Overestimation of the effectiveness of the bicycle helmet by the use of odds ratios.

Th. Zeegers[1]

[1] Eikenlaan 24, NL-3768 EV Soest, The Netherlands
e-mail: th.zeegers@xs4all.nl

ABSTRACT

The risk of getting a head injury per kilometre wearing a helmet relative to the same risk without helmet is the most appropriate measure to assess the effectiveness of the bicycle helmet. Due to lack of data on exposure rates, odds ratios of helmeted versus unhelmeted cyclists for head injury and other injuries on hospitalized victims are broadly used in case-control studies.
A general necessary and sufficient condition can be formulated rigorously, for which odds ratios indeed equal risk ratios. However, this condition is not met in case-control studies on bicycle helmets. As a consequence, the real risk of cycling with a helmet can be underestimated by these studies and therefore the effectiveness of the bicycle helmet can be overestimated. The central point is that a wrong estimate of the risk for non-head injuries (the controls) paradoxically can lead to an overestimation of the usefulness of the helmet in protecting against head injuries.
Three cases could be found in the literature with sufficient data to assess both risk ratios and odds ratios: the Netherlands, Victoria (Australia) and Seattle (U.S.A). In all three cases, the problem of overestimation of the effectiveness of the helmet by using odds ratios did occur. The effect ranges from small (+ 8 %) to extremely large (> + 400 %). Contrary to the original claim of these studies, in two out of three cases the risk of getting a head injury proved not to be lower for helmeted cyclists. Moreover, in all three cases the risk of getting a non-head injury proved to be higher for cyclists with a helmet.
It must be concluded that any case-control study in which the control is formed by hospitalized bicyclists is unreliable and likely to overestimate the effectiveness of the bicycle helmet. As a direct consequence, also meta-analyses based on these case-control studies overestimate the effectiveness of the bicycle helmet. Claims on the effectiveness of the bicycle helmet can no longer be supported by these kind of studies. This might explain the discrepancy between case-control studies and other studies, such as time-analysis. It is recommended to use other methods to estimate the risk ratio for the bicycle helmet, along the lines described in this article.

Keywords: bicycle helmet, risk ratio, odds ratio, case-control study, bias, overestimation.

1 INTRODUCTION

Few topics in the field of bicyclists' safety have drawn more attention than the bicycle helmet. The protectiveness of the bicycle helmet to its user has been the subject of much dispute [1]. Case-control studies with hospitalized victims tend to find a much higher effectiveness for the bicycle helmets than other studies, such as time series analysis of the number of head injuries around helmet legislation [2]. One of the oldest case-control studies claiming a big positive effect on head injuries dates back to 1989 [3]. This study was followed by many others, with varying but less strong results. A recent meta-analysis on case-control studies [4] has shown that the protectiveness of bicycle helmets has been overestimated in the past. This overestimation is at least partly due to bias in the original studies. After corrections for these, a total positive net effect of 15 % was reported [4]. This number decreases over the years and recent studies do not show a net effect.

There seems to be consensus on the fact that helmet laws result in a drop of bicycle usage of typically around one-third [2, 5]. Since cycling generally has a large positive effect on health [6], it has been argued that not only the risk on head injury, but the total health effects for the cyclist should be taken into consideration [7]. De Jong [8] concluded on theoretical grounds that the total effects of a helmet law are bound be negative both for the individual cyclist and to society, since the effect of loss of health due to less cycling is much higher than the effect of prevented head injuries. This result is true in nearly all conditions and therefore very generally valid. Later, it has been found in regional studies as well [9].

This study will restrict itself to the claim of others that helmets do reduce the risk of getting head injuries and its substantiation from case-control studies. For this, the risk of getting a head injury while cycling with a helmet should be compared to the same without a helmet. In other words, the risk ratio needs to be established. In case-control studies, however, the effectiveness of the bicycle helmet is measured by odds ratios [4]. It is not obvious at first glance that the odds ratio is equivalent to the risk ratio between cycling with and without helmet. This highly technical matter is the issue of this investigation. It starts with a very general discussion on the relation between odds ratios and risk ratios, cumulating in a sufficient and necessary condition for the two to be equivalent. However, this condition will be shown not to be fulfilled in the case of the bicycle helmet. The consequences of this finding will be investigated.

2 THEORY

2.1 General theoretical background on risk and odds ratios

Consider a negative event, like an accident or a disease. The case with this negative event present is denoted with capital 'N', the case without as 'n'. In this article, N will be head injury of a cyclist in traffic. Consider a potential protection measure against this negative event. This measure can be present (implemented), denoted in capital 'M', or absent, denoted 'm'. Of course, a central question is whether the potential protection measure M is effective. In other words: is the risk of being a victim of the negative event N less if the protection measure M has been implemented, or not. To assess this, we also need an exposure measure. The exposure measure for the case with protection is denoted capital 'K', without as 'k'. In traffic, the exposure is generally measured in mobility, ie. the distance travelled [10, 11, 12]. In the case of cycling, the exposure rate is the distance cycled.

Suppose in some investigation, we count the number of people with and without negative event and with or without protection measure. Let NM denote the number of people with negative event with the preventive measure present, mutatis mutandis for the other three cases.

The risk R_M of being victim of the negative event with protective measure is by definition[1]

[1] This definition is more general than the one used in epidemiology [13].

$$R_M = \frac{NM}{K} \tag{1}$$

The risk ratio ρ, ie. the relative risk of protected versus unprotected exposure, follows as

$$\rho = \frac{NM/K}{Nm/k} \tag{2}$$

If and only if $\rho < 1$, the supposed protective measure indeed results in a lower risk. Therefore, the risk ratio ρ as in (2) is our main interest. This ratio is considered to be the most relevant quantity in evaluating the usefulness of a helmet [1]. Of course, its statistical significance should be tested as well in concrete cases.

In many cases, like the bicycle helmet one, the exposure measures K and k are generally unknown and therefore the risk ratio (2) cannot be determined. To circumvent this, one usually assumes (often implicitly) that the exposure measure is proportional with the number of cases without a negative event, for both the protected and the unprotected case

$$K \sim nM$$

and

$$k \sim nm$$

This leads to the definition of odds ratio Ω

$$\Omega = \frac{NM/nM}{Nm/nm} \tag{3}$$

This approach is justified by the following lemma.

Lemma 1

The odds ratio Ω (3) equals the risk ratio ρ (2)

$$\rho = \Omega$$

if and only if the exposure ratio equals the ratio of cases without the negative event occurring

$$\frac{K}{k} = \frac{nM}{nm} \tag{4}$$

Note that (4) can be read as an equality of usage and non-usage of the protective measure in case without negative event relative to the exposure

$$\frac{nM}{K} = \frac{nm}{k} \tag{4*}$$

Proof

Start with (2) and substitute (4)

$$\rho = \frac{NM/K}{Nm/k} = \frac{NM/Nm}{K/k} = \frac{NM/Nm}{nM/nm} = \Omega$$

Qed.

Lemma 1 is the general justification of the use of odds ratios. However, the assumption condition (4) limits this justification. The degree in which this condition is not met, is also a measure for the discrepancy between risk and odds ratios, as shown by the following lemma.

Lemma 2

If for some positive number α

$$\frac{k}{K} > \alpha.\frac{nm}{nM} \tag{5}$$

or, alternatively and equivalently

$$\frac{nM}{K} > \alpha.\frac{nm}{k} \tag{5*}$$

then, the risk ratio exceeds the odds ratio by a factor α:

$$\rho > \alpha.\Omega \tag{6}$$

Proof

Similar to the proof of Lemma 1, now using (5) instead of (4)

$$\rho = \frac{NM/K}{Nm/k} = \frac{NM/Nm}{K/k} > \alpha.\frac{NM/Nm}{nM/nm} = \alpha.\Omega$$

Qed.

The relevance of this lemma is that the real effect of the measure (risk ratio) can be lower than suggested by odds ratios. More specifically, a measure can actually be negative (risk ratio > 1) even though the odds ratio suggests it is positive (odds ratio < 1), leading to incorrect conclusions on the effectiveness of the measure!

2.2 The case of bicycle helmets

So far, the treatment has been very general. Now we focus on the specifics of the case of head injuries of cyclists and the possible protection by bicycle helmets. The negative event N will be a cyclist getting a head injury in traffic, the possible protection measure M for this wearing a bicycle helmet. The risk ratio ρ (2) measures the effect of the use of a bicycle helmet on the risk of getting a head injury. The absence of the negative event 'n' would be the lack of head injury. This case has two components: the total lack of injury (majority) and the presence of non-head injuries. The latter will be denoted with 'v'.

NM	number of cyclists with head injury, wearing a helmet
Nm	number of cyclists with head injury, not wearing a helmet
nM	number of cyclists without head injury, wearing a helmet
nm	number of cyclists without head injury, not wearing a helmet
vM	number of cyclists with an injury but without head injury, wearing a helmet
vm	number of cyclists with an injury but without head injury, not wearing a helmet
K	total distance cycled with helmet
k	total distance cycled without helmet

Table 1: Explanation of notation as applied to the bicycle helmet casus.

One might use odds ratio Ω (3) in order to estimate the risk ratio ρ (2), Lemma 1 is the justification for this. However, in practice in the bicycle helmet case, we are not able to calculate the real odds ratio Ω (3), since information on non-injured bicyclists is generally lacking. Therefore, in practice [4, 14], the alternative odds ratio Ω_{alt} is used instead, defined by

$$\Omega_{alt} = \frac{NM/Nm}{vM/vm} \qquad (7)$$

in which vM denotes the number of non-head injured cyclists in the survey wearing a helmet and vm the same but not wearing a helmet. So one compares the head injuries with the other (non-head) injuries. These data are generally available from hospitals and victim studies.

The question is whether (and under what conditions) this approach can be justified. The answer follows by applying Lemma 1 and Lemma 2 to this case, simply by reading 'v' instead of 'n'.

Lemma 3

Consider the alternative odds ratio Ω_{alt} (7) as commonly used to estimate the risk ratio (2) for the effect of helmet wearing on head injuries of cyclists. If, for some number $\alpha > 1$, the risk of getting a non-head injury while wearing a helmet is α times bigger than the same without a helmet,

$$\frac{\nu M}{K} > \alpha . \frac{\nu m}{k} \tag{8}$$

the risk ratio (2) of getting a head injury while helmeted is underestimated by the alternative odds ratio (and hence the effectiveness of the helmet is overestimated) by at least the same number α

$$\rho > \alpha . \Omega_{alt} \tag{9}$$

Note that alpha as defined in (8) is exactly the risk ratio of getting a non-head injury.

The central point is that a wrong estimate of non-head injuries leads paradoxically to a systematic overestimation of the usefulness of the helmet in protecting against head injuries.

3 PRACTICE

3.1 Estimating the systematic bias

There are indications in the literature [15] that bicyclists wearing a helmet are at bigger risk of getting injuries than bicyclists without a helmet, especially getting a non-head injury. Data presented in the next paragraph will confirm this. For cyclists on mountain bikes and racing bikes, this might not be surprising, but it seems to be even true for ordinary cyclists [16] (Fyhri et al., 2009). Possible explanations are risk compensation by the cyclist himself [15] or by other road users [17].

In order to be able to use Lemma 3 in concrete casus, we need studies providing information on bicycle victims with injuries to head and to other body parts versus helmet or non-helmet usage and information on total helmet usage (hence: also on non-victims). Such complete studies are rare and difficult to find. Here I provide all three cases for which I was able to find sufficient data: the Netherlands [18], Victoria, Australia [19] and Seattle [3, 20].

3.2 Case the Netherlands [18]

Ormel et al. [18] investigated bicyclists injured in the Netherlands in such a way that they had to be treated at the first aid department of a hospital. The research has been done by a questionnaire performed among all patients admitted to the first aid departments of 13 hospitals in the Netherlands. In total, 1032 cases of injured bicyclists have been studied, of which 732 without involvement of motorized vehicles. Ormel et al. [18] reported only on the last group of victims, however, I had access to the full dataset of Veiligheid.nl (Den Hertog, in litt.).

The total numbers of injured victims, translated in the terminology of this paper, are given in table 2, those for accidents without involvement of motorized vehicles in table 3.

	M	m
N	13	231
v	97	691

Table 2: Number of bicyclists treated at the first aid in the survey in the Netherlands [18], with head injury (N) or injury on other body part (v) while wearing (M) or not wearing (m) a helmet [database Veiligheid.nl, P. den Hertog in litt.].

	M	m
N	9	159
v	72	492

Table 3: Number of bicyclists treated at the first aid due to an accident without involvement of motorized vehicles in the survey in the Netherlands [18], with head injury (N) or injury on other body part (v) while wearing (M) or not wearing (m) a helmet [database Veiligheid.nl, P. den Hertog in litt.].

In the appendix, I derive a best estimation for the exposure rate K/k in the Netherlands to be not higher than 0.05 with a hard upper boundary of 0.09. With this boundary and the numbers provided in tables 2-3, we find an estimate for alpha of (8) to be 2.8 in the case of all victims and 2.9 in the case of victims in accidents without motorized vehicles, with in both cases a lower boundary of 1.6.

Originally, the study [18] concluded that more head injuries were found in cyclists not wearing a helmet. The conclusion of this re-analysis shows that the risk ratio for the bicycle helmet has been significantly overestimated. A best estimate for this overestimation yields 180 %, an extremely conservative estimate still yields an overestimation of 60 %. Based on the data presented, the best estimate for the risk ratio equals 1.13, hence it exceeds 1, although this difference is not statistically significant (Chi2, $p > 0.8$). Therefore, we conclude that the hypothesis of absence of effect of the helmet on head injuries cannot be rejected. For non-head injuries, cyclists with a helmet have a much higher risk (nearly three times higher) than non-helmet cyclists. As a consequence, the total effect of helmet usage on injury risk is definitely negative in this study (more than twice as high).

3.3 Case Victoria, Australia [19]

McDermott et al. [19] reported on the 1710 bicycle victims observed in two public hospitals in the Australian state of Victoria over the period 1987 – 1989. Robinson [1] gives numbers on the helmet usage in this state over the relevant period. These numbers are based on counts on 64 sites in Melbourne. They have been provided more accurately by Robinson (in litt.) to the author. The results [19] are presented in Table 4 in the notation of this article.

	M	m
N	90	468
v	276	876

Table 4: Number of bicyclists treated at two public hospitals in Victoria in 1987-1989, with head injury (N) or injury on other body part (v) while wearing (M) or not wearing (m) a helmet [19].

The helmet usage as reported by Robinson [1, specified in litt.] proved to be for this period 22.6 %, leading to an exposure rate of 0.29 (= 0.226 / (1 - 0.226). This leads to an estimation of alpha in (8) of at least 1.08. As a consequence, the reported risk ratios are underestimated (and hence the effectiveness of the helmet is overestimated) by at least 8 %. Still, the risk ratio for head injuries is smaller than 1 (risk ratio 0.66), indicating a positive effect of the helmet. The risk ratio for all injuries does not significantly differs from 1 (Chi2, p > 0,2), hence, this study rejects the effectiveness of the helmet in reducing total injuries.

3.4 Case Seattle, U.S.A. [3, 20]

Thompson et al. [3] reported on 668 cases of injured cyclists treated in the emergency rooms of 5 hospitals in the Seattle area (U.S.A.) over the period December 1986 - November 1987. Thompson et al. [20] provided information of the rate of helmet usage by these victims. The results for children under 15 years old are presented in table 5 in the notation of this article. DiGuiseppi et al. [21] reported the helmet usage for these ages to be 4.6 % based on own extensive field observations of 4940 children. This number is adjusted from the raw data by the authors for some non-representativeness in the observed group. The corresponding risk ratio is 0.048.

children	M	m
N	8	130
v	27	99

Table 5: Number of bicyclists under the age of 15 years old treated at five hospitals in the Seattle area over the period December 1986 – November 1987, with head injury (N) or injury on other body part (v) while wearing (M) or not wearing (m) a helmet [20].

Based on these numbers, we find an estimate for alpha in (8) to be 5.6. Hence, the effectiveness of the helmet is overestimated by this study by at least this factor 5.6. The risk ratio for head injuries is found to be 1.28, however, it is not significantly different from 1 (hence: no effect of helmet). Since the risk of getting a non-head injury is so much higher while wearing a helmet according to this study, the total effect of helmet usage is strongly negative (risk ratio higher than 3).

4 CONCLUSION

The results of the review of these three studies are summarized in Table 6.

		alternative odds ratio	risk ratio		
		head	head	non-head	total
Netherlands	All	0.40	1.13*	2.81	2.39
	no motorized vehicles involved	0.39	1.13*	2.93	2.49
Victoria (Au)		0.61	0.66	1.08*	0.93*
Seattle (USA)	children	0.23	1.28*	5.66	3.17

Table 6: Overview on alternative odds ratio (7) and risk ratio (2) estimates (both head and non-head) for the three main studies on bicycle helmets [18, 19, 20] discussed.
* = not statistically significant different from 1.

The first conclusion is that in all three cases there is an overrepresentation of non-head injuries for cyclists with a helmet, i.e. the non-head risk ratio is bigger than 1. As a direct consequence, the theoretical possibility (9) of an overestimation of the helmet effectiveness by using the alternative odds ratio does indeed occur in all three cases. This overestimation varies from relatively small (8 %) in the case of Victoria to extremely large (more than 400 %) in the case of Seattle.

The second conclusion is that in two out of three cases we no longer find a positive effect of the helmet on head injuries. The risk ratio increases over 1, though in both cases the difference is not statistically significant due to the low numbers reported. Still, the hypothesis that there is no effect of the helmet on head injuries cannot be rejected in these cases.

Only in the case for Victoria we still find a positive result for the effectiveness of the bicycle helmet in protection against head injuries, though the total effectiveness for all injuries cannot be demonstrated in this case either. In both other cases, the effect of the helmet on the total number of injuries is clearly negative.

5 DISCUSSION

The main subject of this investigation is the question whether the common practice in case-control studies on bicycle helmets to use odds ratios based on victims for both case and control is actually valid. The answer with mathematical rigour is that it is not. There is a theoretical possibility that it leads to overestimation of the effectiveness of the bicycle helmet. Of course, it does not follow that this possible overestimation does occur in practice.

To investigate whether it does, I have tried to find as many examples as possible in which both the risk ratio and the alternative odds ratio could be estimated with some reliability. These estimates are based on non-perfect data, often from different sources. This is especially true for the exposure rate. Therefore, the absolute results should be treated with some care. The goal, however, was not to give a highly accurate estimate for the risk ratio for the bicycle helmet, but to investigate whether the above found theoretical possibility of overestimation does in practice occur. In the end, I have included three cases which are reliable enough to make this assessment.

Originally, all three articles mentioned above report a strong positive effect of the bicycle helmet on head injuries. After reanalyzing, in only one the effect was indeed found to be positive. In the other two cases, the actual numbers tended towards a negative effect of the helmet on head injuries, though the hypothesis of non-effectiveness of the helmet on head injuries could not be rejected. Clearly, we must conclude that the original studies reported too positively on the bicycle helmet, given the data they provided. This type of mistake is possible and likely to occur in all case-control studies in also the control-group consisted of hospitalized victims. Therefore, also meta-analysis based on case-control studies, such as [4], are likely to overestimate the effectiveness of the helmet in protecting against head injuries. The primary result of this article is that the effectiveness of the protection of bicycle helmets against head injuries is overestimated by the usage of odds ratios (Lemma 3). Already a relative small effect of 15 % in condition (8) would lead [4] to result into an overall non-positive effect of the bicycle helmet in protecting against head injuries. It has been made plausible that the bias using odds ratios does occur frequently and can be several tens of percentages in magnitude, in extreme cases even more. Therefore, the bias could annihilate the reported overall positive effect of the bicycle helmet.

It must be concluded that any case-control study in which the control is formed by hospitalized bicyclists is unreliable and likely to overestimate the effectiveness of the bicycle helmet. This might explain the discrepancy between case-control studies and other studies. It is recommended to use other methods to estimate the risk ratio for the bicycle helmet, along the lines described in this article. More specifically, the helmet usage amongst non-victims should be measured in a proper way, i.e. by street observations [1, 21]. With this, risk ratios (and hence the effectiveness of the measure) can easily and directly be calculated using (2).

I am not the first to observe the non-random distribution of casualties in the cross table head/non-head vs. helmet/non-helmet. Already Thompson et al. [20] noted the big difference in their data and Ormel et al. [18] tested the difference and found the differences to be statistically significant. Thompson et al. had data available on helmet use among the general population [21], but they failed to see its relevance. Both studies attributed the difference to the effectiveness of the cycle helmet, clearly overlooking the other possible explanation: the overrepresentation of non-head injuries among helmeted cyclists. This study has shown the latter to be valid, at least in these two examples. The wrong interpretation of the statistical test is again an example of bias among some investigators [4]. It is ironical that the one study that started off the modern bicycle helmet dispute [3, 20] failed to see the relevance of their observation on non-head injuries.

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APPENDIX

Estimation of the bicycle helmet usage in the Netherlands

The study on victims in Dutch hospitals [18] was performed in the period February – June 2008. Therefore, we need to estimate the exposure rate K/k for this period. In this period, nearly all kilometers cycled with a helmet in the Netherlands have been cycled by sportive cyclists.

The exposure rate K/k can be estimated for the Netherlands from the general mobility figures, as provided by the National Mobility Research (MON) for the year 2008. According to this research, on average Dutch citizen cycle 2.62 km. each day, of which 0.39 touring. Of course, many kilometers are cycled touring in a more relaxed manner (and thus in the Netherlands without helmet). Touring in a sportive fashion on a race-bicycle or mountainbike usually occurs in longer trips. A quarter of all kilometers cycled touring occurs on trips shorter than 20 kilometers and more than half of the kilometers cycled touring occurs on trips between 20- 50 kilometers long (NIPO, 2011). Most of the kilometers in the first category and many in the second will be none-sportive and therefore non-helmeted in the Netherlands. As a consequence, the distance cycled in a sportive way per person per day is unlikely to be higher than 50 % of 0.39 km = 0.2 km and a hard upper boundary is 75 % of 0.39 km. = 0.3 km.

At the time of the investigation, the helmet use amongst speed cyclists and mountainbikers varies between 50 % - 75 % [18]. Therefore, 0.12 km. per person per day is a best estimate for the helmeted cycled kilometers per person averaged in the Netherlands and 0.22 is an obvious upper limit.

It follows that the inverse exposure rate k/K can be estimated as (2.62 – 0.12)/0.12 ≈ 20. The upper bound given above leads to a lower bound of 11 for this ratio. As a consequence, the exposure rate K/k for the Netherlands in 2008 can be estimated to be unlikely higher than 0.05 with a hard upper bound of 0.09.