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A Simple Estimation of Relative Risk

Hyo-Il Park[1)] and Seungman Hong[2)]

Abstract

In this paper, we propose a simple estimate of relative risk based on a functional equation. We derive the asymptotic normality with a restricted condition. Then we discuss some interesting features as concluding remarks. Finally we comment briefly about application of the estimate to the testing problems and compare our estimate with that of Begun through simulation study.

Keywords: Asymptotic normality; proportional hazards model; relative risk; two-sample problem.

1. Introduction

In survival analysis and reliability theory, the proportional hazards model (*cf.* Cox, 1972) has played prominent and distinguished roles for the analysis of life-time data and has been developed extensively to accommodate various situations. In this study, we consider the case of two-sample problem setting without censored observation. For $t \in [0, \infty)$, let $\lambda_i(t)$ be the hazard function of the i^{th} population, $i = 1, 2$. Then under the proportional hazards model, there exists a positive real number θ such that

$$\lambda_2(t) = \theta\lambda_1(t) \quad \text{for all} \quad t \in [0, \infty). \tag{1.1}$$

We call θ the relative risk. Let $\Lambda_i(t)$ be the corresponding cumulative hazard function for each i. Then (1.1) can be re-written as

$$\Lambda_2(t) = \theta\Lambda_1(t) \quad \text{for all} \quad t \in [0, \infty). \tag{1.2}$$

1) Professor, Department of Statistics, Chong-ju University, Chong-ju, Choong-book 360-764, Korea.
Correspondence : hipark@cju.ac.kr
2) Professor, Department of Informational Statistics, Korea University, Jochiwon, Choong-Nam 361-763, Korea.
E-mail : smhong@korea.ac.kr

Also if $S_i(t)$ denotes the corresponding survival function for each i, then (1.1) can be re-expressed as

$$S_2(t) = S_1^\theta(t) \quad \text{for all} \quad t \in [0, \infty). \tag{1.3}$$

We note that the family of survival functions which satisfy the relation (1.3) has been known as Lehmann alternatives in the literature (*cf.* Miller *et al.*, 1981). From (1.3), we see that $S_2(t) > S_1(t)$ for all $t \in [0, \infty)$ when $\theta < 1$. This means that individuals from the second population are likely to survive longer than those from the first population if $\theta < 1$ and vice versa. Instead of (1.1), Cox (1972) proposed the following form for the proportional hazards model:

$$\lambda_2(t) = e^\eta \lambda_1(t) \quad \text{for all} \quad t \in [0, \infty), \tag{1.4}$$

where η is a real number and called as the regression coefficient. We note that θ and η have the following relation:

$$\theta = e^\eta \quad \text{or} \quad \eta = \log(\theta),$$

where log is the natural logarithm. Since η can take all the real numbers, the model (1.4) has an advantage over the model (1.1) for the estimation of η. Using the conditional likelihood, Cox (1972) considered to obtain a maximum likelihood estimate of η by treating the conditional likelihood as an ordinary likelihood. Since the conditional likelihood function is not linear in η, no explicit form of the solution can be obtained. As a result, the estimating procedure requires an iterative method which should be accompanied with excessive amount of computational work. Therefore in order to resolve or alleviate the mentioned inconvenience of the estimating procedure induced by the conditional likelihood, several modified estimation methods have been proposed. Among others, Kalbfleisch and Prentice (1973), Breslow (1975) and Thompson (1977) are well-known. Bernstein *et al.* (1981) reviewed and compared some of these estimates through extensive simulation study. Also we note that under (1.3), for every $t \in [0, \infty)$,

$$S_1(t) dF_2(t) = \theta S_2(t) dF_1(t), \tag{1.5}$$

where $F_i = 1 - S_i,\ i = 1, 2$. From (1.5), we see that

$$\theta = \frac{\int_0^\infty w(F_1, F_2) S_1(t) dF_2(t)}{\int_0^\infty w(F_1, F_2) S_2(t) dF_1(t)} \tag{1.6}$$

holds for some suitable real-valued weight function $w(\cdot,\cdot)$, which depends on F_1 and F_2. The necessary conditions for $w(\cdot,\cdot)$, which are needed for the analytic aspect, are listed in Begun (1987). Using (1.6), Begun and Reid (1983) and Begun (1987) proposed a class of estimates as follows:

$$\widetilde{\theta} = \frac{\int_0^\infty w(\widetilde{F}_1, \widetilde{F}_2)\widetilde{S}_1(t)d\widetilde{F}_2(t)}{\int_0^\infty w(\widetilde{F}_1, \widetilde{F}_2)\widetilde{S}_2(t)d\widetilde{F}_1(t)}, \tag{1.7}$$

where for each i, $\widetilde{F}_i$ and $\widetilde{S}_i$ are any consistent estimates of F_i and S_i, respectively. Usually one may use the empirical counterparts for uncensored case and the Kaplan-Meier estimates for censored case. We note that when $w = 1$, the estimate $\widetilde{\theta}$ is the ratio of the two Wilcoxon rank-sum statistic (*cf.* Begun, 1987) for the complete data case. In this research, we also consider to propose an estimate for θ based on a functional equation for the uncensored case. The estimate will have an explicit form and may be easier to compute and simpler than any other competitors.

2. Estimation of Relative Risk

Let $X_1, \ldots, X_{n_1}$ and $X_{n_1+1}, \ldots, X_n$ be two independent non-negative life-time random samples of sizes n_1 and n_2 from populations with continuous distribution functions F_1 and F_2, respectively. Here $n = n_1 + n_2$. If the corresponding two survival functions or hazard functions satisfy one of the three relations (1.1)–(1.3), then we have that

$$\theta = \int_0^\infty S_1(t)d\Lambda_2(t). \tag{2.1}$$

Therefore one may propose an estimate $\hat{\theta}$ for the relative risk θ as follows:

$$\hat{\theta} = \int_0^\infty \hat{S}_1(t)d\hat{\Lambda}_2(t), \tag{2.2}$$

where $\hat{S}_1$ is the empirical survival function based on $X_1, \ldots, X_{n_1}$ and $\hat{\Lambda}_2$ is the empirical cumulative hazard function based on $X_{n_1+1}, \ldots, X_n$ such as $d\hat{\Lambda}_2 = d\hat{F}_2/\hat{S}_2$. For the computational purpose, let $Y_i(t)$ be the number of observations whose values are equal or greater than t for the i^{th} sample and $N_2(t)$, the number of observations whose values are equal or less than t for the second sample. Then

(2.2) can be re-written as

$$\hat{\theta} = \frac{1}{n_1} \sum_{j=n_1+1}^{n} \frac{Y_1(X_j)}{Y_2(X_j)} dN_2(X_j), \tag{2.3}$$

where $dN_2(t) = N_2(t) - N_2(t_-)$, where $N_2(t_-)$ is the left-hand limit of N_2 at t. We note that the form of (2.3) may be considered as a member of generalized log-rank statistics used for testing the equality between hazard functions. We will discuss the application to the testing problems with $\hat{\theta}$ in later section. In this study we only consider the case that $\theta \leq 1$. The reason for this will be shown later. In the next section, we will consider the consistency and asymptotic normality for $\hat{\theta}$.

3. Asymptotic Properties for $\hat{\theta}$

In this section, we consider the asymptotic behavior of $\hat{\theta}$. First of all, we note that $\hat{\theta}$ consists of the empirical distribution and cumulative functions which are strongly consistent of the population counterparts. Therefore the consistency of $\hat{\theta}$ follows easily. For the asymptotic normality, first of all, we note that

$$\begin{aligned}
&\sqrt{n}\left[\int_0^\infty \hat{S}_1(t) d\hat{\Lambda}_2(t) - \int_0^\infty S_1(t) d\Lambda_2(t)\right] \\
&= \sqrt{n}\left[\int_0^\infty \hat{S}_1(t)\frac{d\hat{F}_2(t)}{\hat{S}_2(t)} - \int_0^\infty S_1(t)\frac{dF_2(t)}{S_2(t)}\right] \\
&= \sqrt{n}\left[\int_0^\infty \frac{\hat{S}_1(t)}{\hat{S}_2(t)} d\hat{F}_2(t) - \int_0^\infty \frac{S_1(t)}{S_2(t)} dF_2(t)\right] \\
&= \sqrt{n}\int_0^\infty \frac{\hat{S}_1(t)}{\hat{S}_2(t)} d\left(\hat{F}_2(t) - F_2(t)\right) + \sqrt{n}\int_0^\infty \left\{\frac{\hat{S}_1(t)}{\hat{S}_2(t)} - \frac{S_1(t)}{S_2(t)}\right\} dF_2(t) \\
&= \sqrt{\frac{n}{n_2}}\int_0^\infty \frac{\hat{S}_1(t)}{\hat{S}_2(t)} d\left\{\sqrt{n_2}\left(\hat{F}_2(t) - F_2(t)\right)\right\} \\
&\quad + \sqrt{n}\int_0^\infty \frac{\hat{S}_1(t)S_2(t) - S_1(t)\hat{S}_2(t)}{S_2(t)\hat{S}_2(t)} dF_2(t) \\
&= \sqrt{\frac{n}{n_2}}\int_0^\infty \frac{\hat{S}_1(t)}{\hat{S}_2(t)} d\left\{S_2(t)\frac{\sqrt{n_2}\left(\hat{F}_2(t) - F_2(t)\right)}{S_2(t)}\right\} \\
&\quad + \sqrt{n}\int_0^\infty \frac{\hat{S}_1(t)S_2(t) - S_1(t)\hat{S}_2(t)}{S_2(t)\hat{S}_2(t)} dF_2(t).
\end{aligned}$$

Now we need the following basic result (*cf.* Shorack and Wellner, 1986).

Lemma 3.1 *For each* i, $i = 1, 2$, *we have*

$$\frac{\sqrt{n_i}\left(\hat{F}_i(t) - F_i(t)\right)}{S_i(t)} = \int_0^t \frac{1}{S_i(s)} dM_{in\ i}(s),$$

where $M_{in\ i}(t)$ *is a martingale with* $\text{Cov}\left(M_{in\ i}(s), M_{in\ i}(t)\right) = V_i(s \wedge t)$ *with*

$$V_i(t) = \int_0^t (1 - \Delta\Lambda_i) dF_i.$$

We note that when F_i is continuous, $V_i(t) = F_i(t)$ since $\Delta\Lambda_i = 0$ for all $t \in [0, \infty)$. Then using Lemma 3.1, we have that

$$\begin{aligned}
&\sqrt{n}\left[\int_0^\infty \hat{S}_1(t) d\hat{\Lambda}_2(t) - \int_0^\infty S_1(t) d\Lambda_2(t)\right] \\
&= \sqrt{\frac{n}{n_2}} \int_0^\infty \frac{\hat{S}_1(t)}{\hat{S}_2(t)} d\left\{S_2(t) \int_0^t \frac{dM_{2n_2}(s)}{S_2(s)}\right\} + \int_0^\infty \frac{\sqrt{n}\left(\hat{S}_1(t) - S_1(t)\right)}{\hat{S}_2(t)} dF_2(t) \\
&\quad - \int_0^\infty \frac{\sqrt{n}\left(\hat{S}_2(t) - S_2(t)\right) S_1(t)}{\hat{S}_2(t) S_2(t)} dF_2(t).
\end{aligned}$$

Since $d\left\{S_2(t) \int_0^t \frac{dM_{2n_2}(s)}{S_2(s)}\right\} = \int_0^t \frac{dM_{2n_2}(s)}{S_2(s)} dS_2(t) + dM_{2n_2}(t)$ and by Lemma 3.1, we have

$$\begin{aligned}
&\sqrt{n}\left[\int_0^\infty \hat{S}_1(t) d\hat{\Lambda}_2(t) - \int_0^\infty S_1(t) d\Lambda_2(t)\right] \\
&= \sqrt{\frac{n}{n_2}} \int_0^\infty \frac{\hat{S}_1(t)}{\hat{S}_2(t)} dM_{2n_2}(t) + \sqrt{\frac{n}{n_2}} \int_0^\infty \frac{\sqrt{n_2}\left(\hat{F}_2(t) - F_2(t)\right)}{S_2(t)} \frac{\hat{S}_1(t)}{\hat{S}_2(t)} dS_2(t) \\
&\quad + \sqrt{\frac{n}{n_1}} \int_0^\infty \frac{\sqrt{n_1}\left(\hat{F}_1(t) - F_1(t)\right)}{S_1(t)} \frac{S_1(t)}{\hat{S}_2(t)} dS_2(t) \\
&\quad - \sqrt{\frac{n}{n_2}} \int_0^\infty \frac{\sqrt{n_2}\left(\hat{F}_2(t) - F_2(t)\right)}{S_2(t)} \frac{S_1(t)}{\hat{S}_2(t)} dS_2(t) \\
&= \sqrt{\frac{n}{n_2}} \int_0^\infty \frac{\hat{S}_1(t)}{\hat{S}_2(t)} dM_{2n_2}(t) + \sqrt{\frac{n}{n_1}} \int_0^\infty \left[\int_0^t \frac{dM_{1n_1}(s)}{S_1(s)}\right] \frac{S_1(t)}{\hat{S}_2(t)} dS_2(t) \\
&\quad + \sqrt{\frac{n}{n_2}} \int_0^\infty \frac{\sqrt{n_2}\left(\hat{F}_2(t) - F_2(t)\right)}{S_2(t)} \frac{\left(\hat{S}_1(t) - S_1(t)\right)}{\hat{S}_2(t)} dS_2(t).
\end{aligned}$$

From the integration by parts, we note that

$$\begin{aligned}
&\sqrt{\frac{n}{n_1}}\int_0^\infty \left[\int_0^t \frac{dM_{1n_1}(s)}{S_1(s)}\right]\frac{S_1(t)}{S_2(t)}dS_2(t)\\
&= \sqrt{\frac{n}{n_1}}\int_0^\infty \left[\int_0^t \frac{dM_{1n_1}(s)}{S_1(s)}\right][S_2(t)]^{1/\theta-1}\,dS_2(t)\\
&= -\sqrt{\frac{n}{n_1}}\int_0^\infty \theta\,[S_2(t)]^{1/\theta}\,\frac{dM_{1n_1}(t)}{S_1(t)}\\
&= -\theta\sqrt{\frac{n}{n_1}}\int_0^\infty dM_{1n_1}(t)\\
&= -\theta\sqrt{\frac{n}{n_1}}M_{1n_1}(\infty),
\end{aligned}$$

since $S_i(\infty)$ for all i, $i=1,2$. Also we note that from the Glivenko-Cantelli theorem (*cf.* Chung, 1974), for each i,

$$||\hat{S}_i - S_i||_0^\infty \rightarrow_{a.s.} 0$$

where $||\cdot||$ is the supremum norm. Thus we have that

$$\sqrt{\frac{n}{n_2}}\int_0^\infty \frac{\sqrt{n_2}\left(\hat{F}_2(t)-F_2(t)\right)}{S_2(t)}\frac{\left(\hat{S}_1(t)-S_1(t)\right)}{\hat{S}_2(t)}dS_2(t) \rightarrow_{a.s.} 0.$$

Therefore finally we obtain the asymptotically equivalent expression for $\sqrt{n}(\hat{\theta}-\theta)$ as follows:

$$\sqrt{n}\left(\hat{\theta}-\theta\right) \doteq \sqrt{\frac{n}{n_2}}\int_0^\infty \frac{S_1(t)}{S_2(t)}dM_{2n_2}(t) - \theta\sqrt{\frac{n}{n_1}}M_{1n_1}(\infty)$$

where $A_n \doteq B_n$ means $A_n - B_n \rightarrow_p 0$ as $n \rightarrow \infty$. Also we need the following result (*cf.* Shorack and Wellner, 1986).

Lemma 3.2 *For each i, $i=1,2$, we have*

$$||M_{in_i} - M_i||_0^\infty \rightarrow_{a.s.} 0$$

where M_i is a Gaussian process with covariance function V, which was defined in Lemma 3.1.

Finally we need the following assumption.

Assumption 3.1 *For each i, let* $\lim_{n\to\infty} n/n_i = \gamma_i < \infty$.

Then we have that as $n \to \infty$,

$$\sqrt{n}\left(\hat{\theta}-\theta\right) \quad \to_d \quad -\sqrt{\gamma_1}\theta M_1(\infty)+\sqrt{\gamma_2}\int_0^\infty \frac{S_1(t)}{S_2(t)}dM_2(t), \tag{3.1}$$

where $\to_d$ stands for the convergence in distribution. Therefore we arrive at the following conclusion.

Theorem 3.1 *With the assumption that* $\lim_{n\to\infty} n/n_i = \gamma_i < \infty$, *for* $0 < \theta \leq 1, \sqrt{n}(\hat{\theta}-\theta)$ *converges in distribution to a normal random variable with 0 mean and variance* σ^2, *where* $\sigma^2 = \begin{cases} \gamma_1\theta^2 + \gamma_2\frac{\theta}{2-\theta}, & \text{when } 0<\theta<1 \\ \gamma_1+\gamma_2, & \text{when } \theta = 1 \end{cases}$.

Proof: The result can be easily drawn from (3.1) by noting that M_i's are perpendicular martingales and so Gaussian processes. Now in order to check the condition $0 < \theta \leq 1$, we note the second part of (3.1). The variance of

$$\int_0^\infty \frac{S_1(t)}{S_2(t)}dM_2(t)$$

is of the form

$$\int_0^\infty \left(\frac{S_1(t)}{S_2(t)}\right)^2 dF_2(t) = \int_0^\infty \left(\frac{1-F_1(t)}{1-F_2(t)}\right)^2 dF_2(t).$$

Then under the proportional hazards assumption that $S_2(t) = S_1^\theta(t)$ or $S_1(t) = S_2^{1/\theta}(t)$ for all $t \in [0,\infty)$, we have

$$\int_0^\infty \left(\frac{S_1(t)}{S_2(t)}\right)^2 dF_2(t) = \int_0^\infty (1-F_2(t))^{2/\theta-2}dF_2(t).$$

Then by change-of-variable technique, we have

$$\int_0^\infty \left(\frac{S_1(t)}{S_2(t)}\right)^2 dF_2(t) = \int_0^1 (1-y)^{2/\theta-2}dy.$$

Now we consider the three cases separately of the integration result as follows:

(i) $0<\theta<1: \int_0^1 (1-y)^{2/\theta-2}dy = -\frac{\theta}{2-\theta}(1-y)^{2/\theta-1}|_0^1 = \frac{\theta}{2-\theta}$,

(ii) $\theta = 1: \int_0^\infty \left(\frac{S_1(t)}{S_2(t)}\right)^2 dF_2(t) = \int_0^\infty dF_2(t) = 1$,

(iii) $\theta > 1: \int_0^1 (1-y)^{2/\theta-2}dy = \infty$ for all $\theta > 1$ since $\int_0^1 \frac{dy}{(1-y)^\alpha} = \infty$ for all $\alpha > 0$.

This completes the proof. □

4. Concluding Remarks and Simulation Results

We note that the functional (2.1) satisfy all the three conditions in Begun (1987) of the definition for the measures of relative risk. Therefore the estimate (2.2) can be used as a measure of relative risk even when the underlying assumption of proportionality between hazard functions fails to hold.

From the last part of the proof of Theorem 3.1, we saw the reason why we should confine our discussions to the case that $0 < \theta \leq 1$. Therefore before the estimation of θ, we must decide on whether which one is the first sample between two samples. However for the application to the real problems, there seems to be no difficulty to decide the first one since the treatment and control groups are determined by experimenter and known to statistician beforehand.

When $\theta < 1$, we note that $S_1(t) < S_2(t)$ or $F_1(t) > F_2(t)$ for all $t \in [0, \infty)$ from (1.3). Then for testing $H_0 : F_1 = F_2$ (or $H_0 : \theta = 1$) using $\hat{\theta}$, the alternative can not be the general one such that $H_1 : F_1 \neq F_2$ (or $H_1 : \theta \neq 1$) since the value of θ can not exceed unit. Therefore the form of alternative should be one-sided or stochastically ordered such as

$$H_1 : F_2(t) \leq F_1(t) \text{ and strict inequality holds at some } t \in [0, \infty).$$

Also one may use $\hat{\theta}$ for testing $H_0 : \theta = \theta_0$ against $H_1 : \theta \neq \theta_0$ for some $0 < \theta_0 < 1$ by simply comparing $\hat{\theta}$ with the value θ_0. This would be an advantage of our estimate over others. However we note that even though (2.3), which is another form of $\hat{\theta}$, consists of the ranks, it is not a linear rank statistic. Therefore the derivation of the distribution for $\hat{\theta}$ is not obvious even under $H_0 : \theta = \theta_0$ and so we have to take the asymptotic approach to obtain the critical value for any given significance level or the p-value. The necessary tool of this approach for the analysis may be furnished well by Theorem 3.1. Also we note that we do not need to estimate for the limiting variance of $\hat{\theta}$ under $H_0 : \theta = \theta_0$ for testing problems since the limiting variance σ^2 is free from the underlying distributions when they hold the proportionality between hazard functions. Therefore the test procedure based on $\hat{\theta}$ becomes relatively simple compared to other competitors.

Begun and Reid (1983) and Begun (1987) derived the following form for the weight function $w_{op}(s,t)$ using the likelihood ratio of the rank vector

$$w_{op}(s,t) = \{\gamma_1(1-s) + \theta\gamma_2(1-t)\}^{-1} \tag{4.1}$$

in order to obtain an optimal estimate which may be asymptotically efficient in the sense that the limiting variance of the estimate based on the weight function

$w_{op}(s,t)$ does achieve the lower bound. They took the two-step procedure with a preliminary estimate of θ for the estimation because of the involvement of the parameter itself into the optimal weight function (4.1). We note that when $\theta = 1$, the limiting variance, $\sigma_{op}^2(1)$, of $\sqrt{n}(\tilde{\theta} - \theta)$ with the optimal weight (4.1) is

$$\sigma_{op}^2(1) = \gamma_1 + \gamma_2,$$

which coincides with that of our proposed estimate for $\theta = 1$. Therefore one may consider that our simple procedure may be a resonable alternative to the Begun's method. Also we note that when $w(s,t) = 1$ and $\theta = 1$, the limiting variance of $\sqrt{n}(\tilde{\theta} - \theta)$ is

$$\sigma_{w=1}^2(1) = \frac{4}{3}(\gamma_1 + \gamma_2),$$

which is greater than $\sigma_{op}^2(1)$. However for the other values for θ, it is impossible to obtain the explicit values for the limiting variance for the Begun's estimate. Therefore we compare the performance between our proposed estimate with that of Begun (1987) through simulation studies by obtaining empirical confidence intervals. For the Begun's estimate, we consider two cases such as $w = 1$ and $w = w_{op}$ in (4.1). We consider exponential and Weibull distributions and obtain 90% empirical confidence intervals for $\theta = 1/2$ by varying pairs of sample sizes from (5, 10) to (100, 100) for the two sample problem. The following tables are the results of simulation study. For each case, the pseudo-random numbers were generated 1000 times through IML on SAS in PC version. Since all the three estimates are consistent, the lengths of the empirical confidence intervals shrink as the sample sizes increase and contain the true parameter value 1/2. We note that the estimate of Begun with the optimal weight does not improve much over

Table 4.1: Estimation for exponential distribution

(n_1, n_2)	Exp(1), Exp(2)		
	Proposed estimate	Begun's estimate	
		$w = 1$	$w = optimal$
(5, 10)	(0.100, 1.097)	(0.111, 1.632)	(0.111, 1.256)
(5, 15)	(0.128, 1.107)	(0.136, 1.419)	(0.135, 1.169)
(5, 20)	(0.138, 0.987)	(0.136, 1.273)	(0.143, 1.039)
(15, 15)	(0.221, 0.897)	(0.216, 1.045)	(0.237, 0.974)
(30, 30)	(0.300, 0.768)	(0.289, 0.833)	(0.307, 0.802)
(50, 50)	(0.339, 0.724)	(0.336, 0.766)	(0.346, 0.738)
(100, 100)	(0.382, 0.655)	(0.373, 0.674)	(0.389, 0.659)

Table 4.2: Estimation for Weibull distribution

(n_1, n_2)	Weibull($\sqrt{2}$, 1), Weibull(2,2)		
	Proposed estimate	Begun's estimate	
		$w = 1$	$w = optimal$
(5, 10)	(0.116, 1.062)	(0.111, 1.381)	(0.128, 1.310)
(5, 15)	(0.126, 0.996)	(0.136, 1.273)	(0.137, 1.037)
(5, 20)	(0.148, 0.978)	(0.149, 1.273)	(0.149, 1.003)
(15, 15)	(0.224, 0.846)	(0.230, 0.991)	(0.235, 0.911)
(30, 30)	(0.290, 0.725)	(0.284, 0.793)	(0.311, 0.749)
(50, 50)	(0.337, 0.701)	(0.331, 0.749)	(0.344, 0.707)
(100, 100)	(0.386, 0.638)	(0.380, 0.666)	(0.386, 0.641)

the preliminary ones even when the sample sizes are small. For each case, our proposed estimate shows better performance in the sense of the length of the empirical confidence intervals. Therefore the simulation study shows that our estimate can be a reasonable alternative for the estimates of the relative risk.

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