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

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1 **Individual and environmental factors associated with death on cyclists involved in road**

2   **crashes in Spain**

3

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31 **ABSTRACT**

32 **Objective:** To quantify the magnitude of associations between cyclist fatalities and both cyclist-

33 and environment-related characteristics in Spain during the first 24 hours after a crash.

34 **Methods:** We designed a case series study to analyze data for all 65,977 cyclists recorded

35 between 1993 and 2013 in the Spanish Register of Road Crashes with Victims. To mitigate the

36 effect of missing values, we used a multiple imputation procedure. Differences between regions

37 were assumed and managed with a multilevel approach including cyclist and province levels.

38 Incidence density ratios (IDR) with 95% confidence intervals (95%CI) were calculated with a

39 multivariate Poisson model.

40 **Results:** Lack of helmet use was directly associated with death (IDR 1.43, 95%CI 1.25–1.64).

41 Among other cyclist´s characteristics, age after the third decade of life was also directly

42 associated with death, especially in older cyclists ("over 74" category, IDR 4.61, 95%CI 3.49–

43 6.08). Work-related cyclists showed no differences compared to other types of cyclists.

44 There was a direct association with death for crashes on rural roads and highways. Any adverse

45 meteorological condition also showed a direct association but altered road surfaces were

46 associated inversely. Crashes during night-time were directly associated with death, with its peak

47 between 3:00 to 5:00 am (IDR 1.58, 95%CI 1.03–2.41).

48 **Conclusions:** We found strong associations between several cyclist- and environment-related

49 variables and death, either directly or inversely. These variables should be considered in efforts

50 to prioritize public health measures aimed at reducing the number of cycling-related fatalities.

51

52 **Keywords:** cyclist; risk factor; road crash; fatality

53

54 **Word count**: 2933

55

56 **ARTICLE SUMMARY**

57 **Strengths and limitations of this study**

58 - We used a nationwide database which contains information of nearly 66,000 cyclists.

59 - The database compiles huge information on the characteristics of the people involved, their

60 vehicles and the environment.

61 - As the database is a police-based registry, it can be assumed that less serious crashes are

62 underrepresented

63 - We had to cope with missing data, so information biases cannot be discarded even if we used a

64 multiple imputation procedure.

65

67 **BACKGROUND**

68   Cycling is increasing as an alternative to private cars.[1] But it can also be harmful: there

69 are about 5.5 times more traffic deaths per kilometer traveled by bicycle than by car.[2] In Spain,

70 the number of people who use bicycles daily or almost daily has nearly doubled since the mid-

71 2000s.[3] Although the annual number of cyclist deaths decreased from 75 to 58 between 2006 and

72 2015,[4] there are still peaks in certain years, highlighting the importance of cycling as a cause of

73 death. Nevertheless, relatively few studies have aimed to quantify the association between

74 different factors and cycling fatalities, given that most previous studies were based mainly on

75 non-fatal injuries, and their results are far from consistent. Furthermore, for factors that have

76 shown a clear association in one direction (for example, the protective effect of helmets) there is

77 no consensus regarding the magnitude of effect.[5] The present study was designed to quantify the

78 magnitude of the associations between cyclist- and environment-related characteristics and the

79 likelihood of cyclist fatality within the first 24 hours post-crash in Spain between 1993 and 2013.

80

81 **METHODS**

82   We analyzed the case series comprising all 65,977 cyclists involved in road crashes

83 recorded in the Spanish National Registry of Road Crashes with Victims between 1993 and

84 2013. Crashes in the autonomous cities of Ceuta and Melilla were excluded because of their

85 specific characteristics and low mortality: both cities are located in northern Africa, and all road

86 crashes involving cyclists occurred in urban areas. The aforementioned nationwide database,

87 maintained and anonymized by the Spanish National Directorate of Traffic, contains information

88 recorded by national police agents at the crash scene, and compiles information on the

89 characteristics of the persons involved (e.g. age, sex), their vehicles (e.g. type, condition), and

90   the environment (e.g. type of crash, road characteristics).[6] A detailed description of this database

91   can be consulted in a previous publication.[7]

92   From this Registry we collected information about a subset of variables which, according

93   to previous studies and based on univariate analysis, could be associated (directly or indirectly)

94   with injury severity (see the list below). The categories used in our analysis of each variable are

95   shown in parentheses, along with their original categories from the database (see Appendices A.1

96   and A.2 for frequencies).

97

98   **Study variables**

99   - Death within the first 24 hours after the crash (Yes/No)

100   - Helmet use (Yes/No)

101   - Age (3 to 94 years, stratified in 5-year subgroups except in the categories "under 10"

102   and "75 and older")

103   - Sex (Male/Female)

104   - Psychophysical circumstances (No/Yes – including alcohol consumption with breath

105   test, alcohol consumption without breath test, drug consumption, sudden illness,

106   sleepiness or drowsiness, tiredness, or appearing worried, as perceived by the police

107   officer –)

108   - Nationality (Spanish/Other – including French, Moroccan, German, British, Italian,

109   Swiss, Belgian, Dutch, American, other Magreb countries, other countries –)

110   - Commission of infraction (None/Distraction/Incorrect use of lighting/Wrong

111   way/Crossing into opposite lane/Incorrect turning/Illegal passing/Disregarding safety

112   distance/Failure to yield right of way/Disregarding traffic lights/Disregarding stop

113   lights/Disregarding crossing signals/Disregarding other signals/Not signaling a

114   maneuver/Entering traffic flow without caution/Cycling while standing/Cycling in

115   parallel/Cycling off traffic lanes/Other)

116   - Reason for cycling (To or From work, Other work-related/Other reasons – leaving for

117   or returning from vacation, leaving for or returning from holiday or long weekend,

118   emergency, leisure –)

119   - Type of crash (Collision with moving vehicle/Other – collision with an obstacle

120   including stopped vehicles, collision with a pedestrian, collision with an animal,

121   overturning, running off the road, other type of crash –)

122   - Traffic lane characteristics (Intersection – T or Y configuration, X or + configuration,

123   entrance ramp, exit ramp, traffic circle, other intersection – /Other – straightaway, gentle

124   curve, unmarked sharp curve, marked sharp curve without posted speed limit, marked

125   sharp curve with posted speed limit –)

126   - Area (Highway/Urban area/Community road)

127   - Meteorological conditions (Good weather/Any adverse circumstances – heavy fog, light

128   fog, light rain, heavy rain, hail, snow, strong winds, other –)

129   - Road surface (Normal/Altered – shaded, wet, ice, snow, slick formed from water + dirt

130   + oil, loose gravel, oil, other –)

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

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

133   - Province (see below)

134

135   **Statistical analysis**

136   We built a fixed-effect multivariate Poisson regression model (a generalized linear model

137   which uses log [rate] as the link function) to obtain adjusted incidence density ratios (IDR) of

138   death for each category of every variable, to assess the magnitude of associations with cyclist

139   death rates. IDR is a good estimate of the relative risk (RR) of death across categories of

140   independent variables when, as in this analysis, the risk of death yields exactly the same value as

141   the death rate for a fixed amount of persons-time (i.e., the number of cyclists involved in road

142   crashes multiplied by the same follow-up period for all of them). For each IDR, its

143   corresponding 95% confidence interval (95%CI) was also calculated.

144   Spain is divided in 50 provinces, which differ markedly regarding cycling density, cycler-

145   friendly environment, socioeconomic conditions and health care facilities, among other

146   important factors potentially related with cyclists' risk of death. Therefore, we first tested the

147   hypothesis that the province level would explain a significant part on the total variance in the

148   outcome variable (cyclist fatalities). For this purpose, we constructed both unilevel (Appendices

149   A.3 and A.4) and multilevel (province level) empty models, and compared the variances

150   explained by each. Significant differences (P<0.001 for the likelihood ratio test) between the two

151   models were obtained, thus confirming our hypothesis. This led us to choose a multilevel

152   multivariate model for the main results.

153   More than 25% of the data were missing for some variables (e.g. helmet use) (see

154   Appendices A.1 and A.2 for details). The overall amount of these missing values may be

155   explained by missing at random (MAR) and missing not at random (MNAR) mechanisms.

156   Although we cannot compensate for MNAR values, we can control MAR values through a

157   multiple imputation procedure. Therefore, we initially assumed that some missing values might

158   be explained by the combination of the values observed for some of the remaining variables in

159 the database. To test this assumption, for each variable with missing values we constructed a

160 multivariate regression model with the existence or not of missing values as the dependent

161 variable, and the observed values for the remaining variables as independent terms. In all cases

162 we observed parameters of association significantly away from the null. These results supported

163 our initial hypothesis and led us to build 50 files in which missing data were represented as

164 stabilized variances estimated from different variables, according to the chained equations

165 method described by van Buuren[8] and implemented with the ice command in Stata.[9] This is a

166 community-contributed Stata command focused on simplifying the imputation of categorical

167 variables. However, this procedure was unable to provide missing values for many categorical

168 variables with more than two strata when the frequency of responses in different categories was

169 low, and we thus opted to dichotomize these variables. Age was imputed based on its logarithm

170 to maintain positive values, and its antilogarithm was then used to transform it into a categorical

171 variable. We therefore built a multilevel (including cyclist-level and province-level) fixed-effect

172 multivariate Poisson regression model for each of our 50 complete datasets to obtain adjusted

173 incidence density ratios (IDR). We then used the community-contributed mim command for

174 Stata[10] to combine the estimates obtained for each imputed file according to the Rubin method.[11]

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

176

RESULTS

178   Appendices A.1 and A.2 summarize descriptive information on cyclist- and

179 crash/environment-related characteristics. Fatality was a rare event (2.49%). The male-to-female

180 ratio was greater than 8:1. The main mechanism for crashes was collision with another vehicle

181 (69.40%), and most crashes occurred in urban areas (60.71%) followed by highways (35.71%)

182 and community roads (3.58%). Although most crashes occurred during the day (83.44% between

183 9:00 and just before 21:00), many of them (47.48%) occurred shortly after the end of the

184 morning and afternoon work shifts, i.e. from 12:00 to just before 15:00, and from 18:00 to just

185 before 21:00.

186   Table 1 shows the IDR for the association between cyclist characteristics and the risk of

187 death. A direct association was found with cyclists' age from the 30-to-34 years old group

188 onward, and was greatest in the "over 74 years" category (IDR 4.61, 95%CI 3.49–6.08). Non-use

189 of a helmet was associated with a 43.45% higher chance of death (IDR 1.43, 95%CI 1.25–1.64).

190 Male gender, psychophysical circumstances, nationality other than Spanish, and committing an

191 infraction (except for "distraction" and "disregarding safety distance") showed also a direct

192 association with death. Work-related cyclists showed no differences compared to other types of

193 cyclists (i.e., those who cycled as a leisure activity or for other reasons).

194

195 **Table 1.** Adjusted incidence-density ratios (IDR) for the association between cyclist-related

196 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

197

198   Table 2 shows the IDR for the association between environmental characteristics and the

199 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						

210

DISCUSSION

212   Our results are generally in agreement with those of previous studies regarding the

213 direction and magnitude of the associations between cyclist- and environment-related factors and

214 the severity of crashes involving cyclists.[5,13-25] Perhaps our most important finding is the

215 association between non-use of a helmet and a higher chance of death. Although the protective

216 effect of helmet use on the risk of head trauma is widely accepted,[13,22] this effect has not been

217 shown for risk of death given that relatively few studies to date have focused on this association,

218 and their results are inconsistent.[5] Although our study is observational and causality cannot be

219 demonstrated, it is unlikely that residual confounding could entirely explain an association of the

220 magnitude we observed. We are confident that our approach to the analysis was robust given that

221 it included appropriate management of missing values, controlling for between-province-level

222 variance, and multivariate adjustment for most well-known confounders of the association

223 between helmet use and death. Therefore, taking into account that helmet use is the most easily

224 modifiable cyclist-dependent risk factor, our results suggest that a non-negligible amount of

225 cyclist deaths might be prevented by increasing helmet use in our population of cyclists.

226   Regarding other cyclist-related variables, the association we found between age and risk

227 of death is consistent with previous studies.[14,18,19,25] This association is usually explained on the

228 basis of mechanisms such as greater fragility, loss of physical agility, decreased visual acuity and

229 concomitant diseases. In contrast to other authors,[23,26] we found no association between young

230 age and death.

231 In relation to gender, we found that hazard of death was higher for males, as it was

232 reported previously.[17,25,26] This association has been explained as a result of either physical

233 differences or safer behaviors in females,[16] which may be associated with the severity of the

234 crash itself. However, some authors have not observed this association[18,19] or have found an

235 association in the opposite direction.[14]

236 We identified a direct association between alcohol consumption, along with other

237 psychophysical circumstances, and death, which was also noted previously.[19,24] According to

238 some authors, alcohol consumption is associated with risky behaviors[15,21] when cycling and

239 driving other types of vehicles. However, the association found in our study should be viewed

240 with caution because of potential shortcomings in the validity of our data source. The low

241 number of cyclists in the original categories for this variable forced us to combine alcohol

242 consumption, drug consumption, tiredness, sleepiness and other psychophysical circumstances

243 into the single category "altered", obscuring the true association between each type of

244 psychophysical circumstance and death. Non-Spanish nationality also showed a higher

245 probability of death, but this should likewise be interpreted with care. We could not obtain

246 information about cyclists' expertise, and for non-Spanish cyclists, we did not know how long

247 they had been living in Spain, or whether they had changed their cycling patterns while living

248 abroad. Furthermore, all non-Spanish cyclists were clustered in a single subgroup which included

249 people from countries which may differ widely in a large variety of aspects such as social and

250 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

274   association is probably related with the speeds reached by cyclists or the other vehicles involved

275   in crashes.

276   Adverse meteorological conditions were directly associated with death, as reported by

277   other authors.[20] This association is probably due to lower cyclist conspicuity under adverse

278   weather conditions. On the other hand, altered road surfaces were inversely associated with risk

279   of death, which may be a result of cycling or driving at lower speeds. More research is needed to

280   characterize the influence of weather and road conditions on risk of death among cyclists, given

281   that our findings differ from previous studies.[19]

282   Although the frequency of crashes was much greater during daylight hours, there was a

283   direct association between night hours and death, with a peak in the early morning hours.[14] Apart

284   from lack of conspicuity,[28] factors such as alcohol consumption, speed and exhaustion may play

285   major roles in this association.[29] Finally, the lower risk of death in crashes recorded in more

286   recent years may be explained by improvements in cycling infrastructure,[28] improved health care

287   for injured cyclists,[1] and increased reporting of less serious road crashes by the police.

288   **Limitations**

289   A main limitation of our study is its observational nature, which prevents us from

290   suggesting causal interpretations of the associations we found. Given that our analysis is based

291   on information from a police-based registry designed to collect information on all types of road

292   traffic crashes, as noted in the Methods section, selection bias is an important issue because it

293   can be assumed that less serious crashes were underrepresented.[30-33] Although we used a multiple

294   imputation procedure to address missing information, this method only partially resolves issues

295   related with missing data; therefore our results may still be affected by biases of an undetermined

296   magnitude. Information bias is also a potential limitation, due to the subjective nature of some

297   variables recorded by police officers at the scene of the crash.

298   Finally, the lack of information regarding vehicle speed is an important limitation in our

299   study. Although this is probably the most important factor affecting the severity of cyclists'

300   injuries, no direct information was available for vehicle speed when the crash occurred.

301

302   **CONCLUSIONS**

303   We found strong associations between several cyclist- and environment-related variables

304   and the probability of death, and suggest that these associations should be taken into account in

305   efforts to prioritize public health measures aimed at reducing the number of cycling-related

306   fatalities. In particular, we believe helmet use by cyclists needs to be encouraged. Although we

307   are aware that the magnitude of the association between non-helmet use and death is not entirely

308   causal, it supports the hypothesis that helmet use may significantly reduce the risk of death

309   among cyclists involved in road crashes. Although using a helmet is now mandatory for all

310   cyclists on open roads in Spain, our data show that even in recent years, the proportion of non-

311   helmet-use has been non-negligible. Another topic which deserves attention is the risk in older

312   cyclists, considering that this subgroup of cyclists will very likely grow in the coming years.

313   Finally, the reasons for the higher risk of death during nighttime cycling merit further

314   investigation in order to manage factors which are potentially modifiable by, for example,

315   encouraging measures to improve the conspicuity of cyclists.

316

338   **KEY MESSAGES**

339

340   **What is already know on this subject**

341   - Cycling is increasing but it can be harmful

342   - Helmets are intended to protect against injury severity, but its effect on death remains

343   unclear.

344

345   **What this study adds**

346   - Helmet non-use is associated directly with death in cyclists, especially on highways

347   - Work-related cyclists showed no difference in their association with death than other

348   cyclists

349   - As age increases, direct association with death increases, especially after the third decade

350   of life.

351

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APPENDICES

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

Variable	Category For analysis	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
	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*
Nationality		*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
	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
Commission of infraction	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
	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
Reason for cycling		*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.

5
6

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
	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*
Type of crash		*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
	Intersection		28,283	42.87	28,283	43.23
		T or Y configuration	*11,263*	*17.07*	*11,263*	*17.22*
Traffic lane characteristics		*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
	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*
Road surface		*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
	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
Time of day (hours)		*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
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*
Years	*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

Appendix A.4. 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**
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

15

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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1 **Individual and environmental factors associated with death of cyclists involved in road**

2 **crashes in Spain: a cohort study**

3

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31

32 **ABSTRACT**

33 **Objective:** To quantify the magnitude of associations between cyclist fatalities and both cyclist-

34 and environment-related characteristics in Spain during the first 24 hours after a crash.

35 **Design:** Cohort study

36 **Setting:** Spain

37 **Participants:** 65,977 cyclists injured in road crashes recorded between 1993 and 2013 in the

38 Spanish Register of Road Crashes with Victims

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

40 **Methods:** A multiple imputation procedure was used to mitigate the effect of missing values.

41 Differences between regions were assumed and managed with multilevel analysis at the cyclist

42 and province levels. Incidence density ratios (IDR) with 95% confidence intervals (95%CI) were

43 calculated with a multivariate Poisson model.

44 **Results:** Non-use of a helmet use was directly associated with death (IDR 1.43, 95%CI 1.25–

45 1.64). Among other cyclist characteristics, age after the third decade of life was also directly

46 associated with death, especially in older cyclists ("over 74" category, IDR 4.61, 95%CI 3.49–

47 6.08). The association with death did not differ between work-related cycling and other reasons

48 for cycling.

49 There was an inverse association with death for crashes in urban areas and on community roads.

50 Any adverse meteorological condition also showed a direct association with death, whereas

51 altered road surfaces showed an inverse association. Crashes during nighttime were directly

52 associated with death, with a peak between 3:00 and 5:59 am (IDR 1.58, 95%CI 1.03–2.41).

53 **Conclusions:** We found strong direct and inverse associations between several cyclist- and

54 environment-related variables and death. These variables should be considered in efforts to

55 prioritize public health measures aimed at reducing the number of cycling-related fatalities.

56

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

58

59 **Word count**: 4142

60

61 **ARTICLE SUMMARY**

62 **Strengths and limitations of this study**

63 - We used a nationwide database with information on 65,977 cyclists.

64 - The database compiles abundant information on the characteristics of the people involved, their

65 vehicles and the environment.

66 - Because the database is a police-based registry, it can be assumed that less serious crashes are

67 underrepresented.

68 - Because of missing data, information biases cannot be ruled out despite the multiple imputation

69 procedure used.

70 **INTRODUCTION**

71   Cycling is considered a healthy alternative to private cars because it helps increase

72 physical activity and reduce carbon emissions.[1] But it can also be harmful: there are about 5.5

73 times more traffic deaths per kilometer traveled by bicycle than by car.[2] In fact, cyclists along

74 with pedestrians are the most vulnerable road users because of their lack of protection and

75 comparatively greater likelihood of suffering severe injuries or dying after a crash.[3] These

76 outcomes can be caused mainly by factors related to the cyclist (as in single-vehicle crashes) or

77 related to other road users (as in collisions with other vehicles), or even by environment-related

78 factors. Understanding the factors involved in cyclist injuries and deaths is necessary in order to

79 design and promote better public policies worldwide to encourage safe cycling. The current

80 transition in commuting patterns in Spain merits attention, because the number of people who

81 use bicycles daily or almost daily has nearly doubled since the mid-2000s.[4] Public policies in

82 this country promote cycling not only as a leisure activity, but as a regular mode of transport.

83 Although the annual number of cyclist deaths decreased from 75 to 58 between 2006 and

84 2015,[5] this tendency is expected to revert in the absence of interventions aimed at making

85 cycling a safer activity.

86   Many previous studies have identified individual and/or environmental factors associated

87 with injury severity or fatalities among cyclists.[6-17] However, there is no consensus regarding

88 the magnitude or even the direction of some observed associations. Death is sometimes

89 considered the most severe injury category along with other serious injuries, rather than as a

90 specific category itself.[6–8,10,15] Because death of one or more cyclists after a crash is

91 uncommon, some studies found no statistically significant associations between this outcome and

92 a number of variables,[6] and multivariate analysis was not possible in some studies because of

93 the small numbers involved.[15] In studies that did report significant associations, the findings

94 may still be debatable: recent metaanalyses have consistently shown an inverse association

95 between helmet use and head injury severity, although these studies focused mainly on non-fatal

96 injuries.[18,19] Olivier and Creighton[18] found only two studies that reported effect sizes for

97 fatalities, and Høye[19] was obliged to merge fatalities with serious injuries in a single category

98 for most of her analyses.

99   Regarding age and gender differences, the biological effect of aging is a plausible cause

100 for the association between cyclist involvement in a road crash and greater injury severity,[7–

101 11,13,15,17] but the relationship between age and death in some age groups (e.g. children or

102 adolescents) awaits clarification.[8,12,13,15,17] Both males[12,15,17] and females[11] have

103 been reported to be at increased risk of more severe injuries. Physical and behavioral aspects

104 related to gender have been argued to explain differences in injury severity,[20–22] but there is

105 no consensus.

106   Although alcohol consumption is known to be associated with risky behavior while

107 cycling,[23,24] studies focusing on the association between this factor and injury severity or

108 fatality are inconclusive.[9,11,13,16,17] The commission of infractions is reportedly associated

109 with injury severity or death, but only in bicycle collisions with a motor vehicle, not on other

110 types of crashes.[9]

111   Environmental factors can also play a major role as independent variables in fatal

112 outcomes. Traffic lane characteristics, e.g. intersections as opposed to open roadways, are

113 usually related to an increased risk of collision but not necessarily with more severe injuries

114 [10,11,13] except in unsignalized intersections.[8] Road surface and adverse weather

115 circumstances appear to be related to the likelihood of crashes, but their association with injury

116 severity or death also requires clarification, given that previous studies have found both a direct

117 association with injuries or death[8,9,13] and no association.[6,10–12] Time of day is related to

118 conspicuity, and has been linked to crash rates. However, the association found for injury

119 severity has not shown a clear direction: a direct association with severity has been reported

120 during daytime[6,9,13] and during nighttime,[8,10] with some analyses finding no association at

121 all.[11,12]

122   It seems obvious that cycling speed would be related to death after a crash. Because it is

123 almost impossible to measure speed at the time of the crash, proxy variables such as speed limit

124 at the site of the crash,[9,10,12,13] or the area of the crash[6,10,13] have been widely used. In

125 fact, speed may be the main reason for the greater severity of cyclists' injuries in crashes

126 involving a motor vehicle compared to single crashes, as reported in previous studies.[11,12,15]

127   Previous research in Spain has focused on impacts on cyclists' health,[25,26] their

128 behavior and other correlates with crash involvement,[20,21,27,28] and the causal chain of

129 events related to death after a crash.[29] However, to our knowledge there have been no attempts

130 to analyze personal and environmental characteristics and their relationship with the risk of

131 death.

132   To help fill the gaps in our current knowledge, we designed a large nationwide study to

133 quantify the magnitude of the associations between cyclist- and environment-related

134 characteristics and the likelihood of cyclist fatality within the first 24 hours post-crash in Spain

135 between 1993 and 2013.

136

137 **METHODS**

138 **Data source and study population**

139   We analyzed the cohort comprising all 65,977 cyclists involved in road crashes recorded

140   in the Spanish National Registry of Road Crashes with Victims between 1993 and 2013 once the

141   crashes in the autonomous cities of Ceuta and Melilla were excluded because of their specific

142   characteristics and low mortality: both cities are located in northern Africa, and all road crashes

143   involving cyclists occurred in urban areas.

144   The aforementioned registry is a nationwide electronic database maintained by the

145   Spanish General Directorate of Traffic. It has high security standards to protect anonymity, and

146   was developed to support the design and evaluation of public policies concerning road safety.

147   Researchers can use this data upon specific request, after a motivation letter is accepted by the

148   Directorate authorities. This database contains information from the Statistical Questionnaire of

149   the Accident documents submitted for every crash resulting in injury or death and involving at

150   least one moving vehicle in areas subject to traffic laws. Information in the registry includes the

151   characteristics of the persons involved (e.g. age, sex), their vehicles (e.g. type, condition), and

152   the environment (e.g. type of crash, geographic coordinates, road characteristics). It does not

153   include information that may lead to personal identification. Victims are categorized as injured if

154   they are seen by a health care service, or as dead if they die at the crash scene or within the first

155   30 days. This questionnaire is completed by national police agents at the crash scene, and filed

156   within the first 24 hours for crashes that result in death or severe injury (needing hospitalization),

157   or within the next 10 days after the crash. All data must be submitted within the first 30 days

158   post-event, including follow-up information from health care services. Amendments to the

159   infrastructure data recorded at the crash scene can be made within the next 30 days by the

160   appropriate authorities.[30]

161

162 **Patient and public involvement**

163   This study relies on data collected by the Spanish General Directorate of Traffic; no

164 patients or participants interacted with the study authors.

165

166 **Variables**

167   We collected information about a subset of variables which, according to previous studies

168 and based on univariate analysis, may be associated directly or indirectly with injury severity.

169 Our dependent variable was death within the first 24 hours after the crash as our main outcome,

170 and the independent variables were cyclist-related (age, sex, helmet use, psychophysical

171 circumstances, nationality, commission of infraction and reason for cycling) and crash- or

172 environment-related (type of crash, traffic lane characteristics, area, meteorological conditions,

173 road surface, time of day, year and province). Original categories and dichotomized categories

174 (see "Statistical analysis") can be viewed in the frequency distribution tables (Table 1 and Table

175 2).

176

177 **Statistical analysis**

178   Univariate analysis was first done for each variable included as an independent variable

179 and for death as the dependent variable. Then we built a Poisson regression model (a generalized

180 linear model which uses log [rate] as the link function). Spain is divided in 50 provinces which

181 differ markedly regarding cycling density, cycler-friendly environment, socioeconomic

182 conditions and health care facilities, among other important factors potentially related with

183 cyclists' risk of death. Therefore, we first tested the hypothesis that the province level would

184 explain a significant part on the total variance in the outcome variable (cyclist fatalities). For this

185 purpose, we constructed both unilevel (Appendices 1 and 2) and multilevel empty models

186 (including cyclist-level and province-level), and compared the variances explained by each.

187 Significant differences ($P<0.001$ for the likelihood ratio test) between the two models were

188 obtained, thus confirming our hypothesis. This led us to choose a multilevel multivariate model

189 for the main results.

190   More than 25% of the data were missing for some variables (e.g. helmet use) (see Tables

191 1 and 2 for details). The overall amount of these missing values may be explained by missing at

192 random (MAR) and missing not at random (MNAR) mechanisms. Although we cannot

193 compensate for MNAR values, we can control MAR values through a multiple imputation

194 procedure. Therefore, we initially assumed that some missing values might be explained by the

195 combination of the values observed for some of the remaining variables in the database. To test

196 this assumption, for each variable with missing values we constructed a multivariate regression

197 model with the existence or not of missing values as the dependent variable, and the observed

198 values for the remaining variables as independent terms. In all cases we observed parameters of

199 association significantly away from the null. These results supported our initial hypothesis and

200 led us to build 50 files in which missing data were represented as stabilized variances estimated

201 from different variables, according to the chained equations method described by van

202 Buuren[31] and implemented with the "ice" command in Stata.[32] This is a community-

203 contributed Stata command focused on simplifying the imputation of categorical variables.

204 However, this procedure was unable to provide missing values for many categorical variables

205 with more than two strata when the frequency of responses in different categories was low, and

206 we thus opted to dichotomize these variables. The dichotomization process considered

207 theoretical similarities between original categories (e.g. any adverse weather circumstances such

208 as rain, snow and hail were grouped in the category "any adverse circumstances") and tried to

209 keep the most important category for analysis unaltered (e.g. intersections). Age was imputed

210 based on its logarithm to maintain positive values, and its antilogarithm was then used to

211 transform it into a categorical variable. We used this approach to build a multilevel fixed-effect

212 multivariate Poisson regression model for each of our 50 complete datasets. Thus we obtain

213 adjusted incidence density ratios (IDR) for death for each category of every variable, to assess

214 the magnitude of associations with cyclist death rates. IDR is a good estimate of the relative risk

215 (RR) of death across categories of independent variables when, as in this analysis, the risk of

216 death yields exactly the same value as the death rate for a fixed amount of persons-time (i.e., the

217 number of cyclists involved in road crashes multiplied by the same follow-up period for all of

218 them). For each IDR, its corresponding 95% confidence interval (95%CI) was also calculated.

219 We then used the community-contributed "mim" command for Stata[33] to combine the

220 estimates obtained for each imputed file according to the Rubin method.[34]

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

222

223 **RESULTS**

224   Table 1 and Table 2 summarize descriptive information on cyclist- and

225 crash/environment-related characteristics. Fatality was a rare event (2.49%). The male-to-female

226 ratio was almost 8:1. The main mechanism for crashes was collision with another vehicle

227 (69.40%), and most crashes occurred in urban areas (60.71%), followed by highways (35.71%)

228 and community roads (3.58%). Although most crashes occurred during the day (83.44% between

229 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

235

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

237

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

238

239   Table 3 shows the IDR for the association between cyclist characteristics and the risk of

240   death. A tendency towards a direct association between cyclists' age and death was observed

241   from the third decade of life; the association was statistically significant (P<0.05) in categories

242   from 35-to-39 years and older, and was greatest in the "over 74 years" category (IDR 4.61,

243   95%CI 3.49–6.08). Non-use of a helmet was associated with a 43.45% higher chance of death

244   (IDR 1.43, 95%CI 1.25–1.64). Male gender, psychophysical circumstances, and nationality other

245   than Spanish showed a direct association with death. Committing an infraction was, in general,

246   directly associated with death. "Disregarding safety distance" and "distraction" were inversely

247   associated with death, but this association was statistically significant only for the latter

248   (P<0.05). The association for work-related cycling did not differ compared to other motives for

249   cycling (i.e., for leisure or for other reasons).

250

251   **Table 3.** Adjusted incidence-density ratios (IDR) for the association between cyclist-related

252   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

253

254   Table 4 shows the IDR for the association between environmental characteristics and the

255 risk of death. There were no conclusive trends according to the type of crash (IDR 0.89, 95%CI

256 0.78–1.00), but cycling through an intersection (IDR 1.65 for "other", 95%IC 1.46–1.87), in

257 urban areas, and on community roads were inversely association with death. This association

258 was also found for adverse meteorological conditions. However, when the road surface was

259 altered, the association was inverse. A direct association with death was found after midnight, in

260 the category "03:00-05:59" (IDR 1.58, 95%CI 1.03–2.41), whereas an inverse association was

261 found during the day, with a peak at midday between 12:00 and 14:59 (IDR 0.40, 95%CI 0.29–

262 0.56). Over the 10-year period analyzed here, there was a trend toward a higher likelihood of

263 death in the earlier years.

264

265 **Table 4.** Adjusted incidence-density ratios (IDR) for the association between crash- and

266 environment-related variables and the risk of death in the first 24 hours after a road crash. Spain,

267 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
	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
Years	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

268

DISCUSSION

270   Our results are generally in agreement with those of previous studies regarding the

271 direction and magnitude of the associations between cyclist- and environment-related factors and

272 the severity of crashes involving cyclists.[6–17] Perhaps our most important finding is the

273 association between non-use of a helmet and a higher chance of death. Although the protective

274 effect of helmet use on the risk of head trauma is widely accepted,[7–10,12–15] its association

275 with injury severity has been addressed mostly for non-fatal injuries given that relatively few

276 studies to date have focused on its association with death.[18,19] Although our study is

277 observational and causality cannot be demonstrated, it is unlikely that residual confounding

278 could entirely explain an association of the magnitude we observed. We are confident that our

279 approach to the analysis was robust given that it included appropriate management of missing

280 values, controlling for between-province-level variance, and multivariate adjustment for most

281 well-known confounders of the association between helmet use and death. Therefore, taking into

282 account that helmet use is the most easily modifiable cyclist-dependent risk factor, our results

283 suggest that a non-negligible amount of cyclist deaths might be prevented by increasing helmet

284 use in our population of cyclists.

285   Regarding other cyclist-related variables, the association we found between age and risk

286 of death is consistent with previous studies.[7,9,10] This association is usually explained on the

287 basis of mechanisms such as greater fragility, loss of physical agility, decreased visual acuity and

288 concomitant diseases. In contrast to other authors,[8,13,17] we found no association between

289 younger age and death.

290   In relation to gender, we found that the risk of death was higher for males, as reported

291 previously.[15,17] This association has been explained as a result of either physical differences

292 or safer behaviors in females,[22] which may be associated with the severity of the crash itself.

293 Other explanations have been based on the presumably riskier behavior in males when failing to

294 stop for red lights[36] and when their risk perception is lower.[20] On the other hand, female

295 gender has been associated with higher rates of reporting road crashes.[37] Because we

296 considered only injured cyclists or death as our main outcomes, and assuming there was no

297 difference between genders in deaths recorded in our database, differences in reporting non-fatal

298 road crashes could lead to overestimation of the association with death (if any) in the

299 underreported category. In fact, some authors did not observe this association,[7] or found female

300 gender to be related with injury severity.[11]

301   According to some authors, alcohol consumption is associated with risky

302 behaviors[23,24] when cycling and driving other types of vehicles, and is directly associated

303 with injury severity.[9,11,13,16] This condition could not be investigated in our study because of

304 the dichotomization process used to account for missing values. The low number of cyclists in

305 the original categories for the "psychophysical circumstances" variable forced us to combine

306 alcohol consumption, drug consumption, tiredness, sleepiness and other psychophysical

307 circumstances into a single "altered" category, obscuring the true association between each type

308 of psychophysical circumstance and death. Nevertheless, alcohol consumption with and without

309 a breath test was the most prevalent condition included in the "altered" category, and showed a

310 direct association with death. However, this association should be viewed with caution because

311 of potential shortcomings in the validity of our data source.

312 Non-Spanish nationality also showed a stronger association with death, but this should

313 likewise be interpreted with care. We could not obtain information about cyclists' expertise, and

314 for non-Spanish cyclists, we did not know how long they had been living in Spain, or whether

315 they had changed their cycling patterns while living abroad. Furthermore, all non-Spanish

316 cyclists were clustered in a single subgroup which included people from countries which may

317 differ widely in a large variety of aspects such as social and cultural characteristics as well as

318 cycling infrastructure in their country of origin. This subgroup was thus too heterogeneous for

319 informative comparisons. Consequently, the association found in our study undoubtedly deserves

320 further research designed to address its underlying factors.

321 Like Kim and colleagues,[9] we observed that most traffic infractions (11 out of 18) were

322 directly associated with death. "Distraction" was the only infraction inversely associated with

323 death, perhaps because it may be inversely associated with speed, an unobserved variable. In

324 relation with the reason for cycling, we found no associations with the likelihood of death.

325 However, previous studies showed that work-related or utilitarian cycling was associated with

326 less severe injuries because of cyclists' expertise, choice of safer routes and helmet use,[12]

327 although greater injury severity was also associated with more experience and more frequent

328 cycling.[11] Although some authors have reported different injury severity depending on the

329   type of crash, especially when a motor vehicle was involved,[11,12,15,38] in the present study

330   the direct association between death and collisions with moving vehicles did not differ

331   significantly in comparison to other types of crashes (IDR 0.89, 95%CI 0.78–1.00).

332   Nevertheless, because type of crash was a binary variable in our analysis (see Statistical

333   analysis), all other types of collisions with moving vehicles were included in a single category

334   and compared to other types of crashes (such as collisions with an obstacle, overturning or

335   running off the road), hence the two groups were heterogeneous. Furthermore, unless the cyclist

336   is fatally injured, cyclists are probably more likely to receive police assistance when they collide

337   with another vehicle. Therefore cyclists who sustained minor injuries in the "other crashes"

338   category were likely to be underrepresented in our sample.

339   Regarding environment-related variables, although some authors found no clear

340   association with traffic lane characteristics or road geometry,[10,11] we identified an inverse

341   association between intersections and death compared to other road configurations (straight

342   roads or curves), in accordance with previous findings for injury severity.[13] But again, our two

343   categories were heterogeneous, and the risks may differ among for different types of

344   intersection.[8,39]

345   The location of the crash showed a close relationship with fatalities. Previous studies

346   have reported less severe injuries in dense urban settings, and more severe injuries on rural or

347   community roads. We found an inverse association with death for crashes in urban areas and

348   community roads compared to highways. This association is probably related to the higher

349   speeds reached on highways by cyclists or the other vehicles involved in crashes. In fact, speed

350   has been previously associated with injury severity.[9,10,12,13,15]

351   Adverse meteorological conditions were directly associated with death, as reported by

352 other authors.[8,9] This association is probably due to lower cyclist conspicuity under adverse

353 weather conditions, although other authors found no clear association.[6,11,12] On the other

354 hand, altered road surfaces were inversely associated with risk of death, which may be the result

355 of cycling or driving at lower speeds. Nevertheless, other authors have reported more severe

356 injuries on altered surfaces,[8,13] or found no association at all.[6,10] More research is needed to

357 characterize the influence of weather and road conditions on risk of death among cyclists, given

358 the discrepancies among findings from different studies.

359   Although the frequency of crashes was much greater during daylight hours, there was a

360 direct association between crashes that occurred at night and death, as also found by Boufous et

361 al.[10] and Wang et al.,[8] with a peak in the early morning hours, as reported by Asgarzadeh et

362 al.[6] Other authors, however, found no association between time of the crash and injury severity

363 or death, although one Danish study reported an association with daylight hours, probably

364 because of the high standard of nighttime roadway lighting in Denmark[13]. Apart from the lack

365 of conspicuity,[40] factors such as alcohol consumption, speed and exhaustion may play major

366 roles in this association.[6,41] Finally, the lower risk of death in crashes recorded in more recent

367 years in Spain may be explained by improvements in cycling infrastructure,[42] improved health

368 care for injured cyclists,[1] and increased reporting of less serious road crashes by the police.

369 **Strengths and limitations**

370   Our data source for this analysis was the Spanish National Registry of Road Crashes with

371 Victims. This registry contains information recorded over many years by police officers on a

372 standard form. Our large sample size and total number of cyclist deaths made it possible for us to

373 precisely estimate the magnitude of the associations between each variable in the model and fatal

374 injuries. Our choice of main outcome categories reduced the possible effect of misrepresentation

375 for certain independent variables in this police-based registry. Furthermore, the statistical

376 approach used here considered variability in the outcome variable across provinces in Spain, and

377 was intended to decrease the effect of missing values that could be explained by the remaining

378 variables.

379 Nevertheless, a main limitation of our study is its observational nature, which prevents us

380 from suggesting causal interpretations for the associations we found. Given that our analysis is

381 based on information from a police-based registry designed to collect information on all types of

382 road traffic crashes, as noted in the Methods section, selection bias is an important issue given

383 the assumption that less serious crashes were underrepresented, because of a direct association

384 between injury severity and reporting rates to the police.[43–45] Behavioral differences and

385 differences in representation rates related to the categories for specific variables (e.g. gender)

386 could not be measured with the available data, and this may have led to over- or underestimation

387 of some of the observed associations. Regarding helmet use, we do not have information on the

388 characteristics of the helmets, and cannot confirm that they were being worn correctly at the

389 moment of the crash. Although we used a multiple imputation procedure to compensate for

390 missing information, this method only partially resolves issues related with missing data;

391 therefore our results may still be affected by biases of an undetermined magnitude. Furthermore,

392 the dichotomization used for our multiple imputation procedure forced us to combine

393 heterogeneous categories for some of the variables (e.g. psychophysical circumstances), so the

394 results for these variables should be considered with due caution. Bias is also a potential

395 limitation, because of the subjective nature of some variables recorded by police officers at the

396 crash scene.

397   Finally, the lack of information regarding vehicle speed is an important limitation in our

398   study. Although this is probably the most important factor affecting the severity of cyclists'

399   injuries, no direct information was available for vehicle speed when the crash occurred.

400

401   **CONCLUSIONS**

402   We found strong associations between several cyclist- and environment-related variables

403   and the probability of death, and suggest that these associations should be taken into account in

404   efforts to prioritize public health measures aimed at reducing the number of cycling-related

405   fatalities. In particular, we believe helmet use by cyclists needs to be encouraged. Although we

406   are aware that the magnitude of the association between non-helmet use and death is not entirely

407   causal, it supports the hypothesis that helmet use may significantly reduce the risk of death

408   among cyclists involved in road crashes. Although using a helmet is now mandatory for all

409   cyclists on open roads in Spain, our data show that even in recent years, the proportion of non-

410   helmet-use has been non-negligible. Another topic which deserves attention is the risk in older

411   cyclists, considering that this subgroup of cyclists will very likely grow in the coming years.

412   Finally, the reasons for the higher risk of death during nighttime cycling merit further

413   investigation in order to manage factors which are potentially modifiable by, for example,

414   encouraging measures to improve cyclist conspicuity.

415

439 **KEY MESSAGES**

440

441 **What is already know on this subject**

442 - Cycling is increasing but is associated with risks.

443 - Helmets are intended to protect against severe injury, but their effect on the risk of death

444   remains unclear.

445

446 **What this study adds**

447 - Helmet non-use is directly associated with cyclist deaths, especially on highways.

448 - Work-related and non-work-related cycling did not differ in their association with the risk

449   of death.

450 - Increasing age was directly associated with increasing risk of death, especially after the

451   third decade of life.

452

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575

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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31

32   **ABSTRACT**

33   **Objective:** To quantify the magnitude of associations between cyclist fatalities and both cyclist-

34   and environment-related characteristics in Spain during the first 24 hours after a crash.

35   **Design:** Cohort study

36   **Setting:** Spain

37   **Participants:** 65,977 cyclists injured in road crashes recorded between 1993 and 2013 in the

38   Spanish Register of Road Crashes with Victims

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

40   **Methods:** A multiple imputation procedure was used to mitigate the effect of missing values.

41   Differences between regions were assumed and managed with multilevel analysis at the cyclist

42   and province levels. Incidence density ratios (IDR) with 95% confidence intervals (95%CI) were

43   calculated with a multivariate Poisson model.

44   **Results:** Non-use of a helmet use was directly associated with death (IDR 1.43, 95%CI 1.25–

45   1.64). Among other cyclist characteristics, age after the third decade of life was also directly

46   associated with death, especially in older cyclists ("over 74" category, IDR 4.61, 95%CI 3.49–

47 6.08). The association with death did not differ between work-related cycling and other reasons

48 for cycling.

49 There was an inverse association with death for crashes in urban areas and on community roads.

50 Any adverse meteorological condition also showed a direct association with death, whereas

51 altered road surfaces showed an inverse association. Crashes during nighttime were directly

52 associated with death, with a peak between 3:00 and 5:59 am (IDR 1.58, 95%CI 1.03–2.41).

53 **Conclusions:** We found strong direct and inverse associations between several cyclist- and

54 environment-related variables and death. These variables should be considered in efforts to

55 prioritize public health measures aimed at reducing the number of cycling-related fatalities.

56

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

58

59 **Word count**: 4325

60

61 **ARTICLE SUMMARY**

62 **Strengths and limitations of this study**

63 - We used a nationwide database with information on 65,977 cyclists.

64 - The database compiles abundant information on the characteristics of the people involved, their

65 vehicles and the environment.

66 - Because the database is a police-based registry, it can be assumed that less serious crashes are

67 underrepresented.

68 - Because of missing data, information biases cannot be ruled out despite the multiple imputation

69 procedure used.

70 **INTRODUCTION**

71   Cycling is considered a healthy alternative to private cars because it helps increase

72 physical activity and reduce carbon emissions.[1] But it can also be harmful: there are about 5.5

73 times more traffic deaths per kilometer traveled by bicycle than by car.[2] In fact, cyclists along

74 with pedestrians are the most vulnerable road users because of their lack of protection and

75 comparatively greater likelihood of suffering severe injuries or dying after a crash.[3] These

76 outcomes can be caused mainly by factors related to the cyclist (as in single-vehicle crashes) or

77 related to other road users (as in collisions with other vehicles), or even by environment-related

78 factors. Understanding the factors involved in cyclist injuries and deaths is necessary in order to

79 design and promote better public policies worldwide to encourage safe cycling. The current

80 transition in commuting patterns in Spain merits attention, because the number of people who

81 use bicycles daily or almost daily has nearly doubled since the mid-2000s.[4] Public policies in

82 this country promote cycling not only as a leisure activity, but as a regular mode of transport.

83 Although the annual number of cyclist deaths decreased from 75 to 58 between 2006 and

84 2015,[5] this tendency is reverting, and interventions aimed at making cycling a safer activity are

85 needed.[6]

86   Many previous studies have identified individual and/or environmental factors associated

87 with injury severity or fatalities among cyclists.[7 -18] However, there is no consensus regarding

88 the magnitude or even the direction of some observed associations. Death is sometimes

89 considered the most severe injury category along with other serious injuries, rather than as a

90 specific category itself.[7–9,11,16] Because death of one or more cyclists after a crash is

91 uncommon, some studies found no statistically significant associations between this outcome and

92 a number of variables,[7] and multivariate analysis was not possible in some studies because of

93 the small numbers involved.[16] In studies that did report significant associations, the findings

94 may still be debatable: recent meta-analyses have consistently shown an inverse association

95 between helmet use and head injury severity, although these studies focused mainly on non-fatal

96 injuries.[19,20] Olivier and Creighton[19] found only two studies that reported effect sizes for

97 fatalities, and Høye[20] was obliged to merge fatalities with serious injuries in a single category

98 for most of her analyses.

99   Regarding age and gender differences, the biological effect of aging is a plausible cause

100 for the association between cyclist involvement in a road crash and greater injury severity,[8–

101 12,14,16,18] but the relationship between age and death in some age groups (e.g. children or

102 adolescents) awaits clarification.[9,13,14,16,18] Both males[13,16,18] and females[12] have

103 been reported to be at increased risk of more severe injuries. Physical and behavioral aspects

104 related to gender have been argued to explain differences in injury severity,[21–23] but there is

105 no consensus.

106   Although alcohol consumption is known to be associated with risky behavior while

107 cycling,[24,25] studies focusing on the association between this factor and injury severity or

108 fatality are inconclusive.[10,12,14,17,18] The commission of infractions is reportedly associated

109 with injury severity or death, but only in bicycle collisions with a motor vehicle, not on other

110 types of crashes.[10]

111   Environmental factors can also play a major role as independent variables in fatal

112 outcomes. Traffic lane characteristics, e.g. intersections as opposed to open roadways, are

113 usually related to an increased risk of collision but not necessarily with more severe injuries

114 [11,12,14] except in unsignalized intersections.[9] Road surface and adverse weather

115 circumstances appear to be related to the likelihood of crashes, but their association with injury

116 severity or death also requires clarification, given that previous studies have found both a direct

117 association with injuries or death[9,10,14] and no association.[7,11–13] Time of day is related to

118 conspicuity, and has been linked to crash rates. However, the association found for injury

119 severity has not shown a clear direction: a direct association with severity has been reported

120 during daytime[7,10,14] and during nighttime,[9,11] with some analyses finding no association

121 at all.[12,13]

122   It seems obvious that cycling speed would be related to death after a crash. Although the

123 speed at the time of the crash can be estimated with ad hoc studies using accident reconstruction

124 techniques,[26] proxy variables such as speed limit at the site of the crash,[10,11,13,14] or the

125 area of the crash[7,11,14] have been widely used. In fact, speed may be the main reason for the

126 greater severity of cyclists' injuries in crashes involving a motor vehicle compared to single

127 crashes, as reported in previous studies.[12,13,16]

128   Previous research in Spain has focused on impacts on cyclists' health,[27,28] their

129 behavior and other correlates with crash involvement,[21,22,29,30] and the causal chain of

130 events related to death after a crash.[31] However, to our knowledge there have been no attempts

131 to analyze personal and environmental characteristics and their relationship with the risk of

132 death.

133   To help fill the gaps in our current knowledge, we designed a large nationwide study to

134 quantify the magnitude of the associations between cyclist- and environment-related

135 characteristics and the likelihood of cyclist fatality within the first 24 hours post-crash in Spain

136 between 1993 and 2013.

137

138 **METHODS**

Data source and study population

140   We analyzed the cohort comprising all 65,977 cyclists involved in road crashes recorded

141   in the Spanish National Registry of Road Crashes with Victims between 1993 and 2013 once the

142   crashes in the autonomous cities of Ceuta and Melilla were excluded because of their specific

143   characteristics and low mortality: both cities are located in northern Africa, and all road crashes

144   involving cyclists occurred in urban areas.

145   The aforementioned registry is a nationwide electronic database maintained by the

146   Spanish General Directorate of Traffic. It has high security standards to protect anonymity, and

147   was developed to support the design and evaluation of public policies concerning road safety.

148   Researchers can use this data upon specific request, after a motivation letter is accepted by the

149   Directorate authorities. This database contains information from the Statistical Questionnaire of

150   the Accident documents submitted for every crash resulting in injury or death and involving at

151   least one moving vehicle in areas subject to traffic laws. Information in the registry includes the

152   characteristics of the persons involved (e.g. age, sex), their vehicles (e.g. type, condition), and

153   the environment (e.g. type of crash, geographic coordinates, road characteristics). It does not

154   include information that may lead to personal identification. Victims are categorized as injured if

155   they are seen by a health care service, or as dead if they die at the crash scene or within the first

156   30 days. This questionnaire is completed by national police agents at the crash scene, and filed

157   within the first 24 hours for crashes that result in death or severe injury (needing hospitalization),

158   or within the next 10 days after the crash. All data must be submitted within the first 30 days

159   post-event, including follow-up information from health care services. Amendments to the

160   infrastructure data recorded at the crash scene can be made within the next 30 days by the

161   appropriate authorities.[32]

162

Patient and public involvement

163

164   This study relies on data collected by the Spanish General Directorate of Traffic; no

165   patients or participants interacted with the study authors.

166

167   **Variables**

168   We collected information about a subset of variables which, according to previous studies

169   and based on univariate analysis, may be associated directly or indirectly with injury severity.

170   Our dependent variable was death within the first 24 hours after the crash, and the independent

171   variables were cyclist-related (age, sex, helmet use, psychophysical circumstances, nationality,

172   commission of infraction and reason for cycling) and crash- or environment-related (type of

173   crash, traffic lane characteristics, area, meteorological conditions, road surface, time of day, year

174   and province). Original categories and dichotomized categories (see "Statistical analysis") can be

175   viewed in the frequency distribution tables (Table 1 and Table 2).

176

177   **Statistical analysis**

178   Univariate analysis was first done for each variable included as an independent variable

179   and for death as the dependent variable. Then we built a Poisson regression model (a generalized

180   linear model which uses log [rate] as the link function). Spain is divided in 50 provinces which

181   differ markedly regarding cycling density, cycler-friendly environment, socioeconomic

182   conditions and health care facilities, among other important factors potentially related with

183   cyclists' risk of death. Therefore, we first tested the hypothesis that the province level would

184   explain a significant part on the total variance in the outcome variable (cyclist fatalities). For this

185 purpose, we constructed both unilevel (Appendices 1 and 2) and multilevel empty models

186 (including cyclist-level and province-level), and compared the variances explained by each.

187 Significant differences (P<0.001 for the likelihood ratio test) between the two models were

188 obtained, thus confirming our hypothesis. This led us to choose a multilevel multivariate model

189 for the main results.

190 More than 25% of the data were missing for some variables (e.g. helmet use) (see Tables

191 1 and 2 for details). The overall amount of these missing values may be explained by missing at

192 random (MAR) and missing not at random (MNAR) mechanisms. Although we cannot

193 compensate for MNAR values, we can control MAR values through a multiple imputation

194 procedure. Therefore, we initially assumed that some missing values might be explained by the

195 combination of the values observed for some of the remaining variables in the database. To test

196 this assumption, for each variable with missing values we constructed a multivariate regression

197 model with the existence or not of missing values as the dependent variable, and the observed

198 values for the remaining variables as independent terms. In all cases we observed parameters of

199 association significantly away from the null. These results supported our initial hypothesis and

200 led us to build 50 files in which missing data were represented as stabilized variances estimated

201 from different variables, according to the chained equations method described by van

202 Buuren[33] and implemented with the "ice" command in Stata.[34] This is a community-

203 contributed Stata command focused on simplifying the imputation of categorical variables.

204 However, this procedure was unable to provide missing values for many categorical variables

205 with more than two strata when the frequency of responses in different categories was low, and

206 we thus opted to dichotomize these variables. The dichotomization process considered

207 theoretical similarities between original categories (e.g. any adverse weather circumstances such

208 as rain, snow and hail were grouped in the category "any adverse circumstances") and tried to

209 keep the most important category for analysis unaltered (e.g. intersections). Age was imputed

210 based on its logarithm to maintain positive values, and its antilogarithm was then used to

211 transform it into a categorical variable. We used this approach to build a multilevel fixed-effect

212 multivariate Poisson regression model for each of our 50 complete datasets. Thus we obtain

213 adjusted incidence density ratios (IDR) for death for each category of every variable, to assess

214 the magnitude of associations with cyclist death rates. IDR is a good estimate of the relative risk

215 (RR) of death across categories of independent variables when, as in this analysis, the risk of

216 death yields exactly the same value as the death rate for a fixed amount of persons-time (i.e., the

217 number of cyclists involved in road crashes multiplied by the same follow-up period for all of

218 them). For each IDR, its corresponding 95% confidence interval (95%CI) was also calculated.

219 We then used the community-contributed "mim" command for Stata[35] to combine the

220 estimates obtained for each imputed file according to the Rubin method.[36]

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

222

223 **RESULTS**

224   Table 1 and Table 2 summarize descriptive information on cyclist- and

225 crash/environment-related characteristics. Fatality was a rare event (2.49%). The male-to-female

226 ratio was almost 8:1. The main mechanism for crashes was collision with another vehicle

227 (69.40%), and most crashes occurred in urban areas (60.71%), followed by highways (35.71%)

228 and community roads (3.58%). Although most crashes occurred during the day (83.44% between

229 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

Variable	Category	N	% Total	N	% Excluding missing values
	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

235

236 **Table 2.** Distribution of crash- and environment-related variables. Spain, 1993–2013
237

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

238

239   Table 3 shows the IDR for the association between cyclist characteristics and the risk of

240   death. A tendency towards a direct association between cyclists' age and death was observed

241   from the third decade of life; the association was statistically significant (P<0.05) in categories

242   from 35-to-39 years and older, and was greatest in the "over 74 years" category (IDR 4.61,

243   95%CI 3.49–6.08). Non-use of a helmet was associated with a 43.45% higher chance of death

244   (IDR 1.43, 95%CI 1.25–1.64). Male gender, psychophysical circumstances, and nationality other

245   than Spanish showed a direct association with death. Many recorded cyclist infractions were

246   directly associated with death, with IDR higher than 2 for infractions such as disregarding stop

247   lights or other signals, cycling while standing, illegal passing, invading the opposite lane and

248   cycling outside traffic lanes. However, "Disregarding safety distance" and "distraction" were

249   inversely associated with death, but this association was statistically significant only for the latter

250   (P<0.05). The association for work-related cycling did not differ compared to other motives for

251   cycling (i.e., for leisure or for other reasons).

252

253   **Table 3.** Adjusted incidence-density ratios (IDR) for the association between cyclist-related

254   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

255

256   Table 4 shows the IDR for the association between environmental characteristics and the

257 risk of death. There were no conclusive trends according to the type of crash (IDR 0.89, 95%CI

258 0.78–1.00), but cycling through an intersection (IDR 1.65 for "other", 95%IC 1.46–1.87), in

259 urban areas, and on community roads were inversely associated with death. This association was

260 also found when the road surface was altered. However, for adverse meteorological conditions

261 the association was direct. A direct association with death was also found after midnight, in the

262 category "03:00-05:59" (IDR 1.58, 95%CI 1.03–2.41), whereas an inverse association was found

263 during the day, with a peak at midday between 12:00 and 14:59 (IDR 0.40, 95%CI 0.29–0.56).

264 Over the 10-year period analyzed here, there was a trend toward a higher likelihood of death in

265 the earlier years.

266

267 **Table 4.** Adjusted incidence-density ratios (IDR) for the association between crash- and

268 environment-related variables and the risk of death in the first 24 hours after a road crash. Spain,

269 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

270

271 **DISCUSSION**

272   Our results are generally in agreement with those of previous studies regarding the

273 direction and magnitude of the associations between cyclist- and environment-related factors and

274 the severity of crashes involving cyclists.[7–18] Perhaps our most important finding is the

275 association between non-use of a helmet and a higher chance of death. Although the protective

276 effect of helmet use on the risk of head trauma is widely accepted,[8–11,13–16] its association

277 with injury severity has been addressed mostly for non-fatal injuries given that relatively few

278 studies to date have focused on its association with death.[19,20] Although our study is

279 observational and causality cannot be demonstrated, it is unlikely that residual confounding

280 could entirely explain an association of the magnitude we observed. We are confident that our

281 approach to the analysis was robust given that it included appropriate management of missing

282   values, controlling for between-province-level variance, and multivariate adjustment for most

283   well-known confounders of the association between helmet use and death. Therefore, taking into

284   account that helmet use is the most easily modifiable cyclist-dependent risk factor, our results

285   suggest that a non-negligible amount of cyclist deaths might be prevented by increasing helmet

286   use in our population of cyclists.

287   Regarding other cyclist-related variables, the association we found between age and risk

288   of death is consistent with previous studies.[8,10,11] This association may be explained on the

289   basis of mechanisms such as greater fragility, loss of physical agility, decreased visual acuity and

290   concomitant diseases[38]. In contrast to other authors,[9,14,18] we found no association between

291   younger age and death.

292   In relation to gender, we found that the risk of death was higher for males, as reported

293   previously.[16,18] This association has been explained as a result of either physical differences

294   or safer behaviors in females,[23] which may be associated with the severity of the crash itself.

295   Other explanations have been based on the presumably riskier behavior in males when failing to

296   stop for red lights[39] and when their risk perception is lower.[21] On the other hand, female

297   gender has been associated with higher rates of reporting road crashes.[40] Because we

298   considered only injured cyclists or death as our main outcomes, and assuming there was no

299   difference between genders in deaths recorded in our database, differences in reporting non-fatal

300   road crashes could lead to overestimation of the association with death (if any) in the

301   underreported category. In fact, some authors did not observe this association,[8] or found female

302   gender to be related with injury severity.[12]

303   According to some authors, alcohol consumption is associated with risky

304   behaviors[24,25] when cycling and driving other types of vehicles, and is directly associated

305   with injury severity.[10,12,14,17] This condition could not be investigated in our study because

306   of the dichotomization process used to account for missing values. The low number of cyclists in

307   the original categories for the "psychophysical circumstances" variable forced us to combine

308   alcohol consumption, drug consumption, tiredness, sleepiness and other psychophysical

309   circumstances into a single "altered" category, obscuring the true association between each type

310   of psychophysical circumstance and death. Nevertheless, alcohol consumption with and without

311   a breath test was the most prevalent condition included in the "altered" category, and showed a

312   direct association with death. However, this association should be viewed with caution because

313   of potential shortcomings in the validity of our data source.

314   Non-Spanish nationality also showed a stronger association with death, but this should

315   likewise be interpreted with care. We could not obtain information about cyclists' expertise, and

316   for non-Spanish cyclists, we did not know how long they had been living in Spain, or whether

317   they had changed their cycling patterns while living abroad. Furthermore, all non-Spanish

318   cyclists were clustered in a single subgroup which included people from countries which may

319   differ widely in a large variety of aspects such as social and cultural characteristics as well as

320   cycling infrastructure in their country of origin. This subgroup was thus too heterogeneous for

321   informative comparisons. Consequently, the association found in our study undoubtedly deserves

322   further research designed to address its underlying factors.

323   Like Kim and colleagues,[10] we observed that most traffic infractions (11 out of 18)

324   were directly associated with death. Distraction while walking or driving has been deeply

325   explored, but it is not the case while bicycling.[41] There are inherent limitations to record

326   distractions when the cyclist died at the crash scene. In our study, "Distraction" was

327   unexpectedly the only infraction inversely associated with death and statistically significant, but

328 this category included a wide range of sources of distraction, such as involuntary risky behaviors

329 and intentionally committed behaviors (e.g. use of technological devices). Although other

330 authors have found distraction to be associated with a higher risk of crash [22], to our knowledge

331 the association between distractions and the severity of the crash has not been previously

332 assessed. A possible explanation for this inverse association with death could be the lower speed

333 (an unobserved variable) while cycling distracted.[41] In relation with the reason for cycling, we

334 found no associations with the likelihood of death. However, previous studies showed that work-

335 related or utilitarian cycling was associated with less severe injuries because of cyclists'

336 expertise, choice of safer routes and helmet use,[13] although greater injury severity was also

337 associated with more experience and more frequent cycling.[12] Although some authors have

338 reported different injury severity depending on the type of crash, especially when a motor

339 vehicle was involved,[12,13,16,42] in the present study the direct association between death and

340 collisions with moving vehicles did not differ significantly in comparison to other types of

341 crashes (IDR 0.89, 95%CI 0.78–1.00). Nevertheless, because type of crash was a binary variable

342 in our analysis (see Statistical analysis), all other types of collisions with moving vehicles were

343 included in a single category and compared to other types of crashes (such as collisions with an

344 obstacle, overturning or running off the road), hence the two groups were heterogeneous.

345 Furthermore, unless the cyclist is fatally injured, cyclists are probably more likely to receive

346 police assistance when they collide with another vehicle. Therefore cyclists who sustained minor

347 injuries in the "other crashes" category were likely to be underrepresented in our sample.

348 Regarding environment-related variables, although some authors found no clear

349 association with traffic lane characteristics or road geometry,[11,12] we identified an inverse

350 association between intersections and death compared to other road configurations (straight

351   roads or curves), in accordance with previous findings for injury severity.[14] But again, our two

352   categories were heterogeneous, and the risks may differ among for different types of

353   intersection.[9,43]

354   The location of the crash showed a close relationship with fatalities. Previous studies

355   have reported less severe injuries in dense urban settings, and more severe injuries on rural or

356   community roads. We found an inverse association with death for crashes in urban areas and

357   community roads compared to highways. This association is probably related to the higher

358   speeds reached on highways by cyclists or the other vehicles involved in crashes. In fact, speed

359   has been previously associated with injury severity.[10,11,13,14,16]

360   Adverse meteorological conditions were directly associated with death, as reported by

361   other authors.[9,10] This association is probably due to lower cyclist conspicuity under adverse

362   weather conditions, although other authors found no clear association.[7,12,13] On the other

363   hand, altered road surfaces were inversely associated with risk of death, which may be the result

364   of cycling or driving at lower speeds. Nevertheless, other authors have reported more severe

365   injuries on altered surfaces,[9,14] or found no association at all.[7,11] More research is needed to

366   characterize the influence of weather and road conditions on risk of death among cyclists, given

367   the discrepancies among findings from different studies.

368   Although the frequency of crashes was much greater during daylight hours, there was a

369   direct association between crashes that occurred at night and death, as also found by Boufous et

370   al.[11] and Wang et al.,[9] with a peak in the early morning hours, as reported by Asgarzadeh et

371   al.[7] Other authors, however, found no association between time of the crash and injury severity

372   or death, although one Danish study reported an association with daylight hours, probably

373   because of the high standard of nighttime roadway lighting in Denmark[14]. Apart from the lack

374 of conspicuity,[44] factors such as alcohol consumption, speed and exhaustion may play major

375 roles in this association.[7,45] Finally, the lower risk of death in crashes recorded in more recent

376 years in Spain may be explained by improvements in cycling infrastructure,[46] improved health

377 care for injured cyclists,[1] and increased reporting of less serious road crashes by the police.

378 **Strengths and limitations**

379   Our data source for this analysis was the Spanish National Registry of Road Crashes with

380 Victims. This registry contains information recorded over many years by police officers on a

381 standard form. Our large sample size and total number of cyclist deaths made it possible for us to

382 precisely estimate the magnitude of the associations between each variable in the model and fatal

383 injuries. Our choice of main outcome categories reduced the possible effect of misrepresentation

384 for certain independent variables in this police-based registry. Furthermore, the statistical

385 approach used here considered variability in the outcome variable across provinces in Spain, and

386 was intended to decrease the effect of missing values that could be explained by the remaining

387 variables.

388   Nevertheless, a main limitation of our study is its observational nature, which prevents us

389 from suggesting causal interpretations for the associations we found. Given that our analysis is

390 based on information from a police-based registry designed to collect information on all types of

391 road traffic crashes, as noted in the Methods section, selection bias is an important issue given

392 the assumption that less serious crashes were underrepresented, because of a direct association

393 between injury severity and reporting rates to the police.[47–49] Behavioral differences and

394 differences in representation rates related to the categories for specific variables (e.g. gender)

395 could not be measured with the available data, and this may have led to over- or underestimation

396 of some of the observed associations. Regarding helmet use, we do not have information on the

397   characteristics of the helmets, and cannot confirm that they were being worn correctly at the

398   moment of the crash. Although we used a multiple imputation procedure to compensate for

399   missing information, this method only partially resolves issues related with missing data;

400   therefore our results may still be affected by biases of an undetermined magnitude. Furthermore,

401   the dichotomization used for our multiple imputation procedure forced us to combine

402   heterogeneous categories for some of the variables (e.g. psychophysical circumstances), so the

403   results for these variables should be considered with due caution. Bias is also a potential

404   limitation, because of the subjective nature of some variables recorded by police officers at the

405   crash scene.

406   Finally, the lack of information regarding vehicle speed is an important limitation in our

407   study. Although this is probably the most important factor affecting the severity of cyclists'

408   injuries, no direct information was available for vehicle speed when the crash occurred.

409

410   **CONCLUSIONS**

411   We found strong associations between several cyclist- and environment-related variables

412   and the probability of death, and suggest that these associations should be taken into account in

413   efforts to prioritize public health measures aimed at reducing the number of cycling-related

414   fatalities. In particular, we believe helmet use by cyclists needs to be encouraged. Although we

415   are aware that the magnitude of the association between non-helmet use and death is not entirely

416   causal, it supports the hypothesis that helmet use may significantly reduce the risk of death

417   among cyclists involved in road crashes. Although using a helmet is now mandatory for all

418   cyclists on open roads in Spain, our data show that even in recent years, the proportion of non-

419   helmet-use has been non-negligible. Another topic which deserves attention is the risk in older

420   cyclists, considering that this subgroup of cyclists will very likely grow in the coming years.

421   Finally, the reasons for the higher risk of death during nighttime cycling merit further

422   investigation in order to manage factors which are potentially modifiable by, for example,

423   encouraging measures to improve cyclist conspicuity.

424

448

KEY MESSAGES

450

What is already know on this subject

452   -   Cycling is increasing but is associated with risks.

453   -   Helmets are intended to protect against severe injury, but their effect on the risk of death

454   remains unclear.

455

What this study adds

457   -   Helmet non-use is directly associated with cyclist deaths, especially on highways.

458   -   Work-related and non-work-related cycling did not differ in their association with the risk

459   of death.

460   -   Increasing age was directly associated with increasing risk of death, especially after the

461   third decade of life.

462

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597   and associated factors. *Accid Anal Prev* 2018;**110**:177–86. doi:10.1016/j.aap.2017.09.018

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1 **Appendix 1.** Adjusted incidence-density ratios (IDR) in a multivariate unilevel model for the
2 imputed associations between cyclist-related variables and the risk of death in the first 24 hours
3 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

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1 **Appendix 2.** Adjusted incidence-density ratios (IDR) in a multivariate unilevel model for the
2 imputed associations between crash- and environment-related variables and the risk of death in
3 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

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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.