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Eye Injury epidemiology of workers by age, sex and occupation over the last 10 years in Spain

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Eye Injury epidemiology of workers by age, sex and occupation over the last 10 years in Spain

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ABSTRACT:

OBJECTIVE: To describe the epidemiological characteristics of work-related eye injuries (WREI) in a mutual insurance company in Spain.

DESIGN AND SETTINGS: A descriptive, retrospective and longitudinal study based on data from workers insured by a labour insurance company in Spain from 1st January 2008 to 31st December 2018 was presented. The study considered the ratio of the number of WREI per 100000 population and the relative risk of suffering an ocular injury. The work-related eye injuries were characterised by sex, age and occupation.

PRIMARY AND SECONDARY OUTCOME MEASURES: Epidemiology of work-related eye injuries (WREI).

PARTICIPANTS: In Spain, all workers are insured by a labour insurance company that provides cover in the event of work-related accidents. In this study, we have included all workers insured by one such company, which has insured workers in all provinces of Spain over the study period.

RESULTS: The study included 50,265 WREI in the company over the 10-year period. Most of the injuries occurred in males (44,445; 88.4%), in the 35-44 age group (15,992; 31.8%), and in industry workers (18,899; 42.6%). The average incidence was 429.75/100,000 working population and 4,273.36/100,000 IBERMUTUA accidents. The incidence of WREI decreased over the study period in all variables. Males, 16-24 age group and industry occupation group have the highest relative risk (RR) and incidence for WREI.

CONCLUSIONS: Specific programs for ocular protection and changes in occupation over the 10-year study period were the most probable causes of the decrease in WREI incidence in our study.

STRENGTHS AND LIMITATIONS OF THIS STUDY:

- This study covers the largest area and the highest number of workers of those published in Europe to date.
- The long period of study indicates the results are not only due to specific changes in the insured company but rather to changes in Spanish workers.
- Because of characteristic statistical analysis in our study, it is very easy to check the relevance of sex, age and occupation with respect to WREI.

METHODS

The research described herein adhered to the tenets of the Declaration of Helsinki and approved by ethic investigation committee of Universidad Europea de Madrid (CEI-UE). All medical records were anonymous; only statistical information was provided by IBERMUTUA for research purposes.

A descriptive, retrospective and longitudinal study was performed. We analysed WREI that affect any ocular structure during work time in a mutual insurance company. Study data were provided by IBERMUTUA. This company's medical specialists evaluate work accidents reported by the companies it insures, analysing the work-related injury and its consequences for insured workers. The study period was from 1st January 2008 to 31st December 2018.

The area of study covered all regions in Spain including Ceuta and Melilla, comprising an approximate area of 505,983 km² and a population of 46,650,300 in 2018 (8) (latest census). In these years, we analysed 11,696,259 subjects (table 1), all of them IBERMUTUA-insured workers during the study period, and we related them to 201,167,800 workers in Spain.

INCLUSION CRITERIA

We studied WREI that affect any ocular structure during work time and *in itinere*. These injuries were evaluated and classified by medical specialists according to CIE-9-MC classification (correlations with ICD-9 where ocular injury is secondary to an accident involving other primary structures of the body).

We analysed sex (males and females), age and occupation. We established five age groups (16-24, 25-34, 35-44, 45-54, and ≥ 55) according to the Labour, Migrations and Social Security Ministry of Spain (3). Occupation was classified according to the same Ministry's 2009 National Economic Activities Code (CNAE-2009 in Spanish), whereby occupation was divided into four groups: Agricultura, Industry, Construction and Services (3).

STATISTICAL ANALYSIS

Quantitative variables are given as a mean \pm standard deviation (SD). For qualitative variables, absolute and relative frequencies are given in percentages. To standardize data, the relationship between number of WREI and insured/accident per 100,000 population in IBERMUTUA (ratio/100,000 population) was

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2
3 calculated. A relative risk (RR) was computed to check the effects that exist between different groups of
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5 sex, age and occupation.
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8 The chi-square test and the Fisher exact test was used to analyse qualitative variables. The student's T
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10 test and the Mann-Whitney U Test were used, as appropriate, to search for significant differences
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12 between preferences.
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14 The statistical analysis was performed using SPSS, v.21.0 (IBM Corp; Armonk, NY; USA), with $p < 0.05$
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16 considered significant for all analyses.
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18 **RESULTS**

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21 There were 50,265 WREI in IBERMUTUA over the 10-year period (table 1). These accidents affected 0.45%
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23 of all workers insured by IBERMUTUA and represented 4.22% of all accidents suffered by IBERMUTUA-
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25 insured workers (1,179,067 total accidents (table 1)). The average age was 38.62 ± 10.57 and the majority
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27 of all injuries occurred in 35-44 age group (15,992; 32.0%). Within the subject population, 44,445 were
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29 male (89.3%) and 5,349 female (10.7%), and industry workers were the most affected group (18,899,
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31 42.6%) (Table 1).
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34 The incidence of WREI was 429.75/100,000 IBERMUTUA-insured workers and the incidence of WREI
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36 among IBERMUTUA-insured accidents was 4,273.36/100,000.
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39 Workers insured by IBERMUTUA constituted an average of 5.81% (SD ± 0.221) of all workers in Spain, and
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41 the rate of change between workers insured in IBERMUTUA and total workers in Spain in the study period
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43 did not show statistically significant differences ($p = 0.9987$) (Figure 1).
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45 *INCIDENCE AND RELATIVE RISK (RR) PER 100,000 IBERMUTUA INSURED*

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47 The incidence of WREI over 10-year period was 680.12 for males and 103.63 for females. Therefore, males
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49 had 6.56 (95% CI 6.38-6.75) times more risk of suffering WREI than females (Table 2). If we analyse the
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51 evolution over the period, there was a decrease in incidence in both groups which was statistically
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53 significantly bigger in males than females ($p = 0.00027$) (Figure 2a).
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56 Highest incidence by age group corresponds to the 16-24 group (561.16). Incidence decreases with age.
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58 487.27 in 25-34, 435.57 in 35-44, 369.42 in 45-54, and 316.69 in ≥ 55 group (Table 2). The ≥ 55 age group
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3 is the reference for calculating the RR of suffering a WREI in the other groups because it is the group with
4 the lowest incidence. In this case, RR decreases with age in the same way as the incidence (1.77 (95% CI
5 1.71-1.83), 1.54 (95% CI 1.51-1.57), 1.38 (95% CI 1.35-1.41), and 1.17 (95% CI 1.13-1.21)) (Table 2). Over
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7
8 the study period, a decrease in the incidence of WREI in all age groups was observed, and it was
9 statistically significant ($p < 0.05$) when we compared 16-24 age group with the other groups, as well as
10 when we compared 25-34 age group with 45-54 age group ($p = 0.035$), and 25-34 age group with ≥ 55 age
11 group ($p = 0.021$) (Figure 2b).

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18 Industry workers were the occupation group with the highest incidence of WREI (1538.17), followed by
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Construction workers (1381.52), Agriculture workers (479.65) and, finally, Services workers (198.92)
(Table 2). Therefore, in comparison with Services workers, the risk of suffering an accident (RR) is 7.73
(95% CI 7.55-7.92) times higher in Industry workers, 6.94 (95% CI 6.77-7.12) times higher in Construction
workers, and 1.53 (95% CI 1.45-1.61) times higher in Agriculture workers (Table 2). A decrease in incidence
was observed in all occupation groups over the period. There were statistically significant differences
($p < 0.05$) when we compared all groups with each other, except for the two groups with the highest
incidence, Industry workers and Construction workers ($p = 0.827$) (Figure 2c).

INCIDENCE AND RELATIVE RISK (RR) PER 100,000 IBERMUTUA ACCIDENTS

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WREI incidence was 5125.26 for males and 1762.18 for females, with a RR 2.91 (95% CI 2.83-299) higher
in males (table 2). Incidence throughout the period decreases over time and is statistically significant
higher in males ($p < 0.001$) than females (Figure 3a).

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In the same way as when we compared the incidence per 100,000 IBERMUTUA insured, incidence and RR
decrease with age. We observed the highest incidence and RR in 16-24 age group (5083.64 and RR 1.51
(95% CI 1.46-1.56)), followed by 25-34 age group (4800.23 and RR 1.43 (95% CI 1.40-1.46)), 35-44 age
group (4364.93 and RR 1.30 (95% CI 1.27-1.33)), 45-54 years group (3729.39 y RR 1.11 (95% CI 1.07-1.15)),
and, used as reference and with the lowest incidence of all, the ≥ 55 age group (3368.01). WREI incidence
decreased in all age groups over time, and there was a statistically significant ($p < 0.05$) decrease when we
compared 16-24 and 25-34 age groups with each other and both groups with the other groups (Figure
3b).

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3 Industry workers suffer the highest incidence and RR of WREI in the four occupation groups (8050.69; RR
4 3.83 (95% CI 3.74-3.92)), followed by Construction workers (6650; RR 2.54 (95% CI 2.48-5.60)), Agriculture
5 workers (4495.75; RR 1.72 (95% CI 1.64-1.81)), and, with the lowest incidence and RR of all, Services
6 workers (2615.64), the latter therefore being reference group for RR. Although we observed a decrease
7 in incidence over the period, it was not statistically significant when we compared different groups (Figure
8 3c).

15 DISCUSSION

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18 Of all the long-term studies we have observed in Europe, this is the one which covers the largest area and
19 the highest number of cases. The close relationship between IBERMUTUA-insured workers and the
20 evolution in number of workers in Spain ($p=0.9987$) indicates the importance of our data analysis.

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23 The percentage of WREI in our study was lower than Gomez Villa et al. observed in two villages on the
24 island of Mallorca (Spain) (0.84%). The difference was maybe due to the smaller area and population (only
25 two villages and 50,851 workers) and the shorter study period (two years).

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28 The total incidence of WREI falls between the values of other studies (4,5) and is very similar to that found
29 by Karlsen et al. in Wisconsin (USA) in 1986 (423/100,000) (10). However, in all of these studies, the
30 incidence does not relate exclusively to work-related injuries. If we compare only with WREI, in our study
31 we observe higher incidence than in Hong Kong (around 125/100,000) (11). However, it is very difficult to
32 compare these two values because the Hong Kong study covered a period of only 3 months.

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35 The higher impact in males is similar to other studies where the percentage of eye injuries in males was
36 between 87 and 95.1% (5,12–14). A very similar RR was observed in Modena (Italy) (7:1 male/female
37 ratio) (5), although it was lower in Taiwan (3.99) (12). This higher impact in males might be due to the
38 different occupations in each group. In the last quarter of 2018 in Spain, there were 2.8 times more men
39 than women working in Industry and 10.6 times more in Construction. These are the two workers
40 occupations where the highest WREI incidence was observed in our study. However, there were 1.054
41 million more female workers in Services (15).

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44 35-44 was the most affected age group in our study. Our data match those found in an area in the
45 southwest of China (14). The highest percentage observed in other studies was in 25-34 age group in
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3 Western Turkey (13) and in 16-24 age group in Modena (Italy) (5). However, we observed more incidence
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5 of WREI for 100,000 insured in the lowest age group (16-24) in our study, and this incidence decreases
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7 with age. We only analysed workers population, and we think this is why we found more eye injuries in
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9 the lowest age group. These workers have less experience and perform more manual jobs.

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11 As in other studies (5), we observed the highest incidence and percentage of WREI in Industry workers.
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13 Agriculture was the most affected group in other studies (16,17) but in all of them, Services was the least
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15 affected group. This is due to the lower risk of trauma or other external agents that can affect Services
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17 workers.

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20 When we analysed the evolution of WREI for 100,000 IBERMUTUA insured/accidents, we standardized
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22 data and eliminated WREI due to population variation. Therefore, we need to find reasons for the
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24 reduction in WREI in all study variables. This generalized decrease is probably due to the implementation
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26 of specific eye protection plans by the companies and IBERMUTUA. Variation in occupation over the study
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28 period could be another reason, namely:

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31 - Decrease in incidence is statistically significantly higher in males than females because in Spain a
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33 decrease in Industry and Construction workers was observed (18).
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35 - The statistically significant decrease in 16-24 and 25-34 age groups could be due to the
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37 decreasing number of Spanish workers in these two occupation groups.
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40 There are no studies that compare WREI for accidents only (as opposed to total population). We
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42 considered it worth making this comparison in order to find out the mechanism and the importance that
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44 WREI have in total accidents in Spain. Using this data could make it easier to devise specific programs
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46 aimed at reducing ocular accidents and the associated costs.

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48 As we do not have the same number of cases in all variables (Table 1), this becomes a limitation of our
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50 study and should be taken into account in future research in this area.
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52 **CONCLUSIONS**

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54 Specific knowledge of the incidence and relative risk of work-related eye injuries could be essential for
55
56 designing programs to prevent accidents in the workplace. This study contains the highest number of
57
58 cases of any published in Europe to date, so the results are significant.
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CONTRIBUTORSHIP STATEMENT:

Alvarez-Peregrina, Villa-Collar and Sanchez-Tena designed the study.

Catalina-Romero and Calvo-Bonacho obtained the data.

The obtained data was analysed by Martín-Prieto and Thuissard-Vasallo.

All authors contributed to the writing of the manuscript.

COMPETING INTERESTS

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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DATA SHARING STATEMENT

All data relevant to the study are included in the article or uploaded as supplementary information. Data are also available upon reasonable request.

Table 1: Total cases (N) of IBERMUTUA insured, IBERMUTUA accidents and total WREI (Work-related eye injuries) according to sex, age and workers occupation. Losses: total number of losses out of total number of cases (50265) of WREI in all different groups.

	TOTAL		LOSSES	
	N	%	N	%
Ibermutua insured	11,696,259			
Ibermutua accidents	1,17,9067			
Spanish workers	201,167,800			
WREI	50,265			
Sex WREI				
Male	44,445	89.3		
Female	5,349	10.7		
Total	49,794	100	471	0.9
Age group WREI				
16-24	4,388	8.8		
25-34	14,981	29.9		
35-44	15,992	32.0		
45-54	10,278	20.5		
>55	4,390	8.8		
Total	50,029	100	236	0.5
Occupation WREI				
Agriculture	1,624	3.7		
Industry	18,899	42.6		
Construction	10,455	23.6		
Services	13,394	30.2		
Total	44,369	100	5,893	11.7

Table 2: Incidence of WREI over 100,000 IBERMUTUA insured/accidents and relative risk (RR) of WREI over the period study according to sex, age and workers occupation.

	WREI incidence out of 100,000 IBERMUTUA insured	WREI incidence out of 100,000 IBERMUTUA accidents	RR WREI according to IBERMUTUA insured		RR WREI according to IBERMUTUA accidents	
			RR	95% CI	RR	95% CI
Sex						
Total	425,73	4253,29				
Male	680,13	5125,27	6,56	6,38-6,75	2,91	2,83-2,99
Female	103,63	1762,19	REF		REF	
Age						
Total	427,74	4273,36				
16-24 years	561,16	5083,65	1,77	1,71-1,83	1,51	1,46-1,56
25-34 years	487,27	4800,23	1,54	1,51-1,57	1,43	1,40-1,46
35-44 years	435,58	4364,94	1,38	1,35-1,41	1,30	1,27-1,33
45-54 years	369,43	3729,40	1,17	1,13-1,21	1,11	1,07-1,15
>55 Years	316,69	3368,01	REF		REF	
Occupation						
Total	479,65	4719,61				
Agriculture	305,14	4495,75	1,53	1,45-1,61	1,72	1,64-1,81
Industry	1538,18	8050,69	7,73	7,55-7,92	3,83	3,74-3,92
Construction	1381,53	6650,00	6,94	6,77-7,12	2,54	2,48-2,60
Services	198,92	2615,65	REF		REF	

Figure Legends:

Figure 1: Relation between IBERMUTUA insured (triangle line) and Spanish workers (circle line) over the study period. There were no statistically significant differences in evolution over the 2008-2018 period ($p=0.9987$).

Figure 2: Evolution of WREI incidence per 100000 IBERMUTUA insured over the study period. A decrease in incidence according to sex (A), age (B) and occupation (C) was observed.

Figure 3: Evolution of WREI incidence per 100000 IBERMUTUA accidents over the study period. A decrease in incidence according to sex (A), age (B) and occupation (C) was observed.

STROBE CHECKLIST

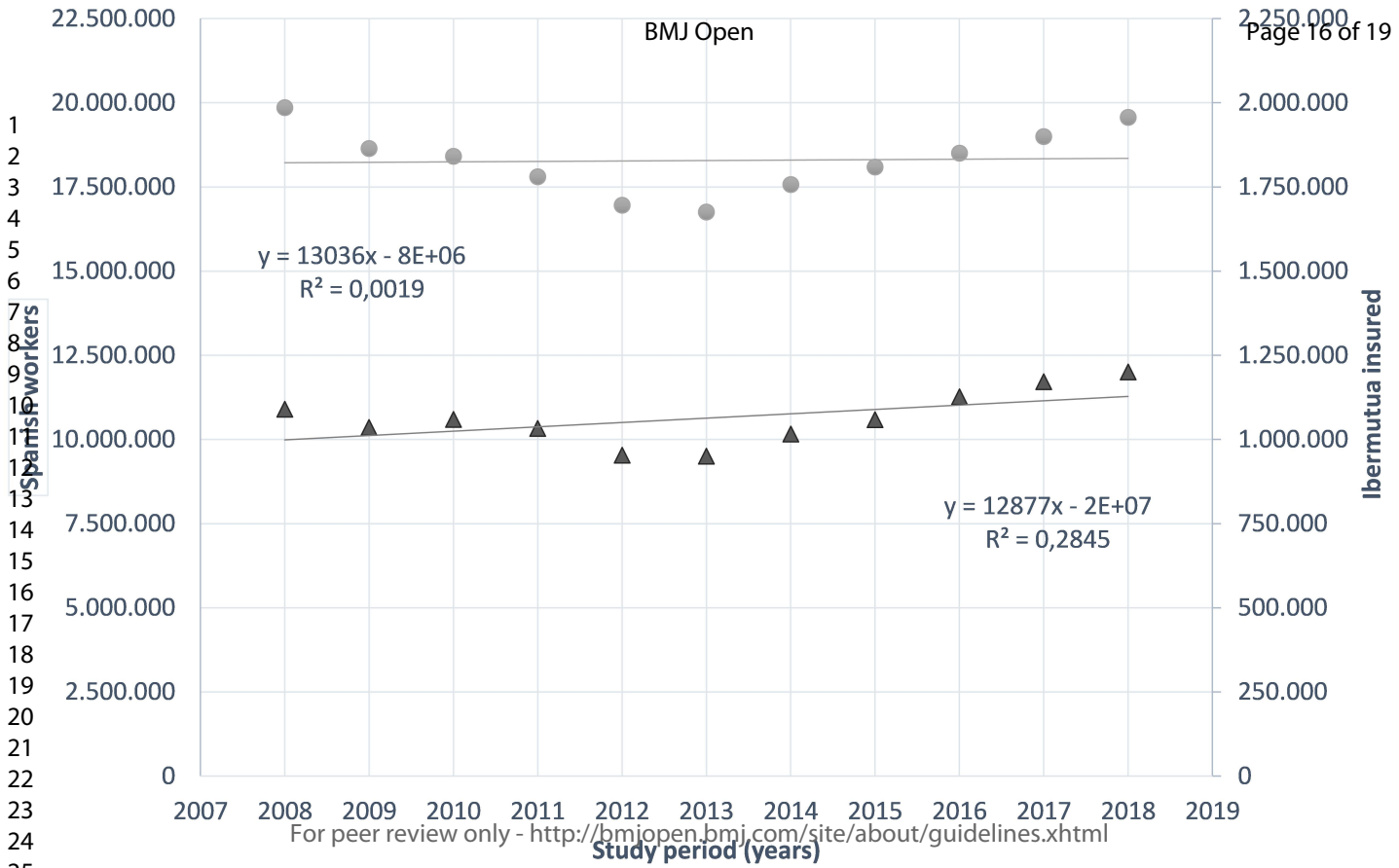
STROBE CHECKLIST ITEM NUMBER	NUMBER OF PAGE ON MANUSCRIPT
Title and Abstract 1	Page 1, 2
Background/rationale 2	Page 3
Objectives 3	Page 3
Study design 4	Page 4
Setting 5	Page 4
Participants 6	Page 4
Variables 7	Page 4
Data sources/measurements 8	Page 4
Bias 9	n/c
Study size 10	Page 4
Quantitative variables 11	Page 4
Statistical methods 12	Page 5
Participants 13	Page 5
Descriptive data 14	Page 5
Outcome data 15	n/c
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Other analyses 17	Page 5, 6 y 7
Key results 18	Page 7, 8

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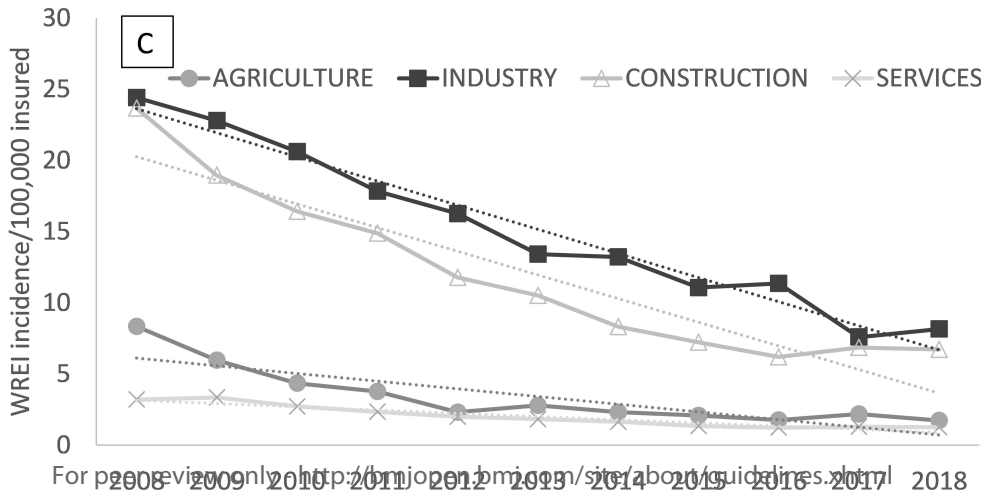
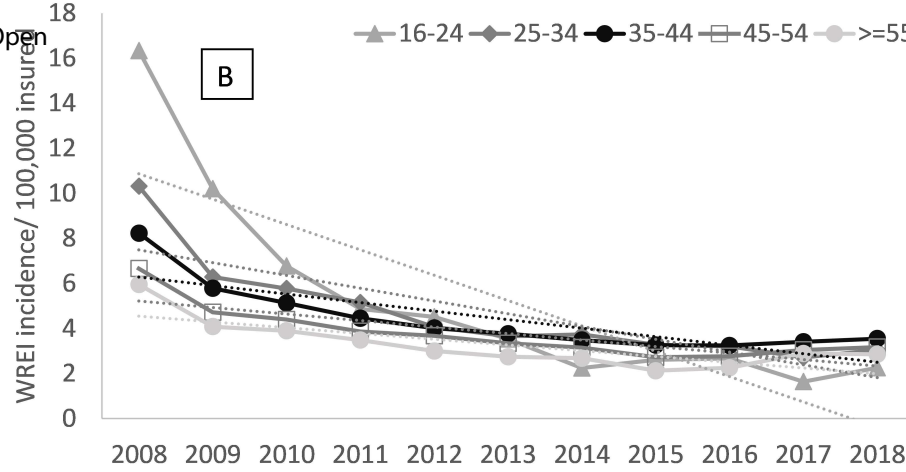
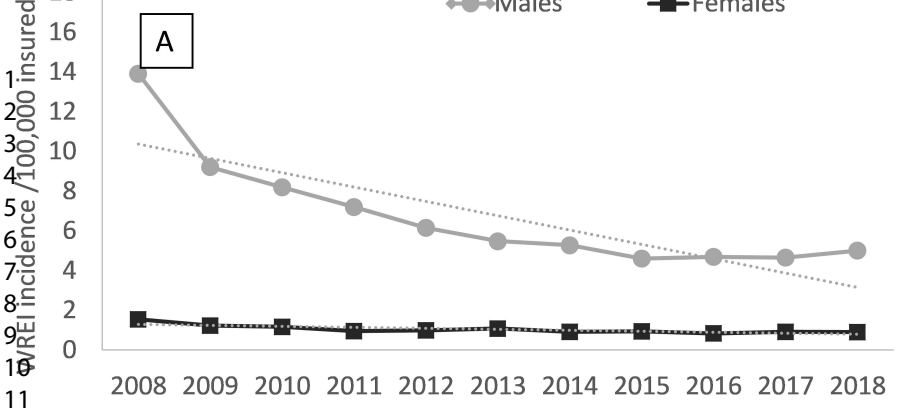
Limitations 19	Page 8
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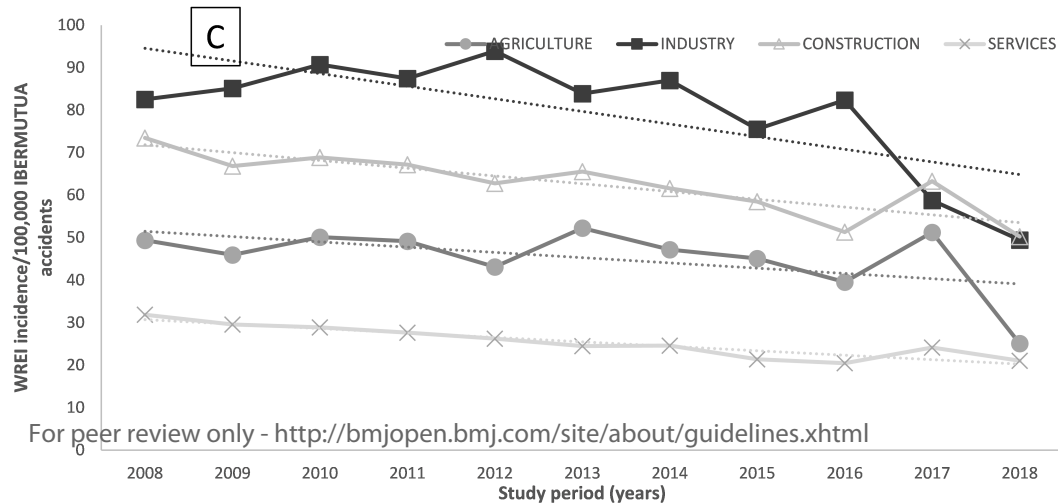
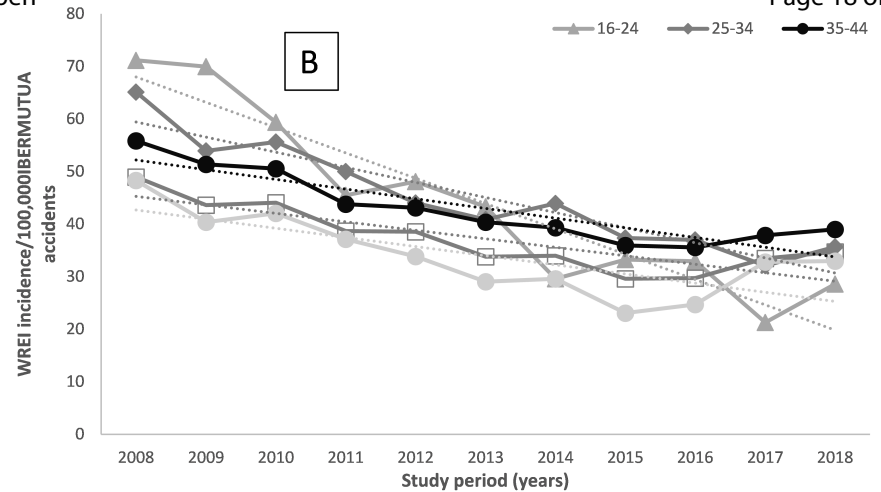
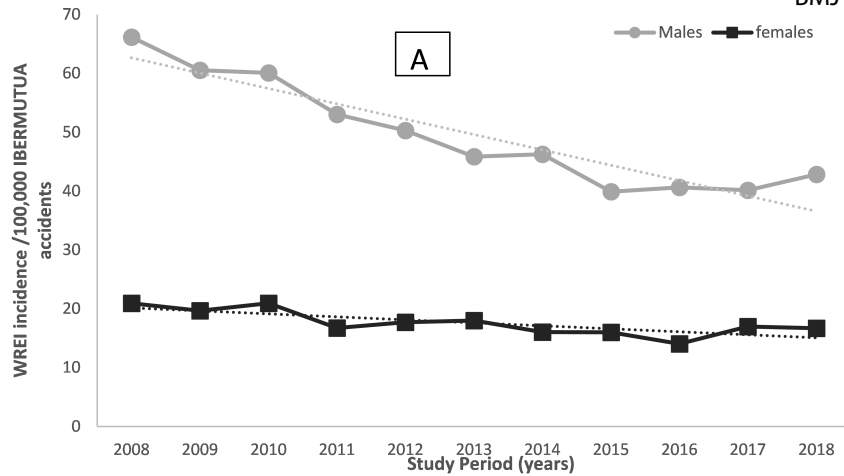
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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
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
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses

Continued on next page

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 (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures
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 (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

Discussion

Key results	18	Summarise key results with reference to study objectives
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
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results

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
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*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

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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Description of the epidemiological characteristics of work-related eye injuries in Spain. A retrospective study.

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Description of the epidemiological characteristics of work-related eye injuries in Spain. A retrospective study.

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ABSTRACT:

OBJECTIVE: To describe the epidemiological characteristics and trends of work-related eye injuries (WREI) in Spain over a 10-years period by sex, age, and occupational sector.

DESIGN AND SETTINGS: A descriptive, retrospective and longitudinal study based on data from workers insured by a labour insurance company in Spain from 2008 to 2018 was presented. The study considered the ratio of the number of WREI per 100000 population and the relative risk of suffering an ocular injury. WREI were characterized by sex, age and occupational sector of injured workers.

PRIMARY AND SECONDARY OUTCOME MEASURES: Ratio of the number of WREI.

PARTICIPANTS: In Spain, all workers are insured by a labour insurance company that provides cover in the event of work-related accidents. In this study, we have included all workers insured by one of these insurance companies, IBERMUTUA, with workers in all areas of Spain.

RESULTS: The study included 50,265 WREI in the company over the 10-year period. Most of the injuries occurred in males (44,445; 88.4%), in 35-44 age group (15,992; 31.8%), and in industry workers (18,899; 42.6%). The average incidence was 429.75 per 100,000 workers insured and 4,273.36 per 100,000 IBERMUTUA accidents (related and not related to eyes). Males, 16-24 age group and industry occupational sector group have the highest incidence for WREI. The incidence of WREI decrease over the study period in all variables. Males have 6,56 (95% CI 6.38-6.75) times more risk of suffering WREI than females. 16-24 age group have 1.77 (95% CI 1.71-1.83) times more risk than in the group of workers older than 55. Finally, industry workers have 7.73 (95% CI 7.55-7.92) times more risk than services workers.

CONCLUSIONS: Specific knowledge and description of the incidence and relative risk of work-related eye injuries is the first step for designing programs to prevent accidents in the workplace.

STRENGTHS AND LIMITATIONS OF THIS STUDY:

- Data is collected from Ibermutua, one of the largest mutual insurance companies in Spain
- This study has the highest number of workers in a research across Europe.
- This study covers a 10 years period, including an economic crisis during the period studied.
- Data is collected from only one mutual insurance company

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3 - Economic activities have been classified according to CNAE-2009 and not divided into specific
4
5 groups

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7 **FUNDING STATEMENT:** The authors received no financial support for the research, authorship, and/or
8
9 publication of this article.

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11 **COMPETING INTERESTS STATEMENT:** The authors declare that there are no conflicts of interest regarding
12
13 the publication of this paper.

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15 **WORD COUNT:** 2556 words.

16 17 18 **INTRODUCTION**

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20 An accident at work is defined in European Statistics on Accidents at Work (ESAW) methodology as a
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22 discrete occurrence during the course of work which leads to physical or mental harm (1). According to
23
24 the Labour Force Survey (LFS), 6.9 million accidents at work occurred in the European Union in 2007,
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26 affecting 3.2% of the population (2). In 2017, a total of 1.33 million of these accidents occurred in Spain,
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28 affecting 2.86% of the population (3). Within these statistics, WREI caused 16,245 workers to be absent
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30 from work in 2017 and the eye was the most affected structure in the head.

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33 The prevalence of ocular injuries in developed countries ranges from 88 to 1,920 out of a 100,000
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35 population (4,5), depending on the origin and the type of ocular injury. León Hernández et al. found that
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37 20.2% of all ocular traumas in Spain in 1991 occurred in the workplace (6). The percentage of ocular
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39 injuries related to work changes along with the world from 0.84 to 3.4% (7-9). It depends on the type of
40
41 population, the medical attention and the type of injury included in the study.

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44 The universal plan of ocular health established by WHO for the period 2014-2019, has as a main goal
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46 decreasing vision impairment around the world (7). One of their secondary objectives is the generation
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48 of scientific data about the magnitude and causes of vision impairment in order to follow the progress
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50 and could define priorities. WREI are one of these lesions related to vision impairment. Due to the
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52 characteristics of these injuries, they could be prevented by the creation of specific plans that just could
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54 be defined through the knowledge about the epidemiology and mechanism of WREI.

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56 The main objective of this study was the epidemiological characterization of WREI causing ocular injury in
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58 Spain by sex, age and occupational sectors over a 10-years period.
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METHODS

A descriptive, retrospective and longitudinal study were performed. We analyzed WREI that affects any ocular structure during work time in a mutual insurance company. Study data were provided by IBERMUTUA, a mutual insurance company that collaborates with the Spanish Social Security system. Mutual insurance companies are non-profit private associations of business owners which are duly authorized by the Spanish Ministry of Employment and Social Security and registered with the Special Register operated by the said ministry. They aim to collaborate with the management of the Spanish Social Security system under its direction and auspices with members jointly assuming liability for the situations and with the scope established by the law. On these companies, medical specialists evaluate work accidents reported by the companies it insures, analyzing the work-related injury and its consequences for insured workers. The study period was from 1st January 2008 to 31st December 2018.

The area of study covered all regions in Spain including Ceuta and Melilla with a population of 46,650,300 in 2018 (7) (latest census). In these years, we analysed 11,696,259 subjects (table 1), all of them IBERMUTUA-insured workers during the study period, and we related them to 201,167,800 workers in Spain (8).

The research described herein adhered to the tenets of the Declaration of Helsinki and approved by the ethic investigation committee of Universidad Europea de Madrid (CEI-UE). All medical records were anonymous; only statistical information was provided by Ibermutua for research purposes.

INCLUSION CRITERIA

We studied WREI that affects any ocular structure during work time and in itinere. These injuries were evaluated and classified by medical specialists according to CIE-9-MC classification, correlations with ICD-10 that's the new classification. According to WHO, ICD is the foundation for the identification of health trends and statistics globally, and the international standard for reporting diseases and health conditions. This allows making data comparisons in the same location across different periods. Ocular injuries are included in this classification with codes from 360 to 379. Only injuries where any ocular structure was affected as the main injury were included in the study.

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3 We analysed sex (males and females), age and occupational sector. We established five age groups (16-
4 24, 25-34, 35-44, 45-54, and ≥ 55) according to the Labour, Migrations and Social Security Ministry of
5 Spain (3). The occupational sector was classified according to the same Ministry's 2009 National Economic
6 Activities Code (CNAE-2009 in Spanish), whereby occupational sector was divided into four groups:
7 Agricultura, Industry, Construction, and Services (3).
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10 11 12 13 14 STATISTICAL ANALYSIS

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16 Quantitative variables are given as a mean \pm standard deviation (SD). For qualitative variables, absolute
17 and relative frequencies are given in percentages. To standardize data, the relationship between the
18 number of WREI per 100,000 population in Ibermutua (ratio/100,000 population) was calculated.
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20
21 Ibermutua data was divided into Ibermutua insured, which are the total number of workers insured by
22 IBERMUTUA, and IBERMUTUA accidents. Accidents refer to all the workers insured by Ibermutua that
23 have suffered an accident in the 10-year period studied. A relative risk (RR) was computed to check the
24 effects that exist between different groups of sex, age, and occupational sector. To compare different
25 groups in each variable, the lowest incidence per 100.000 population on each group was considered as
26 reference. RR shows how many times more of risk have a worker to suffer an accident respect the
27 reference.
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31 The chi-square test and the Fisher exact test was used to analyse qualitative variables. The student's T-
32 test and the Mann-Whitney U-Test were used, as appropriate, to search for significant differences
33 between preferences.
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37 The statistical analysis was performed using SPSS, v.21.0 (IBM Corp; Armonk, NY; USA), with $p < 0.05$
38 considered significant for all analyses.
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41 42 43 44 45 46 47 48 PATIENT AND PUBLIC INVOLVEMENT

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50 No patient involved.
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52 53 54 55 56 57 58 59 60 **RESULTS**

There were 50,265 WREI in Ibermutua over the 10-year period (Table 1). These accidents affected 0.45%
of all workers insured by IBERMUTUA and represented 4.22% of all accidents suffered by Ibermutua-
insured workers (1,179,067 total accidents (Table 1)). The average age was 38.62 ± 10.57 and the majority

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3 of all injuries occurred in the 35-44 age group (15,992; 32.0%). Within the subject population, 44,445 were
4 male (89.3%) and 5,349 females (10.7%), and industry workers were the most affected group (18,899,
5 42.6%) (Table 1).
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9 The incidence of WREI was 429.75/100,000 Ibermutua-insured workers and the incidence of WREI among
10 Ibermutua-insured accidents was 4,273.36/100,000.
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14 Workers insured by Ibermutua constituted an average of 5.81% (SD \pm 0.221) of all workers in Spain, and
15 the rate of change between workers insured in Ibermutua and total workers in Spain in the study period
16 did not show statistically significant differences ($p=0.9987$) (Figure 1). This rate of change did not show
17 statistically significant differences in services and industry. The decrease in Spanish construction workers
18 was higher than Ibermutua construction insured over the study period, however, the trend is very
19 similar. This trend was very different in Agriculture where Spanish workers decrease against Ibermutua
20 insured who increased its number.
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28 INCIDENCE AND RELATIVE RISK (RR) PER 100,000 IBERMUTUA INSURED

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30 The incidence of WREI over 10-year period was 680.12 for males and 103.63 for females. Therefore, males
31 had 6.56 (95% CI 6.38-6.75) times more risk of suffering WREI than females (Table 2). If we analyse the
32 evolution over the period, there was a decrease in incidence in both groups which was statistically
33 significantly bigger in males than females ($p=0.00027$) (Figure 2a).
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40 The highest incidence by age group corresponds to the 16-24 group (561.16). The incidence decreases
41 with age. 487.27 in 25-34, 435.57 in 35-44, 369.42 in 45-54, and 316.69 in \geq 55 group (Table 2). The \geq 55
42 age group is the reference for calculating the RR of suffering a WREI in the other groups because it is the
43 group with the lowest incidence. In this case, RR decreases with age in the same way as the incidence
44 (1.77 (95% CI 1.71-1.83), 1.54 (95% CI 1.51-1.57), 1.38 (95% CI 1.35-1.41), and 1.17 (95% CI 1.13-1.21))
45 (Table 2). Over the study period, a decrease in the incidence of WREI in all age groups was observed, and
46 it was statistically significant ($p<0.05$) when we compared 16-24 age group with the other groups, as well
47 as when we compared 25-34 age group with 45-54 age group ($p=0.035$), and 25-34 age group with \geq 55
48 age group ($p=0.021$) (Figure 2b).
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3 Industry workers were the occupation group with the highest incidence of WREI (1538.17), followed by
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5 Construction workers (1381.52), Agriculture workers (479.65) and, finally, Services workers (198.92)
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7 (Table 2). Therefore, in comparison with Services workers, the risk of suffering an accident (RR) is 7.73
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9 (95% CI 7.55-7.92) times higher in Industry workers, 6.94 (95% CI 6.77-7.12) times higher in Construction
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11 workers, and 1.53 (95% CI 1.45-1.61) times higher in Agriculture workers (Table 2). A decrease in incidence
12
13 was observed in all occupation groups over the period. There were statistically significant differences
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15 ($p < 0.05$) when we compared all groups with each other, except for the two groups with the highest
16
17 incidence, Industry workers and Construction workers ($p = 0.827$) (Figure 2c).

INCIDENCE AND RELATIVE RISK (RR) PER 100,000 IBERMUTUA ACCIDENTS

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22 WREI incidence was 5125.26 for males and 1762.18 for females, with a RR 2.91 (95% CI 2.83-299) higher
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24 in males (table 2). Incidence throughout the period decreases over time and is statistically significantly
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26 higher in males ($p < 0.001$) than females (Figure 3a).

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29 In the same way as when we compared the incidence per 100,000 Ibermutua insured, incidence and RR
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31 decrease with age. We observed the highest incidence and RR in 16-24 age group (5083.64 and RR 1.51
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33 (95% CI 1.46-1.56)), followed by 25-34 age group (4800.23 and RR 1.43 (95% CI 1.40-1.46)), 35-44 age
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35 group (4364.93 and RR 1.30 (95% CI 1.27-1.33)), 45-54 years group (3729.39 y RR 1.11 (95% CI 1.07-1.15)),
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37 and, used as a reference and with the lowest incidence of all, the ≥ 55 age group (3368.01). WREI incidence
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39 decreased in all age groups over time, and there was a statistically significant ($p < 0.05$) decrease when we
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41 compared 16-24 and 25-34 age groups with each other and both groups with the other groups (Figure
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43 3b).

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46 Industry workers suffer the highest incidence and RR of WREI in the four occupation groups (8050.69; RR
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48 3.83 (95% CI 3.74-3.92)), followed by Construction workers (6650; RR 2.54 (95% CI 2.48-5.60)), Agriculture
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50 workers (4495.75; RR 1.72 (95% CI 1.64-1.81)), and, with the lowest incidence and RR of all, Services
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52 workers (2615.64), the latter therefore being reference group for RR. Although we observed a decrease
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54 in incidence over the period, it was not statistically significant when we compared different groups (Figure
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56 3c).

DISCUSSION

Of all the long-term studies we have observed in Europe, this is the one which covers the largest area and the highest number of cases. The close relationship between Ibermutua-insured workers and the evolution in the number of workers in Spain ($p=0.9987$) indicates the importance of our data analysis.

The percentage of WREI in our study was lower than Gomez Villa et al. observed in two villages on the island of Mallorca (Spain) (0.84%) (9), Torino (Italy) (1.3%) (10) and much lower than another with a similar number of study cases in the USA (3.4%) (11). The difference was maybe due to the smaller area and population (only two villages and 50,851 workers) and the shorter study period (two years) in Mallorca and the population in the USA and Torino is not only insured workers.

The total incidence of WREI falls between the values of other studies (4,5) and is very similar to that found by Karlsen et al. in Wisconsin (USA) in 1986 (423/100,000) (12). However, in all of these studies, the incidence does not relate exclusively to work-related injuries. If we compare only with WREI, in our study we observe higher incidence than in Hong Kong (around 125/100,000) (13). However, it is very difficult to compare these two values because the Hong Kong study covered a period of only 3 months.

The higher impact on males is similar to other studies where the percentage of eye injuries in males was between 87 and 95.1% (5,14–16). A very similar RR was observed in Modena (Italy) (7:1 male/female ratio) (5), although it was lower in Taiwan (3.99) (14). It is important to highlight that these studies included not only the active population, so results are Eye Injuries but not only related to work. This higher impact on males might be due to the different occupations in each group too. In the last quarter of 2018 in Spain, there were 2.8 times more men than women working in Industry and 10.6 times more in Construction. These are the two workers' occupational sectors where the highest WREI incidence was observed in our study. However, there were 1.054 million more female workers in Services (17).

35-44 was the most affected age group in our study. Our data match those found in an area in the southwest of China (16). The highest percentage observed in other studies was in the 25-34 age group in Western Turkey (15) and the 16-24 age group in Modena (Italy) (5). However, we observed more incidence

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3 of WREI for 100,000 insured in the lowest age group (16-24) in our study, and this incidence decreases
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5 with age. We only analysed workers population, and we think this is why we found more eye injuries in
6
7 the lowest age group. These workers have less experience and perform more manual jobs.

8
9 As in other studies (5), we observed the highest incidence and percentage of WREI in Industry workers.
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11 Agriculture was the most affected group in other studies (18,19) but in all of them, Services was the least
12
13 affected group. This is due to the lower risk of trauma or other external agents that can affect Services
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15 workers.

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18 When we analysed the evolution of WREI for 100,000 Ibermutua insured/accidents, we standardized data
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20 and eliminated WREI due to population variation. Therefore, we need to find reasons for the reduction in
21
22 WREI in all study variables. This generalized decrease might be the result of unknown specific eye
23
24 protection plans proposed by the companies and Ibermutua. Variation in occupational sector incidence
25
26 over the study period could be another reason for this decrease. So, sectors with lower risk (agriculture
27
28 and services) have increased his proportion (81% in 2018 vs 73% in 2008) and this makes that incidence
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30 of WREI also decrease in general.

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33 There are no studies that compare WREI for accidents only (as opposed to total population). We
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35 considered it worth making this comparison in order to find out the mechanism and the importance that
36
37 WREI have in total accidents in Spain. Using this data could make it easier to devise specific programs
38
39 aimed at reducing ocular accidents and the associated costs.

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41 Because of the higher number of data, a certain number of cases in the different variables was missing.
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43 These missed cases were not relevant in the sex and age group but were important in occupational sector
44
45 groups (Table 1). This becomes a limitation of our study and should be taken into account in future
46
47 research in this area. Another limitation was the difficulty to compare with other studies where eye
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49 injuries are not only related to work, as far as they are carried out in the hospital's emergency
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51 departments.

52 53 54 **CONCLUSIONS**

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56 Specific and descriptive knowledge of the incidence and relative risk of work-related eye injuries is the
57
58 first step for designing programs to prevent accidents in the workplace.
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3 There is a higher risk of WREI for workers from Industry and Construction when compare to Agriculture
4 and Services. Experience is also an important factor for WREI, having younger workers more risk of
5 suffering WREI.
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CONTRIBUTORSHIP STATEMENT:

Alvarez-Peregrina, Villa-Collar and Sanchez-Tena designed the study.

Catalina-Romero and Calvo-Bonacho obtained the data.

The obtained data was analysed by Martín-Prieto and Thuissard-Vasallo.

All authors contributed to the writing of the manuscript.

COMPETING INTERESTS

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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DATA SHARING STATEMENT

All data relevant to the study are included in the article or uploaded as supplementary information. Data are also available upon reasonable request.

Table 1: Total cases (N) of Ibermutua-insured, Ibermutua accidents and total WREI (Work-related eye injuries) according to sex, age and workers occupation. Losses: total number of losses out of total number of cases (50265) of WREI in all different groups.

	TOTAL		LOSSES	
	N	%	N	%
Ibermutua insured	11,696,259			
Ibermutua accidents	1,179,067			
Spanish workers	201,167,800			
WREI	50,265			
Sex WREI				
Male	44,445	89.3		
Female	5,349	10.7		
Total	49,794	100	471	0.9
Age group WREI				
16-24	4,388	8.8		
25-34	14,981	29.9		
35-44	15,992	32.0		
45-54	10,278	20.5		
>55	4,390	8.8		
Total	50,029	100	236	0.5
Occupation WREI				
Agriculture	1,624	3.7		
Industry	18,899	42.6		
Construction	10,455	23.6		
Services	13,394	30.2		
Total	44,369	100	5,893	11.7

Table 2: Incidence of WREI over 100,000 insured and 1000,000 accidents and relative risk (RR) of WREI over a 10-year period according to sex, age and sector.

	WREI incidence per 100,000 insured	WREI incidence per 100,000 accidents	RR WREI according to insured		RR WREI according to accidents	
			RR	95% CI	RR	95% CI
Sex						
Total	425,73	4253,29				
Male	680,13	5125,27	6,56	6,38-6,75	2,91	2,83-2,99
Female	103,63	1762,19	REF		REF	
Age						
Total	427,74	4273,36				
16-24 years	561,16	5083,65	1,77	1,71-1,83	1,51	1,46-1,56
25-34 years	487,27	4800,23	1,54	1,51-1,57	1,43	1,40-1,46
35-44 years	435,58	4364,94	1,38	1,35-1,41	1,30	1,27-1,33
45-54 years	369,43	3729,40	1,17	1,13-1,21	1,11	1,07-1,15
>55 Years	316,69	3368,01	REF		REF	
Sector						
Total	479,65	4719,61				
Agriculture	305,14	4495,75	1,53	1,45-1,61	1,72	1,64-1,81
Industry	1538,18	8050,69	7,73	7,55-7,92	3,83	3,74-3,92
Construction	1381,53	6650,00	6,94	6,77-7,12	2,54	2,48-2,60
Services	198,92	2615,65	REF		REF	

Figure Legends:

Figure 1: Relation between Ibermutua insured (triangle line) and Spanish workers (circle line) over the study period. There were no statistically significant differences in evolution over the 2008-2018 period ($p=0.9987$).

Figure 2: Evolution of WREI incidence per 100000 Ibermutua insured over the study period. A decrease in incidence according to sex (A), age (B) and occupation (C) was observed.

Figure 3: Evolution of WREI incidence per 100000 Ibermutua accidents over the study period. A decrease in incidence according to sex (A), age (B) and occupation (C) was observed.

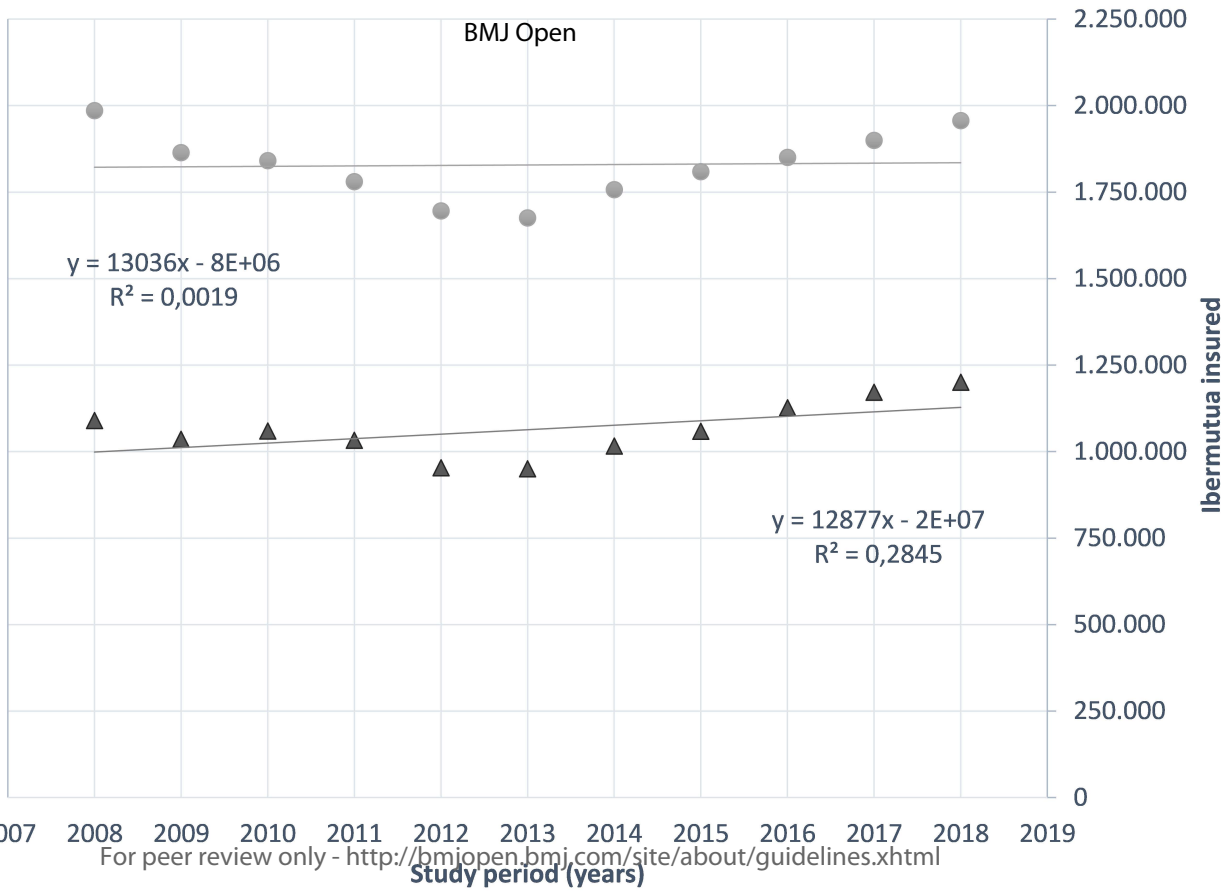
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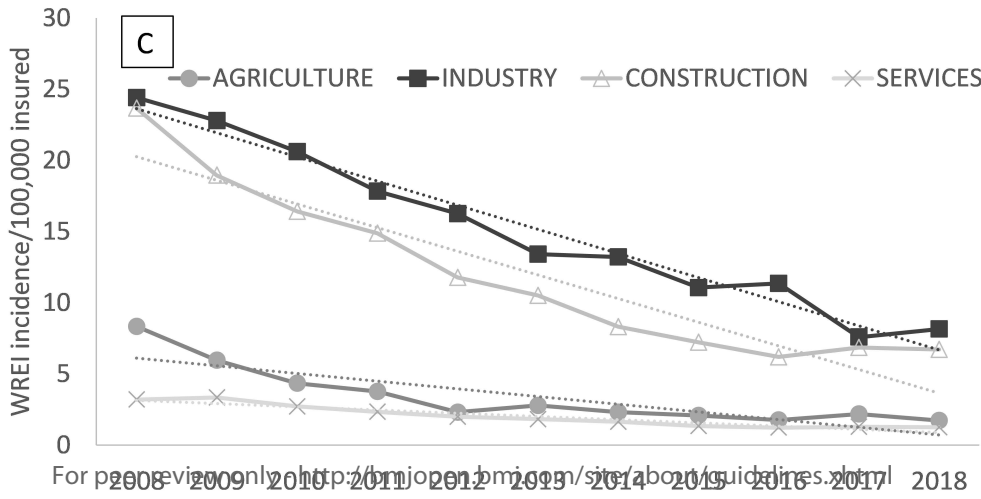
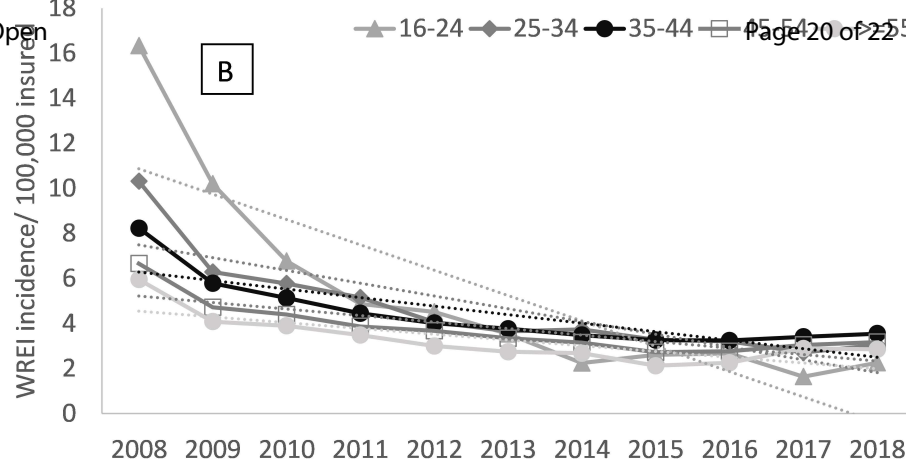
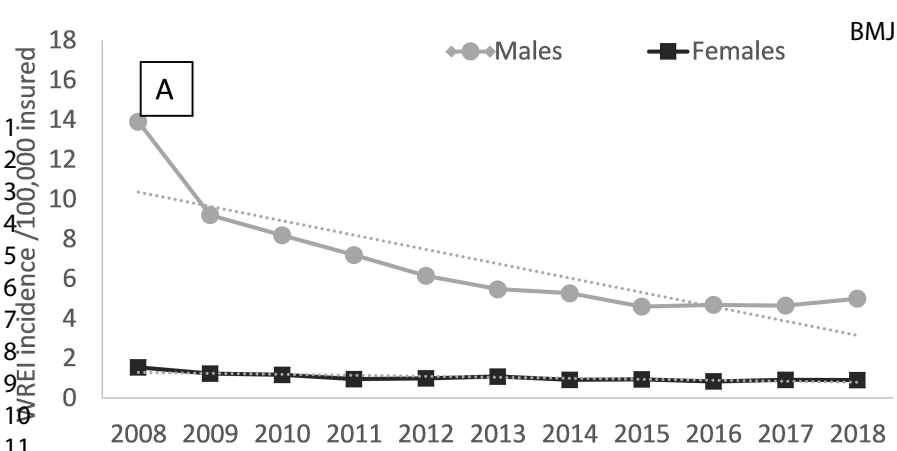
STROBE CHEKLIST ITEM NUMBER	NUMBER OF PAGE ON MANUSCRIPT
Title and Abstract 1	Page 1, 2
Background/rationale 2	Page 3
Objectives 3	Page 3
Study design 4	Page 4
Setting 5	Page 4
Participants 6	Page 4, 5
Variables 7	Page 4, 5
Data sources/measurements 8	Page 4, 5
Bias 9	n/c
Study size 10	Page 4
Quantitative variables 11	Page 4
Statistical methods 12	Page 5
Participants 13	Page 4, 5

Descriptive data 14	Page 5, 6
Outcome data 15	n/c
Main results 16	Page 5, 6 y 7
Other analyses 17	Page 5, 6 y 7
Key results 18	Page 8, 9
Limitations 19	Page 9
Interpretation 20	Page 9, 10
Generalisability 21	Page 8, 9
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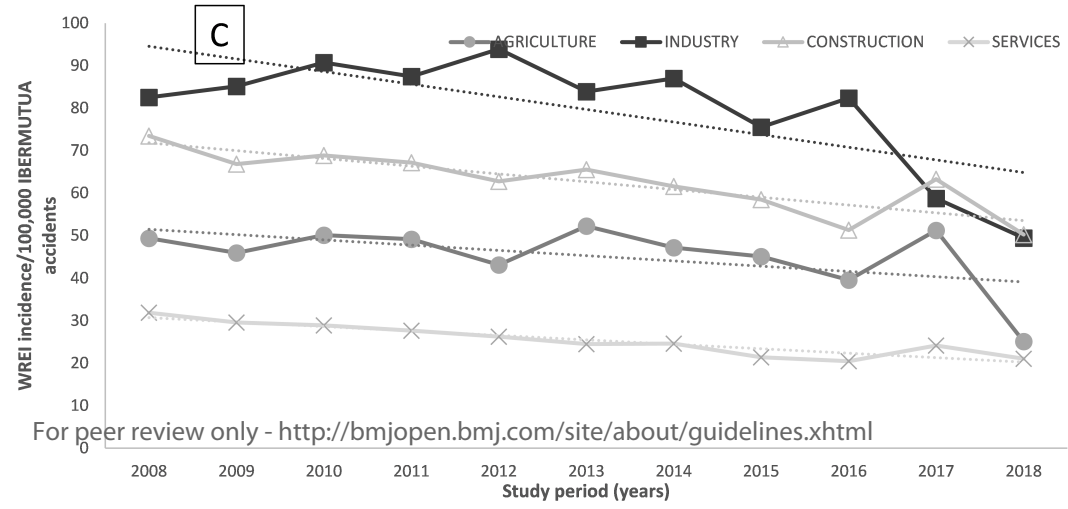
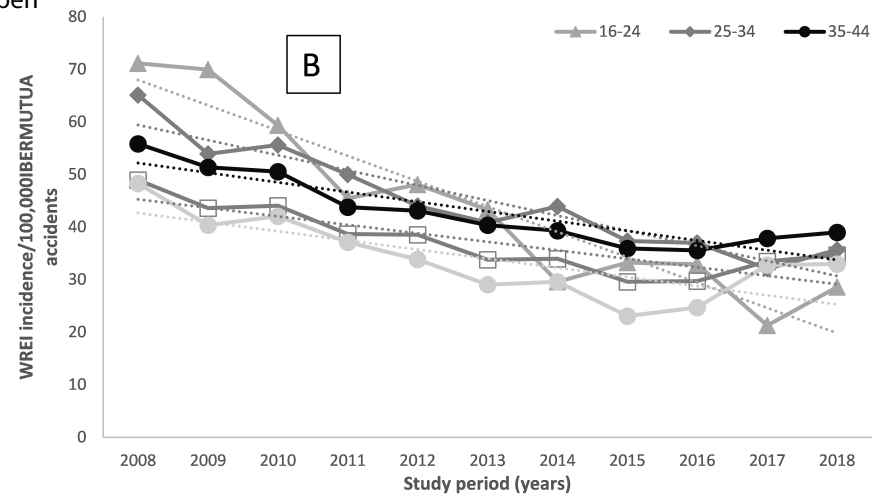
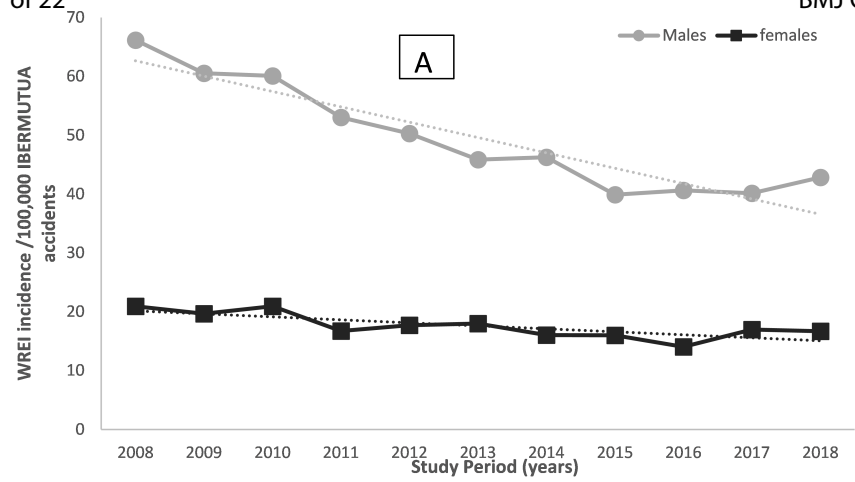
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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
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
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses

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60**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 (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures
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 (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

Discussion

Key results	18	Summarise key results with reference to study objectives
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
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results

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
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*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

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.

BMJ Open

Description of the epidemiological characteristics of work-related eye injuries in Spain. A retrospective study.

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Primary Subject Heading:	Occupational and environmental medicine
Secondary Subject Heading:	Ophthalmology, Epidemiology
Keywords:	ACCIDENT & EMERGENCY MEDICINE, EPIDEMIOLOGY, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, OCCUPATIONAL & INDUSTRIAL MEDICINE, Medical ophthalmology < OPHTHALMOLOGY

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Description of the epidemiological characteristics of work-related eye injuries in Spain. A retrospective study.

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ABSTRACT:

OBJECTIVE: To describe the epidemiological characteristics and trends of work-related eye injuries (WREI) in Spain over a 10-years period by sex, age, and occupational sector.

DESIGN AND SETTINGS: A descriptive, retrospective and longitudinal study based on data from workers insured by a labour insurance company in Spain from 2008 to 2018 was presented. The study considered the ratio of the number of WREI per 100000 population and the relative risk of suffering an ocular injury. WREI were characterized by sex, age and occupational sector of injured workers.

PRIMARY AND SECONDARY OUTCOME MEASURES: Ratio of the number of WREI.

PARTICIPANTS: In Spain, all workers are insured by a labour insurance company that provides cover in the event of work-related accidents. In this study, we have included all workers insured by one of these insurance companies, IBERMUTUA, with workers in all areas of Spain.

RESULTS: The study included 50,265 WREI in the company over the 10-year period. Most of the injuries occurred in males (44,445; 88.4%), in 35-44 age group (15,992; 31.8%), and in industry workers (18,899; 42.6%). The average incidence was 429.75 per 100,000 workers insured and 4,273.36 per 100,000 IBERMUTUA accidents (related and not related to eyes). Males, 16-24 age group and industry occupational sector group have the highest incidence for WREI. The incidence of WREI decrease over the study period in all variables. Males have 6,56 (95% CI 6.38-6.75) times more risk of suffering WREI than females. 16-24 age group have 1.77 (95% CI 1.71-1.83) times more risk than in the group of workers older than 55. Finally, industry workers have 7.73 (95% CI 7.55-7.92) times more risk than services workers.

CONCLUSIONS: The risks of suffering WREI is higher for males, younger and less experienced workers, and for those who works in a manual task.

STRENGTHS AND LIMITATIONS OF THIS STUDY:

- Data is collected from Ibermutua, one of the largest mutual insurance companies in Spain
- This study has the highest number of workers in a research across Europe.
- This study covers a 10 years period, including an economic crisis during the period studied.
- Data is collected from only one mutual insurance company

- Economic activities have been classified according to CNAE-2009 and not divided into specific groups

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INTRODUCTION

An accident at work is defined in European Statistics on Accidents at Work (ESAW) methodology as a discrete occurrence during the course of work which leads to physical or mental harm [1]. According to the Labour Force Survey (LFS), 6.9 million accidents at work occurred in the European Union in 2007, affecting 3.2% of the population [2]. In 2017, a total of 1.33 million of these accidents occurred in Spain, affecting 2.86% of the population [3]. Within these statistics, WREI caused 16,245 workers to be absent from work in 2017 and the eye was the most affected structure in the head.

The prevalence of ocular injuries in developed countries ranges from 88 to 1,920 out of a 100,000 population [4,5], depending on the origin and the type of ocular injury. León Hernández et al. found that 20.2% of all ocular traumas in Spain in 1991 occurred in the workplace [6]. The percentage of ocular injuries related to work changes along with the world from 0.84 to 3.4% [7-9]. It depends on the type of population, the medical attention and the type of injury included in the study.

The universal plan of ocular health established by WHO for the period 2014-2019, has as a main goal decreasing vision impairment around the world [7]. One of their secondary objectives is the generation of scientific data about the magnitude and causes of vision impairment in order to follow the progress and could define priorities. WREI are one of these lesions related to vision impairment. Due to the characteristics of these injuries, they could be prevented by the creation of specific plans that just could be defined through the knowledge about the epidemiology and mechanism of WREI.

The main objective of this study was the epidemiological characterization of WREI causing ocular injury in Spain by sex, age and occupational sectors over a 10-years period.

METHODS

A descriptive, retrospective and longitudinal study were performed. We analyzed WREI that affects any ocular structure during work time in a mutual insurance company. Study data were provided by IBERMUTUA, a mutual insurance company that collaborates with the Spanish Social Security system. Mutual insurance companies are non-profit private associations of business owners which are duly authorized by the Spanish Ministry of Employment and Social Security and registered with the Special Register operated by the said ministry. They aim to collaborate with the management of the Spanish Social Security system under its direction and auspices with members jointly assuming liability for the situations and with the scope established by the law. On these companies, medical specialists evaluate work accidents reported by the companies it insures, analyzing the work-related injury and its consequences for insured workers. The study period was from 1st January 2008 to 31st December 2018.

The area of study covered all regions in Spain including Ceuta and Melilla with a population of 46,650,300 in 2018 [7] (latest census). In these years, we analyzed 11,696,259 subjects (table 1), all of them IBERMUTUA-insured workers during the study period, and we related them to 201,167,800 workers in Spain [8].

The research described herein adhered to the tenets of the Declaration of Helsinki and approved by the ethic investigation committee of Universidad Europea de Madrid (CEI-UE). All medical records were anonymous; only statistical information was provided by Ibermutua for research purposes.

INCLUSION CRITERIA

We studied WREI that affects any ocular structure during work time and in itinere. These injuries were evaluated and classified by medical specialists according to CIE-9-MC classification, correlations with ICD-10 that's the new classification. According to WHO, ICD is the foundation for the identification of health trends and statistics globally, and the international standard for reporting diseases and health conditions. This allows making data comparisons in the same location across different periods. Ocular injuries are included in this classification with codes from 360 to 379. Only injuries where any ocular structure was affected as the main injury were included in the study.

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3 We analyzed sex (males and females), age and occupational sector. We established five age groups (16-
4 24, 25-34, 35-44, 45-54, and ≥ 55) according to the Labour, Migrations and Social Security Ministry of
5 Spain [3]. The occupational sector was classified according to the same Ministry's 2009 National Economic
6 Activities Code (CNAE-2009 in Spanish), whereby occupational sector was divided into four groups:
7 Agricultura, Industry, Construction, and Services [3].
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13 STATISTICAL ANALYSIS

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16 Quantitative variables are given as a mean \pm standard deviation (SD). For qualitative variables, absolute
17 and relative frequencies are given in percentages. To standardize data, the relationship between the
18 number of WREI per 100,000 population in Ibermutua (ratio/100,000 population) was calculated.
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22 Ibermutua data was divided into Ibermutua insured, which are the total number of workers insured by
23 IBERMUTUA, and IBERMUTUA accidents. Accidents refer to all the workers insured by Ibermutua that
24 have suffered an accident in the 10-year period studied. A relative risk (RR) was computed to check the
25 effects that exist between different groups of sex, age, and occupational sector. To compare different
26 groups in each variable, the lowest incidence per 100.000 population on each group was considered as
27 reference. RR shows how many times more of risk have a worker to suffer an accident respect the
28 reference.
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37 A multiple logistic regression has been used to analyze the relationship between WREI and sex, age and
38 occupation. The risk of suffering WREI was calculated from the Odds Ratio (OR) obtained on this analysis
39 taking as the reference the group with the lowest incidence.
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43 The chi-square test and the Fisher exact test was used to analyze qualitative variables. The student's T-
44 test and the Mann-Whitney U-Test were used, as appropriate, to search for significant differences
45 between preferences.
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50 The statistical analysis was performed using SPSS, v.21.0 (IBM Corp; Armonk, NY; USA), with $p < 0.05$
51 considered significant for all analyses.
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54 PATIENT AND PUBLIC INVOLVEMENT

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56 No patient involved.
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RESULTS

There were 50,265 WREI in Ibermutua over the 10-year period (Table 1). These accidents affected 0.45% of all workers insured by IBERMUTUA and represented 4.22% of all accidents suffered by Ibermutua-insured workers (1,179,067 total accidents (Table 1)). The average age was 38.62 ± 10.57 and the majority of all injuries occurred in the 35-44 age group (15,992; 32.0%). Within the subject population, 44,445 were male (89.3%) and 5,349 females (10.7%), and industry workers were the most affected group (18,899, 42.6%) (Table 1).

The incidence of WREI was 429.75/100,000 Ibermutua-insured workers and the incidence of WREI among Ibermutua-insured accidents was 4,273.36/100,000.

Workers insured by Ibermutua constituted an average of 5.81% (SD ± 0.221) of all workers in Spain, and the rate of change between workers insured in Ibermutua and total workers in Spain in the study period did not show statistically significant differences ($p=0.9987$) (Figure 1). This rate of change did not show statistically significant differences in services ($p=0.070$) and industry ($p=0.453$). The decrease in Spanish construction workers was statistical significance higher ($p=0.009$) than Ibermutua construction insured over the study period, however, the trend is very similar. This trend was statistical significance different ($p=0.02$) in Agriculture where Spanish workers decrease against Ibermutua insured who increased its number.

INCIDENCE AND RELATIVE RISK (RR) PER 100,000 IBERMUTUA INSURED

The incidence of WREI over the 10-year period was 680.12 per 100,000 insured for males and 103.63 per 100,000 insured for females. Therefore, males had 6.56 (95% CI 6.38-6.75) times more relative risk of suffering WREI than females (Table 2). If we analyze the evolution over the study period, a decrease in the incidence in both groups was observed. This decrease was statistically significant bigger in males than females ($p=0.00027$) (Figure 2a).

The highest incidence by age group corresponds to the 16-24 group (561.16). The incidence decreases with age. 487.27 in 25-34, 435.57 in 35-44, 369.42 in 45-54, and 316.69 in ≥ 55 group (Table 2). The ≥ 55 age group is the reference for calculating the RR of suffering a WREI in the other groups because it is the group with the lowest incidence. In this case, RR decreases with age in the same way as the incidence

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3 (1.77 (95% CI 1.71-1.83), 1.54 (95% CI 1.51-1.57), 1.38 (95% CI 1.35-1.41), and 1.17 (95% CI 1.13-1.21))
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5 (Table 2). Over the study period, a decrease in the incidence of WREI in all age groups was observed, and
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7 it was statistically significant ($p<0.05$) when we compared 16-24 age group with the other groups, as well
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9 as when we compared 25-34 age group with 45-54 age group ($p=0.035$), and 25-34 age group with ≥ 55
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11 age group ($p=0.021$) (Figure 2b).

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14 Industry workers were the occupation group with the highest incidence of WREI (1538.17), followed by
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16 Construction workers (1381.52), Agriculture workers (479.65) and, finally, Services workers (198.92)
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18 (Table 2). Therefore, in comparison with Services workers, the risk of suffering an accident (RR) is 7.73
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20 (95% CI 7.55-7.92) times higher in Industry workers, 6.94 (95% CI 6.77-7.12) times higher in Construction
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22 workers, and 1.53 (95% CI 1.45-1.61) times higher in Agriculture workers (Table 2). A decrease in incidence
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24 was observed in all occupation groups over the period. There were statistically significant differences
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26 ($p<0.05$) when we compared all groups with each other, except for the two groups with the highest
27
28 incidence, Industry workers and Construction workers ($p=0.827$) (Figure 2c).

30 31 INCIDENCE AND RELATIVE RISK (RR) PER 100,000 IBERMUTUA ACCIDENTS

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33 WREI incidence was 5125.26 for males and 1762.18 for females, with a RR 2.91 (95% CI 2.83-2.99) higher
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35 in males (table 2). Incidence throughout the period decreases over time and is statistically significantly
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37 higher in males ($p<0.001$) than females (Figure 3a).

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40 In the same way as when we compared the incidence per 100,000 Ibermutua insured, incidence and RR
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42 decrease with age. We observed the highest incidence and RR in 16-24 age group (5083.64 and RR 1.51
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44 (95% CI 1.46-1.56)), followed by 25-34 age group (4800.23 and RR 1.43 (95% CI 1.40-1.46)), 35-44 age
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46 group (4364.93 and RR 1.30 (95% CI 1.27-1.33)), 45-54 years group (3729.39 y RR 1.11 (95% CI 1.07-1.15)),
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48 and, used as a reference and with the lowest incidence of all, the ≥ 55 age group (3368.01). WREI
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50 incidence decreased in all age groups over time, and there was a statistically significant ($p<0.05$) decrease
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52 when we compared 16-24 and 25-34 age groups with each other and both groups with the other groups
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54 (Figure 3b).

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56 Industry workers suffer the highest incidence and RR of WREI in the four occupation groups (8050.69; RR
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58 3.83 (95% CI 3.74-3.92)), followed by Construction workers (6650; RR 2.54 (95% CI 2.48-5.60)), Agriculture
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3 workers (4495.75; RR 1.72 (95% CI 1.64-1.81)), and, with the lowest incidence and RR of all, Services
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5 workers (2615.64), the latter therefore being reference group for RR. Although we observed a decrease
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7 in incidence over the period, it was not statistically significant when we compared different groups (Figure
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9 3c).

10 11 INTERACTION ANALYSIS BETWEEN SEX, AGE AND OCCUPATION

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14 Table 3 shows how according to the the results of the multiple logistic regression analysis, there was
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16 significant relationship between WREI and sex, age and occupation. Males had 80.11% (95% CI 79.61-
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18 80.61) more risk of suffering WREI than females. In addition, 16-24 age group showed the highest risk of
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20 suffering WREI compared to the lowest group (>55 years) (64.15% (95% CI 63.11-65.19)) and followed by
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22 the 25-34 age group (60.79% (CI 95% 59.93-61.65)), the 35-44 age group (58.24% (CI 95% 57.37-59.11)
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24 and the 45-54 age group (55.45% (CI 95% 54.50-56.39)).

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27 Workers from the Industry group had the highest risk of suffering WREI compared with those from the
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29 Services group (85.29% (CI 95% 85.00-85.57)). They were followed by workers from the Construction
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31 (80.85% (CI 95% 80.43-81.26)) and Agriculture sectors (53.50% (CI 95% 52.33-54.93)).

32 33 **DISCUSSION**

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36 Of all the long-term studies we have observed in Europe, this is the one which covers the largest area and
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38 the highest number of cases. The close relationship between Ibermutua-insured workers and the
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40 evolution in the number of workers in Spain ($p=0.9987$) indicates the importance of our data analysis. The
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42 highest WREI incidence per 100.000 Ibermutua insured/accidents and the highest relative risk (RR) was
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44 observed in males, aged between 16-24 that worked in the Industry sector. The evolution of WREI
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46 incidence per 100.000 insured/accidents over the study period showed a decrease in all the groups (both
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48 sexes and all ages and sectors)

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51 The percentage of WREI in our study was lower than Gomez Villa et al. observed in two villages on the
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53 island of Mallorca (Spain) (0.84%) [9], Torino (Italy) (1.3%) [10] and much lower than another with a
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55 similar number of study cases in the USA (3.4%) [11]. The difference was maybe due to the smaller area
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57 and population (only two villages and 50,851 workers) and the shorter study period (two years) in
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59 Mallorca and the population in the USA and Torino is not only insured workers.

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3 The total incidence of WREI falls between the values of other studies [4,5] and is very similar to that found
4 by Karlsen et al. in Wisconsin (USA) in 1986 (423/100,000) [12]. However, in all of these studies, the
5 incidence does not relate exclusively to work-related injuries. If we compare only with WREI, in our study
6 we observe higher incidence than in Hong Kong (around 125/100,000) [13]. However, it is very difficult to
7 compare these two values because the Hong Kong study covered a period of only 3 months.
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13 The higher impact on males is similar to other studies where the percentage of eye injuries in males was
14 between 87 and 95.1% [5,14–16]. A very similar RR was observed in Modena (Italy) (7:1 male/female
15 ratio) [5], although it was lower in Taiwan (3.99) [14]. It is important to highlight that these studies
16 included not only the active population, so results are Eye Injuries but not only related to work. This
17 higher impact on males might be due to the different occupations in each group too. In the last quarter
18 of 2018 in Spain, there were 2.8 times more men than women working in Industry and 10.6 times more
19 in Construction. These are the two workers' occupational sectors where the highest WREI incidence was
20 observed in our study. However, there were 1.054 million more female workers in Services [17].
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35-44 was the most affected age group in our study. Our data match those found in an area in the
southwest of China [16]. The highest percentage observed in other studies was in the 25-34 age group in
Western Turkey [15] and the 16-24 age group in Modena (Italy) [5]. However, we observed more incidence
of WREI for 100,000 insured in the lowest age group (16-24) in our study, and this incidence decreases
with age. We only analyzed workers population, and we think this is why we found more eye injuries in
the lowest age group. These workers have less experience and perform more manual jobs too. Our results
suggest that work-experience plays a protective role in Spanish workers as well as in other countries [5,
15, 18].

As in other studies [5], we observed the highest incidence and percentage of WREI in Industry workers.
Agriculture was the most affected group in other studies [19,20] but in all of them, Services was the least
affected group. This is due to the lower risk of trauma or other external agents that can affect Services
workers.

The multiple logistic regression analysis to study the interaction of the different variables, confirmed the
results from the descriptive analysis. So, the highest incidence was observed in younger workers (aged
between 16 and 24) and in males, confirming results from previous studies [21].

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3 When we analyzed the evolution of WREI for 100,000 Ibermutua insured/accidents, we standardized data
4 and eliminated WREI due to population variation. Therefore, we need to find reasons for the reduction in
5 WREI in all study variables. This generalized decrease might be the result of unknown specific eye
6 protection plans proposed by the companies and Ibermutua. Variation in occupational sector incidence
7 over the study period could be another reason for this decrease. So, sectors with lower risk (agriculture
8 and services) have increased his proportion (81% in 2018 vs 73% in 2008) and this makes that incidence
9 of WREI also decrease in general.
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18 There are no studies that compare WREI for accidents only (as opposed to total population). We
19 considered it worth making this comparison to find out the mechanism and the importance that WREI
20 have in total accidents in Spain. Using this data could make it easier to devise specific programs aimed at
21 reducing ocular accidents and the associated costs.
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26 The high number of data of our database makes that a certain number of cases in the different variables
27 was missing. Because of that, we don't have the same number of cases in all variables. These missed cases
28 were not relevant in the sex and age group but were important in occupational sector groups (Table 1).
29 This becomes a limitation of our study and should be taken into account in future research in this area.
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32 Another limitation was the difficulty to compare with other studies where eye injuries are not only related
33 to work, as far as they are carried out in the hospital's emergency departments.
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39 **CONCLUSIONS**

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41 There is a higher risk of WREI for workers from Industry and Construction when compare to Agriculture
42 and Services. Our results suggesting that experience is also an important factor for WREI, because
43 younger workers shown more risk of suffering WREI. With these results, the main risk factors for
44 suffering WREI was to be male, to be young and less experienced and work in manual task.
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50 According to these results, specific protection programs for higher protection in Industry and Services
51 sectors should be proposed. We suggest the implantation of protective glasses and face shields in
52 Industry workers and visual ergonomic measures or instilling eye drops in workers of the services sector.
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CONTRIBUTORSHIP STATEMENT:

Alvarez-Peregrina, Villa-Collar and Sanchez-Tena designed the study.

Catalina-Romero and Calvo-Bonacho obtained the data.

The obtained data was analyzed by Martín-Prieto and Thuissard-Vasallo.

All authors contributed to the writing of the manuscript.

COMPETING INTERESTS

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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DATA SHARING STATEMENT

All data relevant to the study are included in the article or uploaded as supplementary information. Data are also available upon reasonable request.

Table 1: Total cases (N) of Ibermutua-insured, Ibermutua accidents and total WREI (Work-related eye injuries) according to sex, age and workers occupation. Losses: total number of losses out of total number of cases (50265) of WREI in all different groups.

	TOTAL		LOSSES	
	N	%	N	%
Ibermutua insured	11,696,259			
Ibermutua accidents	1,179,067			
Spanish workers	201,167,800			
WREI	50,265			
Sex WREI				
Male	44,445	89.3		
Female	5,349	10.7		
Total	49,794	100	471	0.9
Age group WREI				
16-24	4,388	8.8		
25-34	14,981	29.9		
35-44	15,992	32.0		
45-54	10,278	20.5		
>55	4,390	8.8		
Total	50,029	100	236	0.5
Occupation WREI				
Agriculture	1,624	3.7		
Industry	18,899	42.6		
Construction	10,455	23.6		
Services	13,394	30.2		
Total	44,369	100	5,893	11.7

Table 2: Incidence of WREI over 100,000 insured and 1000,000 accidents and relative risk (RR) of WREI over a 10-year period according to sex, age and sector.

	WREI incidence per 100,000 accidents	Risk percentage of WREI (%)	WREI incidence per 100,000 accidents	RR WREI according to insured		RR WREI according to accidents	
				RR	95% CI	RR	95% CI
Sex							
Total	425.73		4253.29				
Male	680.13	80.11% (95% CI 79.61-80.61)	5125.27	6.56	6.38-6.75	2.91	2.83-2.99
Female	103.63	REF	1762.19	REF		REF	
Age							
Total	427.74		4273.36				
16-24 years	561.16	64.15% (95% CI 63.11-65.19)	5083.65	1.77	1.71-1.83	1.51	1.46-1.56
25-34 years	487.27	60.79% (CI 95% 59.93-61.65)	4800.23	1.54	1.51-1.57	1.43	1.40-1.46
35-44 years	435.58	58.24% (CI 95% 57.37-59.11)	4364.94	1.38	1.35-1.41	1.30	1.27-1,33
45-54 years	369.43	55.45% (CI 95% 54.50-56.39).	3729.40	1.17	1.13-1.21	1.11	1,07-1.15
>55 Years	316.69	REF	3368.01	REF		REF	
Occupation							
Total	479.65		4719.61				
Agriculture	305.14	53.50% (CI 95% 52.33-54.93)	4495.75	1.53	1.45-1.61	1.72	1.64-1.81
Industry	1538.18	85.29% (CI 95% 85.00-85.57)	8050.69	7.73	7.55-7.92	3.83	3.74-3.92
Construction	1381.53	80.85% (CI 95% 80.43-81.26)	6650.00	6.94	6.77-7.12	2.54	2.48-2.60
Services	198.92	REF	2615.65	REF		REF	

Table 3. Relationship between WREI and study variables according to multivariate logistic regression analysis

	OR (95% CI)	p-value
Sex		
Male	4,030(3,904-4,159)	< 0,001
Female	REF	REF
Age (years)		
16-24 years	1,790(1,711-1,873)	< 0,001
25-34 years	1,551(1,496-1,608)	< 0,001
35-44 years	1,395(1,346-1,446)	< 0,001
45-54 years	1,245(1,198-1,293)	< 0,001
>55 Years	REF	REF
Occupation		
Agriculture	1,151(1,098-1,219)	< 0,001
Industry	4,222(4,111-4,336)	< 0,001
Construction	5,799(5,668-5,933)	< 0,001
Services	REF	REF

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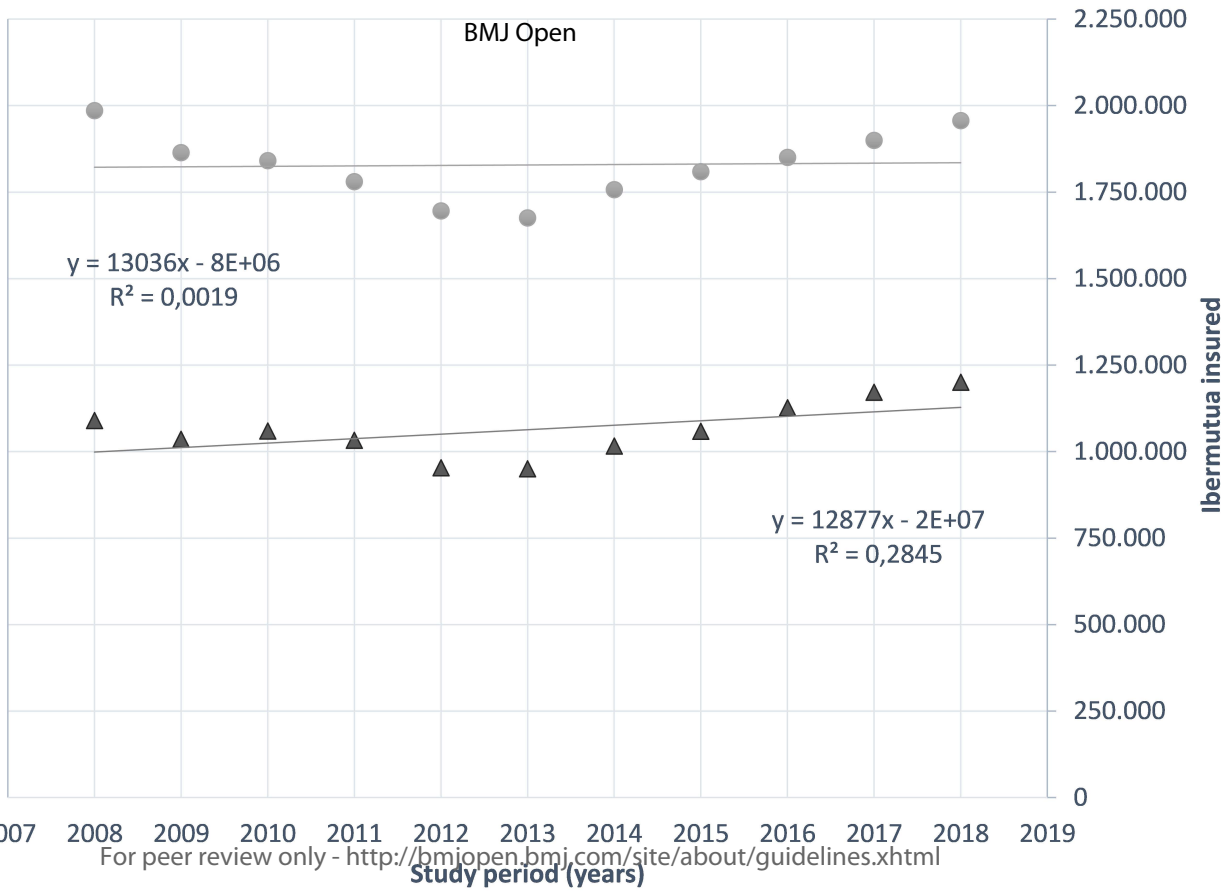
6 **Figure 1:** Relation between Ibermutua insured (triangle line) and Spanish workers (circle
7 line) over the study period. There were no statistically significant differences in
8 evolution over the 2008-2018 period ($p=0.9987$).
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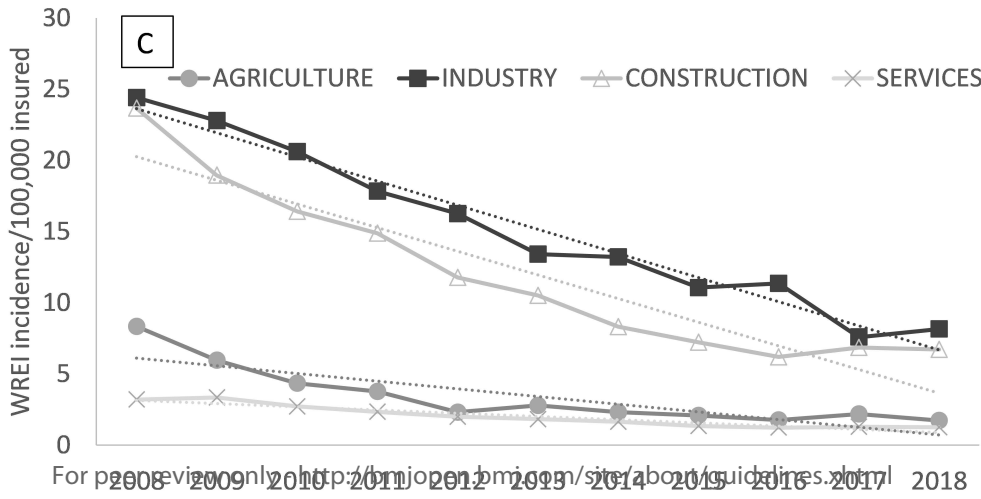
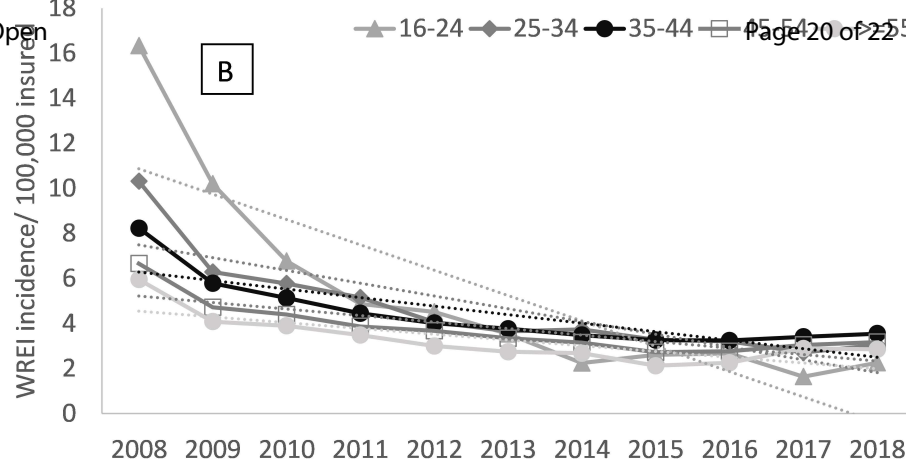
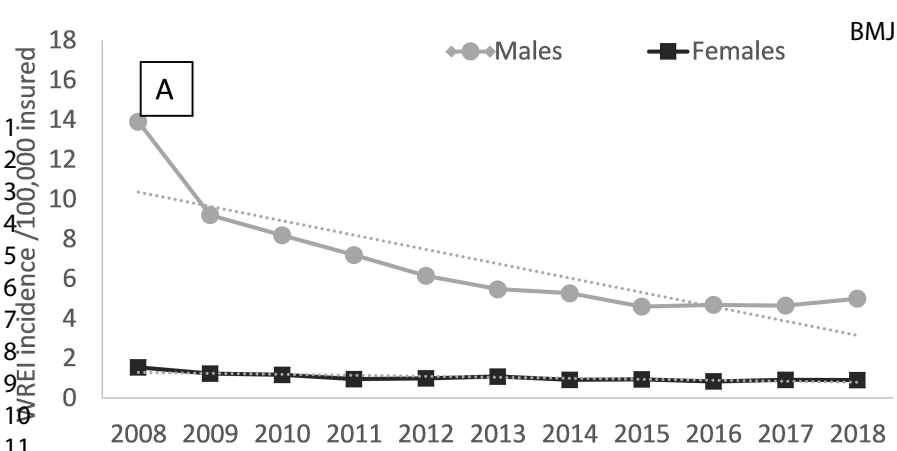
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11 **Figure 2:** Evolution of WREI incidence per 100000 Ibermutua insured over the study
12 period. A decrease in incidence according to sex (A), age (B) and occupation (C) was
13 observed.
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17 **Figure 3:** Evolution of WREI incidence per 100000 Ibermutua accidents over the study
18 period. A decrease in incidence according to sex (A), age (B) and occupation (C) was
19 observed.
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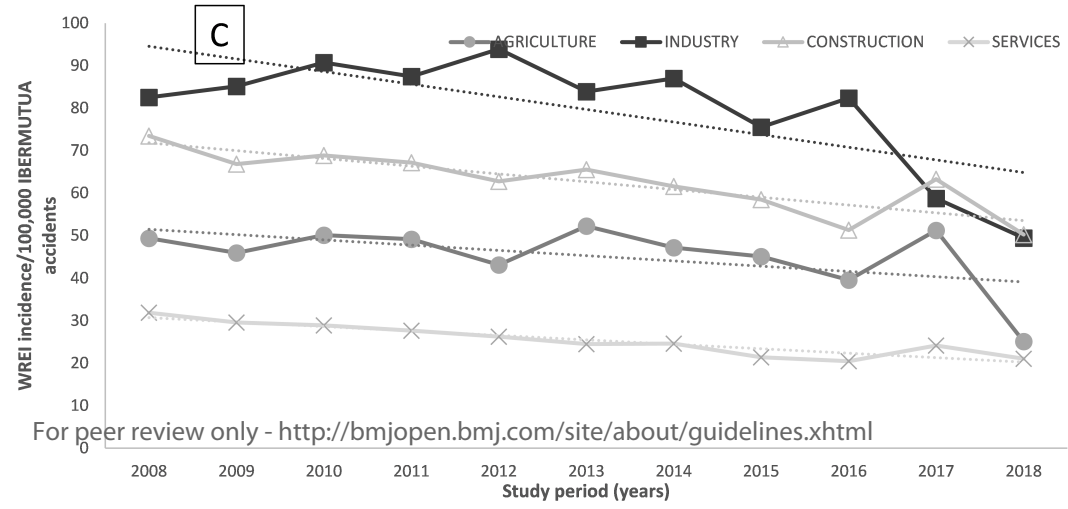
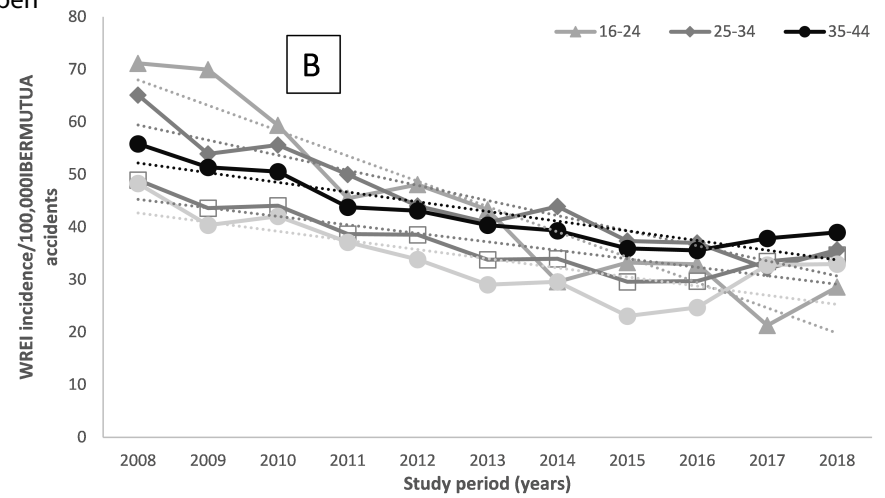
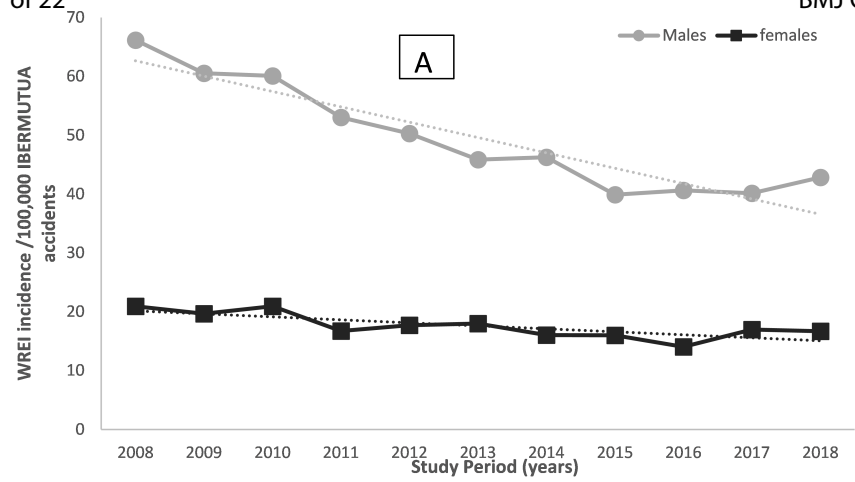
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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
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
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses

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60**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 (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures
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 (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

Discussion

Key results	18	Summarise key results with reference to study objectives
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
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results

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
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*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

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.