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The Cochrane Collaboration and bicycle helmets

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Abstract

Effective interventions for care of health need to be based on scientific evidence. To this end, the Cochrane Collaboration insists that its reviews should be based on reliable data, normally obtained by randomised controlled trial. To constitute evidence, data should also support a hypothesis in accord with scientific laws and knowledge. From these considerations, an appraisal is made of the conclusion of the Cochrane review *Helmets for preventing head and facial injuries in bicyclists*, that it establishes scientific evidence that all types of standard helmet protect against injuries to the brain. It is concluded that the review takes no account of scientific knowledge of types and mechanisms of brain injury. It provides, at best, evidence that hard-shell helmets, now rarely used, protect the brain from injury consequent upon damage to the skull. The review therefore is not a reliable guide to the efficacy of helmets and to interventions concerning their use.

Keywords: Cochrane review; Bicycle helmet; Scientific evidence

1. Introduction

The Cochrane Collaboration serves to evaluate interventions in health care by doing systematic review of studies of their efficacy, which are normally randomised controlled trials, because with human subjects these provide data most closely approximating the reliability of a scientific experiment. Case-control studies are considered to be less reliable, but, either way, to constitute evidence data should also relate to a hypothesis that links, in accord with scientific knowledge, a defined intervention with measurable effects. By such application of experimental science, Cochrane reviews have shown whether or not interventions are effectual, giving assured guidance to medical professionals and the public to adopt or discard them.

The Cochrane review *Helmets for preventing head and facial injuries in bicyclists* (Thompson et al., 2004) is clearly intended as a guide to intervention. It synthesises the results of five "included studies" of cyclists who crashed: Thompson et al. (1989, 1996), McDermott et al. (1993), Thomas et al. (1994) and Maimaris et al. (1994). All are case-control studies, which compare cases that sought care at a hospital for injury to the head, brain or face with controls that sought it for other injury or reported having an accident. All conclude that helmets are efficacious and urge programs to increase their use, such as legislation. With respect to the brain, the review concludes that the five studies establish scientific evidence that standard helmets reduce the risk of injury by 88% and severe injury by at least 75%.

Fear of death and chronic disability is the main motive for wearing helmets (Curnow, 2003) and injury to the brain is their main cause. Therefore, the important question, to which this article is directed, is whether helmets protect the brain from serious injury. On this question, the review is compared with experimental science and its suitability for publication in the Cochrane Library is examined.

2. Brain injury and helmets

Brain injury that kills or severely disables is typically of severity AIS 4–6. It is rare, comprising less than 6% of 558 head injuries to cyclists treated in hospital in the study of McDermott et al. (1993). Its main causes are a blow that damages the skull and angular acceleration of the head (see

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Curnow, 2003, ibid.). By the first cause, skull bone or an external object strikes the brain, leading to focal injury such as laceration and contusion. Fatal subdural haematoma may follow. By the second, an oblique impulse makes the head rotate. Bone within it may then strike the brain, causing focal injury, including the so-called *coup* and *contre-coup*. Even if the brain is not struck, diffuse injury to its small blood vessels and neurons may occur, including diffuse axonal injury, which is often fatal and is the commonest cause of severe disability.

Bicycle helmets evolved from those designed for soldiers, miners and the like. Their helmets have a hard shell, which protects the skull from damage from moving objects and the brain from consequent focal injury. It has been shown that hard-shell motorcycle helmets protect the skull. Until the early 1990s, standards required hard-shells for bicycle helmets too; in the studies of *Thompson 1989*, *McDermott* and *Thomas*, nearly all helmets had them. Use of hard shells has since declined, being only half for *Thompson 1996*, less still by the time of the review and now rare. Whether soft bicycle helmets can protect the skull is problematic.

For soldiers and the like, the risk of brain injury is slight if the skull is undamaged. Bullets, for instance, have insufficient mass to generate injurious angular acceleration, but Corner et al. (1987) measured it at 12 times the 4500 rad/s^2 for onset of vein rupture when dummies wearing bicycle helmets struck a floor at 45 km/h and showed by experiment that the mass added by wearing a helmet can increase it. In the design and testing of helmets, angular acceleration is disregarded, however. Instead, helmets are lined with plastic foam and tested for capacity to reduce linear acceleration, according to a discredited theory that it is a major cause of brain injury.

3. Hypotheses, bias

To establish evidence of the efficacy of helmets against brain injury, a hypothesis in accord with knowledge including the foregoing, and with scientific laws, should be tested. Neither the review nor any of the five studies follow this method; indeed, the reviewers appear to reject it (Thompson et al., 2000). Their hypothesis is simply that helmets reduce brain injury. It implies at least four hypotheses suitable for research, concerning effects of hard and soft helmets on focal and diffuse injury, respectively, but none of the studies of the review distinguishes these types of injury or obtains, collates and interprets data specific to each and their mechanisms of occurrence. Of the four, the only plausible hypothesis would seem to be that hard-shell helmets protect against damage to the skull and consequent focal injury. As it is not clear that soft helmets can protect the skull from damage (see Curnow, 2003, ibid.), the simple hypothesis is prima facie implausible.

Lacking theoretical underpinning, the included studies are vulnerable to bias. It is important that the controls should approximate closely the exposure experience of the whole population of cyclists at risk for head injury. The review states that they do—but that is not established because none of the control groups is a random sample of it.

Another possible source of bias is that cyclists who wore helmets may have been more careful than non-wearers, and also were over-represented in the control groups compared to the whole population. The latter would appear to be so for *Thompson 1989*, because the wearing rates of its control groups were much higher than for children in the whole population. A bias in the other direction would arise if helmeted cyclists compensated for a feeling of greater safety by taking more risks. The review in effect dismisses these possibilities by defining the fundamental issue as whether cyclists who crash and hit their heads benefit by wearing a helmet, but this would be so only if those cyclists were a random sample representative of the whole population. Further, both the review and its studies assume that hitting the head is necessary for the brain to be injured, though it can occur in any accident where an oblique impulse results in angular acceleration of the head, including falls on the buttocks and whiplash (Ommaya and Gennarelli, 1974). Ommaya et al. (1968) showed in experimental whiplash injury to monkeys that angular acceleration without impact produced concussion and haemorrhage and contusion to the brain.

Cases are more involved with a motor vehicle than controls. Only *Thompson 1989 and 1996* and *Thomas* purport to adjust for this source of bias, but the adjustments are simply based on damage to the bicycle. No account is taken of causes of brain injury and possible greater subjection to oblique impulse.

The findings of the studies relate to a time when hard-shell helmets predominated. Since then, the protection which they can provide against focal injury to the brain has largely been lost, but neither the review nor any of the studies recognises this.

4. The included studies

4.1. Thompson 1989 and 1996

Thompson 1989 compares 235 cases having head injury with 433 ER controls, without it all of which sought care at hospital emergency rooms (ER) over 1 year, and with 558 members of a group health co-operative (GHC controls) who reported having a cycling accident. It concludes that the adjusted odds ratio for brain injury no helmet/helmet is 0.12 (risk reduction 88%). Both studies affirm that adjustments take account of unmeasured factors, so that striking the head is equally likely for cases and controls. They would appear to equate this with equal risk of brain injury, neglecting oblique impulse. The 1989 study admits to not being able to rule out bias due to more cautious cyclists choosing to wear helmets and having less severe accidents. It also refers to unmeasured (and unspecified) factors which may have made the controls less likely to strike their heads in an accident. To confirm its adjustments, it makes a sub-analysis of cyclists known to have struck their heads, using, in effect, 99 with brain injury as cases and 148 with other head injury as controls. The adjusted odds ratio for brain injury increases from 0.12 to 0.23 (risk reduction 77%), but the confidence intervals overlap and the protective effect of a helmet is stated to be similar to that of the central analysis.

Thompson 1996, the most recent and detailed of the included studies, starts by declaring that a solid body of scientific evidence indicates that helmets reduce head injuries, reflecting the general acceptance of the 1989 study. The authors then turn to subsidiary questions. From 757 cases and 2633 ER controls, the study puts the adjusted odds ratio for brain injury at 0.35, risk reduction 65%, and for severe brain injury, defined as AIS 3–6 at 0.26 and 74%. Brain injury is defined simply as including concussion, though it is usually a minor trauma with negligible risk of brain damage (Simpson and McLean, 1997), and more serious intracranial injury. Of the latter, only lacerations, contusions and haemorrhages are specified, but no diffuse injuries. Mechanisms of brain injury, signs of rotation or oblique blow are not discussed. The study notes a consistent suggestion that hard-shell helmets are more protective than no shell, but it does not consider why. Similarly, the estimated protective effect against brain injury declines from 81% in 1989 to 65% in 1996, but the confidence intervals overlap and the estimates are stated to be generally similar. There is no thought of a link to the decline in the proportion of hard shells.

The authors of *Thompson 1996* seem to forget their earlier reservations about possible biases. They arbitrarily rule out bias due to differing behaviour of helmet wearers and assert that the fundamental issue is whether cyclists benefit from wearing a helmet when they hit their heads. Though noting that the study design requires both cases and controls to have equal probability of hitting their heads, they adduce no evidence to show it. Nor do they attempt to confirm it by sub-analysis, as in 1989, but data from their Table 4 enable this to be done, as per Table 1 here.

The odds ratios shown in Table 1 are much higher than in Table 4 of *Thompson 1996*. This suggests a lower protective effect than the central analysis, that unmeasured factors are significant and that the assumption of equal probability is wrong. Error due to unmeasured factors may exist. Further, the increase in the disparity between the odds ratios of the respective sub- and central analyses of 1989 and 1996 suggests a decline in protection of the brain, corresponding with a fall in the proportion of hard-shell helmets from about 90 to 50%. In question, then, is why *Thompson 1996* does not make a sub-analysis. Another question is why it cites Cameron et al. (1994), Pitt et al. (1994) and Rivara et al. (1994) for corroborative evidence of efficacy against brain injury when none of those studies even mentions it. In sum, the study is merely statistical analysis and not scientific investigation. At best, it provides evidence that hard helmets protect against focal injury. Neither it nor the other studies of the review shows that soft helmets reduce injury to the brain.

4.2. Maimaris

Maimaris is presented as a comparison of the incidence of injuries to cyclists who were wearing and not wearing helmets, those with head injury being the cases, in effect, and those without it the controls. This presentation obscures the lack of assurance that the controls accurately represent the whole population. It also obscures the important point for fatal and disabling brain injury that 50% of cases but only 25% of controls were in accidents involving a motor vehicle. The statement that there were no significant differences between helmet wearers and non-wearers with respect to type of accident misses this point.

Head injury is defined as skull fracture and brain injury, but the data for the two are not separated, include no recognised severity ratings such as AIS and nothing about types of helmet. These data are inadequate to support valid conclusions about effects of helmets on brain injury.

4.3. McDermott

McDermott also compares the incidence of head injury to helmet wearers and non-wearers, resulting in deficiencies similar to *Maimaris*. It was carried out under the auspices of the Victorian Road Trauma Committee (VRTC) of the Royal Australasian College of Surgeons (RACS), with financial support from the Government of Victoria. As the VRTC had persuaded that Government to adopt the policy of compulsory wearing in 1984, the efficacy of helmets was clearly not in question for either of them. This implies that the study was not done to resolve that question, but to support the policy of its sponsors. Its last conclusion, that its findings provide supporting evidence for this, is impugned, and other tendentiousness further detracts from it, as follows.

Table 1
Risk of brain injury, by helmet and type

Helmet type	Brain injury			Severe brain injury		
	Cases no. ($n=203$)	Controls no. ($n=554$)	OR[a]	Cases no. ($n=62$)	Controls no. ($n=554$)	OR
No helmet	141	394	Reference	47	394	Reference
Hard-shell	23	79	0.81	5	79	0.54
Thin-shell	22	40	1.54	5	40	0.91
No-shell/foam	14	37	1.06	4	37	0.89
Any helmet	59	156	1.06	14	156	0.75

[a] Crude odds ratio.

First, the conclusions relate to approved helmets in use in 1987–1989 and then required to have hard shells (Standards Association of Australia, 1986). Removal of that requirement in 1990 greatly affected the protective value of helmets, but the study makes no mention of it.

Second, while the study notes some symptoms of brain injury, it avoids discussing its causes. This is despite Dr. McDermott, as Chairman of the VRTC, having argued reduced brain damage and life-long disability to convince a federal parliamentary committee to recommend compulsory wearing (McDermott, 1985). When asked then whether brain injury was due to deceleration or rotational forces, Dr. McDermott attributed it wholly to the first, "G forces". His disregard of the second (angular acceleration) contrasts with a statement by his co-author that it plays a major part in brain injury and there is no direct means of damping it (Lane, 1986).

Third, 22 casualties are excluded from the analysis because their helmets were dislodged in the crash, thereby reducing the number of head injuries among helmeted cyclists. This could be justified only if it was certain that, but for dislodgement, those injuries would not have occurred. The exclusion therefore amounts to assuming that helmets are efficacious—what the study then purports to establish! Data of *McDermott's* Tables 3 and 5, Fig. 10 and the text show that most of the helmets of the more severely injured (AIS 3 and 4–6) were dislodged. Hence, support for the study's conclusions that there was a suggestion of a protective effect on head injury of severity AIS 4-6 and that its findings provide evidence of benefit from mandatory wearing is mere assumption.

4.4. Thomas

The Australian Government sponsored *Thomas* after adopting a policy of compulsory wearing. The study concludes that the association between wearing helmets and reduced head injury is compelling and legislation is likely to help, but this is hardly credible because it also admits to not answering the crucial question of cause and effect.

5. Time series studies

The review cites five time series studies as providing additional evidence of helmet effectiveness, namely Carr et al. (1995), Ekman et al. (1997), Pitt et al. (1994), Rivara et al. (1994) and Vulcan et al. (1992). Of these, only *Ekman* considers any kind of brain injury and it merely estimates that concussion was sustained by one-third fewer helmet wearers than non-wearers. The review attributes to *Pitt* a finding of a decline in brain injuries as a result of increased helmet use in Queensland, but that study deals only with head injuries in general and says that the reason for a decrease in them is more complex than increased wearing of helmets.

Other time series studies indicate that the efficacy of helmets against head injury in general falls far short of the predictions of case-control studies. For example, from analysis of statistics before and after helmet laws in New South Wales and Victoria, Robinson (1996) found no decrease in the risk of head injury, fatal and hospitalised. Data suitable for similar studies on brain injury are not available for Australia, but the occurrence of the most severe may be approximated by data for fatal head injuries. For Australia, these are available only for alternate years, in the Fatality File published by the Australian Transport Safety Bureau (ATSB). Table 2 is compiled from it. The table shows numbers of deaths in Australia in 1988, before the first helmet law, and 1994, when all were in force.

Despite a decrease in cycling, deaths to cyclists, even those by head injury, declined by less than other road users. No benefit from the helmet laws is evident.

6. Discussion

Demand for protection of the head stems from fear of fatal and disabling injury to it. A public accustomed to soldiers, miners and construction workers wearing protective helmets naturally looked to the similar products on offer for cyclists, not realising the critical difference between protecting the brain within a stationary head struck by a fast-moving object and that of a moving person in collision. Due to their evolution, bicycle helmets are more suited to the former purpose than what they are used for. This undesirable result has come about because the design of helmets has not been guided by research on mechanisms of brain injury. Consequently, bicycle helmets have been a controversial issue for 20 years or more.

The controversy is manifest in conflicting findings of research on the efficacy of helmets. Broadly, laboratory research has shown up deficiencies of helmets. Some time series studies have suggested that increased wearing of helmets has not resulted in reduced injury. Epidemiological studies, mainly of the case-control kind, have indicated, however, that helmets reduce head injury in general. Though these have not

Table 2
Deaths of road users in Australia, in total and by head injury

Year	Pedestrians		Bicyclists		All road users	
	Total	Head	Total	Head	Total	Head
1988	542	233	86	40	2868	1085
1994	346	145	56	28	1787	631
Change 1988/1994 (%)	−36	−38	−35	−30	−38	−42

dealt with brain injury in a scientific way, they have convinced influential elements of the medical profession and some governments, notably in Australia, to support compulsory wearing of helmets.

There is a need for a disinterested appraisal using all scientific knowledge. This might be a new Cochrane review of bicycle helmets, to meet a high standard of rigour. It should synthesise findings of studies which are directed to a suitable problem and test against reliable data a hypothesis to explain, in accord with scientific laws and relevant knowledge, the effects of an intervention. A sounder basis for policies would result.

7. Conclusions

(a) The critical efficacy of helmets is against fatal and disabling injury to the brain.
(b) The review's conclusion that its five included studies establish scientific evidence that standard bicycle helmets of all types protect against injury to the brain is not supportable because none of the studies possesses the requisite scientific rigour.
(c) Due to the decline in use of hard-shell helmets, past findings of their efficacy are not applicable to most helmets now used.
(d) The review is not a reliable guide to interventions and is not suitable for the Cochrane library.

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References

Cameron, M.H., Vulcan, A.P., Finch, C.F., Newstead, S.V., 1994. Mandatory bicycle helmet use following a decade of helmet promotion in Victoria Australia—an evaluation. Accid. Anal. Prev. 26, 325–337.

Carr, D., Skalova, M., Cameron, M., 1995. Evaluation of the Bicycle Helmet Wearing Law in Victoria During its First Four Years. Monash University Accident Research Centre Report No. 76, Melbourne.

Corner, J.P., Whitney, C.W., O'Rourke, N., Morgan, D.E., 1987. Motorcycle and Bicycle Protective Helmets: Requirements Resulting from a Post Crash Study and Experimental Research. Federal Office of Road Safety Report No. CR 55, Canberra, pp. 26–34.

Curnow, W.J., 2003. The efficacy of bicycle helmets against brain injury. Accid. Anal. Prev. 35, 287–292.

Ekman, R., Schelp, L., Welander, G., Svanstron, L., 1997. Can a combination of local, regional and national information substantially increase bicycle–helmet wearing and reduce injuries? Experiences from Sweden. Accid. Anal. Prev. 29, 321–328.

Lane, J.C., 1986. Helmets for Child Bicyclists, Some Biomedical Considerations. Federal Office of Road Safety Report CR 47, Canberra.

Maimaris, C., Summers, C.L., Browning, C., Palmer, C.R., 1994. Injury patterns in cyclists attending an accident and emergency department: a comparison of helmet wearers and non-wearers. Br. Med. J. 308, 1537–1540.

McDermott, F.T., 1985. Evidence Given to the Australian House of Representatives Standing Committee on Transport Safety, Motorcycle and Bicycle Helmet Safety Inquiry on 18.10.85, p. 1086.

McDermott, F.T., Lane, J.C., Brazenor, G.A., Debney, E.A., 1993. The effectiveness of bicycle helmets: a study of 1710 casualties. J. Trauma 34, 834–845.

Ommaya, A.K., Faas, F., Yarnell, P., 1968. Whiplash injury and brain damage, an experimental study. J. Am. Med. Assoc. 204 (4), 285–289.

Ommaya, A.K., Gennarelli, T.A., 1974. Cerebral concussion and traumatic unconsciousness. Brain 97, 633–654.

Pitt, W.R., Thomas, S., Nixon, J., Battistutta, D., Acton, C., 1994. Trends in head injuries among child bicyclists. Br. Med. J. 308, 177.

Rivara, F.P., Thompson, D.C., Thompson, R.S., Rogers, L.W., Alexander, B., Felix, D., Bergman, A.B., 1994. The Seattle children's bicycle helmet campaign: changes in helmet use and head injury admissions. Pediatrics 93, 567–569.

Robinson, D.L., 1996. Head injuries and bicycle helmet laws. Accid. Anal. Prev. 28, 463–475.

Simpson, D.A., McLean, A.J., 1997. Helmets and bicycle-related injuries in Queensland (lettter). Med. J. Aust. 167, 338.

Standards Association of Australia, 1986. Australian Standard AS 2063.1.

Thomas, S., Acton, C., Nixon, J., Battistutta, D., Pitt, W.R., Clark, R., 1994. Effectiveness of bicycle helmets in preventing head injuries in children: case-control study. Br. Med. J. 308, 173–176.

Thompson, R.S., Rivara, F.P., Thompson, D.C., 1989. A case-control study on the effectiveness of bicycle safety helmets. New Engl. J. Med. 320, 1361–1367.

Thompson, D.C., Rivara, F.P., Thompson, R.S., 1996. Effectiveness of bicycle safety helmets in preventing head injuries: a case-control study. J. Am. Med. Assoc. 276, 1968–1973.

Thompson, D.C., Rivara, F.P., Thompson, R.S., 2000. Reply to comment by Bill Curnow. The Cochrane Library, 2000, Issue 4.

Thompson, D.C., Rivara, F.P., Thompson, R., 2004. Helmets for preventing head and facial injuries in bicyclists (CochraneReview). In: The Cochrane Library, Issue 2, 2004. John Wiley & Sons Ltd., Chichester, UK.

Vulcan, A.P., Cameron, M.H., Watson, W.L., 1992. Mandatory bicycle helmet use: experience in Victoria. Australia. World J. Surg. 16, 389–397.