COMPARISON OF THE LOGISTIC AND COX REGRESSION MODELS WHEN OUTCOME IS DETERMINED IN ALL PATIENTS AFTER A FIXED PERIOD OF TIME

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Abstract—This paper presents an evaluation of the logistic and Cox regression models for a prospective study when the outcome is binary and is determined in all patients after a fixed period of time. The similarities and differences between the regression coefficients and test statistics are given for the two-sample case. Extension of results to the multivariate case and under product binomial sampling are discussed. The results are illustrated using data from a clinical trial designed to evaluate the effect of a lipid lowering drug on progression of coronary artery disease.

Logistic model Cox model Odds ratio Relative risk Product binomial sampling Prospective study

INTRODUCTION

In some prospective studies the outcome is binary and is evaluated in all patients at a single fixed time after entry. As an example, consider a study designed to evaluate the effect of a lipid lowering drug vs placebo on progression of coronary artery disease over 5 years. Patients undergo coronary angiography at two points in time: at entry and at 5 years. Progression of coronary artery disease is measured by the angiographic changes between the two evaluations. Since it is unethical to subject patients to frequent coronary angiography in order to follow the course of progression, actual time to progression is not observed.

In this type of prospective study, the aim is to estimate the risk of having the event both in the absence and presence of a factor such as treatment. The usual method of analysis for data of this kind uses the linear logistic model which gives estimates of the odds ratio and permits adjustment for relevant covariates. Alternatively, the model traditionally used when the response is time to an event is the Cox proportional hazards model. This model can be adapted for use when the outcome is determined after a fixed period of time. One approach is to use standard computer programs for fitting the Cox model and simply assume the follow-up times are identical for all subjects. Such an approach differs from the linear logistic approach both in terms of the distributional assumptions and also in terms of the functional relationship with the covariates.

Three measures of risk are discussed in this report: odds ratio, relative risk and hazard ratio. The first measure is generated by the logistic model and the latter two measures by the proportional hazards model. For a binary outcome (no event vs event) and two treatment groups (control vs treated), the odds ratio is defined as the odds of having the event in the treated group relative to the odds in the control group. The relative risk is the ratio of the probability of

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having the event in the treated group relative to the probability in the control group. The hazard ratio is the instantaneous event rate in the treated group relative to that of the control group.

In this paper we compare the parameter estimates and associated test statistics of the logistic and Cox models when all patients are followed for the same period of time. This analysis evaluates the effect of using different models and of making different distributional assumptions for the outcome variable. The findings are illustrated with data from a clinical trial designed to assess the effect of a lipid lowering drug (cholestyramine) on progression of coronary artery disease in patients with Type II hyperlipidemia and proven coronary disease.

This report is also a note to users of regression models for the analysis of data from prospective epidemiologic studies. Such data as generated, for example from the Framingham Study, provide the unique opportunity to estimate the risk of an event and also the relative risk when the interest lies in the association of the risk with the presence or absence of certain risk factors. The odds ratio statistic was described by Cornfield as an approximation to the relative risk, especially when the outcome event is rare. This statistic could be obtained for retrospective studies, even without knowledge of what the dimensions of the absolute risk may be. With the current software orientation for data analysis in prospective epidemiologic studies, the selection of a measure of association is often no longer guided by epidemiologic principles, but rather by how the outcome is measured. When the outcome of such a study is binary, whether the design is prospective or retrospective, the logistic model is often selected. When not only the occurrence of an event but also the time to event is known, the proportional hazards model is often employed. It is important that the user of these statistical techniques understand the epidemiological interpretation of the estimates obtained so that the correct inferences can be drawn.

REGRESSION MODELS

The type of study under consideration is one in which all subjects are observed for a fixed time interval (0, T). At the end of this period, a binary outcome, indicating the disease status, is known for all patients. In a study with two treatment groups, the probability that the event

Table 1. Notation for the two-sample case

Treatment group	Outco		
	No event	Event	Total
Control 0	$R_0 - m_0$	m_0	R_0
Treated 1	$R_1 - m_1$	m_1	R_1°
Total	R-m	m	R

occurs can be represented by p_0 and p_1 for the control and treated groups, respectively. The results from such a study can be displayed on a 2×2 table as shown in Table 1.

For the linear logistic model,

$$p_0 = \exp(\alpha)[1 + \exp(\alpha)]^{-1}$$

and

$$p_1 = \exp(\alpha + \beta)[1 + \exp(\alpha + \beta)]^{-1}$$

where α is the intercept parameter and β the regression coefficient for the dummy treatment variable. It is well known that the maximum likelihood estimate (MLE) of the regression coefficient β is the logarithm of the odds ratio [1-3], or in our notation

$$\hat{\beta} = \ln[m_1(R_0 - m_0)/m_0(R_1 - m_1)] \tag{1}$$

with the asymptotic variance estimated by

$$Var(\hat{\beta}) = m_0^{-1} + m_1^{-1} + (R_1 - m_1)^{-1} + (R_0 - m_0)^{-1}$$
 (2)

For the proportional hazards model of Cox [4], the hazard for an untreated individual (control) at time t is $\lambda_0(t)$ and for a treated individual is $\lambda_0(t) \exp(\beta^*)$, where β^* is to be estimated from the data. For discrete data, Prentice and Gloeckler [5] derived the "grouped data" version of the proportional hazards model. Following their development, the probability of an event in the interval for an untreated individual is given by $p_0 = 1 - \alpha^*$ and for a treated individual by $p_1 = 1 - \alpha^* \exp(\beta^*)$ where $\alpha^* = \exp[-\int_0^T \lambda_0(t) \, dt]$. The MLE of β^* obtained by solving the likelihood function given in reference [5] for one interval is

$$\hat{\beta}^* = \ln[\ln(1 - m_1/R_1)/\ln(1 - m_0/R_0)]$$
 (3)

and the asymptotic variance can be estimated by

$$V\hat{a}r(\hat{\beta}^*) = \exp(-2\hat{\gamma})[m_0(R_0 - m_0)^{-1}R_0^{-1} + m_1(R_1 - m_1)^{-1}R_1^{-1}\exp(-2\hat{\beta}^*)]$$
 (4)

where $\hat{\gamma} = \ln(-\ln \hat{\alpha}^*) = \ln[-\ln(1 - m_0/R_0)]$. The parameter estimate, $\hat{\beta}^*$, is the log of the hazard ratio, i.e. the log of the ratio of the

hazard among those in the treated relative to the control group.

An alternative estimate which might be used for discrete data arises from a proposal by Breslow [6]. While this approach was not specifically recommended by Breslow, this estimate is obtained if standard computer programs [7, 8] for fitting the Cox model are used and the length of follow-up is allowed to be identical for all individuals. In this case the hazard for the controls and the cases still has the form given by the Cox model, but the estimate of the parameter β^* obtained by maximizing the "likelihood function" is

$$\tilde{\beta}^* = \ln(m_1 R_0 / m_0 R_1) \tag{5}$$

and the estimate of the asymptotic variance is

$$V\tilde{a}r(\tilde{\beta}^*) = m_1^{-1} + m_0^{-1} \tag{6}$$

Thus, the estimate of the log of the hazard ratio, $\tilde{\beta}^*$, is exactly equal to the log of the relative risk, i.e. $\log(p_1/p_0)$ or the log of the ratio of the event rates in the treated relative to the control group.

COMPARISON OF PARAMETER ESTIMATES

The relation between the linear logistic and Cox model parameter estimates given by equations (1) and (3) is displayed in Table 2. The percent difference between the logistic parameter relative to the proportional hazards parameter is presented for a range of proportions for the event in the control (p_0) and treated (p_1) groups when $p_0 < p_1$. Since maximum likelihood estimators are consistent, the

Table 2. Percent difference between the logistic parameter relative to the Prentice-Gloeckler parameter $[100 \times (\hat{\beta} - \hat{\beta}^*)/\hat{\beta}^*]$

25 30
25 30
16.9
18.8 20.9
20.7 23.0
22.8 25.2
24.9 27.5
29.8 32.8
35.9 39.3
44.3 48.2
58.5 63.2

 $[\]dagger p_0$ = percent with event in control group. p_1 = percent with event in treated group.

percent relative differences can be interpreted as the percent relative bias. The agreement between the two estimates depends on p_0 and to some extent on the ratio p_1/p_0 . When p_0 is small (<10%), the percent difference is <10% for a wide range of p_1/p_0 ratios. For $p_0 = 10\%$, the percent difference is <10% only when p_1/p_0 is <3. In contrast, when the proportion with the event in the control group is $\geq 15\%$, the logistic estimate is always more than 10% greater than the proportional hazards estimate unless p_1/p_0 is near 1.

It should be noted that when actual time to the event is recorded, the logistic regression coefficient will approximate that of the Cox model only when the follow-up time is short and the event is rare [9]. With extended follow-up the odds ratio is a poor estimate of the hazard ratio.

Similarly, it can be shown that the log relative risk, equation (5), is an inconsistent estimator of the log hazard ratio, equation (3). For $p_0 < p_1$, the logarithm of the relative risk will be smaller than the logarithm of the hazard ratio, but the estimates converge as the event rate decreases (Table 3).

The relation between the odds ratio and the relative risk was examined by Cornfield [10]. He noted that the odds ratio is a good approximation to the relative risk only when the event is rare. While all three of these measures of association are in good agreement for rare events, the linear logistic parameter is the largest in absolute magnitude, followed by the log hazard ratio and then the log relative risk.

Table 3. Percent difference between the Breslow parameter relative to the Prentice-Gloeckler parameter $[100 \times (\beta^* - \beta^*)/\beta^*]$

		p_0 †						
p_1^{\dagger}	1	5	10	15	20	25	30	
5	-1.3						-	
10	-2.0	-3.7						
15	-2.7	-4.7	-6.4					
20	-3.4	-5.7	- 7.6	9.3				
25	-4.0	-6.7	-8.8	-10.5	-12.2			
30	-4.7	-7.6	-9.9	-11.8	-13.5	-15.2		
35	5.4	-8.6	-11.0	-13.1	-14.9	-16.7	-18.3	
40	-6.1	-9.5	-12.2	-14.4	-16.3	-18.1	-19.9	
45	-6.8	-10.5	-13.4	-15.7	-17.7	19.6	-21.5	
50	,				-19.2			
60					-22.2			
70					-25.7			
80		-,			-29.8			
90	-17.2	-24.0	-28.8	-32.4	-35.6	- 38.4	-41.1	

 $[\]dagger p_0$ = percent with event in control group. p_1 = percent with event in treated group.

DISTRIBUTION ASSUMPTIONS

The logistic and Prentice-Gloeckler models assume an underlying binomial distribution. Although the parameter estimates will become more discrepant as the probability of an event in the study interval increases, the score and the likelihood ratio statistics for testing the null hypothesis that the regression coefficient equals zero are identical [5, 11]. The score statistic in this case is equivalent to the one degree of freedom Pearson chi-square statistic (without correction for continuity) for a 2×2 table and the likelihood ratio statistic is represented by G^2 [12]. The Wald statistics, $\beta^2/\text{Var}(\beta)$, will necessarily differ since the parameter and variance estimates are not identical. In general, all three test statistics are asymptotically equivalent under the null hypothesis [13]. For the logistic model it has been shown that the value of the Wald statistic under the alternative hypothesis approaches zero as the parameter estimate (log odds ratio) increases, while the likelihood ratio statistic is monotone increasing. Under these conditions the Wald statistic is not asymptotically equivalent to the likelihood ratio statistic [14].

Breslow's [6] development of the Cox model assumes an underlying exponential distribution between uncensored follow-up times. If one substitutes a fixed time period for all individuals, it can be shown that the ratio of the resulting score statistic relative to the Pearson chi-square equals 1 - m/R. Thus, this statistic gives a conservative test of the null hypothesis, which can be important if m/R is large. Similar results apply for comparisons among the likelihood ratio and Wald statistics. However, if the variance of the log relative risk is derived assuming an underlying binomial distribution, then the estimate is

$$(1 - m_0/R_0) m_0^{-1} + (1 - m_1/R_1) m_1^{-1}$$
 (7)

and the resulting Wald statistic will be similar in value to those of the other two models. Thus, the variance obtained by manipulating the "Breslow [6] likelihood", equation (6), will be larger than that under the binomial model. However, the variance estimates are very similar when the proportion with events in each treatment group, m_i/R_i , is small.

EXTENSION TO MULTIVARIATE CASE

One can extend these equivalence results to the multivariate case for rare events. To show this we let X be a vector of q covariates and p(X)

be the probability of an event in a fixed time period given X. Then for the linear logistic model

$$p(\mathbf{X}) = \exp(\alpha + \mathbf{X}\boldsymbol{\beta}) [1 + \exp(\alpha + \mathbf{X}\boldsymbol{\beta})]^{-1}.$$
 (8)

For the proportional hazards model,

$$p(\mathbf{X}) = 1 - \exp\left[-\exp(\mathbf{X}\boldsymbol{\beta}^*) \int_0^{\mathsf{T}} \lambda_0(t) dt\right]$$
$$= 1 - \exp\left[-\exp\left(\alpha^* + \mathbf{X}\boldsymbol{\beta}^*\right)\right] \quad (9)$$

where $\alpha^* = \log (\int_0^T \lambda_0(t) dt)$. Finally, for the linear log relative risk model

$$p(\mathbf{X}) = \exp\left(\alpha^{**} + \mathbf{X}\boldsymbol{\beta}^{**}\right). \tag{10}$$

If one lets $A = \alpha + X\beta$ and expands equation (8), then

$$p(\mathbf{X}) = \exp(A) - \exp(A)^2 + \exp(A)^3 - + \dots$$

\(\preceq \exp(A)\) when \(p(\mathbf{X})\) small (i.e. \(\exp(A)\) small).

Expanding equation (9) using an exponential series and letting $A^* = \alpha^* + X\beta^*$, one obtains

$$p(X) = 1 - [1 - \exp(A^*) + \frac{1}{2!} \exp(A^*)^2 - + \dots]$$

$$\cong \exp(A^*) \text{ when } p(X) \text{ small.}$$

Thus, both the logistic and proportional hazards models are approximately the same as the linear log relative risk model (10) when the event is rare, so that the parameters are approximately the same.

EXAMPLE

Data from the NHLBI Type II coronary intervention study [15, 16] are used to illustrate the comparisons among the models. Briefly, this study was designed to evaluate the effect of a lipid lowering drug (cholestyramine) compared to placebo on progression of coronary artery disease. Patients were subjected to coronary angiography at entry and at 5 years. Progression of disease was determined by three panels of three expert readers who read the film pairs side by side without any knowledge of treatment assignment. Each patient was classified as having progression of disease or no progression.

One hundred forty-three patients were randomized (71 placebo, 72 cholestyramine) and of these 116 had both a baseline and 5-year angiogram, 12 died, 10 withdrew and 5 refused the second angiogram. The 27 patients without a second angiogram were excluded from analysis because progression could not be determined. The entry characteristics of the 27 excluded

Table 4. Distribution of patients by progression and treatment for Type II intervention study

	~ .	•			
Treatment	No progression	Progression	Total		
Placebo	29	28	57		
Cholestyramine	40	19	59		
Total	69	47	116		

patients were not significantly different (p <0.05) from those of the 116 analyzed patients. However, for the patients with paired films there were significant differences between the placebo and cholestyramine groups for four baseline variables: alcohol consumption (>10 drinks/ week), abnormal regional contractile function (presence of focal akinesis, hypokinesis or dyskinesis), systolic blood pressure (mmHg) and postdiet triglycerides (mg/100 ml). Alcohol consumption was more prevalent in placebo patients, while abnormal regional contractile function, high systolic blood pressure and elevated triglyceride levels were more prevalent in cholestyramine patients. Abnormal contractile function and high systolic blood pressure were associated with progression. Table 4 displays the endpoint data by treatment and Table 5 shows the results of this analysis. Table 6 presents the analysis of treatment adjusted for the baseline imbalances.

Since the rate of progression is high, 41%, the parameter estimate of the unadjusted treatment effect differs for the logistic (-0.709) and Prentice-Gloeckler (-0.554) models (Table 5). However, the values of the score and of the likelihood ratio statistics are identical for the two models and both indicate a marginally significant (p = 0.06) treatment effect, i.e. the rate of progression is lower with cholestyramine compared to placebo. In contrast, the parameter estimate for the Breslow model is higher (-0.422). As expected, the score and likelihood ratio statistics are about 41% lower than that of the other two models giving a more conservative test of the null hypothesis (p = 0.15). The esti-

Table 5. Summary of analyses of Type II intervention study data shown in Table 4

Statistic	Logistic	Prentice- Gloeckler	Breslow	
β†	-0.709	-0.544	-0.422	
Var (β)	0.148	0.090	0.088	
Risk* (e^{β})	0.492	0.580	0.656	
Wald	3.396	3.288	2.024	
Score	3,444	3.444	2.048	
Likelihood Ratio	3.461	3.461	2.058	

^{*}Risk equals odds ratio for logistic model, hazard ratio for Prentice-Gloeckler model and relative risk for Breslow model.

mate of variance for the log relative risk assuming a binomial model (not shown) is lower than that of the Breslow model, 0.054 vs 0.088, and the resulting Wald statistic, 3.298, is similar to that of the logistic and Prentice-Gloeckler models.

Adjustment for systolic blood pressure, triglycerides, alcohol consumption and abnormal regional contractile function reduced the parameter estimate and increased the Wald statistic of the treatment effect for all three models (Table 6). After adjustment, progression was significantly lower with cholestyramine compared with placebo according to the logistic (p = 0.015) and Prentice-Gloeckler (p = 0.009)analyses. In contrast, the treatment effect was marginally significant by the Breslow model (p = 0.066), however it was significant (p =0.005) for the log relative risk model assuming an underlying binomial distribution. The multivariate analysis comparisons among these models are consistent with those of the twosample comparisons shown in Table 5.

DISCUSSION

In this paper we compared the logistic and Cox regression models applied to a prospective study when all patients were evaluated after being followed for the same fixed period of time. Two versions of the Cox model were examined,

Table 6. Summary of multivariate analyses of Type II intervention study data

	Log	Logistic		ntice-Gloeckler Breslow		slow
Variable	β†	Wald statistic	β†	Wald statistic	β†	Wald statistic
Treatment	-1.110	5.874	-0.895	6.769	-0.605	3.389
Systolic blood pressure	0.033	3.385	0.025	3.712	0.017	1.800
Triglycerides (mg/100 ml)	-0.004	1.223	-0.003	0.981	~0.002	1.567
Alcohol (>10 drinks/week)	0.058	0.017	0.027	0.007	0.002	< 0.001
Abnormal regional contractile function	1.188	6.025	0.862	6.482	0.601	3.561

 $[\]dagger \beta = \text{regression coefficient}.$

 $[\]dagger \beta$ = regression coefficient for treatment.

one which explicitly allows for the fixed time period and one which does not. For the two sample case, the estimates of the risk of having the event in the treated relative to the control groups for the logistic and Prentice-Gloeckler models were similar only when the event was rare, i.e. <5%. As the event rate increased, the two estimates became more discrepant. However, the score and the likelihood ratio statistics for testing the null hypothesis of no treatment effect are identical for both models, regardless of the event rate. The test statistics will generally not be identical when covariate adjustment is applied, since the parameter estimates will differ.

In contrast, using standard computer programs based on the Breslow version of the Cox model when the follow-up times are identical for all subjects gives an estimate of the treatment effect which is inconsistent for the proportional hazards parameter and the corresponding significance test is conservative. The results are expected to be different, since this approach unrealistically assumes an underlying exponential distribution while the Prentice-Gloeckler version of the Cox model (and the logistic) assumes a binomial model. However, the resulting parameter estimate is the logarithm of the relative risk for a 2×2 table and the model is a good approximation to the grouped data version of the proportional hazards model and the linear logistic model when the event is rare. The multivariate findings were also similar.

The logistic and proportional hazards models are appropriate for a binary endpoint provided that the assumptions hold and the models fit the data. Goodness of fit can be assessed by comparing the current model with a more complex model having additional parameters that represent particular types of departures from the current model. The likelihood ratio statistic can be used to test whether the additional regression parameters are equal to zero. For discrete variables, the current model is compared with the full or saturated model which includes all the interaction terms. Other methods of assessing fit for binary outcome data are discussed by Schlesselman [1] and Cox [3].

Since a binary outcome is considered, the product binomial sampling distribution is appropriate. Under this type of sampling, the parameter estimates and test statistics for the logistic and Prentice-Gloeckler probability models are easily generated. The same parameter estimate as the Breslow likelihood can also be obtained for the two-sample case assuming

a linear log relative risk probability model, equation (10). In this case, the correct variance will be generated and the score and likelihood ratio statistics will be the same as those of the logistic and Prentice-Gloeckler representations. Again for multiple covariates, the test statistics will not be identical among these models. The product binomial can be fitted under all three probability models using GLIM [17]. In this program, the Prentice-Gloeckler probability model is referred to as the complementary loglog model. In GLIM, the scaled deviance is used as a measure of goodness of fit and is similar to a likelihood ratio statistic in that the current model is compared with the full model. For the multivariate example given in Table 6, there was no strong evidence of lack of fit for all three probability models.

For the cholestyramine example, a reviewer pointed out a problem with the method for handling early dropouts (e.g. therapy related) and patients without a second angiogram. This problem is not unique to this study and probably has no satisfactory solution, except to ensure that bias is not introduced in the analysis. This was the approach used by the investigators of the Type II study [16]. Since patients without a second angiogram could not be included in an analysis of progression, they compared the entry characteristics of these patients with those who had a determination and concluded that patients with a repeat angiogram were representative of the entire study population. They also compared the entry characteristics of the placebo and cholestyramine patients included in the analysis. Since there were significant differences for some entry characteristics, the treatment comparisons were adjusted to account for the imbalances.

In summary, from the epidemiological viewpoint the proper measure of association in a prospective study is the relative risk. For a study with identical follow-up times, the Breslow model will yield the estimate of relative risk for a 2×2 table. However, the corresponding test statistics will be conservative compared with those of the grouped data version of the proportional hazards model. This result is expected, since it is well known for the continuous case that Breslow's modification of the Cox model gives results equivalent to those of Cox when failure times are unique and produces biased results when the number of individuals who fail at each time point is large relative to the number at risk [18]. Nevertheless, it is the Breslow model that provides an alternative method of analyzing grouped data, when the GLIM is not available, and in this case the estimate of risk has the exact interpretation of relative risk, i.e. the ratio of two event rates. In contrast, although the odds ratio is only an approximation of the relative risk, the logistic model which estimates the odds ratio yields test statistics equivalent to those of the grouped data version of the proportional hazards model, regardless of the frequency of the event. These comparisons extend to multivariate data.

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