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Publication bias and time-trend bias in meta-analysis of bicycle helmet efficacy: A re-analysis of Attewell, Glase and McFadden, 2001

Rune Elvik*

Institute of Transport Economics, Gaustadalléen 21, NO-0349 Oslo, Norway

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ABSTRACT

This paper shows that the meta-analysis of bicycle helmet efficacy reported by Attewell, Glase, and McFadden (Accident Analysis and Prevention 2001, 345–352) was influenced by publication bias and time-trend bias that was not controlled for. As a result, the analysis reported inflated estimates of the effects of bicycle helmets. This paper presents a re-analysis of the study. The re-analysis included: (1) detecting and adjusting for publication bias by means of the trim-and-fill method; (2) ensuring the inclusion of all published studies by means of continuity corrections of estimates of effect rely on zero counts; (3) detecting and trying to account for a time-trend bias in estimates of the effects of bicycle helmets; (4) updating the study by including recently published studies evaluating the effects of bicycle helmets. The re-analysis shows smaller safety benefits associated with the use of bicycle helmets than the original study.

1. Introduction

Numerous studies have found that bicycle helmets are effective in reducing head injury to bicyclists. A meta-analysis based on 13 estimates of the effect on head injury of wearing a bicycle helmet concluded that the risk of head injury is reduced by 60% (Attewell et al., 2001). The same study concluded that the risk of brain injury is reduced by 58% and the risk of facial injury reduced by 47%. All these reductions in risk were statistically significant at the 5% level. These results were confirmed in a meta-analysis performed for the Cochrane collaboration by Thompson et al. (2009), who reported even more impressive reductions in the risk of head injury, brain injury and facial injury. A meta-analysis by Elvik et al. (2009) reported a 64% reduction in the risk of head injury when a hard helmet is worn and a 41% reduction in risk when a soft helmet is worn. According to this meta-analysis, the risk of facial injury is reduced by 34% if a hard helmet is worn; wearing a soft helmet was associated with a statistically non-significant (5% level of significance) increase of 14% in the risk of facial injury.

While these meta-analyses are broadly in agreement with respect to the effects of wearing a bicycle helmet, they have been criticised for being biased (Curnow, 2005). In response to this criticism, it has been argued that it is based on misunderstandings (Cummings et al., 2006). The meta-analyses do, however, differ in important respects. The most important difference between them concerns the set of studies included. The Cochrane review (Thompson et al., 2009) is the most restrictive, omitting several studies because they were judged not to employ an appropriate study design. The review of Elvik et al. (2009), on the other hand, included all studies that were retrieved.

In meta-analysis, an ideal of including all studies that deal with a topic has wide support. Assessing study quality is also widely supported, but there are many ways of doing so, none of them without a large element of subjectivity. Rather than omitting studies classified as poorly designed, most meta-analysts would prefer to include these studies and assess how excluding them would influence summary estimates of effect as part of a sensitivity analysis.

The objective of this paper is to critically assess the meta-analysis reported by Attewell et al. (2001). The authors of that study discussed the possibility of publication bias, admitting that it could not be ruled out, but concluding that it was unlikely to greatly influence summary estimates of effect. Since publication of the paper, new techniques for detecting and adjusting for publication bias have been developed (Rothstein et al., 2005). It is now possible to test and adjust for the possible presence of publication bias more rigorously than at the time when Attewell et al. (2001) prepared their paper. Moreover, analysts have become increasingly aware of other potential biases that may influence meta-analyses. A case can therefore be made for re-analysing the study of Attewell et al. (2001) in order to test for the possible presence of various sources of bias in the study.

* Tel.: +47 22 573800; fax: +47 22 570290.
E-mail address: re@toi.no

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2. Biases in meta-analysis

There are many sources of bias in meta-analyses. Briefly, the following are the most important (Rothstein et al., 2005; Sweeting et al., 2004; Borenstein et al., 2009):

1. Publication bias, which denotes a tendency not to publish studies if findings are not statistically significant or contradict prior expectations or the vested interests of sponsors of the research,
2. Time trend bias, which refers to a tendency for study findings to change over time; if all findings are pooled independently of when they were published, the trend will be pasted over and the summary estimate of effect will be misleading,
3. Zero count bias, which is bias arising if studies with zero counts are omitted or if inefficient continuity corrections are applied to such studies,

It is possible to detect and adjust for all these sources of bias. The techniques for doing so are not perfect and some of them rely on assumptions whose validity cannot be tested in each study. It is nevertheless of interest to examine the extent to which summary estimates of effect could be influenced by the various sources of bias.

3. Biases in meta-analysis of Attewell et al. (2001)

3.1. Publication bias

The possible presence of publication bias in the meta-analysis reported by Attewell et al. (2001) was tested for by means of the trim-and-fill technique (Duval and Tweedie, 2000a,b; Duval, 2005). This is a non-parametric method based on funnel plots. A funnel plot is a diagram that shows estimates of effect on the abscissa and the statistical precision of each estimate of effect on the ordinate. Data points in a funnel plot should, ideally speaking distribute like a funnel turned upside down, since precise estimates, located near the top of the diagram, should display less dispersion than imprecise estimates, located near the bottom of the diagram. The trim-and-fill technique is based on the assumption that a funnel plot should be symmetric if there is no publication bias. If one of the tails of the distribution is missing, or is markedly thinner populated by data points than the other, this is taken to indicate publication bias. For an easily accessible technical introduction to the trim-and-fill technique, see Duval (2005).

The meta-analysis reported by Attewell et al. (2001) presents summary estimates of the effect of bicycle helmets in five categories: (1) head injury, (2) brain injury, (3) facial injury, (4) neck injury, and (5) fatal injury. The trim-and-fill technique has been applied to four of these categories. There were only three estimates of effect with respect to neck injury; too few for meaningfully testing for publication bias. Evidence suggesting publication bias was found in all the four categories of results for which it was tested. An example of how the trim-and-fill technique fills in "missing" (i.e., not published) data points is given in Fig. 1. It refers to the effects of bicycle helmets on head injury.

The scales of the axes have been chosen as recommended by Sterne and Egger (2001). The abscissa shows the logarithm of the odds ratio (log odds ratio). Negative values indicate a reduction in risk; positive values indicate an increase in risk. The ordinate shows the fixed-effects value of the standard error of each estimate of effect, with the scale inverted so that the most precise estimates are located at the top of the funnel plot. As can be seen, three data points were added to make the funnel plot more symmetric.

Table 1 shows the original and adjusted summary estimates of effect according to a fixed-effects model of analysis and a random-effects model of analysis. A fixed-effects model is based on the assumption that the variation of estimates of effect between studies is random only. A random-effects model allows for systematic between-study variation in estimates of effects. A random-effects model was applied in all cases except for fatal injury, where the heterogeneity test did not indicate that there was any systematic between-study variation in estimates of effect.

Summary estimates of effect adjusted for publication bias invariable indicate smaller effects than unadjusted summary estimates. In some cases, in particular effects on facial injury according to a fixed-effects model, the effects of adjusting for publication bias are large. In most cases, however, adjusting for publication bias has a very small effect on summary estimates of effect. Attewell et al. (2001) were therefore correct in their conjecture that the possible presence of publication bias did not greatly influence summary estimates of effect.

3.2. Time trend bias

The effects of a safety measure, like bicycle helmets, may change over time. Often, one would expect that technological innovation made a safety measure more effective over time. As far as bicycle helmets are concerned, however, the opposite appears to be the case. Fig. 2 shows changes in the summary effect of bicycle helmets on head injury as a function of cumulative statistical weights.

The first studies, based on small samples, indicated a reduction in the risk of head injury of about 75% (odds ratio 0.25). As new studies were added, the summary estimate of effect became smaller, reducing to about 55% (odds ratio 0.45). This means that, on the average, recently published studies show considerably smaller benefits of bicycle helmets than older studies. It is important to keep in mind that the data points in Fig. 2 are cumulative; thus the rightmost data point summarises the contributions of all studies, not just the most recent studies. A summary estimate of effect not recognising this trend may be misleading and give a too optimistic impression of the effects of new bicycle helmets.

One may test if the time trend bias is stable using it to predict the summary estimate of effect when new studies are added. In Section 4 of the paper, the analysis is updated by adding new studies to test the persistence of the time trend.

3.3. The treatment of zero counts

Attewell et al. (2001) included studies in which one of the four numbers used to calculate the odds ratio was zero by adding 0.25 to each cell of the 2×2 table. Various approaches that can be taken to continuity correction in meta-analysis are discussed by Sweeting et al. (2004). They argue that adding a constant to each cell of a 2×2 table is arbitrary and propose two other techniques that can be used for continuity correction. One of these techniques, empirical continuity correction, has been applied in the re-analysis of the Attewell et al. (2001) study.

Empirical continuity correction starts by estimating a summary effect based on studies with non-zero counts. The factors used for continuity correction are then derived by adding a constant to each cell in a 2×2 table in which both cells in the case group (those sustaining any of the five types of injury specified by Attewell et al. (2001)) are assumed to be zero. The constants are determined so that the odds ratio becomes identical to the summary odds ratio of the non-zero studies. These adjustment factors are then applied to the real counts.

To give an example in the study reported by Attewell et al. (2001) the summary estimate of effect on head injury based on studies with no zero counts was 0.419 (i.e., 58% reduction in the risk of injury; fixed-effects model). In one study, the following counts were observed:

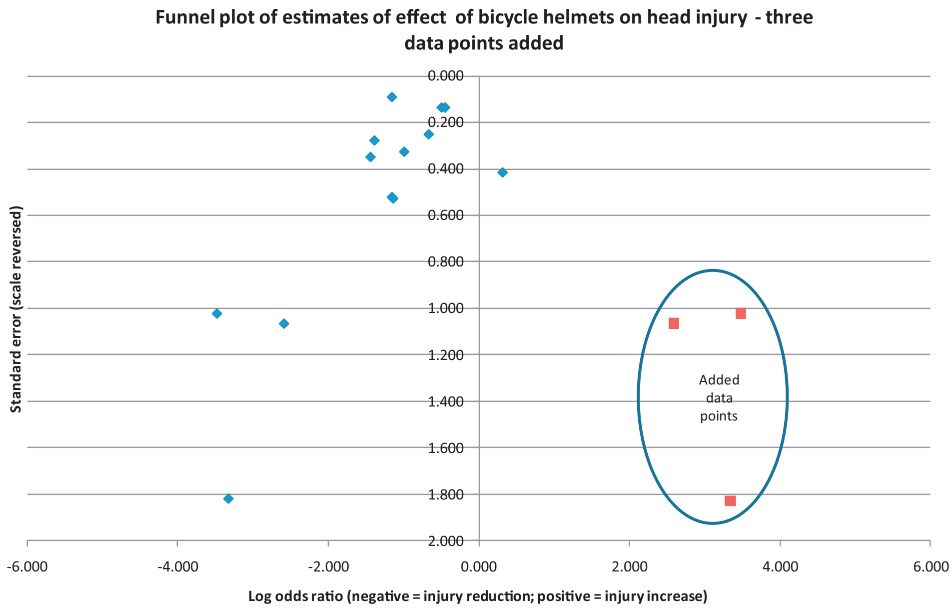

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Fig. 1. Funnel plot of estimates of effect of bicycle helmets on head injury – three data points added.

Head injury, helmet worn: 0
Head injury, no helmet: 7
Other injury, helmet worn: 8
Other injury, no helmet: 6

The odds ratio based on the crude counts is (0/3)/(8/6) = 0.000. It is (counterfactually) assumed that both case counts (i.e., those with head injury) were zero. This results in the following adjustment factors:

$$\left(\frac{0.344/0.656}{8.344/6.656}\right) = 0.419 = \text{summary odds ratio of non-zero studies}$$

The adjusted estimate then becomes:

$$\left(\frac{0.344/3.656}{8.344/6.656}\right) = 0.036$$

which suggests that the zero count of head injuries among helmeted cyclists in this sample is consistent with a larger effect of bicycle helmets than observed in other studies, but not a 100% protective effect. Other effects based on zero counts were similarly adjusted and included in the meta-analysis in adjusted form.

4. Updating the meta-analysis

Since the analysis presented by Attewell et al. (2001) was published, new studies evaluating the effects of bicycle helmets have been published. The analysis has been updated by including stud-

Table 1
Summary estimates of effects of bicycle helmets. Original estimates and estimates based on re-analysis.

Type of injury	Summary odds ratios; 95% confidence intervals ( ); number of estimates [ ]	Summary odds ratios; fixed-effects model; 95% confidence interval in parentheses ( ); number of estimates in brackets [ ]		Summary odds ratios; random-effects model; 95% confidence interval in parentheses ( ); number of estimates in brackets [ ]	
	Original study	Re-analysis, not adjusting for publication bias	Re-analysis, adjusting for publication bias	Re-analysis, not adjusting for publication bias	Re-analysis, adjusting for publication bias
Head injury	0.40 (0,29, 0.55) [12]	0.42 (0.37, 0.47) [13]	0.43 (0.38, 0.48) [16]	0.39 (0.28, 0.53) [13]	0.47 (0.34, 0.64) [16]
Brain injury	0.42 (0.26, 0.67) [8]	0.42 (0.34, 0.52) [8]	0.42 (0.34, 0.53) [9]	0.46 (0.28, 0.73) [8]	0.47 (0.29, 0.75) [9]
Facial injury	0.53 (0.39, 0.73) [7]	0.63 (0.56, 0.71) [8]	0.88 (0.80, 0.98) [13]	0.56 (0.42, 0.74) [8]	0.59 (0.45, 0.78) [9]
Neck injury	1.36 (1.00, 1.86) [3]	1.36 (1.00, 1.86) [3]	Not adjusted	1.40 (0.97, 2.02) [3]	Not adjusted
Fatal injury	0.27 (0.10, 0.72) [6]	0.22 (0.08, 0.62) [6]	0.23 (0.08, 0.66) [9]	0.22 (0.08, 0.62) [6]	0.23 (0.08, 0.66) [9]

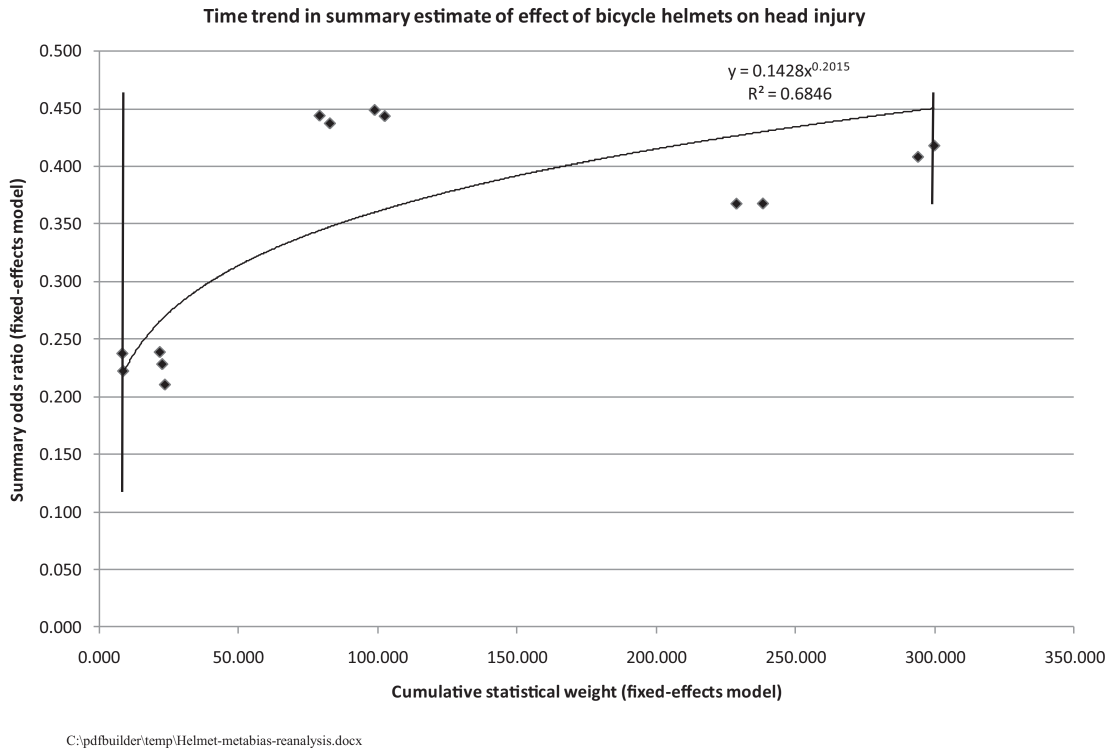

Fig. 2. Time trend in summary estimates of effect of bicycle helmets on head injury.

ies reported by Hausotter (2000), Hansen et al. (2003), Heng et al. (2006) and Amoros et al. (2009). Inclusion of these studies produced five new estimates for head injury, three new estimates for facial injury and one new estimate for neck injury. A new-meta-analysis was performed, adding the new estimates to those included in the study by Attewell et al. (2001).

As far as effects of bicycle helmets on head injury are concerned, the addition of five new estimates confirmed the time trend observed for the original thirteen estimates. This is shown in Fig. 3. Fig. 3 reproduces the data points in Fig. 2 as well as the function fitted to those data points. When the new estimates are added to the original, the new data point to right in Fig. 3 is created. As can be seen, extrapolating the curve fitted to the original data points predicts this new data point remarkably well.

Table 2 shows summary estimates of effect based on the original estimates, the new estimates and all estimates. Estimates based on recently published studies show much smaller effects of bicycle helmets on head injury and facial injury than the original study. In fact, in the random-effects model, there is a statistically non-significant tendency for the wearing of bicycle helmets to be associated with an increase of the risk of injury. As far as neck injury is concerned, the tendency found in the original study for the risk of injury to increase when a helmet is worn is confirmed when a new estimate is added.

The head, the face and the neck can be viewed as three distinct regions of the body. Hence, it makes sense to develop summary estimates of effect of bicycle helmets for the head, the face and the neck. These estimates are shown at the bottom of Table 2. In general, the estimates suggest a modest overall effect of bicycle helmets. In the random-effects analysis, based on the new estimates only, the effect vanishes entirely. For all studies, based on a random-effects model adjusted for publication bias, the best estimate is a 15% reduction of the risk of injury to the head, the face or the neck if a bicycle helmet is worn. This summary estimate is statistically significant at the 5% level.

The addition of new estimates did not remove publication bias. Fig. 4 shows that six new data points were added in a trim-and-fill analysis of estimates of the effect of bicycle helmets on head injury. The new estimates added have been identified by the letter “N” and surrounded by an ellipse in Fig. 4. As can be seen, these data points exhibit the same skewness as the original estimates of effect.

The trim-and-fill analysis was applied to all data points (thirteen original plus five new). It was judged that the five new data points were too few to apply the trim-and-fill technique. A trim-and-fill analysis was nevertheless attempted for these five data points and it converged at the value of three, suggesting that three new data points should be added to adjust for publication bias. No test of publication bias was performed for the four estimates of effect bicycle helmets on neck injury.

5. Discussion

Do bicycle helmets reduce the risk of injury to the head, face or neck? With respect to head injury, the answer is clearly yes, and the re-analysis of the meta-analysis reported by Attewell et al. (2001) in this paper has not changed this answer. As far as facial injury is concerned, evidence suggests that the protective effect is smaller, but on balance there does seem to be a slight protective effect. The risk of neck injury does not seem to be reduced by bicycle helmets. There are only four estimates of effect, but they all indicate an increased risk of injury. When the risk of injury to head, face or neck is viewed as a whole, bicycle helmets do provide a small protective effect. This effect is evident only in older studies. New studies, summarised by a random-effects model of analysis, indicate no net protective effect.

These findings raise a number of issues. In the first place, why do recent studies show a smaller protective effect of bicycle helmets than older studies? In the second place, should a meta-analysis include all studies or just studies that satisfy certain selection criteria, like those applied in the Cochrane review of bicycle helmets

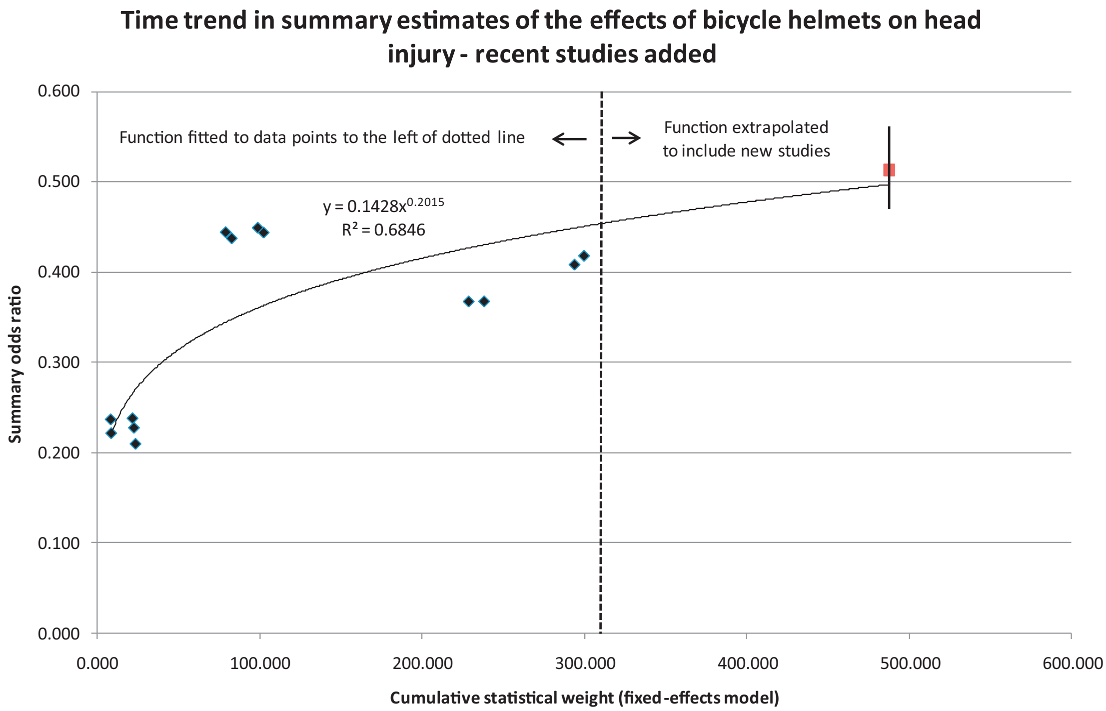

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Fig. 3. Time trend in summary estimates of effect of bicycle helmets on head injury – recent studies added.

Table 2
Summary estimates of effects of bicycle helmets. New studies added.

Type of injury	Studies included	Summary odds ratios; fixed-effects model; 95% confidence interval in parentheses ( ); number of estimates in brackets [ ]		Summary odds ratios; random-effects model; 95% confidence interval in parentheses ( ); number of estimates in brackets [ ]	
		Re-analysis, not adjusting for publication bias	Re-analysis, adjusting for publication bias	Re-analysis, not adjusting for publication bias	Re-analysis, adjusting for publication bias
Head injury	As in Attewell et al. (2001)	0.42 (0.37, 0.47) [13]	0.43 (0.38, 0,48) [16]	0.39 (0.28, 0.54) [13]	0.47 (0.34, 0.64) [16]
	New studies	0.71 (0.62, 0.82) [5]	Too few to adjust	0.56 (0.34, 0.90) [5]	Too few to adjust
	All studies	0.51 (0.47, 0.56) [18]	0.57 (0.52, 0.62) [24]	0.43 (0.33, 0.57) [18]	0.58 (0.45, 0.75) [23]
Facial injury	As in Attewell et al. (2001)	0.63 (0.56, 0.71) [8]	0.88 (0.80, 0.98) [13]	0.56 (0.42, 0.74) [8]	0.59 (0.45, 0.78) [9]
	New studies	0.94 (0.81, 1.09) [3]	Too few to adjust	1.17 (0.78, 1.76) [3]	Too few to adjust
	All studies	0.74 (0.67, 0.81) [11]	0.82 (0.75, 0.90) [13]	0.71 (0.57, 0.90) [11]	0.83 (0.67, 1.03) [13]
Neck injury	As in Attewell et al. (2001)	1.36 (1.00, 1.86) [3]	Too few to adjust	1.40 (0.97, 2.02) [3]	Too few to adjust
	New studies	1.24 (0.98, 1.57) [1]	Too few to adjust	1.24 (0.85, 1.82) [1]	Too few to adjust
	All studies	1.28 (1.06, 1.55) [4]	Too few to adjust	1.32 (1.01, 1.72) [4]	Too few to adjust
Head, face or neck injury	As in Attewell et al. (2001)	0.54 (0.50, 0.59) [24]	0.67 (0.62, 0.72) [32]	0.63 (0.52, 0.75) [24]	0.67 (0.56, 0.80) [32]
	New studies	0.87 (0.79, 0.95) [9]	Not adjusted	1.00 (0.78, 1.27) [9]	Not adjusted
	All studies	0.66 (0.62, 0.70) [33]	0.73 (0.68, 0.77) [41]	0.74 (0.64, 0.86) [33]	0.85 (0.74, 0.98) [40]

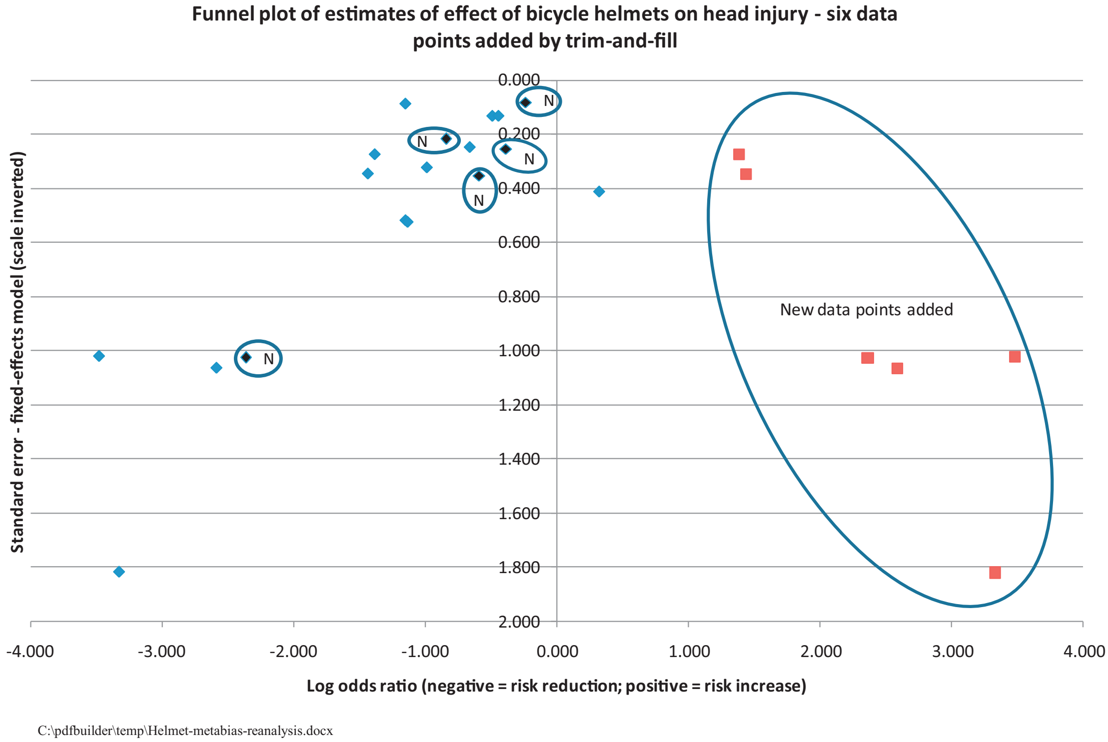

Fig. 4. Funnel plot of estimates of effect of bicycle helmets on head injury – six data points added by trim-and-fill.

(Thompson et al., 2009)? In the third place, why are the findings of some studies that have evaluated the effects of laws mandating the use of bicycle helmets apparently inconsistent with the findings of studies of the protective effect of bicycle helmets for each user?

There are two main reasons why the findings of studies that have evaluated the effects of bicycle helmets can vary: substantive and methodological. One reason for varying findings is that different types of helmets do not have the same protective effect. The first studies of bicycle helmets included mostly hard shell helmets. These have been found to offer better protection against head injury than soft shell helmets, which have become more popular over time. Thus, in the study of Hansen et al. (2003) more than one third of the helmets were soft shell helmets and these helmets were found to protect less well against head injury than hard shell helmets. Thompson et al. (2009) dismiss this argument, claiming that (page 7): "Bicycle helmets of all types . . . provide substantial protection for cyclists of all ages." However, the same authors (Rivara et al., 1997) reported a study which found that only hard shell helmets protected against neck injury; use of a soft shell helmet was associated with an increased incidence of neck injury. On balance, the evidence suggests that: (1) soft shell helmets offer less protection than hard shell helmets, and (2) soft shell helmets appear to have become more common over time.

Thompson et al. (2009) were concerned about the quality of studies that have evaluated the effects of bicycle helmets and defined a set of selection criteria for including studies in a meta-analysis. Applying these criteria, seven studies were included and eight studies were omitted. Two studies were awaiting assessment at the time of publication of the review. Four of the seven studies that were included were performed by the same researchers as the Cochrane review. In short, Thompson et al. (2009) classified four of their own studies as good enough to be included in the meta-analysis, but excluded eight studies, none of which they were involved in. Littell et al. (2008) regard involvement in the conduct of one or more studies included in a review, or publication of a previous review on the same topic as a case of conflict of interest. This conflict of interest is relevant for the Cochrane review reported by Thompson et al. (2009). They were themselves authors of four of the seven studies included and had performed a similar Cochrane review twice before (in 2003 and 2006). To their credit, however, Thompson et al. (2009) included a very comprehensive section discussing criticisms of their review.

Study quality assessment is not an exact science. The Department for Transport in Great Britain issued a report in 2002 entitled: "Bicycle helmets – a review of their effectiveness: a critical review if the literature". The report includes an assessment of the quality of 16 studies that have evaluated the effects of bicycle helmets. Studies were rated as good, reasonable or weak. Of the seven studies Thompson et al. (2009) included in the Cochrane review, one was rated as good, two as good/reasonable, three as reasonable and one as reasonable/weak. Three of the eight studies Thompson et al. (2009) omitted were also rated by the Department for Transport (2002). One was rated as good, one as good/reasonable and one as reasonable. Thus, if the rating developed by the Department for Transport (2002) is applied, it is by no means obvious that all the seven studies that were included by Thompson et al. (2009) ought to have been included. Nor is it clear that all the omitted studies were of lower quality than the studies included.

An alternative to omitting studies classified as bad would be to develop a quality score for each study and use that score in a sensitivity analysis, as illustrated by Elvik (2005). Although it is clear that any numerical quality score will contain an element of arbitrariness, including all studies and performing a sensitivity analysis allows readers to judge how study quality influences study findings. This opportunity does not exist if studies rated as "bad" are simply omitted.

Several researchers have been puzzled by the fact that, on the one hand, studies have reported large protective effects of bicycle helmets; on the other hand, studies of the effect of legislation that has been associated with large increases in the rate of helmet wearing have not always shown a clear decline in the number of head injuries among cyclists. There are at least two reasons why even a large increase in the rate of helmet wearing will not necessarily lead to a major reduction of the number of cyclists sustaining head injury. One reason could be selective recruitment, which means that it is the most cautious and safety-minded cyclists, with a lower rate of accident involvement than other cyclists, who first start wearing helmets. If, for example, in a population of cyclists 60% have a 20% lower rate of accident involvement than an average cyclist (i.e., a relative risk of 0.8), and these cyclists start wearing helmets that reduce their risk of head injury by 40%, the total number of head injuries would be reduced by 19% ($0.8 \times 0.60 = 0.48$; i.e., the safe cyclists are involved in 48% of all accidents before starting to wear helmets; this reduces to $0.8 \times 0.6 \times 0.60 = 0.29$; ceteris paribus the number of injuries is reduced by 19%). This is less than one would expect if aggregate effects were strictly proportional to individual effects. In the latter case, one would expect the number of head injuries to be reduced by $0.40 \times 0.60 = 0.24 = 24\%$. If there is very selective recruitment, aggregate effects could be substantially smaller than implied by the individual protective effects of bicycle helmets.

Another possible reason why the aggregate effects of bicycle helmets could be smaller than expected on the basis of individual effects is behavioural adaptation. Once helmeted, cyclists might feel better protected and adopt more risky riding behaviour. While this cannot be ruled out, there is no direct evidence for it and performing a convincing study of such behavioural adaptation would be very difficult. The issue remains unresolved (Robinson, 2007).

6. Conclusions

Based on the studies reviewed in this paper, the following conclusions can be drawn:

1. A re-analysis has been performed of a meta-analysis of the protective effects of bicycle helmets reported in Accident Analysis and Prevention (Attewell et al., 2001). The original analysis was found to be influenced by publication bias and time-trend bias that were not controlled for.
2. When these sources of bias are controlled for, the protective effects attributed to bicycle helmets become smaller than originally estimated.
3. When the analysis is updated by adding four new studies, the protective effects attributed to bicycle helmets are further reduced. According to the new studies, no overall effect of bicycle helmets could be found when injuries to head, face or neck are considered as a whole.
4. The findings of this study are inconsistent with other meta-analyses, in particular a Cochrane review published in 2009. However, the study inclusion criteria applied in the Cochrane review are debatable.

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