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INFERENCE FOR THE MIXED DISCRETE AND CONTINUOUS COX REGRESSION MODEL VIA EMPIRICAL LIKELIHOOD

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Abstract

Cox's proportional hazards model has so far been the most popular model for the regression analysis of censored survival data. By retaining the multiplicative hazard rate form of the absolutely continuous model the Cox regression model has also been extended to mixed discrete-continuous Cox regression model.

In this paper we apply empirical likelihood ratio method to the mixed discrete and continuous Cox regression model with right-censoring and derive its limiting distribution. Based on the result we construct a confidence region for the regression parameter. Simulation studies are conducted to evaluate the performance of the proposed empirical likelihood method under different circumstances.

1. Introduction

Emerged in the twentieth century, survival analysis has received a lot of research attention and experienced tremendous growth in medical studies. We are particularly interested in the regression model for the survival rate incorporating information from the covariates. Several models have been introduced to allow us to quantify the relationship

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between the failure time and a set of explanatory variables. In survival analysis, Cox [6] model has been considered as a major tool for regression analysis of survival data, often called the *proportional hazards model*. Let $\lambda(t \mid Z)$ denote the hazard function for the life time T under covariate $Z(t)$. The hazard function for the failure time T associated with a p-vector of possibly time-varying covariates $Z(\cdot)$ takes the form

$$\lambda(t \mid Z) = \lambda_0(t) \exp(\beta_0^T Z(t)), \tag{1.1}$$

under the Cox [6, 7] model, where $Z(t)$ is a p-vector of possibly time-varying covariates, β_0 is a true p-vector of regression parameters, and $\lambda_0(t)$ is an unspecified baseline hazard function. Under this model, the covariates $Z(\cdot)$ have multiplicative effects on the hazard function, and the regression parameters are interpreted as the logarithms of the hazard ratios or relative risks. Cox [6, 7] introduced a semiparametric approach to inference based on the proportional hazards model (1.1). The valuable model for the analysis of survival data seems simple and easy to interpret for medical researchers and the Cox regression models in various forms have been successfully applied in biostatistical research and clinical trial studies.

However, the proportional hazards assumption may not be appropriate for some data analyses. In medical studies, the failure times can be either continuous or discrete. Many researchers have extended the model (1.1) to accommodate discrete failure time. Prentice and Kalbfleisch [21] have proposed a new model which included discrete and continuous failure time data by defining the cumulative hazard function instead of hazard function. The mixed discrete and continuous model is given as

$$\Lambda\{dt \mid Z\} = \Lambda_0(dt) \exp(\beta_0^T Z(t)), \tag{1.2}$$

where $\Lambda_0(dt) = \Lambda_0(t) - \Lambda_0(t-)$ if t is a mass point of the failure distribution, while $\Lambda_0(dt) = \{d\Lambda_0(t)/dt\}dt = \lambda_0(t)dt$ at a continuity point of the failure distribution. The regression parameter in (1.2) retains a natural and useful relative risk interpretation, even if the failure time distribution includes discrete elements. The discrete hazard $\Lambda_0(dt)$ at any mass point of the failure distribution must be equal to or less than one.

Empirical likelihood method is a powerful nonparametric method. It holds some unique features, such as range respecting, transformation-preserving, asymmetric confidence interval, and Bartlett correctability. The use of empirical likelihood (EL) in survival analysis traces back to Thomas and Grunkemeier [26] who derived pointwise confidence intervals for survival function with right censored data (see also Li [11] and Murphy [15]). For right-censoring data, this approach has been used in the construction of simultaneous confidence band under a variety of setting, see Hollander et al. [9], Einmahl and McKeague [8], Li and Van Keilegom [12], and McKeague and Zhao [14], among others.

Owen [16, 17] introduced empirical likelihood confidence regions for the mean of a random vector based on i.i.d. complete data. Since, the empirical likelihood has been widely applied to do inference for the parameter of interest. For instance, Owen [18] and Chen [3, 4] derived empirical likelihood inference procedures for linear model. Qin and Lawless [24] applied it to a general estimating equation. Adimari [1] extended it to smooth functions of *M*-functionals. Wang and Rao [29, 30] extended it to linear model for missing data. Kolaczyk [10] and Chen and Cui [5] considered empirical likelihood for generalized linear models based on constraints derived from the score function of the quasi-likelihood. Partial linear regression model was investigated by Wang and Jing [27] and Shi and Lau [25]. Cox proportional hazard model was studied by Qin and Jing [22]. Qin and Jing [23] and Li and Wang [13] developed empirical likelihood methods for regression coefficients in the linear regression model with right censored data. Under right censoring, Adimari [2] derived confidence interval for a class of *M*-functional (e.g., mean, quantile), and Wang and Jing [28] developed an adjusted empirical likelihood confidence interval for a functional of survival function. Pan and Zhou [20] studied the empirical likelihood ratios for parameters which are linear functionals of the cumulative hazard functions based on a Poisson extension of the likelihood. More recently, Wang and Rao [30] constructed empirical likelihood confidence interval for the mean under missing response data.

However, to the best of our knowledge the inference for the parameter under mixed discrete and continuous Cox regression model has not been developed yet via empirical likelihood. In the present paper, we propose an empirical likelihood approach for the model (1.2). Based on the idea of empirical likelihood (cf. Owen [16, 17]) estimating equation concerning with regression parameter is essential. We focus on model (1.2), make full use of the estimating function of Prentice and Kalbfleisch [21], and find one tractable likelihood-ratio based confidence region for the unknown regression parameter. Our approach does not require to estimate the limiting covariance matrices; instead one carries out a constrained maximization of the empirical likelihood, which can be done reliably by Newton-Raphson method. Moreover, the EL confidence region is adapted to the data set. The proposed confidence region and main asymptotic result are presented in Section 2. In Section 3, we conduct simulation to investigate the performance of the empirical likelihood method in terms of coverage probability. Proof is given in the Appendix.

2. Main Results

2.1. Preliminaries

Consider model (1.2). Under it, we define the cumulative intensity process

$$\Lambda_i(t) = \int_0^t Y_i(s) \exp\{\beta_0^T Z_i(s)\} \Lambda_0(ds). \tag{2.1}$$

Let T denote the failure time and C denote the censoring time. Assume T and C are conditionally independent given covariate $Z(t)$. Suppose that data consist of n independent samples of (X_i, δ_i, Z_i), where $X_i = \min(T_i, C_i)$, $\delta_i = I(X_i \leq C_i)$. Let $N_i(t) = \delta_i I(X_i \leq t)$ $(i = 1, \ldots, n)$ be a counting process for the i-th subject, which indicates that the failure time of the i-th subject is observed up to time t. Let $Y_i(t) = I(X_i \geq t)$ denote the predictable indicator process indicating whether or not the i-th subject is at risk just before time t. Let τ satisfy $P(X_i > \tau) > 0$. Prentice and Kalbfleisch [21] proposed the following estimating function:

$$U(\beta) = \sum_{i=1}^{n} \int_0^\tau \{Y_i(t) Z_i(t) - \overline{Z}(t)\} N_i(dt), \tag{2.2}$$

where

$$\overline{Z}(t) = \frac{\sum_{j=1}^{n} Y_j(t) Z_j(t) \exp\{\beta^T Z_j(t)\}}{\sum_{j=1}^{n} Y_j(t) \exp\{\beta^T Z_j(t)\}}.$$

The regression coefficients are estimated by solving the equation $U(\hat{\beta}) = 0$. The resulting estimator $\hat{\beta}$ is obtained by Newton-Raphson algorithm.

Under model (1.2), the counting process $N_i(t)$ can be uniquely decomposed so that for every i and t,

$$N_i(t) = M_i(t) + \Lambda_i(t), \tag{2.3}$$

where $M_i(t)$ is a square integrable martingale.

It follows that from (2.2) and (2.3),

$$U(\beta_0) = \sum_{i=1}^{n} \int_0^{\tau} \{Y_i(t) Z_i(t) - \overline{Z}(t)\} dM_i(t), \tag{2.4}$$

which is a martingale.

2.2. EL confidence region

Now consider empirical likelihood approach. It is clear that $EU(\beta_0) = 0$ from the estimating equation (2.4). For $1 \leq i \leq n$, we define

$$W_{n,i} = \int_0^{\tau} \left(Z_i(t) - \frac{\hat{\alpha}_1(t)}{\hat{\alpha}_0(t)} \right) dM_i(t),$$

where $\hat{\alpha}_r(t) = n^{-1} \sum_i Z_i^{\otimes r} Y_i(t) \exp\{\beta_0^T Z_j(t)\}$ with $a^{\otimes 0} = 1$, $a^{\otimes 1} = a$. Therefore, an empirical likelihood at the true value β_0 is given by

$$L(\beta_0) = \sup\left\{ \prod_{i=1}^{n} p_i : \sum p_i = 1,\ p_i \geq 0,\ \sum_{i=1}^{n} p_i W_{n,i} = 0 \right\},$$

by standard empirical likelihood (cf. Owen [16, 17]). Let $p = (p_1, \ldots, p_n)$ be a probability vector, i.e., $\sum_{i=1}^{n} p_i = 1$ and $p_i \geq 0$ for $1 \leq i \leq n$. Note that $\prod_{i=1}^{n} p_i$ attains its maximum at $p_i = 1/n$. Thus, empirical likelihood ratio at the β_0 is defined by

$$R(\beta_0) = \sup\left\{\prod_{i=1}^{n} np_i : \sum p_i = 1,\ p_i \geq 0,\ \sum_{i=1}^{n} p_i W_{n,i} = 0\right\}.$$

By using Lagrange multipliers, we know that $R(\beta_0)$ is maximized when

$$p_i = \frac{1}{n}\{1 + \lambda^T W_{n,i}\}^{-1}, \quad i = 1, \ldots, n,$$

where $\lambda = (\lambda_1, \ldots, \lambda_p)^T$ satisfies the equation

$$\frac{1}{n}\sum_{i=1}^{n} \frac{W_{n,i}}{1 + \lambda^T W_{n,i}} = 0. \tag{2.5}$$

The value of λ may be found by numerical search (e.g., Newton-Raphson method), see the discussion in Chapter 12 of Owen [19]. Thus combining above equalities, we have

$$-2\log R(\beta_0) = -2\log \prod_{i=1}^{n}(np_i) = 2\sum_{i=1}^{n} \log\{1 + \lambda^T W_{n,i}\},$$

where λ satisfies equation (2.5).

Let $s^{(j,k)}(t, \beta) = EZ_1^{\otimes j} Y_1(t) \exp\{k\beta^T Z_1(t)\}$ with $a^{\otimes 0} = 1$, $a^{\otimes 1} = a$, and $a^{\otimes 2} = aa^T$ for $j = 0, 1, 2$ and $k = 1, 2$. Also, we define the matrices

$$A = \int_0^{\tau} c_1(u, \beta_0) s^{(0,1)}(u, \beta_0) \Lambda_0(du),$$

and

$$\Gamma = A - \int_0^{\tau} c_2(u, \beta_0) s^{(0,1)}(u, \beta_0)^2 \Lambda_0(\Delta u) \Lambda_0(du),$$

where $e = s^{(1,1)}/s^{(0,1)}$, $c_1 = s^{(2,1)}/s^{(0,1)} - ee^T$ and $c_2 = \{s^{(2,2)} - s^{(1,2)}e^T - e(s^{(1,2)})^T + ee^T s^{(0,2)}\}\{s^{(0,1)}\}^{-2}$.

Assume Γ is positive definite. Suppose that $\lambda_0(t)$ is continuous. We assume that covariate vector Z_i is time-invariant and bounded. Now, we state our main result and explain how it can be used to construct confidence region for β.

Theorem 2.1. *Under above conditions, we have*

$$-2 \log R(\beta_0) \xrightarrow{\mathcal{D}} \chi_p^2,$$

where χ_p^2 *is the chi-square distribution with degrees of freedom* p.

Under the conditions of Theorem 2.1 an asymptotic $100(1-\alpha)\%$ confidence region for β is given by

$$\mathcal{R} = \{\beta : -2 \log R(\beta) \leq \chi_p^2(\alpha)\}, \tag{2.6}$$

where $\chi_p^2(\alpha)$ is the upper α-quantile of the distribution of χ_p^2.

3. Simulation Study

In this section we investigate the performance of the proposed empirical likelihood (EL) confidence interval in terms of coverage probability.

Consider one simple mixed discrete and continuous Cox regression model with true regression parameter β_0. The model is

$$\Lambda\{dt \mid Z\} = \Lambda_0(dt) \exp\{\beta_0 Z\},$$

where Z's are drawn from Bernoulli variable with $P(Z = 0.5) = P(Z = -0.5) = 0.5$. Let β_0 be 0 and 0.693, respectively.

To simulate failure time T_i, we assume that baseline cumulative hazard function $\Lambda_0(dt)$ is 0.1 at integer values $t = 1, 2, \ldots$ and $\Lambda_0(dt) = 0$ otherwise. Censoring variable C's are from the exponential distribution with parameter λ, where λ is chosen to obtain a desired censoring rate (CR). CR is chosen to be 10%, 30%, and 50%, respectively. Finally, simulated observations from the mixed discrete and continuous Cox regression model are (X_i, Z_i, δ_i) for $i = 1, \ldots, n$, where $X_i = \min(T_i, C_i)$, and $\delta_i = I(T_i \leq C_i)$.

Such simulation is repeated 2000 times to generate simulated data. Then the coverage probabilities for the empirical likelihood (EL) methods based on these 2000 simulated data sets are simply the proportions of these data sets which satisfy the inequality (2.6). The sample size n is chosen to be 50, 75, 100, and 200, respectively. We take 0.90, 0.95, and 0.99 as the nominal confidence level $1 - \alpha$, respectively. The simulation results are presented in Tables 1 and 2, respectively.

We make the following observations from the numerical studies. The empirical likelihood coverage probabilities tend to achieve the nominal levels with moderate sample sizes. At each nominal confidence level, the accuracy of coverage probabilities increases as the sample size n increases. Under lower censoring rate (CR = 10%, 30%) confidence intervals have close coverage probability when sample size n is 50, 70, 100, and 200, respectively. In general, the accuracy of coverage probability for empirical likelihood method decreases as the censoring rate increases. The empirical likelihood confidence interval works well in terms of coverage probability. The proposed approach can be applied to this model and leads to reasonable results.

Table 1. $\beta_0 = 0$ and $\Lambda_0(dt) = 0.1$ at integer values of t

CR(%)	n	$1 - \alpha = 0.90$	$1 - \alpha = 0.95$	$1 - \alpha = 0.99$
10	50	0.895	0.946	0.986
	70	0.899	0.946	0.988
	100	0.902	0.952	0.988
	200	0.899	0.948	0.990
30	50	0.896	0.945	0.988
	70	0.892	0.954	0.989
	100	0.896	0.945	0.991
	200	0.897	0.948	0.989
50	50	0.894	0.940	0.976
	70	0.888	0.942	0.985
	100	0.895	0.942	0.986
	200	0.897	0.945	0.987

Table 2. $\beta_0 = 0.693$ and $\Lambda_0(dt) = 0.1$ at integer values of t

CR(%)	n	$1-\alpha = 0.90$	$1-\alpha = 0.95$	$1-\alpha = 0.99$
10	50	0.874	0.933	0.984
	70	0.876	0.935	0.984
	100	0.881	0.934	0.986
	200	0.886	0.940	0.986
30	50	0.878	0.936	0.976
	70	0.887	0.937	0.983
	100	0.890	0.940	0.986
	200	0.891	0.945	0.986
50	50	0.873	0.929	0.971
	70	0.877	0.933	0.975
	100	0.884	0.931	0.978
	200	0.885	0.942	0.985

Appendix: Proof of Theorem 2.1

Proof of Theorem 2.1. Let

$$W_i = \int_0^{\tau} \left(Z_i - \frac{\alpha_1(t)}{\alpha_0(t)} \right) dM_i(t),$$

where $\alpha_r(t) = E(Z_i^{\otimes r} Y_i \exp\{\beta_0^T Z_i(t)\})$, $r = 0, 1$.

For any $a \in \mathbf{R}^p$, we have $\sup_{0 \le t \le \tau} E[n(\hat{\alpha}_0(t) - \alpha_0(t))^2] = O(1)$, and $\sup_{0 \le t \le \tau} E[n(a^T \hat{\alpha}_1(t) - a^T \alpha_1(t))^2] = O(1)$. By the monotone property of $\Lambda_0(t)$, we know that $\Lambda_0(t)$ can have at most countably many points of discontinuity in $[0, \tau]$. We denote them $\tau_1, \tau_2, \ldots,$ respectively. Following the proof of Lemma 2 of Qin and Jing [22], we have for each i,

$$E(a^T(W_{n,i} - W_i))^2 = \int_0^{\tau} E\left(\frac{a^T \hat{\alpha}_1(t)}{\hat{\alpha}_0(t)} - \frac{a^T \alpha_1(t)}{\alpha_0(t)} \right)^2 (1 - \Lambda_i(\Delta t))\Lambda_i(dt)$$

$$
\begin{aligned}
&= \int_0^\tau E\left(\frac{a^T\hat{\alpha}_1(t)}{\hat{\alpha}_0(t)} - \frac{a^T\alpha_1(t)}{\alpha_0(t)}\right)^2 \\
&\quad (1 - Y_i(t)\exp\{\beta_0^T Z_i\}\Lambda_0(\Delta t))Y_i(t)\exp\{\beta_0^T Z_i\}\Lambda_0(dt) \\
&\le M\int_0^\tau E\left(\frac{a^T\hat{\alpha}_1(t)}{\hat{\alpha}_0(t)} - \frac{a^T\alpha_1(t)}{\alpha_0(t)}\right)^2 dt \\
&\quad + M\sum_{i=1}^{\infty} E\left(\frac{a^T\hat{\alpha}_1(\tau_i)}{\hat{\alpha}_0(\tau_i)} - \frac{a^T\alpha_1(\tau_i)}{\alpha_0(\tau_i)}\right)^2 \Lambda_0(\Delta\tau_i) \\
&\le M\int_0^\tau E\left(\frac{a^T\hat{\alpha}_1(t)}{\hat{\alpha}_0(t)} - \frac{a^T\alpha_1(t)}{\alpha_0(t)}\right)^2 dt \\
&\quad + M\sup_{0\le t\le\tau} E\left(\frac{a^T\hat{\alpha}_1(t)}{\hat{\alpha}_0(t)} - \frac{a^T\alpha_1(t)}{\alpha_0(t)}\right)^2 \Lambda_0(\tau) \\
&= o(1),
\end{aligned}
$$

where in the third step we use the fact that $\Lambda_0(dt)$ is bounded at any mass point, $\lambda_0(t)$ is continuous, Z_i is bounded, here M is a constant. Applying the same argument as that in Qin and Jing [22], we get $\sum_{i=1}^n W_{n,i}W_{n,i}^T/n \xrightarrow{P} \Gamma$ and then, we have

$$\max_{1\le i\le n}|W_{n,i}| = o_p(n^{1/2}), \tag{A.1}$$

$$\frac{1}{n}\sum_{i=1}^n |W_{n,i}|^3 = o_p(n^{1/2}). \tag{A.2}$$

Let $\lambda = \rho\theta$, where $\rho \ge 0$ and $|\theta| = 1$. Recall $\Gamma_n = 1/n\sum_{i=1}^n W_{n,i}W_{n,i}^T = \Gamma + o_p(1)$, where Γ is the limit of $1/n\sum_{i=1}^n W_i W_i^T$. Let $\sigma_p > 0$ be the smallest eigenvalue of Γ. Then, $\theta\Gamma_n\theta \ge \sigma_p + o_p(1)$. From Prentice and Kalbfleisch [21], it is obvious that $n^{-1/2}\sum_{i=1}^n W_{n,i} \xrightarrow{\mathcal{D}} N(0, \Gamma)$. Thus, $1/n\left|\sum_{i=1}^n W_{n,i}\right| = O_p(n^{-1/2})$. By (A.1), the equation (2.5) and the argument used in Owen [17], we know that

$$|\lambda| = O_p(n^{-1/2}). \tag{A.3}$$

Consider a Taylor expansion to the right-hand side of $-2\log R(\beta_0)$,

$$-2\log R(\beta_0) = 2\sum_{i=1}^{n}\left\{\lambda^T W_{n,i} - \frac{1}{2}(\lambda^T W_{n,i})^2\right\} + r_n, \tag{A.4}$$

where $|r_n| = O_p(1)\sum_{i=1}^{n}|\lambda^T W_{n,i}|^3$. Hence, by (A.2), $|r_n| = O_p(1)|\lambda|^3 \sum_{i=1}^{n}|W_{n,i}|^3 = o_p(1)$. Furthermore, since

$$\begin{aligned}\frac{1}{n}\sum_{i=1}^{n}\frac{W_{n,i}}{1+\lambda^T W_{n,i}} &= \frac{1}{n}\sum_{i=1}^{n} W_{n,i}\left(1 - \lambda^T W_{n,i} + \frac{(\lambda^T W_{n,i})^2}{1+\lambda^T W_{n,i}}\right) \\ &= \frac{1}{n}\sum_{i=1}^{n} W_{n,i} - \left(\frac{1}{n}\sum_{i=1}^{n} W_{n,i}W_{n,i}^T\right)\lambda + \frac{1}{n}\sum_{i=1}^{n}\frac{W_{n,i}(\lambda^T W_{n,i})^2}{1+\lambda^T W_{n,i}} \\ &= 0,\end{aligned}$$

it follows that

$$\lambda = \left(\sum_{i=1}^{n} W_{n,i}W_{n,i}^T\right)^{-1}\sum_{i=1}^{n} W_{n,i} + o_p(1).$$

Similarly, we have

$$\sum_{i=1}^{n}\frac{\lambda^T W_{n,i}}{1+\lambda^T W_{n,i}} = \sum_{i=1}^{n}(\lambda^T W_{n,i}) - \sum_{i=1}^{n}(\lambda^T W_{n,i})^2 + \sum_{i=1}^{n}\frac{(\lambda^T W_{n,i})^3}{1+\lambda^T W_{n,i}} = 0.$$

Since

$$\sum_{i=1}^{n}\frac{(\lambda^T W_{n,i})^3}{1+\lambda^T W_{n,i}} = o_p(1),$$

we know that $\sum_{i=1}^{n}(\lambda^T W_{n,i})^2 = \sum_{i=1}^{n}\sum_{j=1}^{n}\lambda^T W_{n,i} + o_p(1)$. As a result, the following is true

$$-2\log R(\beta_0)$$

$$= \sum_{i=1}^{n} \lambda^T W_{n,i} + o_p(1)$$

$$= \left(n^{-1/2}\sum_{i=1}^{n} W_{n,i}\right)^T \left(n^{-1}\sum_{i=1}^{n} W_{n,i}W_{n,i}^T\right)^{-1} \left(n^{-1/2}\sum_{i=1}^{n} W_{n,i}\right) + o_p(1) \xrightarrow{\mathcal{D}} \chi_p^2.$$

Combining these results, we conclude Theorem 2.1.

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