PROBABILITY
AND
MATHEMATICAL STATISTICS
Vol. 29, Fasc. 1 (2009), pp. 73–89

EMPIRICAL LIKELIHOOD INFERENCE FOR SURVIVAL RATE REGRESSION WITH MISSING INFORMATION PRINCIPLE

BY

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Abstract. Recently, regression model for the long-term survival probabilities of patients was proposed, and a semiparametric inference procedure was developed based on missing information principle. In this paper, we propose an alternative empirical likelihood method. First, we define an estimated empirical likelihood ratio for the regression parameter. The limiting distribution of the empirical likelihood ratio is shown to have a weighted sum of i.i.d. χ_1^2's. We also define an adjusted empirical likelihood ratio for the regression parameter and the adjusted empirical likelihood ratio is shown to have a central chi-squared limiting distribution. Confidence regions for the vector of regression parameter are obtained accordingly. Furthermore, an extensive simulation study is conducted and it shows the proposed method has better coverage probability. Finally, we use a real data set to illustrate our proposed method.

2000 AMS Mathematics Subject Classification: Primary: 62N02; Secondary: 62G20.

Key words and phrases: Confidence region, conditional Kaplan–Meier estimator, link function, right censoring.

1. INTRODUCTION

In biomedical settings, it is of particular interest to study the relationship between the probability of observing an event during a certain pre-specified time interval and covariates. It is well known that the covariates such as tumor size, height, and sex have a significant effect on the survival rate in clinical trials. The survival rate at a pre-specified time is an effective measure of a patient's survival. Due to its simplicity and ease of interpretation, regression model for the survival rate is a valuable and attractive model in survival analysis, which is able to incorporate information from a set of covariates.

In this article, we consider fitting a regression model for a long-term survival rate on the covariate. Suppose T_i $(i = 1, \ldots, n)$ is the failure time to a specific event for patient i. Let $Z_i = (Z_{0i}, Z_{1i}, \ldots, Z_{pi})'$, where $Z_{0i} = 1$, be the corresponding $(p+1)$-dimensional covariate vector. In addition, the censoring variable

C_i is assumed to be conditionally independent of T_i given the covariate Z_i for $1 \leqslant i \leqslant n$. We observe (X_i, δ_i), where $X_i = \min(T_i, C_i)$ and $\delta_i = I(T_i \leqslant C_i)$.

For a fixed study time τ, we assume that, given the covariate, the survival rate at τ of the ith patient, $\pi_i = P(T_i \geqslant \tau | Z_i)$, satisfies

$$\phi(\pi_i) = \beta' Z_i, \tag{1.1}$$

where ϕ is a known, monotonic and differentiable function in [0, 1], and β is a $(p+1) \times 1$ vector of unknown regression parameter. We can choose a different link function ϕ to produce commonly used models in survival analysis. For instance, a regression model with link function $\phi(\pi) = \log\big(\pi/(1-\pi)\big)$ corresponds to the logistic regression model. And a regression model with link function $\phi(\pi) = -\log\big(-\log(\pi)\big)$ for a certain time period τ corresponds to the Cox's [5] regression model.

Jung [12] applied the idea of inverse probability to study the above regression model in which the censoring is independent of the covariate. Recently, Subramanian [27] applied the missing information principle (MIP) to the regression model (1.1) and proposed an alternative estimating function when covariate Z takes only discrete values. The well-known MIP were developed by Orchard and Woodbury [19] (cf. Laird [14]). It provides a general way to construct estimating equations in incomplete data problems. The basic idea is to replace a full-data estimating equation by its estimated conditional expectation given the observed data. The proposed approach is applicable to other censoring schemes such as double censoring and interval censoring; see Chang and Yang [1], and Groeneboom and Wellner [9]. In general, the two estimating functions lead to different estimators of the regression parameter. In [27] Subramanian derived asymptotic properties of the estimator when the censoring depends on the discrete covariates, i.e., the estimator was consistent, asymptotically normal. Moreover, the advantage of Subramanian's estimator over Jung's estimator was discussed in [27].

Empirical likelihood (EL) method is a powerful nonparametric method which can be used to construct confidence interval/region for parameter of interest. It enjoys some unique features, such as range respecting, transformation-preserving, asymmetric confidence interval, and Bartlett correctability, etc. In the breakthrough work, Owen [20], [21] introduced seminal empirical likelihood confidence regions for the mean of a random vector based on i.i.d. complete data. Since then, the EL has been popularly applied to different statistical fields to make inference for the parameter of interest. Some recent work includes: simultaneous confidence band with right censoring (Hollander et al. [11], Einmahl and McKeague [7], Li and Van Keilegom [15], McKeague and Zhao [16]–[18]); linear model (Owen [22], Chen [2], [3], Wang and Rao [30], [31]); generalized linear models (Kolaczyk [13], Chen and Cui [4]); the additive risk model (Zhao and Hsu [34]); weighted empirical likelihood (Glenn and Zhao [8]); missing response problem with application in observational studies (Qin and Zhang [23]); nonlinear errors-in-covariables models

(Stute et al. [26]); censored median regression models (Zhao and Yang [36]); censored regression models of the mean quality-adjusted lifetime (Zhao and Wang [35]), among others.

In this paper, we consider the regression model (1.1). Based on the estimating equation of Subramanian [27], we define an estimated empirical likelihood ratio for the regression parameter. The corresponding constrained maximization of the empirical likelihood can be done reliably by the modified Newton–Raphson method with checking the conditions. We apply the profiled EL to obtain the estimator of regression parameter. In Section 2.2 we see that the MIP and EL based estimators are the same. Thus, our objective is to build proper EL confidence region for the unknown regression parameter, and compare it with normal approximation confidence region other than for the purpose of efficiency estimates. One of the advantages of EL is that the proposed confidence region is adapted to the data set and not necessarily symmetric. Thus, it reflects the nature of the underlying data, and hence give a more representative way to make inferences about the parameter of interest. Moreover, the extensive simulation study demonstrates the EL method outperforms the normal approximation based method in terms of coverage probability for small sample size.

The rest of the paper is organized as follows. The proposed estimated EL and adjusted EL confidence regions and main asymptotic results are presented in Section 2. In Section 3, we conduct an extensive simulation study to compare the proposed method with the normal approximation (NA) based method with MIP. In Section 4, the proposed method is illustrated with real data in clinical trials. Proofs are presented in the Appendix.

2. MAIN RESULTS

2.1. Preliminaries. We consider the regression model (1.1). For uncensored data, Jung [12] proposed the following estimating equation:

$$U_1(\beta) = \sum_{i=1}^{n} \big(I(T_i \geqslant \tau) - \pi(\beta' Z_i)\big) \frac{\pi_\phi(\beta' Z_i)}{\pi(\beta' Z_i)\bar{\pi}(\beta' Z_i)} Z_i = 0, \tag{2.1}$$

where π is the inverse function of ϕ, $\bar{\pi} = 1 - \pi$, $\pi_\phi(\phi) = \partial \pi(\phi)/\partial\phi$.

When the censoring variable depends on the covariate vector Z and Z takes only discrete values, Subramanian [27] applied MIP to the uncensored estimating equation (2.1). He replaces the unobservable $I(T_i \geqslant \tau)$ by its conditional expectation given the data. It can be shown (cf. Efron [6], p. 840, equation (7.4)) that the conditional expectation E_i is given by

$$\begin{aligned} E_i &= E\big(I(T_i \geqslant \tau) | (X_i, \delta_i, Z_i)\big) \\ &= I(X_i \geqslant \tau) + I(X_i < \tau, \delta_i = 0) \frac{S(\tau-, Z_i)}{S(X_i-, Z_i)}, \end{aligned} \tag{2.2}$$

where $S(t,z) = P(T > t|Z = z)$ is the conditional survival function of T given Z, and $S(t-,z)$ is the left limit of $S(t,z)$. The estimated conditional expectation $\hat{E}_i$ is given by

$$\hat{E}_i = I(X_i \geqslant \tau) + I(X_i < \tau, \delta_i = 0)\frac{\hat{S}(\tau-, Z_i)}{\hat{S}(X_i-, Z_i)}, \tag{2.3}$$

where $\hat{S}(t,z)$ is an appropriate estimator of $S(t,z)$. The MIP estimating equation takes the form

$$U(\beta) = \sum_{i=1}^{n}\big(\hat{E}_i - \pi(\beta' Z_i)\big)\frac{\pi_\phi(\beta' Z_i)}{\pi(\beta' Z_i)\bar{\pi}(\beta' Z_i)} Z_i = 0. \tag{2.4}$$

Under mild conditions the estimating equation (2.4) has a unique solution $\hat{\beta}$. In the discrete case, denote the possible values of Z by z_k, $k = 1,\dots,K$, and assume that each occurs with positive probability. Let n_k denote the number of $Z_j, j = 1,\dots,n$, taking the value z_k. Rewrite the sample (X_i, δ_i, Z_i), $i = 1,\dots,n$, as $(X_{k,m}, \delta_{k,m})$, $m = 1,\dots,n_k$, for $k = 1,\dots,K$, where $(X_{k,m}, \delta_{k,m})$ corresponds to (X_i, δ_i) with covariate Z_i having the value z_k. Let $\hat{S}(t, z_k)$ be the local Kaplan–Meier estimator based on the pairs $(X_{k,m}, \delta_{k,m}), m = 1,\dots,n_k$. Let us put

$$\Gamma = \lim_{n\to\infty} n^{-1}\sum_{i=1}^{n}\int_0^\tau q(Z_i)q'(Z_i)\frac{I(X_i \geqslant t)}{y^2(t, Z_i)}d\Lambda_{S_{Z_i}}(t),$$

where

$$q(z) = \frac{\pi_\phi(\beta_0' z)}{\bar{\pi}(\beta_0' z)} z,$$

with $\Lambda_{S_Z}(t) = -\log S(t,z)$, and

$$y(t, z_k) = P(X_i \geqslant t | Z_l = z_k) = \lim_{n_k\to\infty} n_k^{-1}\sum_{i=1}^{n_k} I(X_{k,i} \geqslant t).$$

Throughout the paper, we only concern about the case where the censoring variable is dependent on a covariate which can only take finitely many values. Thus, the covariate vector Z is bounded, i.e., $\|Z\| \leqslant M$ for some positive constant M, where $\|\cdot\|$ is the Euclidean norm. To derive the asymptotic normality of $\hat{\beta}$, we also need the following conditions (cf. Subramanian [27]).

Let D be a bounded convex region. The true value β_0 of β is in its interior. Furthermore, we assume the following conditions hold:

C.1. The censoring time C and survival time T are independent given a covariate Z.

C.2. There exists a constant τ not dependent on $\beta \in D$ such that

$$P(X \geqslant \tau | Z = z) > 0 \quad \text{for } z \text{ a.s.}$$

C.3. The function π is twice differentiable with respect to ϕ, the second derivative $\pi_{\phi\phi}(\cdot)$ is bounded, and $0 < \pi(\cdot) < 1$ in a bounded domain.

C.4. The matrix A is positive definite, where

$$A = E\big[ZZ'\big(\pi_\phi(\beta_0' Z)\big)^2 / \{\pi(\beta_0' Z)\bar{\pi}(\beta_0' Z)\}\big].$$

REMARK 2.1. The well-known link functions in the regression model for logistic and probit satisfy conditions C.1–C4.

Under conditions C.1–C.4, it is shown in Subramanian [27] that

$$n^{1/2}(\hat{\beta} - \beta_0) \xrightarrow{\mathcal{D}} N(0, A^{-1}\Gamma A^{-1}). \tag{2.5}$$

Let

$$\hat{\Gamma} = n^{-1} \sum_{i=1}^{n} \delta_i \hat{q}(Z_i) \hat{q}'(Z_i) \left(\frac{\sum_{m=1}^{n} I(Z_m = Z_i)}{\sum_{m=1}^{n} I(X_m \geqslant X_i, Z_m = Z_i)} \right)^2 I(X_i \leqslant \tau),$$

where $\hat{q}(\cdot)$ is obtained by replacing β_0 in $q(\cdot)$ by $\hat{\beta}$.

REMARK 2.2. There is a typo in Subramanian [27]. The term $I(X_i \leqslant \tau)$ of equation (2.6) is missing on p. 217 of Subramanian [27].

Let us put

$$\hat{A} = n^{-1} \sum_{i=1}^{n} \frac{\big(\pi_\phi(\hat{\beta}' Z_i)\big)^2}{\pi(\hat{\beta}' Z_i)\bar{\pi}(\hat{\beta}' Z_i)} Z_i Z_i'.$$

Γ is consistently estimated by $\hat{\Gamma}$ (cf. Subramanian [27]). That A is consistently estimated by $\hat{A}$. Thus, an asymptotic $100(1-\alpha)\%$ NA confidence region for β is given by

$$\mathcal{R}_1 = \{\beta : n(\hat{\beta} - \beta)' \hat{A} \hat{\Gamma}^{-1} \hat{A}(\hat{\beta} - \beta) \leqslant \chi^2_{p+1}(\alpha)\},$$

where $\chi^2_{p+1}(\alpha)$ is the upper α-quantile of the chi-square distribution with $p+1$ degrees of freedom.

2.2. EL confidence region. Now we apply an alternative approach to the regression model (2.1) based on EL. For $1 \leqslant i \leqslant n$, we define

$$W_i = \big(E_i - \pi(\beta_0' Z_i)\big) \frac{\pi_\phi(\beta_0' Z_i)}{\pi(\beta_0' Z_i)\bar{\pi}(\beta_0' Z_i)} Z_i,$$

$$W_{n,i} = \big(\hat{E}_i - \pi(\beta_0' Z_i)\big) \frac{\pi_\phi(\beta_0' Z_i)}{\pi(\beta_0' Z_i)\bar{\pi}(\beta_0' Z_i)} Z_i.$$

It is easy to check that $EW_i = 0$ by the definition of W_i. Then the empirical likelihood is given by

$$L(\beta_0) = \sup\Big\{\prod_{i=1}^{n} p_i : \sum p_i = 1, \sum_{i=1}^{n} p_i W_i = 0, p_i \geqslant 0, i = 1, \ldots, n\Big\}.$$

However, the W_i's depend on $S(t-, z)$ which is unknown; we replace them by the $W_{n,i}$'s. Therefore, using the notation L_n, an estimated empirical likelihood at the true value β_0 is given by

$$L_n(\beta_0) = \sup\Big\{\prod_{i=1}^{n} p_i : \sum p_i = 1, \sum_{i=1}^{n} p_i W_{n,i} = 0, p_i \geqslant 0, i = 1, \ldots, n\Big\}.$$

Let $p = (p_1, \ldots, p_n)$ be a probability vector, i.e., $\sum_{i=1}^{n} p_i = 1$ and $p_i \geqslant 0$ for $1 \leqslant i \leqslant n$. Note that $\prod_{i=1}^{n} p_i$ attains its maximum at $p_i = 1/n$. Thus, the empirical likelihood ratio at the true value β_0 is defined by

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

We profile the estimated empirical likelihood ratio and obtain the profile estimator of β, i.e., $\hat{\beta}_P = \text{argmax}_{\beta} R(\beta)$. We note that $\prod_{i=1}^{n} np_i$ attains its maximum one at $p_i = 1/n$, and then $\hat{\beta}_P$ satisfies the estimating equation (2.4). Thus $\hat{\beta}_P = \hat{\beta}$.

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

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

where $\lambda = (\lambda_1, \ldots, \lambda_{p+1})'$ satisfies the equation

$$\frac{1}{n}\sum_{i=1}^{n} \frac{W_{n,i}}{1 + \lambda' W_{n,i}} = 0. \tag{2.6}$$

The value of λ may be found by Newton–Raphson method with checking the constraint conditions (cf. Hall and La Scala [10]). Thus, we have

$$\hat{l}(\beta_0) = -2\log R(\beta_0) = 2\sum_{i=1}^{n} \log\{1 + \lambda' W_{n,i}\}, \tag{2.7}$$

where $\lambda = (\lambda_1, \ldots, \lambda_{p+1})'$ satisfies the equation (2.6).

Put

$$\Gamma_1 = \lim_{n\to\infty} n^{-1} \sum_{i=1}^{n} \left(\big(E_i - \pi(\beta_0' Z_i)\big) \frac{\pi_\phi(\beta_0' Z_i)}{\pi(\beta_0' Z_i)\bar{\pi}(\beta_0' Z_i)} \right)^2 Z_i Z_i'.$$

Now our main result is the following, and we explain how it can be used to construct a confidence region for β.

THEOREM 2.1. *Under conditions* C1–C4, *the EL statistics* $\hat{l}(\beta_0)$ *converges to* $r_1\chi^2_{1,1} + \ldots + r_{p+1}\chi^2_{1,p+1}$ *in distribution, where* $\chi^2_{1,1}, \ldots, \chi^2_{1,p+1}$ *are independent chi-square random variables with one degree of freedom and* $r_1, \ldots, r_{p+1}$ *are the eigenvalues of* $\Gamma_1^{-1}\Gamma$.

Theorem 2.1 is proved in the Appendix. It is of interest that the limiting distribution of the EL ratio is a weighted sum of i.i.d. χ^2_1's instead of the standard χ^2_{p+1} distribution. Since the W_{ni}'s are dependent, $-2\log R(\beta_0)$ is no longer a sum of standard independent random variables. This phenomenon appears in right censoring and missing data settings; see Wang and Jing [29], Wang and Rao [30], Zhao and Chen [33], Zhao and Wang [35], etc.

From Lemma A.1 we know that Γ_1 is consistently estimated by

$$\hat{\Gamma}_1 = n^{-1}\sum_{i=1}^{n}\left(\big(\hat{E}_i - \pi(\hat{\beta}'Z_i)\big)\frac{\pi_\phi(\hat{\beta}'Z_i)}{\pi(\hat{\beta}'Z_i)\bar{\pi}(\hat{\beta}'Z_i)}\right)^2 Z_iZ_i'.$$

Thus, the r_i's can be estimated by the $\hat{r}_i$'s which are the eigenvalues of $\hat{\Gamma}_1^{-1}\hat{\Gamma}$. An asymptotic $100(1-\alpha)\%$ EL confidence region for β_0 is given by

$$\mathcal{R}_2 = \{\beta : -2\log R(\beta) \leqslant c(\alpha)\},$$

where $c(\alpha)$ is the upper α-quantile of the distribution of $\hat{r}_1\chi^2_{1,1} + \ldots + \hat{r}_{p+1}\chi^2_{p+1,1}$.

Alternatively, the above EL approach can be adjusted to avoid the weighted sum expression. Let

$$\rho(\beta) = (p+1)/\mathrm{tr}\{\Gamma_1^{-1}(\beta)\Gamma(\beta)\}$$

with $\mathrm{tr}(\cdot)$ denoting the trace vector. Then, as in Rao and Scott [24], the distribution of $\rho(\beta_0)(r_1\chi^2_{1,1} + \ldots + r_{p+1}\chi^2_{p+1,1})$ may be approximated by χ^2_{p+1}. Thus, the asymptotic distribution of $\tilde{l}_{\mathrm{ad}}(\beta_0) = \hat{\rho}(\beta_0)\hat{l}(\beta_0)$ may be approximated by χ^2_{p+1}, where the adjustment factor $\hat{\rho}(\beta)$ is $\rho(\beta)$ with $\Gamma_1(\beta)$ and $\Gamma(\beta)$ replaced by $\hat{\Gamma}_1(\beta)$ and $\hat{\Gamma}(\beta)$, respectively.

Motivated by Wang and Rao [30], [31], we define an adjusted empirical likelihood ratio by modifying $\rho(\beta_0)$ in $\tilde{l}_{\mathrm{ad}}(\beta_0)$, whose asymptotic distribution is exactly a χ^2_{p+1}. Note that

$$\hat{\rho}(\beta) = \frac{\mathrm{tr}\{\hat{\Gamma}^{-1}(\beta)\hat{\Gamma}(\beta)\}}{\mathrm{tr}\{\hat{\Gamma}_1^{-1}(\beta)\hat{\Gamma}(\beta)\}}.$$

We define $\hat{r}(\beta)$ to be $\hat{\rho}(\beta)$ with $\hat{\Gamma}(\beta)$ replaced by

$$\hat{S}(\beta) = \Big\{\sum_{i=1}^{n} W_{n,i}(\beta)\Big\} \times \Big\{\sum_{i=1}^{n} W_{n,i}(\beta)\Big\}'.$$

That is,

$$\hat{r}(\beta) = \frac{\mathrm{tr}\{\hat{\Gamma}^{-1}(\beta)\hat{S}(\beta)\}}{\mathrm{tr}\{\hat{\Gamma}_1^{-1}(\beta)\hat{S}(\beta)\}}.$$

We define an adjusted empirical likelihood ratio by

$$\hat{l}_{\mathrm{ad}}(\beta) = \hat{r}(\beta)\hat{l}(\beta).$$

THEOREM 2.2. *Under conditions* C1–C4, *the EL statistic* $\hat{l}_{\mathrm{ad}}(\beta_0)$ *converges to* χ^2_{p+1} *in distribution.*

Based on Theorem 2.2, an asymptotic $100(1-\alpha)\%$ adjusted empirical likelihood (AEL) confidence region for β_0 is given by

$$\mathcal{R}_3 = \{\beta : \hat{l}_{\mathrm{ad}}(\beta) \leqslant \chi^2_{p+1}(\alpha)\},$$

where $\chi^2_{p+1}(\alpha)$ is defined as before.

Discussion. From the above theorems we know that EL method works for the case when censoring depends on discrete covariates. Furthermore, we can use profiled EL to obtain confidence regions for any component of regression parameter. In addition, Zhao [32] developed EL method when censoring is independent of covariate. When censoring depends on a continuous one-dimensional covariate, EL works based on the estimating equation in Subramanian [28] accordingly. It would be of interest to consider the regression model when censoring depends on high-dimensional continuous covariates. We will investigate this challenging issue using EL in the future.

3. SIMULATION STUDY

In this section, we conduct an extensive simulation study to compare the performance of the proposed empirical likelihood confidence region and adjusted empirical likelihood confidence region with the normal approximation based confidence region in terms of coverage probability.

The conditional distribution of T given Z was taken to be $L(0, \pi^2/3z_2^2)$, where $L(0,\sigma^2)$ denotes a logistic distribution with mean zero and variance σ^2. This implies that $\pi(t) = 1/(1+e^{z_2 t})$. Note that $\phi\big(\pi(t)\big) = -z_2 t$, with $\phi(\pi) = \log\{\pi/(1-\pi)\}$, gives a regression model for the long-term survival rate. Thus, the true values of the intercept and the slope are 0 and $-\tau$, respectively. We use a discrete random variable $Z = (1, Z_2)'$ with Z_2 taking values 1.1, 1.3, 1.5, 1.7, and 1.9 each with probability 0.2. The conditional censoring distribution of C given Z is taken to be $\log\big(\mathrm{Uniform}(0, cz_2)\big)$, and the value of c is used to reach the desired censoring rate (CR). Note that, in this case, T and C are independent given Z. We choose τ to be 0 and 0.25, respectively.

We take 0.90, 0.95, and 0.99 as the nominal confidence level $1-\alpha$, respectively. The 15%, 30%, and 45% censoring rates are obtained, which represent light censoring, medium censoring, and heavy censoring. The sample size n is chosen to be 60, 100, 140, and 200, respectively. The coverage probabilities of the normal approximation based method and the empirical likelihood method are estimated from 1 000 simulated data sets. Based on the simulation results in Tables 1 and 2, we report the findings as follows.

TABLE 1. Coverage probabilities for the regression parameter ($\tau = 0$)

		$1-\alpha=0.90$		$1-\alpha=0.95$		$1-\alpha=0.99$	
CR(%)	n	NA	EL	NA	EL	NA	EL
15	60	0.880	0.919	0.919	0.949	0.954	0.983
	100	0.873	0.905	0.917	0.954	0.968	0.983
	140	0.905	0.916	0.934	0.950	0.969	0.988
	200	0.898	0.910	0.941	0.958	0.979	0.991
30	60	0.874	0.926	0.921	0.958	0.968	0.989
	100	0.877	0.901	0.911	0.948	0.953	0.979
	140	0.878	0.906	0.922	0.953	0.967	0.988
	200	0.883	0.896	0.930	0.951	0.977	0.988
45	60	0.859	0.904	0.895	0.933	0.934	0.969
	100	0.864	0.905	0.911	0.950	0.961	0.981
	140	0.873	0.895	0.906	0.940	0.955	0.984
	200	0.885	0.903	0.930	0.950	0.970	0.985

TABLE 2. Coverage probabilities for the regression parameter ($\tau = 0.25$)

		$1-\alpha=0.90$		$1-\alpha=0.95$		$1-\alpha=0.99$	
CR(%)	n	NA	EL	NA	EL	NA	EL
15	60	0.858	0.915	0.902	0.952	0.947	0.976
	100	0.881	0.916	0.916	0.951	0.968	0.989
	140	0.897	0.918	0.938	0.957	0.973	0.988
	200	0.888	0.911	0.934	0.951	0.977	0.992
30	60	0.871	0.920	0.903	0.947	0.948	0.980
	100	0.868	0.904	0.901	0.946	0.957	0.974
	140	0.896	0.911	0.931	0.956	0.966	0.986
	200	0.891	0.910	0.935	0.957	0.974	0.989
45	60	0.824	0.905	0.874	0.938	0.928	0.971
	100	0.855	0.915	0.904	0.948	0.953	0.983
	140	0.865	0.896	0.904	0.943	0.952	0.990
	200	0.897	0.903	0.934	0.952	0.972	0.987

1. At each fixed nominal level, the coverage accuracies for empirical likelihood and normal approximation methods tend to decrease as the censoring rates increase, and tend to increase as the sample size increases.

2. The empirical likelihood outperforms the normal approximation method for $\tau = 0, 0.25$. In particular, for small sample ($n = 60$), the empirical likelihood confidence region has more accurate coverage probabilities than the normal approximation based confidence region.

3. The coverage probabilities for the normal approximation method are consistently lower than the nominal level for small sample size ($n = 60$).

The simulation results of adjusted empirical likelihood method are similar as those of normal approximation method. Thus, they are omitted here. In conclusion, the simulation study suggests that the proposed estimated empirical likelihood confidence region improves the coverage accuracy of normal approximation based confidence region.

4. APPLICATION

In this section, we use multiple myeloma data to illustrate the proposed empirical likelihood method and compare it with the normal approximation method. The data set is presented in SAS/STAT User's guide (1999, pp. 2608–2617). The data come from a study on multiple myeloma in which researchers treated 65 patients with alkylating agents. Of those patients, 48 died during the study and 17 survived. The censoring rate is about 26%. For illustration, one covariate Z, the Platelet (platelets at diagnosis: 0 = abnormal, 1 = normal) is considered for the regression analysis of τ-month survival rate. It is important to ensure that the chosen value of τ does not result in an empty at-risk set, i.e., condition C.2 is satisfied. Here, we choose five different τ values: 25, 30, 35, 40, 45 months in the data set.

Based on the multiple myeloma data, we wish to construct confidence intervals for the regression parameter. For $\pi_i = P(T_i \geqslant \tau)$, we consider the following logistic regression model:

$$\log\{\pi_i/(1-\pi_i)\} = \beta Z,$$

and obtain confidence intervals for β with the normal approximation based method and the empirical likelihood method with 90% and 95% confidence levels.

In Tables 3 and 4 we report the point estimate of β, confidence interval for β, and corresponding confidence interval length at different values of τ. From Tables 3 and 4, we see the empirical likelihood produces slightly wider confidence intervals than normal approximation confidence intervals. We note that the normal approximation confidence interval has the symmetry property which is not desirable since the distribution of the parameter estimator may be skewed. The empirical likelihood confidence intervals are asymmetric about the point estimator, and the empirical likelihood method is able to pick up possible skewness in contrast to the normal approximation method.

TABLE 3. Regression analysis for the multiple myeloma data: point estimate of β, 90% confidence interval and length of confidence interval

		$1-\alpha=0.90$	
τ	β	NA	EL
25	−0.128	(−0.614, 0.358) 0.972	(−0.621, 0.356) 0.977
30	−0.301	(−0.778, 0.176) 0.954	(−0.787, 0.172) 0.959
35	−0.411	(−0.898, 0.076) 0.974	(−0.909, 0.070) 0.979
40	−0.523	(−1.022, −0.024) 0.998	(−1.034, −0.032) 1.002
45	−0.759	(−1.279, −0.239) 1.040	(−1.295, −0.248) 1.047

TABLE 4. Regression analysis for the multiple myeloma data: point estimate of β, 95% confidence interval and length of confidence interval

		$1-\alpha=0.95$	
τ	β	NA	EL
25	−0.128	(−0.708, 0.452) 1.160	(−0.718, 0.449) 1.167
30	−0.301	(−0.870, 0.268) 1.138	(−0.883, 0.262) 1.145
35	−0.411	(−0.992, 0.170) 1.162	(−1.008, 0.162) 1.170
40	−0.523	(−1.117, 0.071) 1.188	(−1.135, 0.062) 1.197
45	−0.759	(−1.379, −0.139) 1.240	(−1.402, −0.152) 1.250

5. APPENDIX — PROOFS OF THEOREMS

LEMMA A.1. *Under the conditions of Theorem* 2.1, *we have*

$$\text{(i)}\ \frac{1}{n}\sum_{i=1}^{n} W_{n,i}W'_{n,i} \xrightarrow{\mathcal{P}} \Gamma_1; \quad \text{(ii)}\ \hat{\Gamma}_1 \xrightarrow{\mathcal{P}} \Gamma_1; \quad \text{(iii)}\ \hat{\Gamma} \xrightarrow{\mathcal{P}} \Gamma.$$

Proof of Lemma A.1. Let

$$\hat{\Gamma}_{1n} = \frac{1}{n}\sum_{i=1}^{n} W_{n,i}W'_{n,i}, \qquad \Gamma_{1n} = \frac{1}{n}\sum_{i=1}^{n} W_iW'_i.$$

In order to prove (i), we only need to show $\hat{\Gamma}_{1n} = \Gamma_{1n} + o_P(1)$.
For any $a \in R^{p+1}$, the following decomposition holds:

$$\text{(A.1)}\quad a'(\hat{\Gamma}_{1n} - \Gamma_{1n})a = \frac{1}{n}\sum_{i=1}^{n}\big(a'(W_{n,i}-W_i)\big)^2 + \frac{2}{n}\sum_{i=1}^{n}(a'W_i)\big(a'(W_{n,i}-W_i)\big) = I_1 + 2I_2.$$

We note that

$$
\begin{aligned}
a'(W_{n,i} - W_i) &= a'(\hat{E}_i - E_i)\frac{\pi_\phi(\beta_0' Z_i)Z_i}{\pi(\beta_0' Z_i)\bar{\pi}(\beta_0' Z_i)} \\
&= \frac{\pi_\phi(\beta_0' Z_i)a'Z_i}{\pi(\beta_0' Z_i)\bar{\pi}(\beta_0' Z_i)} I(X_i < \tau, \delta_i = 0) \\
&\quad \times \frac{\big(\hat{S}(\tau-, Z_i)S(X_i-, Z_i) - S(\tau-, Z_i)\hat{S}(X_i-, Z_i)\big)}{\hat{S}(X_i-, Z_i)S(X_i-, Z_i)}.
\end{aligned}
$$

By condition C.3 and $\|Z\| \leqslant M$, we have for $i = 1, \dots, n$

$$
\frac{1}{n}\frac{\big(\pi_\phi(\beta_0' Z_i)a'Z_i\big)^2}{\big(\pi(\beta_0' Z_i)\bar{\pi}(\beta_0' Z_i)\big)^2} \leqslant M_1.
$$

The condition C.1 implies that, for each $k = 1, \dots, K$, $\hat{S}(\cdot, z_k)$ is strongly uniformly consistent in $[0, \tau]$ (Shorack and Wellner [25], p. 304):

$$
\sup_{0 \leqslant t \leqslant \tau} |\hat{S}(t, z_k) - S(t, z_k)| \xrightarrow{\text{a.s.}} 0. \tag{A.2}
$$

It follows from $\|Z\| \leqslant M$, condition C.3 and (A.2) that

$$
\begin{aligned}
|I_2| &\leqslant \sum_{i=1}^n \frac{I(X_i < \tau)}{n} \frac{|\hat{S}(\tau-, Z_i)S(X_i-, Z_i) - S(\tau-, Z_i)\hat{S}(X_i-, Z_i)|}{\hat{S}(X_i-, Z_i)S(X_i-, Z_i)} \\
&\quad \times \frac{\big(\pi_\phi(\beta_0' Z_i)a'Z_i\big)^2}{\big(\pi(\beta_0' Z_i)\bar{\pi}(\beta_0' Z_i)\big)^2} \\
&\leqslant \sup_{i=1,\dots,K} \frac{I(X_i < \tau)|\hat{S}(\tau-, z_i) - S(\tau-, z_i)|}{\hat{S}(X_i-, z_i)} M_1 \\
&\quad + \sup_{i=1,\dots,K} \frac{I(X_i < \tau)|\hat{S}(X_i-, z_i) - S(X_i-, z_i)|}{\hat{S}(X_i-, z_i)} M_1 \\
&= o_P(1).
\end{aligned} \tag{A.3}
$$

Similarly, we can show that $I_1 = o_P(1)$. Thus, by (A.1), (A.3), we prove (i).

In order to prove (ii), we only need to show that $\hat{\Gamma}_1 = \hat{\Gamma}_{1n} + o_P(1)$. Let us put

$$
J_i = \big(\hat{E}_i - \pi(\hat{\beta}' Z_i)\big)\frac{\pi_\phi(\hat{\beta}' Z_i)}{\pi(\hat{\beta}' Z_i)\bar{\pi}(\hat{\beta}' Z_i)} - \big(\hat{E}_i - \pi(\beta_0' Z_i)\big)\frac{\pi_\phi(\beta_0' Z_i)}{\pi(\beta_0' Z_i)\bar{\pi}(\beta_0' Z_i)}.
$$

Applying the mean value theorem, we obtain the following equalities:

$$\eta_1 =: \pi_\phi(\hat\beta' Z_i) - \pi_\phi(\beta_0' Z_i) = \pi_{\phi\phi}\big(\beta_0' Z_i + \xi_1(\hat\beta' - \beta_0')Z_i\big)(\hat\beta' - \beta_0')Z_i,$$
$$\eta_2 =: \pi(\hat\beta' Z_i)\bar\pi(\hat\beta' Z_i) - \pi(\beta_0' Z_i)\bar\pi(\beta_0' Z_i)$$
$$= \pi_\phi\big(\beta_0' Z_i + \xi_2(\hat\beta' - \beta_0')Z_i\big)\Big(1 - 2\pi\big(\beta_0' Z_i + \xi_2(\hat\beta' - \beta_0')Z_i\big)\Big)(\hat\beta' - \beta_0')Z_i,$$
$$\eta_3 =: \bar\pi(\hat\beta Z_i) - \bar\pi(\beta_0' Z_i) = \bar\pi_\phi\big(\beta_0' Z_i + \xi_3(\hat\beta' - \beta_0')Z_i\big)(\hat\beta' - \beta_0')Z_i,$$

where $0 \leqslant \xi_i \leqslant 1$ for $i = 1, 2, 3$.

Combining the above equalities, $\|Z\| \leqslant M$, condition C.3, (A.2), and (2.5) we have

$$\text{(A.4)} \quad \sup_{1\leqslant i\leqslant n} |J_i|$$
$$= \sup_{1\leqslant i\leqslant n}\left|\frac{\hat E_i \pi_\phi(\hat\beta' Z_i)}{\pi(\hat\beta' Z_i)\bar\pi(\hat\beta' Z_i)} - \frac{\hat E_i \pi_\phi(\beta_0' Z_i)}{\pi(\beta_0' Z_i)\bar\pi(\beta_0' Z_i)} - \frac{\pi_\phi(\hat\beta' Z_i)}{\bar\pi(\hat\beta' Z_i)} + \frac{\pi_\phi(\beta_0' Z_i)}{\bar\pi(\beta_0' Z_i)}\right|$$
$$\leqslant \sup_{1\leqslant i\leqslant n}\left|\frac{\hat E_i\big(\eta_1\bar\pi(\beta_0' Z_i)\pi(\beta_0' Z_i) - \eta_2\pi_\phi(\beta_0' Z_i)\big)}{\pi(\hat\beta' Z_i)\bar\pi(\hat\beta' Z_i)\pi(\beta_0' Z_i)\bar\pi(\beta_0' Z_i)}\right|$$
$$+ \sup_{1\leqslant i\leqslant n}\left|\frac{\eta_1\bar\pi(\beta_0' Z_i) - \eta_3\pi_\phi(\beta_0' Z_i)}{\bar\pi(\hat\beta' Z_i)\bar\pi(\beta_0' Z_i)}\right|$$
$$= O_P(1/\sqrt{n}).$$

Then, for any $a \in R^{p+1}$, by condition C.3, $\|Z\| \leqslant M$, (A.2), and (A.4) we have

$$|a'(\hat\Gamma_1 - \hat\Gamma_{1n})a| \leqslant \frac{1}{n}\sum_{i=1}^n (a' Z_i)^2\left(J_i^2 + 2|J_i||\hat E_i - \pi(\beta_0' Z_i)|\frac{|\pi_\phi(\beta_0' Z_i)|}{\pi(\beta_0' Z_i)\bar\pi(\beta_0' Z_i)}\right)$$
$$\leqslant \sup_{1\leqslant i\leqslant n}(a' Z_i)^2 \frac{1}{n}\sum_{i=1}^n\left(J_i^2 + 2|J_i|(\hat E_i + 1)\frac{|\pi_\phi(\beta_0' Z_i)|}{\pi(\beta_0' Z_i)\bar\pi(\beta_0' Z_i)}\right)$$
$$\leqslant C\left(\frac{1}{n}\sum_{i=1}^n J_i^2 + \frac{1}{n}\sum_{i=1}^n |J_i|\right)$$
$$\leqslant C\big((\sup_{1\leqslant i\leqslant n}|J_i|)^2 + \sup_{1\leqslant i\leqslant n}|J_i|\big)$$
$$= O_P(1/\sqrt{n}).$$

Hence, (ii) follows. Similarly we can show (iii). ■

P r o o f o f T h e o r e m 2.1. By condition C.3, $\|Z\| \leqslant M$, and (A.2),

$$\text{(A.5)} \quad \max_{1\leqslant i\leqslant n}\|W_{n,i}\| \leqslant \max_{1\leqslant i\leqslant n}\left|(\hat E_i + 1)\frac{\pi_\phi(\beta_0' Z_i)}{\pi(\beta_0' Z_i)\bar\pi(\beta_0' Z_i)}\right| \max_{1\leqslant i\leqslant n}\|Z_i\|$$
$$= O_P(1).$$

Let $\lambda = \rho\theta$, where $\rho \geqslant 0$ and $\|\theta\| = 1$. Recall that $\hat{\Gamma}_{1n} = \Gamma_1 + o_P(1)$ (see Lemma A.1). Let $\sigma_1 > 0$ be the smallest eigenvalue of Γ_1. Then

$$\theta'\hat{\Gamma}_{1n}\theta \geqslant \frac{\sigma_1}{2} + o_P(1). \tag{A.6}$$

Subramanian [27] applied the martingale representation and the central limit theorem in the proof of Theorem 1, and derived the asymptotic normality, i.e., $n^{-1/2}\sum_{i=1}^{n} W_{n,i} \xrightarrow{\mathcal{D}} N(0,\Gamma)$. Let e_j be the unit vector in the jth coordinate direction. We have

$$\begin{aligned} \left|\frac{1}{n}\sum_{j=1}^{p+1} e_j' \sum_{i=1}^{n} W_{n,i}\right| &\leqslant (p+1)\left\|\frac{1}{n}\sum_{i=1}^{n} W_{n,i}\right\| \\ &= O_P(n^{-1/2}). \end{aligned} \tag{A.7}$$

Then, it follows from (2.6), (A.6), (A.7), and the argument used in Owen [21] that

$$\|\lambda\| = O_P(n^{-1/2}). \tag{A.8}$$

Applying Taylor's expansion to (2.7), we have

$$\hat{l}(\beta_0) = 2\sum_{i=1}^{n}\left(\lambda' W_{n,i} - \frac{1}{2}(\lambda' W_{n,i})^2\right) + r_n, \tag{A.9}$$

where

$$|r_n| \leqslant C\sum_{i=1}^{n} |\lambda' W_{n,i}|^3 \text{ in probability.}$$

Then we infer from (A.5) and (A.8) that

$$|r_n| \leqslant Cn\|\lambda\|^3(\max_{1\leqslant i\leqslant n}\|W_{n,i}\|)^3 = O_P(n^{-1/2}). \tag{A.10}$$

We note that

$$\begin{aligned} 0 = \frac{1}{n}\sum_{i=1}^{n}\frac{W_{n,i}}{1+\lambda' W_{n,i}} &= \frac{1}{n}\sum_{i=1}^{n} W_{n,i}\left(1 - \lambda' W_{n,i} + \frac{(\lambda' W_{n,i})^2}{1+\lambda' W_{n,i}}\right) \\ &= \frac{1}{n}\sum_{i=1}^{n} W_{n,i} - \left(\frac{1}{n}\sum_{i=1}^{n} W_{n,i}W_{n,i}'\right)\lambda \\ &\quad + \frac{1}{n}\sum_{i=1}^{n}\frac{W_{n,i}(\lambda' W_{n,i})^2}{1+\lambda' W_{n,i}}. \end{aligned} \tag{A.11}$$

By (A.5), (A.8), (A.11), and Lemma A.1 (i) it follows that

$$\lambda = \big(\sum_{i=1}^{n} W_{n,i}W_{n,i}'\big)^{-1}\sum_{i=1}^{n} W_{n,i} + o_P(n^{-1/2}). \tag{A.12}$$

By (A.11), we have

$$\text{(A.13)}\quad 0=\sum_{i=1}^{n}\frac{\lambda' W_{n,i}}{1+\lambda' W_{n,i}}=\sum_{i=1}^{n}(\lambda' W_{n,i})-\sum_{i=1}^{n}(\lambda' W_{n,i})^2+\sum_{i=1}^{n}\frac{(\lambda' W_{n,i})^3}{1+\lambda' W_{n,i}}.$$

Similarly as before, by (A.5) and (A.8), we get

$$\text{(A.14)}\qquad \sum_{i=1}^{n}\frac{(\lambda' W_{n,i})^3}{1+\lambda' W_{n,i}}=o_P(n^{-1/2}).$$

Combining (A.13) and (A.14) we have

$$\text{(A.15)}\qquad \sum_{i=1}^{n}(\lambda' W_{n,i})^2=\sum_{i=1}^{n}\lambda' W_{n,i}+o_P(1).$$

By (A.9), (A.10), (A.12), (A.15) and Lemma A.1 (i), we have

$$\begin{aligned}\hat{l}(\beta_0)&=\sum_{i=1}^{n}\lambda' W_{n,i}+o_P(1)\\&=\big(n^{-1/2}\sum_{i=1}^{n}W_{n,i}\big)'\big(n^{-1}\sum_{i=1}^{n}W_{n,i}W_{n,i}'\big)^{-1}\big(n^{-1/2}\sum_{i=1}^{n}W_{n,i}\big)+o_P(1)\\&=\big(\Gamma^{-1/2}n^{-1/2}\sum_{i=1}^{n}W_{n,i}\big)'(\Gamma^{1/2}\Gamma_1^{-1}\Gamma^{1/2})\big(\Gamma^{-1/2}n^{-1/2}\sum_{i=1}^{n}W_{n,i}\big)+o_P(1).\end{aligned}$$

Recall that $\Gamma^{-1/2}\big(n^{-1/2}\sum_{i=1}^{n}W_{n,i}\big)\xrightarrow{\mathcal{D}}N(0,I_{p+1})$. Note that $\Gamma^{1/2}\Gamma_1^{-1}\Gamma^{1/2}$ and $\Gamma_1^{-1}\Gamma$ have the same eigenvalues. Using Lemma A.2 of Zhao [32], we complete the proof of Theorem 2.1. ∎

P r o o f o f T h e o r e m 2.2. Recall the definition of $\hat{l}_{\mathrm{ad}}(\beta_0)$. It follows that, by (A.9),

$$\hat{l}_{\mathrm{ad}}(\beta_0)=\big(n^{-1/2}\sum_{i=1}^{n}W_{n,i}\big)'\hat{\Gamma}^{-1}\big(n^{-1/2}\sum_{i=1}^{n}W_{n,i}\big)+o_P(1).$$

From Lemma A.1 (iii) we know that $\hat{\Gamma}\xrightarrow{\mathcal{P}}\Gamma$. Thus, Theorem 2.2 is proved. ∎

Acknowledgements. The author would like to thank the editor and the referee for careful reading of the manuscript and suggestions which have improved greatly the paper. The research is partially supported by the NSA Young Investigator Grant and the Faculty Mentoring Grant, Georgia State University.

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Received on 20.12.2005;
revised version on 14.4.2008