An evaluation of the methods used to assess the effectiveness of mandatory bicycle helmet legislation in New Zealand

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Abstract

Mandatory helmet legislation (MHL) was introduced in New Zealand (NZ) in January 1994. Previous studies have shown a significant reduction in cycling head injury associated with MHL; however, one analysis has suggested a diminishing return in head injury reduction with increased helmet wearing rates. The aim of this study is to critically assess the validity of methods and conclusions from studies evaluating the effect of MHL on head injury in NZ. We emphasise the importance of accurately and objectively presenting data and the need for a proper subsequent analysis for valid inference. This plays a paramount role in the communication of research findings as they heavily influence the public perception of road safety and the effectiveness of policy interventions.

Keywords

Mandatory helmet legislation, New Zealand, head injuries, statistical methods, time trends

Introduction

The New Zealand helmet legislation for cyclists came into effect on 1 January 1994. The legislation requires all cyclists to wear a standard approved cycle helmet for all on-road cycling (Cycles: Road rules and equipment (Factsheet1), 2013). Several case-control studies in the past have shown that cycle helmets do reduce the risk of a brain injury (Bambach et al., 2013). Similarly, recent biomechanical testing has shown clear evidence that bicycle helmets reduce substantially potential injury to the head from both linear and angular impact accelerations (McIntosh et al, 2013). Moreover, a recent investigation by the authors investigating the long-term trends in cyclist head and arm injuries, indicate the initial observed benefit of the mandatory helmet law in New South Wales has been maintained over the ensuing decades (Olivier et al, 2013). With this in mind, the aim of the legislation is to increase the helmet wearing rate, in an effort to reduce head injuries to cyclists.

Prior to the law, voluntary helmet use had been widely promoted in New Zealand. This includes national and local publicity and awareness campaigns starting in the late 1980s. As a result, voluntary helmet wearing rates increased steadily during that time. The helmet wearing rate increased from virtually zero in 1986 to 84%, 62% and 39% in September 1992 for primary school children (5-12 years of age), secondary school children (13-18 years) and adult commuters (over 18 years), respectively (Scuffham, et al., 2000). Just after the legislation, helmet wearing rates increased to above 90% for all cyclist age groups. Note that the data used in each of the referenced studies in this paper are from hospitalisation or coronial data. None of these data sources include information on helmet wearing. However, there exist helmet wearing estimates for the general cycling population from yearly studies in New Zealand.

Research has been conducted to examine the association between helmet wearing rates and rates of head injury to cyclists in New Zealand. Scuffham and Langley (1999) studied the effect of voluntary helmet wearing on serious head injury to cyclists. Their results revealed the increase in helmet wearing rates had little association with the percentage of head injuries to injured cyclists for all three age groups. A later study by Povey et al. (1999) assessed the effect of cycle helmet wearing on hospitalised injuries between 1990 and 1996, using cyclist limb fractures as a measure of exposure. They reported that the increase in helmet wearing associated with the mandatory helmet law accounted for a 20% reduction in head injuries to cyclists involved in motor vehicle crashes and between 24 and 32% in non-motor vehicle crashes. Scuffham et al. (2000) extended the study by Scuffham and Langley (1999) by using a longer time frame (1988-1996) and a general finding was helmet wearing significantly reduced head injuries to cyclists in all age groups. In particular, they estimated that the helmet law averted 139 head injuries over a 3-year period. Sandar Tin Tin et al. (2010) investigated exposure-based rates of on-road injuries to cyclists that resulted in death or hospital inpatient treatment over the period 1988-2007. Their analysis showed the rates of traumatic brain injuries were lower in 1996-99 and 2003-07 as compared to 1988-91 while there was an increasing trend in the rates of injuries to other body parts. Clarke (2012) reviewed publically available data, including the injury data in Sandar Tin Tin et al. (2010), to evaluate the efficacy of the New Zealand bicycle helmet law in terms of safety, health, law enforcement, accident compensation, environmental issues and civil liberties. One of the conclusions of Clarke's study was that the New Zealand helmet law reduced cycling usage by 51% and has contributed to 53 premature deaths per year due to reluctance to cycle and lack of exercise.

While conclusions from previous research regarding the effectiveness of the New Zealand helmet law are mixed, it is important to critically assess the methodologies used in those analyses since flawed statistical methods and arguments lead to erroneous results and hence undermine conclusions based on these results. Robinson (2001) reviewed the results of Povey et al. (1999) and suggested the apparent reduction in head injury was not due to increased helmet wearing, but rather "an artefact caused by failure to fit time trends in their model". Olivier (2012), in a commentary regarding Clarke's study (2012), noted the author failed to meet any of the necessary criteria to establish a causal relationship and hence the original conclusions were not fully supported.

The purpose of this paper is to review studies assessing the effectiveness of the New Zealand bicycle helmet law and critically evaluate the statistical methods used in some of the analyses. We conclude with general recommendations for the choice of data and the use of appropriate statistical models for future research on this topic.

Methodology

This evaluation reviews some existing studies on the association of helmet wearing and the mandatory helmet law with head injuries to cyclists in New Zealand. We discuss the suitability of the statistical approaches employed in these studies and suggest alternative approaches where possible. We chose studies based on Google Scholar and Pubmed searches using the keywords 'New Zealand bicycle helmet'. Studies that did not analyse New Zealand data or were unrelated to bicycle helmet use and cycling head injury were excluded.

Results and Discussions

Povey et al. (1999) and Robinson (2001)

Povey et al. (1999) examined the effect of helmet wearing on hospitalised head injuries between 1990 and 1996, using cyclist limb fractures as a measure of cycling exposure. Cycling injuries from motor vehicle and non-motor vehicle crashes were analysed separately. Additionally, injuries from non-motor crashes were further broken down into three age groups: primary school age (5-12 years), secondary school age (13-18) and adult (age 19 and above).

For statistical analysis, a log-linear model was fitted to the ratio of head to limb injuries and the proportion of surveyed cyclists who were wearing a helmet was used as an explanatory variable as below

$$\ln(HEAD_i / LIMB_i) = \alpha + \beta(HELMET_i) + \varepsilon_i \qquad (1)$$

where the errors ε_i are assumed to be independent, identically distributed normal random variables. The authors estimated 24%, 32% and 28% reduction in head injury due to the helmet law for primary, secondary and adult cyclists in non-motor vehicle crashes. For motor vehicle crashes, the estimated reduction was 20% overall.

Robinson (2001) suggested the effects estimated in Povey et al.'s study were an artefact caused by failure to fit time trends in the above model. It is important to note here the potential weakness of Povey's analysis is the assumption of independent errors for sequentially collected data. However, neither Povey et al. nor Robinson appears to have checked the validity of this assumption. For the case where the errors are serially correlated, it is possible to adequately model equation (1) without time trends by assuming an autocorrelation error structure, for example, we can replace the error by

$$v_i = \phi v_{i-1} + \varepsilon_i, \qquad (2)$$

and use readily available estimation methods. Fitting time trends does not directly address this issue for serially correlated data. Using the residuals from model (1), we found little to no serial autocorrelation (Durbin –Watson statistic is 1.8).

To demonstrate the potential bias associated with failure to fit time trends, Robinson created some hypothetical data containing no effect of helmet wearing. The data contains only a linear trend in which the ratio of head to limb injuries falls by 0.1 every year. Robinson then fits the following linear model for this data:

$$ratio = \alpha + \beta(HELMET_i) + \varepsilon_i \qquad (3)$$

and obtained a highly significant estimate for β, which Robinson claimed was "spurious".

However, this result is not as "spurious" as Robinson claimed, since the variable HELMET is highly correlated with time (r=0.90). To investigate this further, we regress HELMET on TIME, and obtained a statistically significant estimate for the slope (p=0.0056). Hence, even the hypothetical data contains no effect of helmet wearing by construction, the variable

HELMET is highly significant in predicting the ratio of head to limb injuries because both the variable and the outcome can be predicted using a linear function of TIME.

We also found the correlation between HELMET and the hypothetical data is the same as the one between HELMET and TIME. This result is not surprising as the time dependent component in the variable HELMET is used to account for the variability in the data. The remaining effect of HELMET does not improve the fit of the model as a simple linear model fits the data (which is nothing else but a straight line) perfectly (R^2=1, residual S.E.=0).

The left graph in Figure 1 plots the hypothetical ratio of head to limb injuries in Robinson's example and the fitted values using HELMET as the only explanatory variable. The plot on the right in Figure 1 illustrates much of the variability in yearly helmet wearing percentages is explained by a linear model in time.

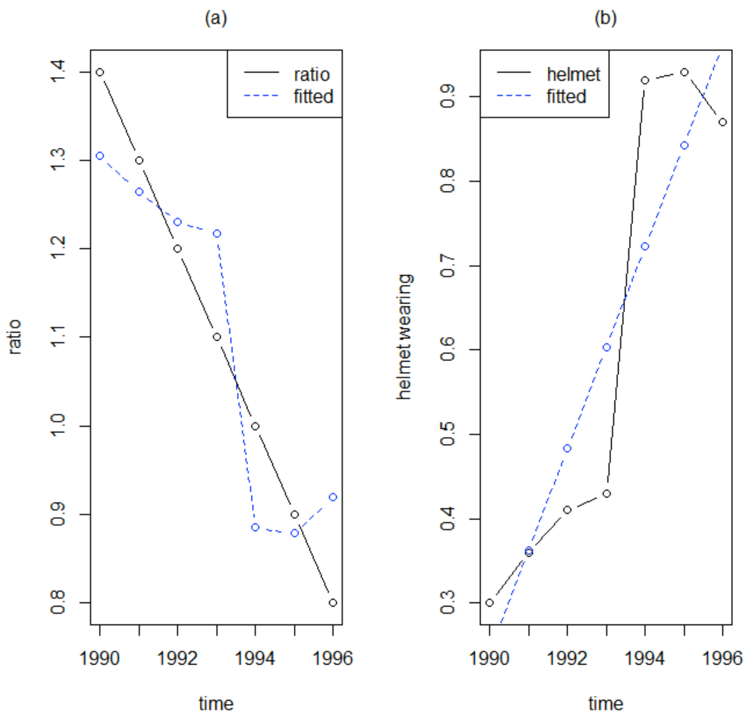

Figure 1
(a): hypothetical ratio of head to limb injuries and fitted values
(b): simple linear regression of helmet wearing percentage on time

Although the example by Robinson aims to demonstrate that ignored time trends result in biases from the model, the approach adopted requires more careful consideration. Firstly, the hypothetical data in Robinson's example is not "simulated data" as stated in the paper because they are not randomly drawn from a data-generating process or model. As a result, there is no random error associated with each observation. Hence, a completely deterministic mathematical model is sufficient for this data, and there is no need to fit model (3). Moreover, a deterministic model assumes that the model parameters are known and the outcome is certain given a fixed input value, which is never the case in real applications. Hence the hypothetical data used in Robinson's example is rather inappropriate in this situation. The original study by Povey et al. used a linear model for the log of head to limb injury counts.

Robinson's example should be at least consistent in modelling the log of that ratio, instead of modelling the ratios themselves.

Robinson argued that trends, if present, should be common to all cyclists. Hence the mean head to limb ratio for primary and secondary school children is used as an estimate of trend. It was then shown, that the mean squared error (MSE), calculated as sum[predicted-actual]^2/[number of cases] (rather than mean[predicted-actual]^2/[number of cases] as stated in Robinson, 2001) was much better when based on predictions from trends as compared to predictions from helmet wearing rates from the model of Povey et al. (1999). However, the most intuitive approach to account for time trend would be to include time as a variable in the model.

We then fit a simple linear regression model to the ratio of adult head to limb injuries using time as the only variable. The fitted values are reported in Table 1. The MSE, based on prediction from only a linear time trend, is better than both MSEs in Povey et al. and Robinson's studies. Hence in terms of MSE as a measure of the model's fit to the observed data, the linear time trend model provides a better fit than the one using estimated trend given by the mean head to limb ratio for primary and secondary school children. Note that provided the data given in Table 1 of Robinson (2001) were correct, we could not reproduce the results given in Table 1 of Povey et al. (1999) using the SAS procedure GENMOD. Hence the predicted values reported in Table 1 under "Povey et al." are what we obtained from estimating model (3). Note also that the original model in Povey et al. (1999) is for the log ratio of head to limb injuries. However, in subsection 4.1 of the paper, the authors mentioned that "the above model was fitted to each of these three data series" in Figure 4 from their paper, which shows the proportion of head injured (head/(head+limb)×100%).

Table 1

Ratio of head to limb injuries according to the model of Povey et al. (1999), from fitting a trend derived from the ratio of head to limb injuries in children (Robinson, 2001) and from fitting a linear time trend

Year	Ratio of head/limb (R=HI/L)	Prediction of R			Helmet wearing (%)
		Povey et al.	Robinson	Time trend	
1990	1.40	1.17	1.25	1.28	30
1991	1.09	1.13	1.15	1.17	36
1992	1.07	1.10	1.16	1.07	41
1993	0.94	1.09	1.00	0.98	43
1994	0.86	0.81	0.80	0.89	92
1995	0.83	0.80	0.85	0.81	93
1996	0.77	0.83	0.75	0.74	87
MSE		0.0113	0.0056	0.0031	
Changes					
1990-1993	-0.45	-0.08	-0.25	-0.30	
1993-1995	-0.11	-0.29	-0.15	-0.17	

Based on Povey et al.'s model (Model (1)), we examine the effect of adding a linear time trend in the log-linear model as follows:

$$\ln(HEAD_i / LIMB_i) = \alpha + \beta(HELMET_i) + \gamma(TIME_i) + \varepsilon_i, \qquad (4)$$

where $TIME_i$ consists of the numbered consecutive time points in the series (TIME=1,2,…,7). We fit the above model using the only available data, namely adult cycling injuries not involving a motor vehicle, using the lm function in R (R Core Team, 2012). Results are reported in Table 2. Again, note that the results under "Povey (Model 3)" are what we estimated from estimating Model 3, instead of the ones taken from Povey et al. (1999).

We found a significant negative estimate of the variable TIME and the variable HELMET becomes highly insignificant in the presence of a linear time trend. The model including a time trend provides a much better fit to the data in terms of adjusted multiple R^2, estimated residual standard error and Akaike information criterion (AIC). Given this result, we are interested in knowing the relative performance of the model involving only the time trend. Hence we fit a third model to the data:

$$\ln(HEAD_i / LIMB_i) = \alpha + \delta(TIME_i) + \varepsilon_i, \quad (5)$$

Results are given in Table 2. Although the estimate of TIME does not change much from Model 4, a much smaller *p*-value is obtained, indicating that it is a highly significant variable in predicting the ratio of head to limb injuries for adult non-motor crashes.

Moreover, Model 5 provides a superior fit as compared to Model 4, in terms of multiple R^2, residual S.E. and AIC. Hence for this data set, adding the variable HELMET to a model which contains a TIME variable does not improve the fit of the model. The original data, with the fitted values under the three models are shown in Figure 2. It can be seen from the plot that the fitted values using Model 4 and Model 5 are almost indistinguishable and the addition of HELMET does not result in very different fitted values.

Table 2

Parameter estimates under three models

	Povey (Model 3)	Model 4	Model 5
Estimate of α	0.34 (0.07, 0.61)	0.37 (0.17, 0.50)	0.34 (0.22, 0.46)
p-value	0.0221	0.0046	0.0008
Estimate of β	-0.61 (-1.02, -0.20)	0.03 (-0.54, 0.60)	-
p-value	0.0123	0.8858	-
Estimate of γ	-	-0.09 (-0.17, -0.02)	-
p-value	-	0.0256	-
Estimate of δ	-	-	-0.09 (-0.12, -0.06)
p-value	-	-	0.0004
Adjusted R^2	0.6943	0.9046	0.9233
Residual S.E.	0.1122	0.0627	0.0562
AIC	-7.12	-14.83	-16.79

The problem with fitting a model with both HELMET and TIME is multi-collinearity: the predictor variables HELMET and TIME are highly correlated. We believe this is the case here because a multiple regression finds an insignificant estimated coefficient of HELMET and yet a simple linear regression on this variable shows the estimate is significantly different from zero. One of the consequences of multi-collinearity is that while controlling for other variables (for example TIME), the estimate of a variable (such as HELMET) tends to be less precise, hence its influence on the dependent variable cannot be as accurately estimated. An alternative method such as ridge regression can be used to cope with the problem of multi-collinearity. However, the major problem here is the lack of data to carry out accurate statistical inference: the degrees of freedom are 5, 4 and 5 for Models 3-5 respectively. In other words, these are the effective sample sizes or the amount of useful information we have for each model.

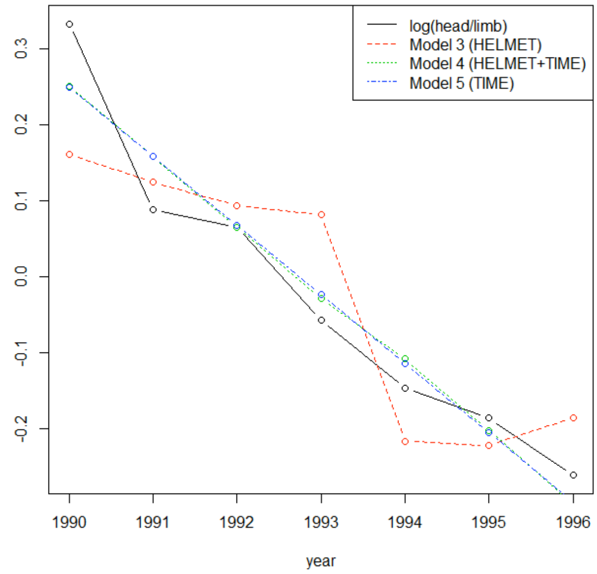

Figure 2
Plot of the log ratio of head to limb injuries and comparison of fitted values under three models

To check for residual independence and normality assumptions, we produced residual plots as well as normal quantile plots for each of the three models as shown in Figure 3. There seems to be some pattern in the residual plots for models 4 and 5, hence the residual independence assumption may not be satisfied in these cases. In fact, since many road safety data consist of sets of observations that are sequentially ordered over time, issues arise in the analysis of these data since they may not be independent. A general approach for dealing with this type of data is to employ specialised time series models such as ARIMA-type and state space models. However, the use of more dedicated time series is discouraged by lack of data in this case. For a discussion of appropriate time series analysis techniques used in road safety research, see Commandeur et al. (2012).

Generally speaking, we recommend the use of monthly data rather than yearly data when monthly data are available. This is because monthly data contain more information and are able to capture particular characteristics (such as seasonal patterns) than the yearly data where these effects are averaged out.

In terms of assessing the effect of cycle helmet wearing on hospitalised head injuries, this data set is limited. The data consists of adult non-motor vehicle injuries; hence certain proportion of this group may be crashes that occurred off-road including recreational cycling, whereas the cycling helmet law applies to all on-road cyclists in New Zealand. Therefore a more informative data set is perhaps the motor vehicle injury counts. Furthermore, it is important to distinguish time trends from the effects of explanatory variables, in this case, helmet wearing. However, how to properly account for time trends in a model remains an open question.

In fact, Robinson (2001) raised a concern regarding the analysis of Povey et al. (1999). However, the main issue is not so much about modifying the model structure, for example, adding an additional variable to model a linear time trend, but more about checking for model assumption, which both Povey et al. and Robinson have omitted. After checking the residual plots and test for serial correlation, it seems that the model assumptions for Model (4) are satisfied and hence the results and conclusions in Povey et al.'s analysis are valid. Nonetheless, we showed that a model with a linear time trend outperformed the one with helmet wearing rate as the explanatory variable. We also showed that including both time trend and helmet wearing rate in the model may cause a multi-collinearity problem since they are highly correlated.

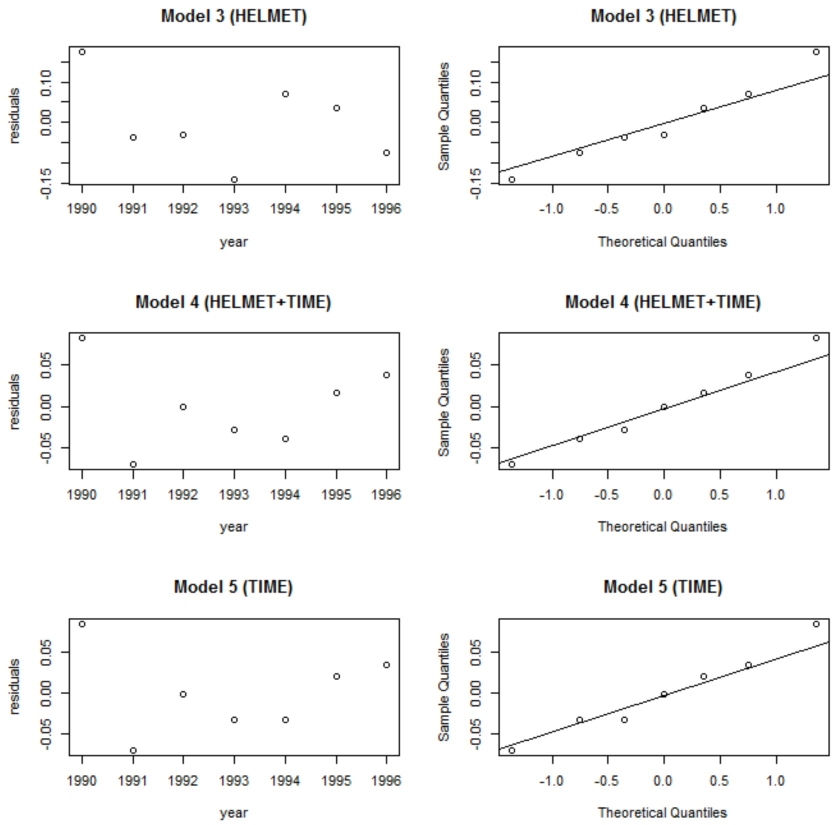

Figure 3

Residual plots and quantile plots for three models

Clarke (2012)

Clarke compared highly aggregated data from before and after the helmet law was introduced. He found that from 1989 to 1990 (four years before the helmet law) to 2003-2006 (13 years after the law), there was a 51% drop in the average number of hours cycled per person. He claimed that this significant drop was completely attributable to helmet law.

Firstly, observations on adjacent dates are more correlated than dates farther apart. That is, injuries and cycling rates near the introduction of the helmet law are more likely to be influenced by the law. However, no data are presented around the date of the helmet law in New Zealand and the conclusion that the 'helmet law discouraged cycling to a significant extent' is undermined by comparing data from time periods that are not near the mandatory helmet law date.

To analyse the effect of an intervention, it is important to effectively estimate the trend before and after the intervention in order to assess whether or not any observed decrease/increase around the time of the intervention is part of a longer downward/upward trend. Hence it is important to account for background trend and the estimation of trends cannot be achieved by simply comparing two points in time on either side of the law. In fact, previous studies have noted a decline in ridership back to 1986 for commuters (Tin Tin, 2009) which began long before the mandatory helmet law in 1994 and before the substantial increase in helmet wearing that began in 1990 (Povey et al., 1999). This downward trend is not in any form captured in Clarke's analysis.

Compared with the pre-law period 1988-1991, Clarke showed that cyclists had a 20% higher accident rate (adjusted for millions of hours spent travelling) by 2003-2007. Clarke then associates this increase in overall accident rate with the helmet use. Reasons provided include 'Safety in Numbers', risk compensation and balance and riding stability aspects. However, when we compare the pre-law data to a period that is more relevant to the mandatory helmet law, that is, 1996-1998, there are substantial drops in cyclist injuries overall (-17%) and serious injuries with an abbreviated injury score (AIS) greater than or equal to 3 (-53%) after adjusting for millions of hours spent travelling.

The article notes the ratio of cyclist and pedestrian fatalities is 0.24 for the five year period 1989-1993 pre-law. A comparison is then made with the four year period 2006-2009 (ratio: 0.27). Firstly the ratio should be 0.26 as the cyclists deaths were 39 instead of the 41 stated in the article. Hence increasing the totals to equate pre law levels of cycling (since the average hours cycling reduced by 51%), would give total of 80 and the ratio is 47% instead of the 49% calculated in the article. However when we choose a time period that is closer to the helmet law, say 1997-1998, the ratio of cyclist to pedestrian fatalities is 0.22 and after adjusting for changes to numbers of hours cycled and walked (average hours walked increased by 2% and cycling reduced by 40%), the ratio is 38%. Additionally, there is a 23% decline in cyclist fatalities in the immediate three years post-law (1994-1996) compared with the preceding three years pre-law (1991-1993) which is not discussed in the article. Clarke also fails to discuss that the change in the cyclist to pedestrian fatality ratio is influenced by changes in general regarding pedestrian and cyclist safety environment and not the helmet law or helmet wearing alone. The author does not address possible confounding factors and attributes all declines in cycling rates and increases in cycling fatalities/injuries to the helmet law. In the article Clarke sourced for bicycle injuries, Tin Tin et al. (2010) lists several reasons apart from the helmet law for declines in cycling rates and increases in injuries. These include the lack of a cycling focus in the New Zealand road safety agenda, an increase in children being driven to school due to parental concerns of safety and pre-law decline in cycling rates.

Hence choosing arbitrary time periods on either side of the law and drawing a conclusion that the higher accident rate is associated with helmet use based on computing ratios rather than statistical inference, may convey misleading information and ideas on the impact of policy interventions, for instance, the mandatory helmet law in New Zealand.

Furthermore, the helmet laws are enacted to increase helmet wearing in an attempt to mitigate bicycle related head injuries and do not offer injury protection to other body parts. However, the fatalities and injury counts presented in Clarke’s paper are for all bicycle related injuries and hence trends in head injuries/fatalities before and after the helmet law cannot be estimated using this data. The exposure data came from the Land Transport Safety Authority collected in the periods 1989-1990, 1997-1998 and 2003-2006 and the Ongoing New Zealand Household Survey was collected in 2006-2009. As a result, injury rates relative to the amount of cycling are only estimable during those years. This study shed no light on the cycling environment in a four year window around the mandatory helmet law.

In conclusion, due to weakness in the analysis and choice of data – particularly the four year absence of data around the time helmet laws were introduced, the conclusion that the mandatory helmet law halved the number of cyclists and contributed to 53 deaths each year is highly questionable if not misleading.

Scuffham and Langley (1997)

The authors examined the serious injury trends for three age groups of cyclists admitted to public hospitals between 1980 and 1992; twelve months before the introduction of helmet legislation. The injury data were grouped into corresponding six-month intervals centred around the month of the helmet survey, totalling a sample size of 26. A Poisson regression model is constructed for the number of injured cyclists with a head injury and the total number of cyclists admitted is used as the offset. Covariates included in the linear part of the regression model include admission policy variable, helmet wearing variable and time. The admission policy variable, defined as the number of head injured non-cyclists divided by the total number of injured non-cyclists, is used to account any possible changes in hospital admission policies for head and non-head injuries; helmet wearing is represented as a categorical variable indicating the helmet wearing period: no helmets (1980-1985), some helmet wearing (1986-mid 1989) and a lot of wearing helmets (mid 1989-1992). Time was a continuous variable representing any underlying time trend to capture any gradual change in risk of head injury.

The results indicated that there was no significant difference in the underlying downward trend between each age group and the only significant variable in the model is time. Also there was no significant difference in cyclists head injuries in the periods of ‘no helmets’ or ‘some helmets’ compared to ‘a lot of helmets’ when helmet wearing was high. Hence the authors concluded that the downward trend in head injuries was simply because of the underlying time trend and was independent of helmet wearing. This result is not surprising when looking at the percentage of head injuries in Figure 2 in Scuffham and Langley (1997). From Figure 2, we observe that the head injury percentages are declining gradually over time for all three age groups. Throughout the sample period, we do not observe any abrupt changes to the percentage of head injuries. Hence the changes in head injuries in this case, may well be explained by just a temporal trend. This is in clear contrast with the study conducted on hospital admission counts of cyclist head injuries from New South Wales, Australia (Walter et al., 2011), where there was an abrupt and significant reduction in head injury rates compared to arm injury rates immediately following the introduction of mandatory helmet legislation.

To examine the effect of the helmet law, the authors choose to model it as a continuous function of helmet wearing rather as a step function because helmet wearing proportion had been increasing steadily in the years leading up to the legislation due to the promotion of voluntary helmet use in New Zealand. On the other hand, the study by Walter et al. (2011)

used an indicator variable to represent the helmet legislation as the helmet wearing rate in New South Wales increased from approximately 20% to more than 60% among children and over 70% for adults within two months of the legislation coming into effect.

The problem with including both helmet wearing and time in the Scuffham and Langley (1997) regression model is again multi-collinearity. Removing the time trend for instance, may result in a significant estimate of the helmet wearing variable. The result of the Scuffham and Langley (1997) study showed that increasing helmet wearing pre-law in New Zealand has had little association with serious head injuries to cyclists, which is inconsistent with the results of some case control studies (Thompson et al. (1989), Thomas et al. (1994)). Scuffham and Langley (1997) also compared their results with a Victorian study (Cameron et al., 1994) who suggested that apart from helmet wearing rate, other factors such as major initiatives at drink/driving and speed reduction may also reduce the number of cyclists involved in crashes.

Scuffham et al. (2000)

This study used a similar model as the one in Scuffham and Langley (1997). However, a negative binomial was assumed for the dependent variable in place of the usual Poisson distribution. Independent variables include hospital admission variable and helmet wearing rate, whereas temporal trend was not included in the model.

The results indicated the helmet wearing rate variable was negative and significant, and that a 1% increase in the helmet wearing rate was associated with a reduction in overall head injuries by 0.43% for all age groups. The authors explained that the reason for not including a linear variable to account for observed trends is that the addition of a time-trend variable caused the helmet wearing proportion to become insignificant. That is, a time-trend variable 'swamped' the real effect. However, what is considered as 'real effect' is not so clear. If adding a linear time variable caused the helmet wearing variable to become insignificant, then perhaps much of the variation in the outcome series (i.e., the number of cyclists with head injury) can be modelled just by a linear temporal trend since the helmet wearing rate itself, can be modelled as a function of time. Hence, the separation of helmet wearing effect from the background temporal trend is the key issue.

As mentioned by Scuffham et al. (2000), there was a substantial seasonal pattern for cyclist head and non-head injuries as seen in Figure 2. However, this seasonal pattern was not explicitly modelled and neither covariates (helmet wearing rate and hospital admission policy variable) are able to take seasonality into account. One way to account for seasonality is to introduce dummy variables to capture seasonal fluctuations in the data series. However, to account for monthly variation for example, an extra 11 dummy variables needs to be added to the model and there must be sufficient data to make it reasonable in terms of degrees of freedom. Another way is to seasonally adjust the data using for example, the X11 method, prior to fitting a model, as was done in Bernat et al. (2004) and Walter et al. (2011).

Conclusion

In evaluations of mandatory helmet laws, researchers need to ensure that their conclusions are not based on statistically flawed analyses and arguments. As an example, based on peer-reviewed studies from several countries, Attewell et al. (2001) performed a formal meta-analysis and concluded that there is a statistically significant effect of bicycle helmets in preventing serious injury and even death. Elvik (2011), however, in a re-analysis of Attewell et al. (2001) reported inflated estimates of the effects of helmets due to their failure to control for publication bias and time trend bias. However, due to data and analytic errors, Elvik (*in press*) has published a full length corrigendum to this paper. Subsequently, Churches (2013) reported difficulty in reproducing Elvik's (*in press*) results and estimated a substantially larger benefit of helmet wearing, using the same data as Elvik. To non-specialists, they may not be aware of the statistical issues involved in reaching certain conclusions. In fact, many statistically flawed studies have been cited extensively in public debate over bicycle helmet laws (Olivier et al., *submitted*). These studies may have influenced how the media, public and policymakers perceive bicycle helmets and mandatory helmet laws.

The assessment of an intervention through the analysis of routinely collected observational data is non-trivial and requires careful model specification and statistical analysis. As shown in this study, failure to address important issues such as checking model assumptions, multi-collinearity between explanatory variables, etc., can result in misleading or incorrect conclusions.

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