the variables (e.g. psychophysical circumstances), so the results for these variables should be considered with due caution. Bias is also a potential limitation, because of the subjective nature of some variables recorded by police officers at the crash scene.

Finally, the lack of information regarding vehicle speed is an important limitation in our study. Although this is probably the most important factor affecting the severity of cyclists' injuries, no direct information was available for vehicle speed when the crash occurred.

CONCLUSIONS

We found strong associations between several cyclist- and environment-related variables and the probability of death, and suggest that these associations should be taken into account in efforts to prioritize public health measures aimed at reducing the number of cycling-related fatalities. In particular, we believe helmet use by cyclists needs to be encouraged. Although we are aware that the magnitude of the association between non-helmet use and death is not entirely causal, it supports the hypothesis that helmet use may significantly reduce the risk of death among cyclists involved in road crashes. Although using a helmet is now mandatory for all cyclists on open roads in Spain, our data show that even in recent years, the proportion of non-helmet-use has been non-negligible. Another topic which deserves attention is the risk in older cyclists, considering that this subgroup of cyclists will very likely grow in the coming years. Finally, the reasons for the higher risk of death during nighttime cycling merit further investigation in order to manage factors which are potentially modifiable by, for example, encouraging measures to improve cyclist conspicuity.

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429 **Author Contributions:** All authors meet the conditions for authorship. PLC conceived and designed the study, helped to draft the manuscript and critically revised it. DMS and VMR carried out the literature review and prepared the first draft of the manuscript. JPM, EMR and LMMR helped with the literature review and critically reviewed the manuscript. EJM critically reviewed the first draft of the manuscript, proposed corrections, and provided methodological advice. All authors approved the final version of this manuscript. The present article is part of the doctoral thesis of Daniel Molina-Soberanes in the Clinical Medicine and Public Health program at the University of Granada.

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445 **Data sharing statement:** All data relevant to the study are included in the article or uploaded as supplementary information.

KEY MESSAGES

What is already know on this subject

- Cycling is increasing but is associated with risks.
- Helmets are intended to protect against severe injury, but their effect on the risk of death remains unclear.

What this study adds

- Helmet non-use is directly associated with cyclist deaths, especially on highways.
- Work-related and non-work-related cycling did not differ in their association with the risk of death.
- Increasing age was directly associated with increasing risk of death, especially after the third decade of life.

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Appendix 1. Adjusted incidence-density ratios (IDR) in a multivariate unilevel model for the imputed associations between cyclist-related variables and the risk of death in the first 24 hours after a road crash. Spain, 1993-2013.

Variable	Category	IDR	95% CI		P value	FMI(2)
Helmet use	Yes(1)	1	-	-	-	-
	No	1.41	1.23	1.62	<0.001	0.091
Age (years)	< 10	0.93	0.58	1.47	0.744	0.020
	10 a 14	1.02	0.75	1.38	0.904	0.038
	15 a 19	1.13	0.85	1.50	0.389	0.036
	20 a 24	0.98	0.71	1.34	0.879	0.046
	25 a 29(1)	1	-	-	-	-
	30 a 34	1.27	0.94	1.73	0.124	0.057
	35 a 39	1.81	1.36	2.41	<0.001	0.035
	40 a 44	1.68	1.25	2.26	0.001	0.039
	45 a 49	1.85	1.37	2.49	<0.001	0.036
	50 a 54	2.15	1.59	2.90	<0.001	0.029
	55 a 59	2.92	2.18	3.91	<0.001	0.033
	60 a 64	3.55	2.67	4.72	<0.001	0.034
	65 a 69	4.43	3.38	5.81	<0.001	0.034
	70 a 74	3.57	2.55	4.99	<0.001	0.028
	> 74	4.48	3.39	5.91	<0.001	0.038
Sex	Male(1)	1	-	-	-	-
	Female	0.82	0.68	1.00	0.045	0.019
Psychophysical circumstances	Normal(1)	1	-	-	-	-
	Altered	1.44	1.09	1.90	0.011	0.309
Nationality	Spanish(1)	1	REF	REF	REF	REF
	Other nationality	1.37	1.16	1.61	<0.001	0.017
Commission of infraction	None(1)	1	-	-	-	-
	Distraction	0.71	0.57	0.89	0.002	0.005
	Incorrect use of lighting	1.48	0.93	2.37	0.097	0.007
	Wrong way	1.19	0.78	1.82	0.423	0.004
	Invading the opposite lane	2.00	1.53	2.60	<0.001	0.004
	Incorrect turning	1.52	1.25	1.85	<0.001	0.004
	Illegal passing	2.12	1.28	3.49	0.003	0.001

	Disregarding safety distance	0.44	0.20	0.99	0.047	0.003
	Failure to yield right of way	1.77	1.38	2.28	<0.001	0.005
	Disregarding traffic lights	1.44	0.87	2.39	0.161	0.016
	Disregarding stop lights	2.53	2.02	3.15	<0.001	0.003
	Disregarding crossing signals	1.65	1.02	2.66	0.041	0.001
	Disregarding other signals	2.94	1.39	6.24	0.005	0.017
	Not indicating a maneuver	1.19	0.53	2.66	0.679	<0.001
	Entering traffic flow without precaution	1.94	1.37	2.74	<0.001	0.004
	Cycling while standing	2.01	0.28	14.39	0.487	<0.001
	Cycling in parallel	1.89	1.04	3.46	0.038	0.002
	Cycling outside traffic lanes	2.09	1.64	2.66	<0.001	0.004
	Other	1.89	1.63	2.19	<0.001	0.014
Reason for cycling	Work-related(1)	1	-	-	-	-
	Other reason	1.13	0.94	1.36	0.204	0.081

(1) Reference category
(2) Fraction of missing information

4

Appendix 2. Adjusted incidence-density ratios (IDR) in a multivariate unilevel model for the imputed associations between crash- and environment-related variables and the risk of death in the first 24 hours after a road crash. Spain, 1993-2013.

Variable	Category	IDR	95% CI		P value	FMI(2)
Type of crash	Collision with moving vehicle(1)	1	-	-	-	-
	Other	0.89	0.78	1.00	0.058	0.014
Traffic lane characteristics	Intersection(1)	1	-	-	-	-
	Other	1.64	1.45	1.86	<0.001	0.007
Area	Highway(1)	1	-	-	-	-
	Urban area	0.18	0.16	0.21	<0.001	0.015
	Community road	0.59	0.47	0.74	<0.001	0.003
Meteorological conditions	Good weather(1)	1	-	-	-	-
	Any adverse circumstances	1.37	1.08	1.73	0.009	0.005
Road surface	Normal(1)	1	-	-	-	-
	Altered	0.76	0.59	0.97	0.030	0.006
Time of day (24-hour clock)	0:00-2:59(1)	1	-	-	-	-
	3:00-5:59	1.55	1.01	2.38	0.043	0.009
	6:00-8:59	0.77	0.54	1.09	0.141	0.012
	9:00-11:59	0.45	0.33	0.64	<0.001	0.014
	12:00-14:59	0.40	0.28	0.55	<0.001	0.014
	15:00-17:59	0.45	0.32	0.63	<0.001	0.012
	18:00-20:59	0.48	0.35	0.67	<0.001	0.012
	21:00-23:59	0.60	0.43	0.85	0.004	0.012
Years	2011 - 2013(1)	1	-	-	-	-
	2008 - 2010	1.34	1.07	1.69	0.010	0.012
	2005 - 2007	2.10	1.70	2.60	<0.001	0.015
	2002 - 2004	2.16	1.75	2.68	<0.001	0.012
	1999 - 2001	2.42	1.96	2.98	<0.001	0.010
	1996 - 1998	2.31	1.87	2.85	<0.001	0.012
	1993 - 1995	2.67	2.17	3.29	<0.001	0.015
Province	Alava	1	-	-	-	-
	Albacete	1.51	0.80	2.87	0.206	0.004
	Alicante	1.02	0.61	1.71	0.928	0.004
	Almería	1.61	0.92	2.83	0.095	0.006
	Ávila	0.29	0.07	1.25	0.097	0.001

Badajoz	1.96	1.06	3.62	0.032	0.007
Baleares	1.25	0.76	2.07	0.373	0.005
Barcelona	1.01	0.62	1.64	0.974	0.009
Burgos	1.35	0.76	2.43	0.308	0.003
Cáceres	1.48	0.64	3.39	0.360	0.002
Cádiz	1.04	0.56	1.91	0.907	0.007
Castellón	1.08	0.61	1.91	0.798	0.005
Ciudad Real	1.28	0.71	2.31	0.417	0.005
Córdoba	1.12	0.60	2.10	0.715	0.003
Coruña, La	1.12	0.62	2.02	0.714	0.003
Cuenca	2.95	1.45	6.02	0.003	0.003
Girona	1.07	0.62	1.85	0.799	0.006
Granada	1.18	0.66	2.10	0.584	0.005
Guadalajara	1.91	0.76	4.80	0.169	0.001
Guipúzcoa	0.65	0.36	1.18	0.157	0.003
Huelva	0.89	0.41	1.93	0.774	0.002
Huesca	1.36	0.70	2.66	0.365	0.003
Jaen	1.41	0.65	3.04	0.386	0.003
León	1.49	0.88	2.54	0.140	0.004
Lleida	1.38	0.75	2.57	0.302	0.003
La Rioja	2.15	1.18	3.92	0.013	0.003
Lugo	1.16	0.60	2.25	0.654	0.003
Madrid	1.10	0.66	1.82	0.725	0.006
Málaga	1.24	0.69	2.21	0.474	0.004
Murcia	1.76	1.05	2.94	0.031	0.005
Navarra	1.91	1.08	3.41	0.027	0.005
Orense	1.96	1.04	3.67	0.037	0.003
Asturias	0.76	0.43	1.33	0.335	0.004
Palencia	1.24	0.63	2.42	0.537	0.004
Palmas, Las	1.70	0.93	3.08	0.084	0.003
Pontevedra	0.96	0.52	1.75	0.886	0.003
Salamanca	1.49	0.74	2.99	0.261	0.003
Santa Cruz	1.43	0.76	2.73	0.270	0.003
Cantabria	0.97	0.53	1.75	0.909	0.004
Segovia	1.53	0.69	3.41	0.298	0.006
Sevilla	1.38	0.82	2.35	0.230	0.003
Soria	1.81	0.72	4.56	0.207	0.002
Tarragona	1.52	0.91	2.54	0.111	0.005
Teruel	1.77	0.74	4.24	0.201	0.002
Toledo	2.37	1.36	4.12	0.002	0.003

Valencia	1.28	0.78	2.10	0.324	0.005
Valladolid	1.58	0.87	2.86	0.134	0.004
Vizcaya	0.68	0.37	1.22	0.193	0.003
Zamora	2.54	1.36	4.73	0.003	0.004
Zaragoza	1.71	0.99	2.95	0.056	0.005

(1) Reference category
(2) Fraction of missing information

4

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*8*
Bias	9	Describe any efforts to address potential sources of bias	9
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	N/A
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	8
		(*c*) Explain how missing data were addressed	9
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Table 1 and Table 2
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10
		(b) Indicate number of participants with missing data for each variable of interest	Table1 and Table 2
Outcome data	15*	Report numbers of outcome events or summary measures	10
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear	14

		which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	Table 1 and Table 2
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	17
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	22
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	23
Generalisability	21	Discuss the generalisability (external validity) of the study results	23
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	25

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.