Bicycle helmet wearing and the risk of head, face, and neck injury: a French case–control study based on a road trauma registry

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ABSTRACT

Background Previous case–control studies on bicycle helmet efficacy are mostly Anglo-Saxon, and based on data from the early 1990s when hard-shell helmets were common.

Methods In France, the Rhône county (1.6 million inhabitants) is covered by a road trauma registry that includes emergency department visits, hospital admissions, and fatalities. Over the 1998–2008 period, 13 797 cyclist casualties were identified. The injuries sustained were coded using the Abbreviated Injury Scale (AIS) for injuries to the head (AIS1+ and AIS3+), face (AIS1+), or neck (AIS1+). The study uses a case–control design where the control group includes cyclists injured below the neck—that is, not injured in the region associated with the helmet. We first adjusted for age, gender, and type of crash, as in a previously published Cochrane review. Then we adjusted for injury severity based on non-head, face, or neck injury, and when relevant, for crash location: type of road, urban/rural area.

Results The fully adjusted ORs of helmeted versus unhelmeted cyclists are: for AIS1+ head injuries, 0.69 (95% CI 0.59 to 0.81); for AIS3+ head injuries sustained in urban areas, 0.34 (95% CI 0.15 to 0.65), those sustained in rural areas, 0.07 (95% CI 0.02 to 0.23); for AIS1+ facial injuries, 0.72 (95% CI 0.62 to 0.83); and for AIS1+ neck injuries, 1.18 (95% CI 0.94 to 1.47).

Conclusion This study confirms the protective effect for head and facial injuries, even though soft-shell helmets have now become more common. The reduction of risk is greater for serious head injuries. The study is inconclusive about the risk for neck injuries.

In both developing and industrialised countries, cycling injuries account for a significant proportion of road traffic injuries.[1] The exact proportion is difficult to evaluate because of widespread under-reporting of cyclist injuries in police crash data. In France, where corrected estimates have been produced,[2] the annual number of seriously injured cyclists equals that of pedestrians, while cycling accounts for only 3% of trips and walking for 22%.[3] In the case of life-threatening injuries among cyclists, the most frequently injured body region is the head.[4] Bicycle helmets are not mandatory in France and only 14% of cyclists always wear one.[3]

Bicycle helmets are designed to protect the head as the thickness and material of the helmet completely or partly absorb a direct impact to the head, but helmets provide no protection against injuries produced by linear or rotational acceleration. Case–control studies have established that helmets do indeed reduce the risk of head or brain injuries.[5–12] The part of the face that is near the edge of the helmet may also be protected, and this has been confirmed by case–control studies.[5 7 12 13] However, it is conceivable that the weight of the helmet (at least in the case of hard-shell helmets) or friction between the helmet and the ground could cause twisting of the neck. The helmet strap might also cause cuts. Three case–control studies on the topic have left some uncertainty about whether helmets increase the risk of neck injuries.[10 14 15]

The majority of these case–control studies were conducted in Anglo-Saxon countries and are based on 1990s data, when most helmets were hard-shell. It is possible that these offer more protection than the soft-shell helmets that have become more common. A recent study[12] analysed the effect of helmet type but was limited by a small sample.

This paper presents the first case–control study on this topic in France. It covers the period 1998–2008, and therefore takes in the recent use of soft-shell helmets. It includes 8000 subjects drawn from a road trauma registry that covers the whole range of injury severity: emergency department visits, hospital admissions, and fatalities. It evaluates the RR of injuries to the head, face, or neck, which are the three body regions where helmets may have an effect. It explores whether the helmet effect differs between bicycle-only crashes and collisions with a motor vehicle, and between urban and rural settings.

MATERIAL AND METHODS

Data source: the Rhône road trauma registry

The Rhône county has a population of 1.6 million inhabitants and includes one large city (Lyon), its suburbs, and a rural area. The county has a road trauma registry that has been certified by the relevant French authority, 'le comité national des registres', and been in operation since 1995.[16] It is based on the participation of all the healthcare units in public and private hospitals that receive road casualties, as well as the forensic medicine institutes. It therefore covers emergency department visits, hospital admissions, and fatalities. Injury assessment is based on all the diagnoses made in the various healthcare units the subject visited. Each injury is coded using the Abbreviated Injury Scale (AIS).[17] For the 1998–2008

study period, the registry included 13 797 cyclist casualties (52 fatalities).

Study design: a case–control study

Using the Haddon matrix terminology,[18] this is an event-phase study. Given that a crash has occurred, how does a helmet affect the risk of injuries to the head, face, or neck? The target population is all crash-involved cyclists. Cases are cyclists with injuries to the head, face, or neck. Ideally, the controls should be drawn from all crash-involved cyclists, injured or not. However, the latter are difficult to identify. Therefore, only the sub-population of cyclists who are actually injured is used.[19] In this study, the cyclists with injuries only below the neck served as controls.[20] Both cases and controls were identified by means of the Rhône road trauma registry.

Case selection

We included four sets of cases, one set for each outcome. The first set consists of cyclists with a head injury of any severity (AIS severity score of 1 and above: 'AIS1+'). The second set are cyclists with a serious head injury (AIS score 3 and above: 'AIS3+'). The third set are cyclists with a facial injury of any severity (AIS1+). The fourth set of cases are cyclists with neck injuries of any severity (AIS1+). We have identified the neck region on the basis of AIS body region 3 (neck), or body region 6 (spinal column), with the cervical column (S02) as the specific anatomical structure.

Control selection

The control group consists of all injured cyclists who did not sustain an injury to the head, face, or neck. This conforms with the stipulation that 'the probability of selecting each non-case should not be related to the exposure of interest (helmet wearing in this instance)'.[21] Thus, our controls were cyclists who only sustained injuries below the neck.

Exposure variable

The exposure of interest is whether a helmet was worn at the time of the crash. This has been a standard item on the registry notification form since January 1998. However, helmet status was not completed for 39% (n=5419) of the registered injured cyclists. In a logistic regression, a case-complete analysis (ie, excluding subjects with missing data) is said to be robust to 'not missing at random' data.[22] Accordingly, we excluded subjects with missing helmet status from the analysis, leaving 8373 subjects.

Statistical analysis

We conducted a logistic regression using SAS V.9.1, and estimated the ORs and partial likelihood 95% CIs. We checked for model fit using the Hosmer–Lemeshow test.

Adjustment for confounding factors

Most studies included in the Cochrane review[7] estimated ORs that were adjusted for age, gender, and type of crash. We therefore began by conducting similar regressions with these three variables (which we call M1 'Cochrane-like'). We also wanted to adjust more for crash force because there may be differences between helmeted and non-helmeted cyclists with regard to risk-taking behaviour, and therefore crash force and injury severity. On the one hand, it is quite possible that cyclists who decided to wear a helmet are more cautious than non-helmeted cyclists, and therefore behave more safely and have less serious crashes. In this case, helmet-wearing would be associated with a lower risk of serious injury. However, at least in France, cyclists who wear helmets are mostly sports cyclists because wearing a helmet is highly recommended or mandatory in sports cycling clubs and events. These cyclists probably have a higher risk of serious injury due to higher speeds (their own speed and that of the surrounding motor vehicles because they mainly ride in rural areas). To control for these two possible (and opposite) confounding biases, we adjusted for the severity of injury to the whole body except for the head, face, and neck (since the injury risk of these body regions is presumably associated with the specific effect of a helmet). We used the Injury Severity Score (ISS), omitting the head–face–neck region from the calculation. We refer to this score as the 'ISS without head, face, or neck'.

We also explored adjustment for additional crash force related variables: road type, and crash location (urban/rural). These were included in the multivariate regression if they were significant at the 5% error level (these analyses are called M2 'with more adjustment').

Table 1 Demographic and crash characteristics of helmeted (n=1720) and non-helmeted (n=6653) injured cyclists, Rhône road trauma registry, 1998–2008

	Helmeted injured cyclists		Non-helmeted injured cyclists		
	N	col. %	N	col. %	χ^2 Test
Gender					
Female	257	14.9	1693	25.4	p<0.0001
Male	1463	85.1	4960	74.6	
Age, y					
0–9	175	10.2	1223	18.3	p<0.0001
10–14	190	11.0	1402	21.1	
15–24	271	15.7	1556	23.4	
25–34	295	17.2	879	13.2	
35–44	299	17.4	632	9.5	
45–54	253	14.7	453	6.8	
55–64	149	8.7	283	4.3	
65+	88	5.1	225	3.3	
ISS					
1–3	1039	60.4	4354	65.4	p<0.0001
4–8	545	31.7	1803	27.1	
9–15	116	6.7	390	5.9	
16–75	20	1.2	106	1.6	
ISS without head, face, or neck					
0	207	12.0	1166	17.5	p<0.001
1–3	951	55.3	3689	55.4	
4–8	455	26.5	1430	21.5	
9–15	96	5.6	338	5.1	
16–75	11	0.6	30	0.5	
Crash opponent					
None	1067	62.4	4394	66.6	p<0.0001
Human, animal	118	6.9	277	4.2	
Stationary obstacle	153	8.9	525	8.0	
Motor vehicle	373	21.8	1406	21.3	
Crash setting					
Urban	933	54.2	4374	65.7	p<0.0001
Rural	570	33.1	1054	15.8	
Unknown	217	12.6	1225	18.4	
Road type					
Major road	171	12.3	220	4.4	p<0.0001
Local road	845	60.7	3795	76.0	
Unknown type of road	88	6.3	310	6.2	
Off road	289	20.7	667	13.4	

ISS, Injury Severity Score.

Table 2 Characteristics of cases and controls among injured cyclists (n=8373), Rhône road trauma registry, 1998–2008

	Cases								Controls (solely injured below the neck) (n=5153)	
	Any head injury (n=1471)		Serious head injury (n=144)		Any facial injury (n=1926)		Any neck injury (n=529)			
	N	col. %	N	col. %	N	col. %	N	col. %	N	col. %
Helmet										
Yes	265	18.0	15	10.4	314	16.3	139	26.3	1137	22.1
No	1206	82.0	129	89.6	1612	83.7	390	73.7	4016	77.9
Gender										
Female	306	20.8	19	13.2	478	24.8	156	29.5	1160	22.5
Male	1165	79.2	125	86.8	1448	75.2	373	70.5	3993	77.5
Age, y										
0–9	263	17.9	6	4.2	557	28.9	19	3.6	652	12.6
10–14	302	20.5	26	18.1	309	16.0	52	9.8	1052	20.4
15–24	268	18.2	21	14.5	364	18.9	135	25.5	1194	23.1
25–34	163	11.1	12	8.3	218	11.3	110	20.8	785	15.2
35–44	151	10.3	19	13.2	175	9.1	80	15.1	600	11.6
45–54	129	8.8	15	10.4	154	8.0	76	14.4	433	8.4
55–64	96	6.5	16	11.1	79	4.1	33	6.2	269	5.2
65+	99	6.7	29	20.2	70	3.7	24	4.5	168	3.3
ISS										
1–3	656	44.6	0	0.0	1443	74.9	387	73.2	3216	62.4
4–8	575	39.1	0	0.0	350	18.2	118	22.3	1586	30.8
9–15	139	9.4	52	36.1	86	4.5	12	2.3	330	6.4
16–75	101	6.9	92	63.9	47	2.4	12	2.3	21	0.4
ISS without head, face, or neck										
0	547	37.2	54	37.5	979	50.8	188	35.5		0.0
1–3	658	44.7	30	20.8	756	39.3	284	53.7	3216	62.4
4–8	177	12.0	22	15.3	129	6.7	43	8.1	1586	30.8
9–15	70	4.8	24	16.7	53	2.8	11	2.1	330	6.4
16–75	19	1.3	14	9.7	9	0.5	3	0.6	21	0.4
Crash opponent										
None	850	58.4	61	42.7	1250	65.5	220	42.1	3517	68.6
Human, animal	77	5.3	4	2.8	92	4.8	30	5.7	237	4.6
Stationary obstacle	99	6.8	13	9.1	203	10.6	51	9.8	388	7.6
Motor vehicle	430	29.5	65	45.5	364	19.1	222	42.4	983	19.2
Crash setting										
Urban	948	64.4	94	65.3	1273	66.1	377	71.3	3180	61.7
Rural	350	23.8	39	27.1	406	21.1	92	17.4	938	18.2
Unknown	173	11.8	11	7.6	247	12.8	60	11.3	1035	20.1
Road type										
Major road	110	9.3	16	13.3	89	5.7	29	6.6	213	5.6
Local road	849	71.7	91	75.8	1099	70.9	345	78.9	2763	73.1
Unknown	50	4.2	6	5.0	88	5.7	16	3.7	267	7.1
Off road	175	14.8	7	5.8	274	17.7	47	10.8	539	14.3

ISS, Injury Severity Score.

Interactions

A number of previous studies have explored the helmet effect in specific situations: crashes involving a motor vehicle, crashes involving children, or separately for urban and rural settings. We hence examined whether there was an interaction between helmet use and each of the following variables: crashes involving a motor vehicle (yes/no), age (children aged 0–10 years/teenagers aged 11–19 years/adults), and setting (urban/rural). We tested for interactions at the 5% error level.

RESULTS

Of the 8373 injured cyclists with known helmet status, 1720 (26%) were wearing a helmet at the time of the crash and 6653 were not. Helmeted and non-helmeted injured cyclists differed (table 1). The helmet wearing rate among injured cyclists was higher in men over 30 years of age, in cyclists involved in collisions with pedestrians or other cyclists, in rural areas, on major roads, or off road. Helmet wearing at the time of the crash was also associated with higher injury severity to body regions other than the head, face, and neck. In other words, helmeted cyclists were involved in more serious crashes than non-helmeted ones.

Of the 8373 injured cyclists with known helmet status, the sets of cyclists with head injuries, serious head injuries, facial injuries, or neck injuries include, respectively, 1471, 144, 1926, and 529 subjects; it should be noted that a cyclist can belong to more than one of these sets. The control group consists of 5153 cyclists only injured below the neck.

Compared with controls, cyclists with head injuries were more likely to be male, over 55 years of age, to have been hit by a motor vehicle, to have sustained more severe injuries not involving the head, face, or neck, and/or to have crashed on a major road (table 2). Compared with controls (table 2), face-injured cyclists were more often under 10 years of age, had

more often hit a stationary obstacle, sustained less serious injuries (often solely facial), and/or have been injured off road. Neck injured cyclists were, compared with controls (table 2), more often female, adults, more often hit by a motor vehicle, and/or more often injured on a major road or a local road.

For head injury of any severity, the crude OR for helmeted cyclists is estimated at 0.78 (95% CI 0.67 to 0.90). The adjusted ORs are slightly lower (table 3). For serious head injury, the crude OR is estimated at 0.41 (95% CI 0.23 to 0.68). The adjusted ORs are lower; there is an interaction between the helmet effect and the type of setting (urban/rural), with a very small OR in rural settings (table 4). For facial injury, any severity, the crude OR for helmeted cyclists is 0.69 (95% CI 0.60 to 0.79); the adjusted ORs are fairly similar (table 5). For neck injury, any severity, the crude OR is 1.41 (95% CI 1.02 to 1.54). The adjusted ORs are closer to 1 and not significant (table 6). However, the statistical power is somewhat low for detecting an OR of 1.2 (at 39%, but sufficient for an OR of 1.5, at 97%).

The test of interaction between helmet (yes/no) and a crash involving a motor vehicle (yes/no) was not significant for the risk of head, face, or neck injuries. The only interaction found was between helmet and type of setting (urban/rural) for serious head injuries. Testing for interaction between helmet and age (children/teens/adults) was not possible because there were too few cases among children.

DISCUSSION

Strengths and weaknesses

We now evaluate our study in light of the Cochrane review inclusion criteria.[7] These are:

1. 'Prospective ascertainment of cases': the injuries of all injured road users (not only cyclists) were diagnosed at the time of hospital consultation or admission. Each injury was then coded according to the AIS as part of the routine work of the registry;
2. 'Determination of the exposure at time of the crash': helmet status at the time of the crash has been an item on the registry notification form since January 1998. It was missing for 39% of the subjects. It may not be 'missing at random' in the sense that it may depend on helmet status (yes/no), as cyclists who were wearing a helmet were probably more

Table 3 Multivariate logistic regression models for the risk of any head injury (AIS1+), adjusted ORs, Rhône road trauma registry, 1998–2008, 1471 cases and 5153 controls

	M1='Cochrane-like' OR (95% CI)	M2='with more adjustment' OR (95% CI)
Helmet		
No	1.00	1.00
Yes	0.76 (0.65 to 0.89)	0.69 (0.59 to 0.81)
Gender		
Female	1.00	1.00
Male	1.13 (0.98 to 1.30)	1.14 (0.99 to 1.33)
Age, y		
0–14	1.37 (1.12 to 1.70)	1.32 (1.07 to 1.63)
15–24	0.86 (0.69 to 1.08)	0.83 (0.66 to 1.04)
25–34	0.82 (0.64 to 1.05)	0.78 (0.61 to 1.00)
35–44	1.00	1.00
45–54	1.19 (0.91 to 1.55)	1.21 (0.92 to 1.60)
55+	1.68 (1.31 to 2.15)	1.69 (1.30 to 2.18)
Crash opponent		
None	1.00	1.00
Human, animal	1.33 (1.01 to 1.73)	1.16 (0.87 to 1.52)
Stationary obstacle	1.09 (0.86 to 1.37)	1.05 (0.82 to 1.34)
Motor vehicle	1.85 (1.60 to 2.12)	1.68 (1.44 to 1.95)
ISS without head, face, or neck		
0–3		1.00
4–8		0.29 (0.25 to 0.35)
9–15		0.47 (0.36 to 0.62)
16–75		1.55 (0.80 to 2.97)
Road type		
Major road		1.55 (1.17 to 2.04)
Local road		1.00
Off road		0.90 (0.75 to 1.08)
Unknown		1.28 (1.04 to 1.56)
Crash setting		
Urban		1.00
Rural		1.30 (1.11 to 1.53)
Unknown		0.75 (0.60 to 0.93)

'Cochrane-like'=adjusted on age, gender, and crash opponent;
'With more adjustment'=adjusted on age, gender, crash opponent, ISS without head, face or neck, road type, and crash setting.
Age is in six categories only, otherwise the 'Cochrane-like' model is rejected (test of fit).
AIS, Abbreviated Injury Scale; ISS, Injury Severity Score.

Table 4 Multivariate logistic regression models for the risk of serious head injury (AIS3+), adjusted ORs, Rhône road trauma registry, 1998–2008, 144 cases and 5153 controls

	M1='Cochrane-like' OR (95% CI)	M2='with more adjustment' OR (95% CI)
Helmet		
No	1.00	See bottom of table
Yes	0.30 (0.16 to 0.50)	
Gender		
Female	1.00	1.00
Male	1.91 (1.19 to 3.24)	1.75 (1.08 to 2.99)
Age, y		
0–9	0.35 (0.12 to 0.83)	0.32 (0.11 to 0.79)
10–14	0.75 (0.41 to 1.41)	0.73 (0.39 to 1.39)
15–24	0.49 (0.26 to 0.93)	0.54 (0.28 to 1.04)
25–34	0.45 (0.21 to 0.93)	0.45 (0.21 to 0.94)
35–44	1.00	1.00
45–54	1.14 (0.56 to 2.28)	1.00 (0.48 to 2.06)
55–64	1.80 (0.89 to 3.60)	1.42 (0.68 to 2.92)
65+	4.99 (2.71 to 9.38)	4.24 (2.24 to 8.19)
Crash opponent		
None	1.00	1.00
Human, animal	0.94 (0.28 to 2.35)	0.95 (0.28 to 2.41)
Stationary obstacle	2.03 (1.05 to 3.64)	2.07 (1.07 to 3.73)
Motor vehicle	3.05 (2.10 to 4.42)	2.48 (1.67 to 3.68)
ISS without head, face, or neck		
0–3		1.00
4–8		0.52 (0.31 to 0.83)
9–15		2.06 (1.22 to 3.34)
16–75		11.83 (5.12 to 26.93)
Helmet × crash setting		
Not helmeted, rural area		1.00
Helmeted, rural area		0.07 (0.02 to 0.23)
Not helmeted, urban area		0.48 (0.31 to 0.74)
Helmeted, urban area		0.16 (0.07 to 0.33)
Place unknown		0.24 (0.11 to 0.47)

The OR of helmeted in urban areas versus not-helmeted in urban areas is 0.34 (95% CI 0.15 to 0.65).
'Cochrane-like'=adjusted on age, gender, and crash opponent;
'With more adjustment'=adjusted on age, gender, crash opponent, ISS without head, face or neck, and interaction of helmet with crash setting.
AIS, Abbreviated Injury Scale; ISS, Injury Severity Score.

Table 5 Multivariate logistic regression models for the risk of any facial injury (AIS1+), adjusted ORs, Rhône road trauma registry, 1998–2008, 1926 cases and 5153 controls

	M1='Cochrane-like' OR (95% CI)	M2='with more adjustment' OR (95% CI)
Helmet		
No	1.00	1.00
Yes	0.74 (0.64 to 0.85)	0.72 (0.62 to 0.83)
Gender		
Female	1.00	1.00
Male	0.92 (0.81 to 1.04)	0.95 (0.83 to 1.08)
Age, y		
0–14	1.71 (1.41 to 2.07)	1.65 (1.35 to 2.01)
15–24	1.01 (0.82 to 1.25)	0.93 (0.75 to 1.15)
25–34	0.94 (0.75 to 1.18)	0.86 (0.68 to 1.09)
35–44	1.00	1.00
45–54	1.23 (0.96 to 1.58)	1.34 (1.03 to 1.74)
55–64	1.02 (0.75 to 1.38)	1.15 (0.84 to 1.58)
65+	1.43 (1.03 to 1.97)	1.50 (1.06 to 2.12)
Crash opponent		
None	1.00	1.00
Human, animal	1.15 (0.89 to 1.48)	1.01 (0.77 to 1.31)
Stationary obstacle	1.55 (1.28 to 1.86)	1.46 (1.20 to 1.78)
Motor vehicle	1.18 (1.02 to 1.35)	1.04 (0.90 to 1.21)
ISS without head, face, or neck		
0–3		1.00
4–8		0.15 (0.12 to 0.18)
9–15		0.27 (0.20 to 0.36)
16–75		0.82 (0.35 to 1.76)
Road type		
Major road		1.31 (0.99 to 1.73)
Local road		1.00
Off road		0.76 (0.66 to 0.87)
Unknown		1.32 (1.10 to 1.58)

'Cochrane-like'=adjusted on age, gender, and crash opponent;
'With more adjustment'=adjusted on age, gender, crash opponent, ISS without head, face or neck, and road type.
AIS, Abbreviated Injury Scale; ISS, Injury Severity Score.

Table 6 Multivariate logistic regression models, for the risk of neck injury (AIS1+), adjusted ORs, Rhône road trauma registry, 1998–2008, 529 cases and 5153 controls

	M1='Cochrane-like' OR (95% CI)	M2='with more adjustment' OR (95% CI)
Helmet		
No	1.00	1.00
Yes	1.15 (0.92 to 1.43)	1.18 (0.94 to 1.47)
Gender		
Female	1.00	1.00
Male	0.65 (0.53 to 0.81)	0.68 (0.55 to 0.84)
Age, y		
0–9	0.28 (0.16 to 0.46)	0.27 (0.15 to 0.44)
10–14	0.47 (0.32 to 0.68)	0.48 (0.33 to 0.70)
15–24	0.92 (0.68 to 1.25)	0.84 (0.62 to 1.14)
25–34	1.07 (0.78 to 1.47)	0.97 (0.70 to 1.33)
35–44	1.00	1.00
45–54	1.30 (0.93 to 1.84)	1.44 (1.01 to 2.04)
55–64	0.86 (0.55 to 1.33)	0.97 (0.62 to 1.51)
65+	1.01 (0.61 to 1.64)	1.15 (0.68 to 1.89)
Crash opponent		
None	1.00	1.00
Human, animal	1.84 (1.20 to 2.74)	1.72 (1.12 to 2.58)
Stationary obstacle	1.87 (1.34 to 2.57)	1.81 (1.29 to 2.49)
Motor vehicle	2.99 (2.44 to 3.67)	2.71 (2.20 to 3.33)
ISS without head, face, or neck		
0–3		1.00
4–8		0.20 (0.14 to 0.27)
9–15		0.23 (0.11 to 0.40)
16–75		0.53 (0.12 to 1.57)

'Cochrane-like'= adjusted on age, gender, and crash opponent;
'With more adjustment'=adjusted on age, gender, crash opponent, and ISS without head, face or neck.
AIS, Abbreviated Injury Scale; ISS, Injury Severity Score.

likely to report doing so than not, and non-wearers would probably tend not to mention the fact. However, a case-complete analysis (ie, excluding subjects with missing data) using logistic regression was robust even to 'not missing at random' data[22]; in other words, the effect on the results should be small. Finally, there is no information on type of helmet (hard-shell/soft-shell).

3. 'Appropriate selection of the control group'; 'controls should be selected from the same population from which the cases were derived': the ideal control group is a random sample of all cyclists who crashed. However, we only have access to injured cyclists. 'This is a valid substitution if the helmet-wearing prevalence is the same in this subgroup as in the group of all those who experienced a crash. It is if (i) the probability of being injured below the neck is independent of wearing a helmet, and if (ii) helmeted cyclists are not more (or less) likely than non-helmeted cyclists, at a given injury severity level, to seek healthcare at a hospital'.[19] These are realistic assumptions. Moreover, we conducted a sensitivity analysis. Since our study misses cyclists who crashed and were uninjured, it misses those who hit their head and were fully protected by a helmet. This leads to underestimation of the protective effect of helmets. Conversely, the study misses cyclists who crashed and did not sustain neck injuries even though they were wearing a helmet. This leads to over-estimation of possible harmful effect of helmets. We can overcome these issues by restricting the study population to cyclists with injuries outside the head, face, and neck region (so that they are included independently of the helmet effect, whether protective or harmful). When we applied this restriction (not shown), we obtained results that were very similar to the models with adjustment for 'ISS without head, face and neck' (with the zero category corresponding to those excluded from this restricted analysis).
4. 'Elimination or control of factors such as selection bias, observation bias, and confounding'. The issue of selection bias has been covered above. With regard to observation bias, we have discussed the fact that helmeted cyclists may have more (or less) risk-taking behaviours and hence a higher (or lower) risk of sustaining serious injuries (among which head injuries are not rare). This possible association has been taken into account by adjusting for 'injury severity without head, face or neck'. We have controlled as much as possible for confounding bias; to fully adjust for the severity of the crash, one would need to know the speed and mass of the vehicle(s) when the crash occurred. This is not available to us (nor to any medical registry).

Interpretation

This study indicates that the helmet is associated with a decreased risk of head injury (whatever the severity), and the decrease seems greater for the risk of serious head injuries.

For serious head injuries, the decrease in risk is of the same order of magnitude as that estimated by the Cochrane review:

What is already known on the subject

In the event of a crash, bicycle helmets reduce the risk of head, brain, and facial injuries.

What this study adds

- Supplementary evidence is provided of a protective effect, in a non-Anglo-Saxon country, in recent years when soft-shell helmets are more common than hard-shell helmets.
- There is no evidence of a difference in protection for bicycle crashes with or without motor vehicle involvement.
- There is no evidence of an increased risk of neck injuries.

our 'Cochrane-like' analysis leads to an OR of 0.30 for head AIS3+ injuries, and the Cochrane review[7] finds an OR of 0.31 (0.23 to 0.42) for brain injuries (which are roughly equivalent).

We have identified an interaction between helmet wearing (yes/no) and crash setting (urban/rural) for the risk of serious head injuries, with the protective effect being much greater (by a factor of five) for bicycle crashes in rural areas. This could be partly due to insufficient adjustment for crash severity (cyclists crashing in rural areas are more seriously injured than those crashing in urban areas, probably because of higher speeds; Amoros, submitted).[4] Another possible explanation lies in the fact that crashes in rural areas are much more likely to involve sports cyclists than commuting cyclists, and it may be that sports cyclists wear better helmets and/or know how to adjust them better.

For head injuries of any severity, our 'Cochrane-like' analysis yields an OR of 0.76 (95% CI 0.65 to 0.89), which seems weaker than the value of 0.31 (95% CI 0.26 to 0.37) obtained in a Cochrane meta-analysis.[7] However, our study is based on AIS1+ head injuries, whereas some studies in the Cochrane review apply a narrower definition of head injuries, corresponding better to AIS2+ injuries. Still, it is possible that soft-shell helmets, which have become more common in recent years, may provide less protection than hard-shell helmets.[23]

Consistent with the results of the Cochrane review, our study indicates that helmet wearing lowers the risk of facial injuries. Finally, our study is not conclusive about the risk for neck injuries. The effect seen in the univariate analysis seems to disappear after adjustment for age. Indeed, age (in this case, being adult) is associated with an increased risk of neck injury and a higher rate of helmet wearing among injured cyclists (which is probably explained by more helmet wearing among sports cyclists). The lower adjusted OR of 1.18 is not significant but the statistical power is low; if there was an increase of risk, it would be small. This finding is consistent with two of the three published case–control studies.[5]

Moreover, the incidence of neck injuries is lower than that of head injuries (7% of unhelmeted cyclists injured in urban areas had sustained a neck injury versus 16% for a head injury; 3% vs 21% among those injured in rural areas[24]). In view of the decrease in the risk of head and face injuries, and in particular the substantial decrease for serious head injuries and the possible small increase in fairly rare neck injuries, the net effect of the bicycle helmet is a protective one. Wearing a helmet while cycling should be strongly encouraged, particularly in rural areas.

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Competing interests None.

Ethics approval This study was conducted with the approval of the road trauma registry: le Comité National des Registres; secrétariat: M Dominique Vuillaume, Institut National de la Santé et de la Recherche Médicale (Inserm) Institut Thématique Santé publique, 101 rue de Tolbiac, 75654 Paris Cedex 13, France.

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